Use these links to rapidly review the document
TABLE OF CONTENTS
INDEX TO FINANCIAL STATEMENTS

Table of Contents

As confidentially submitted to the Securities and Exchange Commission on August 31, 2017.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains confidential.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2
to

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

OPTINOSE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**2834**	**42-1771610**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1020 Stony Hill Road, Suite 300
Yardley, Pennsylvania 19067
(267) 364-3500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Peter K. Miller
Chief Executive Officer
OptiNose, Inc.
1020 Stony Hill Road, Suite 300
Yardley, Pennsylvania 19067
(267) 364-3500
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Steven J. Abrams **Rachael M. Bushey** **Hogan Lovells US LLP** **1735 Market Street, 23rd Floor** **Philadelphia, PA 19103** **(267) 675-4600**	**Michael F. Marino** **Chief Legal Officer** **OptiNose, Inc.** **1020 Stony Hill Road, Suite 300** **Yardley, PA 19067** **(267) 364-3500**	**Divakar Gupta** **Brian F. Leaf** **Jeffrey P. Libson** **Cooley LLP** **1114 Avenue of the Americas** **New York, NY 10036** **(212) 479-6000**

Approximate date of commencement of proposed sale to public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer ☒ (Do not check if a smaller reporting company)	Smaller reporting company o Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☒

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[1]	Amount of registration fee[2]
Common Stock, $0.001 par value per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act and includes the aggregate offering price of shares that the underwriters have an option to purchase.

(2) To be paid in connection with the initial public filing of the registration statement.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

Table of Contents

SUBJECT TO COMPLETION, DATED AUGUST 31, 2017

PRELIMINARY PROSPECTUS

Shares

Common Stock

This is the initial public offering of common stock of OptiNose, Inc. We are offering shares of our common stock. We expect the initial public offering price to be between $ and $ per share.

Prior to this offering, there has been no public market for our common stock. We have applied to list our common stock on The NASDAQ Global Market under the trading symbol " ."

We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we are subject to reduced public company reporting requirements for this prospectus and future filings. See "Implications of Being an Emerging Growth Company" on page 61 of this prospectus.

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 13 of this prospectus.

	PER SHARE	TOTAL
Initial public offering price	$	$
Underwriting discounts and commissions	$	$
Proceeds to OptiNose, Inc., before expenses	$	$

(1) See "Underwriting" beginning on page 164 of this prospectus for information regarding compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of common stock at the initial public offering price, less the underwriting discounts and commissions.

After the closing of this offering, we will be a "controlled company" under the corporate governance standards for NASDAQ listed companies and will be exempt from certain corporate governance requirements under the NASDAQ listing rules. See "Management — Director Independence and Controlled Company Exemptions" on page 129 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to investors on or about , 2017.

Jefferies **Piper Jaffray** **BMO Capital Markets** **RBC Capital Markets**

The date of this prospectus is , 2017.

TABLE OF CONTENTS

PROSPECTUS SUMMARY	1
RISK FACTORS	13
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	59
IMPLICATIONS OF BEING AN EMERGING GROWTH COMPANY	61
MARKET, INDUSTRY AND OTHER DATA	61
USE OF PROCEEDS	62
DIVIDEND POLICY	64
CAPITALIZATION	65
DILUTION	68
SELECTED CONSOLIDATED FINANCIAL DATA	71
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	74
BUSINESS	89
MANAGEMENT	126
EXECUTIVE AND DIRECTOR COMPENSATION	135
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	143
PRINCIPAL STOCKHOLDERS	148
DESCRIPTION OF CAPITAL STOCK	152
SHARES ELIGIBLE FOR FUTURE SALE	158
MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK	160
UNDERWRITING	164
LEGAL MATTERS	172
EXPERTS	172
WHERE YOU CAN FIND MORE INFORMATION	172
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS	F-1

Neither we nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock. Our business, financial condition, results of operations and future growth prospects may have changed since that date.

Through and including , 2017 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

TRADEMARKS

We have received trademark registration for OptiNose® and Breath Powered® in the United States. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and trade names. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

INVESTORS OUTSIDE THE UNITED STATES

For investors outside of the United States: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus.

Unless the context otherwise requires, we use the terms "OptiNose," "Company," "we," "us," "our" and similar designations in this prospectus to refer to OptiNose, Inc. and, where appropriate, our subsidiaries.

OptiNose

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat, or ENT, and allergy specialists. Our lead product candidate, OPN-375, is a therapeutic utilizing our proprietary Breath Powered exhalation delivery system, or EDS, that delivers a topically-acting and potent anti-inflammatory corticosteroid for the treatment of chronic rhinosinusitis with and without nasal polyps. Chronic rhinosinusitis is a serious nasal inflammatory disease that is currently treated using therapies, such as intranasal steroids, or INS, that have significant limitations. We believe OPN-375 has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by current INS. We also believe that payors will respond favorably to OPN-375's clinical, cost and quality-of-care profile, as compared to current and potential future costly drug therapy and surgical treatment options.

In November 2016, we submitted a new drug application, or NDA, for OPN-375 for the treatment of nasal polyposis to the U.S. Food and Drug Administration, or FDA. Subject to FDA approval, we expect to launch OPN-375 in the second quarter of 2018 with a dedicated sales force targeting a specialty prescriber base comprised of approximately 15,000 physicians in the United States. We expect our sales force will initially consist of approximately 75 representatives. We plan to initiate additional clinical trials of OPN-375 in the second half of 2018 to seek a follow-on indication for the treatment of chronic sinusitis to broaden our market opportunity.

We have conducted five clinical trials evaluating over 1,500 adult patients, including two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials in adults with nasal polyposis and two supportive open-label Phase 3 clinical trials in adults with symptoms of chronic sinusitis with and without nasal polyps. In both Phase 3 pivotal clinical trials, patients treated with OPN-375 experienced statistically significant reductions of both nasal congestion/obstruction symptoms and total polyp grade, which were the co-primary endpoints. Treatment benefits were also observed in all four defining symptoms of chronic rhinosinusitis, as well as in polyp elimination, quality of life, need for sinus surgery and patient global impression of change. In addition, the magnitude of improvement for patients treated by OPN-375 in our Phase 3 pivotal clinical trials, as measured by the Sinonasal Outcome Test-22, a validated clinical outcome assessment, was comparable to the reported benefits in third-party studies of endoscopic sinus surgery, or ESS, and balloon sinus dilation. In addition, OPN-375 had an adverse event profile generally comparable to the profile reported in similarly designed studies with conventional INS. In our supportive open-label Phase 3 clinical trials, which evaluated approximately 900 patients with symptoms of chronic sinusitis with and without nasal polyps for a period of up to one year, OPN-375 was generally well tolerated and produced results on efficacy endpoints similar to those observed in our Phase 3 pivotal clinical trials. In these supportive trials, we observed comparable symptom improvements in patients with and without nasal polyps and continuing incremental polyp reduction and symptom improvement through 12 months.

We intend to efficiently launch into the ENT and allergy market segments following approval of OPN-375 for nasal polyposis. Initially, we will focus our marketing efforts on moderate-to-severely symptomatic patients who have not achieved satisfactory results with currently available INS. We plan to educate physicians, payors and patients on OPN-375's unique mechanism of action and differentiated efficacy profile. We also intend to establish a meaningful value proposition for these key stakeholders by highlighting the potential for OPN-375 to reduce or delay the need for surgical intervention, reduce antibiotic prescribing and increase patient satisfaction with treatment outcomes. If approved, we intend to immediately engage payors to secure broad market access for OPN-375 in the commercial segment by targeting Tier 3 payor coverage, single step edit with no prior authorization. This level of coverage indicates that payors would require patients to use a generic INS as a first step in treating their disease prior to the payor covering OPN-375. However, such coverage would not require the prior authorization of the payor. Tier 3 payor coverage requires a patient co-pay that is higher than that required for generics or drugs within a payor's formulary.

Our Market Opportunity

The Unmet Need

Chronic rhinosinusitis is a serious nasal inflammatory disease characterized by chronic inflammation affecting tissues high and deep in the nasal passages, including the area where the openings from the sinuses normally ventilate and drain. This disease significantly impacts the quality of life and daily functioning of an estimated 30 million adults in the United States. The U.S. healthcare system spends approximately $60 billion annually in direct costs treating patients with chronic rhinosinusitis and its associated symptoms, including an estimated $5 billion on sinus surgeries. In the United States, physicians perform over 500,000 sinus surgeries each year, and we estimate that over seven million adults have undergone sinus surgery to treat chronic rhinosinusitis with and without nasal polyps.

In medical literature and practice, chronic rhinosinusitis is commonly divided into two subgroups: chronic rhinosinusitis with nasal polyps and chronic rhinosinusitis without nasal polyps. Chronic rhinosinusitis patients with and without nasal polyps suffer from chronic inflammation of the lining of the deep nasal passages and sinuses. Patients with chronic rhinosinusitis with nasal polyps also develop non-cancerous polyps on these chronically inflamed surfaces, typically originating in the deep crevices or sinus cavities on both sides of the nose. We estimate that up to 10 million adults in the United States have chronic rhinosinusitis with nasal polyps.

Both subgroups of chronic rhinosinusitis also share the same four defining diagnostic symptoms: nasal congestion/obstruction; facial pain and pressure; rhinorrhea, or runny nose, and postnasal drip; and loss of sense of smell and taste. Additional symptoms include headaches, chronic sleep problems, fatigue, frequent episodes of acute rhinosinusitis and mood disorders. There is evidence suggesting that the harm to a sufferer's quality of life from chronic rhinosinusitis, as measured in multiple domains, such as bodily pain, social functioning and mental health, is comparable to or worse than other serious diseases, including chronic obstructive pulmonary disease, congestive heart failure and angina. As a result, many patients eventually seek surgery for symptom relief.

Although the term chronic rhinosinusitis is often used in medical literature and medical practice, the FDA does not recognize chronic rhinosinusitis as a single indication for drug development purposes. Instead, the FDA recognizes chronic sinusitis, defined as inflammation of the sinuses with a duration longer than eight weeks, and nasal polyposis, defined as non-cancerous polyps on the inflamed tissue of the nasal passages and sinuses, as separate indications for drug development purposes. For purposes of this prospectus, we use the terms chronic sinusitis and nasal polyposis when referring to FDA treatment indications and our clinical trials, and use the term chronic rhinosinusitis with and without nasal polyps when referring to disease and economic data reported in the medical literature, medical practice and our estimates of OPN-375's market opportunity.

Our U.S. Market Opportunity

If we obtain FDA approval of OPN-375 for nasal polyposis, our initial target market will consist of ENT physicians, allergists and primary care physicians in the United States that most frequently prescribe INS. This group of approximately 5,000 primary care physicians, which we refer to as high-decile INS-prescribing primary care physicians, account for approximately 25% of all INS prescriptions written by primary care physicians. We refer to these ENT physicians, allergists and high-decile INS-prescribing primary care physicians collectively as the specialty segment of our target market. We believe the approximately 15,000 physicians in this specialty segment together treat an estimated 3.5 million U.S. patients with chronic rhinosinusitis, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. We believe the total annual U.S. market opportunity for OPN-375 in this specialty segment is over $3.4 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. If we are able to obtain approval for the follow-on indication of chronic sinusitis, we intend to broaden our commercialization efforts to target additional primary care physicians that we believe treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. We refer to these additional primary care physicians as the primary care segment of our target market. We believe the total additional annual U.S. market opportunity for OPN-375 in this primary care segment is over $6.0 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. Therefore, we estimate the total annual U.S. market opportunity for the combined specialty and primary care segments is over $9.5 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps.

Landscape of Treatment Therapies for Chronic Rhinosinusitis and Their Limitations

The treatment of chronic rhinosinusitis with and without nasal polyps typically begins with medical management. In cases where patients remain symptomatic despite medical management, physicians often recommend various forms of sinus surgery to help restore normal sinus ventilation and drainage. The following is a brief description of the current and potential future treatment landscape for chronic rhinosinusitis with and without nasal polyps and their limitations:

Current Therapies

- ***Intranasal Steroids.*** Multiple published clinical practice guidelines recommend topically-acting INS as the first line of prescription therapy for the treatment of chronic rhinosinusitis with and without polyps. As a result, physicians typically prescribe INS sprays or aerosols despite the fact that there are no FDA-approved products for the treatment of chronic sinusitis without nasal polyps. Physicians also prescribe INS following sinus surgery to improve symptoms and delay recurrence. Conventional INS are unable to effectively and consistently place the steroids onto the primary site of inflammation and nasal polyp origin, high and deep in the nasal passages, reducing their effectiveness and leaving many patients without sufficient symptomatic relief.

- ***Oral Steroids.*** Physicians may prescribe oral steroids on an episodic basis to patients who have not received sufficient symptomatic relief from INS. Oral steroids are often effective at treating the underlying inflammation associated with the disease and reducing postoperative scarring. However, oral steroids offer only temporary benefit and are limited by the risk of serious systemic side effects associated with both short- and long-term use. As inflammation returns, many patients resume INS therapy.

- ***Other Medical Management.*** Physicians commonly employ a variety of other non-surgical treatments in the medical management of chronic rhinosinusitis, including nasal saline rinses, multi-week courses of antibiotics, leukotriene antagonists, decongestants, aspirin desensitization and antifungals. The recognized limitations of drug deposition with current INS cause some physicians to seek out alternative treatment regimens such as high-volume steroid nasal rinses. These treatments have varying degrees of supporting data and efficacy. In addition, high-volume steroid nasal rinses are difficult to administer, can be costly and may risk systemic side effects.

- ***Sinus surgery and other procedures.*** Physicians generally recommend surgical treatment of chronic rhinosinusitis with and without nasal polyps only after patients fail medical management. The primary

surgical alternative is ESS, which attempts to open the sinus drainage pathways while preserving as much bone and sinus tissue lining as possible. Other surgical alternatives include balloon sinus dilation devices and steroid-releasing sinus implants. The effectiveness of sinus surgery varies significantly and many patients experience persistent or recurrent symptoms and surgery does not address the underlying cause of inflammation. Balloon sinus dilation is costly and also does not address the underlying cause of inflammation. Steroid-releasing sinus implants have limited duration of anti-inflammatory effect, are costly and face reimbursement challenges.

Potential Future Therapies

- ***Biologic monoclonal antibodies.*** Several biologic monoclonal antibodies, some of which are already approved for other indications, are being developed for nasal polyposis and are believed to inhibit specific pathways of inflammation present in nasal polyps. However, the risks and benefits associated with the use of these drugs for the treatment of nasal polyposis are not yet fully established and we expect them to be costly. These drugs also require subcutaneous injections or intravenous administration that require frequent physician office visits.

Market Need for a New Therapy

Given the limitations of current and potential future therapies for chronic rhinosinusitis, we believe there is a significant opportunity for a new treatment that prevents progression to more costly or risky treatment alternatives.

Our Solution

OPN-375 combines our EDS with a liquid formulation of fluticasone propionate, a second-generation anti-inflammatory corticosteroid. OPN-375 is designed to deliver this drug into the high and deep regions of the nasal passages where both nasal polyps and inflamed and swollen membranes can obstruct normal sinus ventilation and drainage. We believe OPN-375 has the potential to become part of the standard of care for the treatment of patients with chronic rhinosinusitis before they progress to more costly treatment alternatives and could also be adopted as a maintenance therapy to improve outcomes following sinus surgery. If approved, we believe the following factors could contribute to the potential success of OPN-375:

- ***High patient dissatisfaction with current INS.*** In a market research study that we commissioned, we surveyed 438 patients with chronic sinusitis with and without nasal polyps. In this study, approximately 80% of the patients reported being frustrated with the symptom relief offered from their current INS medication and approximately 90% of the patients reported they would be interested in using a new product if it would improve symptom relief.

- ***Strong physician interest in OPN-375 product profile.*** We surveyed approximately 700 physicians, consisting of 400 ENT and allergy specialists and 300 primary care physicians that currently treat patients with chronic sinusitis with and without nasal polyps. Approximately 75% of these physicians, including both specialists and primary care physicians, agreed, in part, that INS medications do not work well in patients with chronic sinusitis due to their belief that conventional INS do not sufficiently reach the high and deep regions of the nasal passages where inflammation occurs. In addition, 70% to 80% of these physicians reported that they would "definitely" or "probably" prescribe their patients a product with a clinical profile similar to OPN-375.

- ***Fluticasone propionate is the most widely-prescribed INS.*** OPN-375 contains fluticasone propionate, a potent and well-characterized anti-inflammatory corticosteroid with a low bioavailability, meaning only a small percentage of the drug is absorbed into the body. Corticosteroids provide multiple anti-inflammatory mechanisms of action and are used in various forms to treat many sites of inflammation.

- ***OPN-375 was designed to overcome the limitations of current INS therapies.*** In multiple studies utilizing advanced imaging, our EDS produced a differentiated pattern of drug delivery with significantly more drug deposited at the primary site of inflammation high and deep in the nasal passages where nasal polyps or inflamed and swollen membranes produce nasal symptoms and can obstruct normal sinus ventilation and drainage.

- ***Strong clinical data demonstrating safety and efficacy.*** In two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials evaluating adult patients with nasal polyposis, we met our co-primary endpoints of statistically significant reductions of nasal congestion/obstruction symptoms and total polyp grade and OPN-375 also produced treatment benefits as measured by multiple secondary endpoints. In two supportive open-label Phase 3 clinical trials evaluating approximately 900 patients with symptoms of chronic sinusitis with and without nasal polyps for a period of up to one year, OPN-375 was generally well tolerated. In these supportive trials, we observed comparable symptom improvements in patients with and without nasal polyps, and continuing incremental polyp reduction and symptom improvement through 12 months.

- ***OPN-375 is easy to use.*** In a market study that we commissioned, 98% of patients reported that OPN-375 was easy to use after four weeks of use and 93% stated the ease of use was comparable to other INS.

- ***Potential for broad payor access.*** In a market research study that we commissioned, we surveyed 26 health insurance plans representing over 150 million covered lives. Most payors reacted positively to a profile of OPN-375. A majority of payors surveyed indicated that they do not intend to actively manage INS products priced below a certain dollar threshold and many surveyed payors indicated that they would provide access without prior authorization to INS products priced within a certain dollar range. In addition to this market research study, we obtained formulary data for INS from various sources representing approximately 159 million covered lives. These data indicate that health insurance plans covering 84% of commercial lives do not require prior authorization in the INS category for contracted products.

- ***Cost-effective solution.*** We intend to price OPN-375 comparably to branded INS that are currently approved to treat nasal polyposis. We believe OPN-375 will offer a cost-effective clinical benefit to payors that will reduce the perceived need for multiple step-edits and prior authorizations, which we believe will increase the likelihood of successful commercial adoption of OPN-375.

Our Growth Strategy

Our goal is to become a leading specialty pharmaceutical company dedicated to developing proprietary products that become a part of the standard of care for diseases in the ENT and allergy segments. The key elements of our strategy are to:

- ***Commercialize OPN-375 in the ENT and allergy specialty markets in the United States.*** We have begun building our commercial leadership team and organization. Initially, we intend to engage a dedicated specialty sales force to promote OPN-375 to a defined prescriber base consisting of approximately 10,000 ENT and allergy specialists, as well as approximately 5,000 high-decile INS-prescribing primary care physicians.

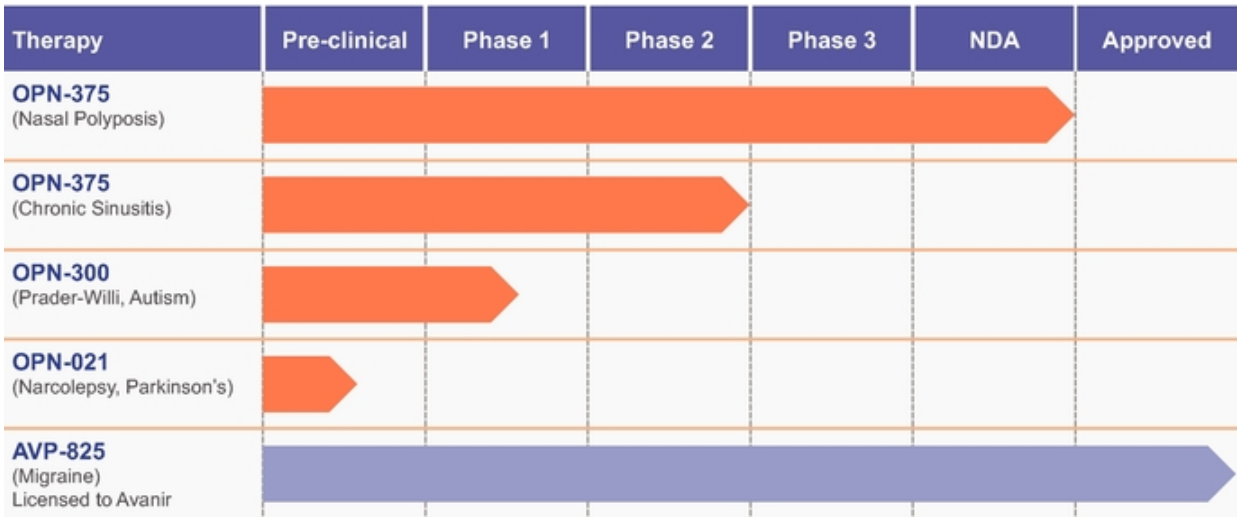
- ***Pursue development of OPN-375 for the treatment of chronic sinusitis to broaden our market opportunity.*** If approved, we plan to seek a follow-on indication for OPN-375 for the treatment of chronic sinusitis. We believe OPN-375 would be the first drug therapy product approved for the treatment of chronic sinusitis. Upon approval, we plan to broaden our marketing to additional primary care physicians. If we obtain approval for this indication, we may also direct promotional resources to an additional estimated 20 million adults who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.

- ***Develop a pipeline of additional products focused on the ENT and allergy specialty markets.*** We are evaluating the use of our EDS to deliver other drugs or drug combinations to treat diseases primarily managed by ENT and allergy specialists. We also intend to explore complementary technologies or products to make effective use of our commercial infrastructure.

- ***Explore business development activities for our EDS outside of the ENT and allergy markets.*** We are exploring the possibility of using our EDS to support nose-to-brain drug delivery and are in the early stages of clinical development of OPN-300, which combines our EDS with oxytocin for the treatment of Prader-Willi syndrome and autism spectrum disorder. We are in preclinical development of OPN-021, which combines our EDS with orexin-A for the treatment of narcolepsy or symptoms of other diseases potentially amenable to the same pharmacologic activity, such as Parkinson's disease.

- ***Expand OPN-375 into international markets.*** We have begun an initial assessment of the development and commercialization of OPN-375 for markets outside the United States and plan to conduct further strategic evaluation of such markets if OPN-375 is approved in the United States. We also intend to explore strategic collaboration opportunities in Europe and the rest of the world in order to maximize the commercial potential and the availability of OPN-375 to patients.

Our Pipeline



Intellectual Property and Barriers to Entry

OPN-375 benefits from substantial intellectual property and other technical barriers to entry, including regulatory and drug delivery complexities. Our patent portfolio for OPN-375 consists of nine issued U.S. patents expiring through 2030 and 12 U.S. patent applications that, if granted, would expire through 2034. We believe the unique features of our EDS, as well as its delivery of a topically-acting drug, will present generic and 505(b)(2) NDA competitors of OPN-375 with human factors engineering challenges specific to drug-device combination products and chemistry, manufacturing and controls challenges unique to suspension and respiratory products. We also believe that any future substitutable generic competitors would be required to conduct, among other things, non-inferiority clinical trials demonstrating equivalent efficacy and safety outcomes to establish clinical bioequivalence to OPN-375. We believe these clinical trials would require a significant amount of time and capital investment and present clinical development uncertainties.

Risks Associated with our Business

Our ability to implement our business strategy is subject to numerous risks and uncertainties. You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors," beginning on page 13 of this prospectus, prior to making an investment in our common stock. These risks include, among others, the following:

- we may not be able to obtain and maintain regulatory approval of OPN-375 for the treatment of nasal polyposis;
- we may not be able to successfully commercialize OPN-375;
- the market opportunities for OPN-375 may be smaller than we believe;
- third-party payors may not provide sufficient coverage or adequate reimbursement for OPN-375;
- we currently have limited sales and marketing capabilities and, if we are unable to enter into a suitable agreement with a contract sales organization, we may not be successful in commercializing OPN-375; and
- we depend on third-party suppliers, manufacturers, wholesalers and distributors in order to commercialize OPN-375, and these third parties may fail to devote sufficient time and resources to the commercialization of OPN-375.

Corporate Information

We were incorporated in Delaware in May 2010. Our predecessor entity OptiNose AS was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became our subsidiary as part of an internal reorganization.

Our primary executive offices are located at 1020 Stony Hill Road, Suite 300, Yardley, Pennsylvania 19067 and our telephone number is (267) 364-3500. Our website address is www.optinose.com. The information contained in, or that can be accessed through, our website is not part of this prospectus and should not be considered as part of this prospectus or in deciding whether to purchase our common stock.

Our Principal Stockholder

Funds affiliated with Avista Capital Partners, or Avista, are expected to own approximately % of our outstanding common stock upon the closing of this offering.

Avista is a leading New York-based private equity firm with approximately $5 billion under management. Founded in 2005, Avista makes controlling or influential minority investments in growth-oriented healthcare businesses. Through its team of seasoned investment professionals and industry experts, Avista seeks to partner with strong management teams to invest in and add value to well-positioned businesses.

THE OFFERING

Issuer	OptiNose, Inc.
Common stock offered by us	shares (shares if the underwriters exercise their option to purchase additional shares in full).
Common stock to be outstanding immediately after this offering	shares (shares if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	We have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $ million, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. We currently estimate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, for the following purposes: § approximately $ million to support the planned launch of OPN-375, including investment to establish and continue to build our commercial infrastructure, supply chain, marketing and sales functions;

	§ approximately $ million to fund research and development efforts for OPN-375, including the initiation of FDA-mandated pediatric studies and the clinical trials necessary to seek approval for a follow-on indication of OPN-375 for the treatment of chronic sinusitis; and § the remainder, if any, to fund working capital, research and development efforts and general corporate purposes, which may include the acquisition or licensing of products, product candidates, technologies, compounds, other assets or complementary businesses. See "Use of Proceeds" on page 62 of this prospectus for a more complete description.
Risk factors	You should read the "Risk Factors" section beginning on page 13 of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.
Proposed NASDAQ Global Market Symbol	" "
Controlling stockholders	Upon the closing of this offering, entities affiliated with Avista and TKWD Ventures LLC as a group will collectively beneficially own a controlling interest in us. We currently intend to avail ourselves of the controlled company exemptions under the NASDAQ listing rules, and so you will not have the same protections afforded to stockholders of companies that do not rely on those exemptions. See

	"Management — Director Independence and Controlled Company Exemptions" on page 129 of this prospectus.

Unless otherwise indicated, the number of shares of our common stock to be outstanding after this offering is based on 10,089,106 shares of common stock outstanding as of June 30, 2017, after giving effect to the conversion of shares of our convertible preferred stock outstanding as of June 30, 2017 into an aggregate of 8,680,566 shares of our common stock upon the closing of this offering, and excludes:

- 1,523,901 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2017 at a weighted-average exercise price of $18.64 per share;
- 654,624 shares of common stock issuable upon the exercise of warrants to purchase common stock outstanding as of June 30, 2017 at an exercise price of $23.56 per share; and
- 99,505 shares of common stock reserved for future issuance under our 2010 Stock Incentive Plan, as amended, as of June 30, 2017.

Unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- a for stock split of our common stock effected on , 2017;
- no exercise by the underwriters of their option to purchase up to an additional shares of our common stock in this offering; and
- the automatic conversion of all of our convertible preferred stock outstanding upon the closing of this offering into an aggregate of 8,680,566 shares of our common stock.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following consolidated summary financial data should be read together with our consolidated financial statements and the related notes, "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus. The summary consolidated financial data in this section is not intended to replace our consolidated financial statements and the related notes. We derived the summary consolidated statement of operations data for the years ended December 31, 2015 and 2016 from our audited consolidated financial statements and the related notes appearing elsewhere in this prospectus. We derived the summary consolidated statement of operations data for the six months ended June 30, 2016 and 2017 and the summary consolidated balance sheet data as of June 30, 2017 from our unaudited interim consolidated financial statements and the related notes appearing elsewhere in this prospectus. The unaudited interim consolidated financial data, in management's opinion, have been prepared on the same basis as the audited consolidated financial statements and the related notes included elsewhere in this prospectus, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the information for the periods presented. Our historical results are not necessarily indicative of the results that may be expected in the future, and results from our interim period may not necessarily be indicative of the results of the entire year or any future period.

(in thousands, except share and per share data)	Years Ended December 31, 2015	Years Ended December 31, 2016	Six Months Ended June 30, 2016	Six Months Ended June 30, 2017
Consolidated Statement of Operations Data:				
Licensing revenues	$ 85	$ 47,500	$ 47,500	$ —
Operating expenses:				
Research and development	22,156	15,311	8,373	8,979
Selling, general and administrative	6,006	6,869	3,296	6,661
Total operating expenses	28,162	22,180	11,669	15,640
(Loss) income from operations	(28,077)	25,320	35,831	(15,640)
Other expense, net	237	2,707	1,524	643
Net (loss) income	(28,314)	22,613	34,307	(16,283)
Accretion of redeemable convertible preferred stock	(12,061)	(13,114)	(6,557)	(8,224)
Net (loss) income attributable to common stockholders	$ (40,375)	$ 9,499	$ 27,750	$ (24,507)
Net (loss) income per share of common stock,				
basic	$ (28.79)	$ 1.15	$ 3.35	$ (17.40)
diluted	$ (28.79)	$ 0.94	$ 2.74	$ (17.40)
Weighted average common shares outstanding,				
basic	1,402,290	1,403,900	1,402,290	1,408,540
diluted	1,402,290	1,724,513	1,717,460	1,408,540
Pro forma net income (loss) per share of common stock[(2)],				
basic (unaudited)		$ 2.73		$ (1.76)
diluted (unaudited)		$ 2.63		$ (1.76)
Pro forma weighted average common shares outstanding,				
basic (unaudited)		8,279,414		9,251,267
diluted (unaudited)		8,600,027		9,251,267

(in thousands)	As of June 30, 2017 Actual	Pro Forma[2]	Pro Forma As Adjusted[3] [4]
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 58,887	$ 58,887	
Working capital[1]	54,689	54,689	
Total assets	63,962	63,962	
Redeemable convertible preferred stock	232,418	—	
Additional paid-in capital	—	232,409	
Accumulated deficit	(174,577)	(174,577)	
Total stockholders' (deficit) equity	(174,681)	57,737	

(1) Working capital is calculated as current assets minus current liabilities.

(2) Gives effect to the conversion of all our outstanding shares of convertible preferred stock into an aggregate of 8,680,566 shares of our common stock, which will occur upon the closing of this offering.

(3) Reflects the pro forma adjustment described in footnote (2) and the sale by us of shares of our common stock in this offering at an assumed initial offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. Similarly, each increase (decrease) of 1.0 million in the number of shares offered by us would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by $ million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding to invest in our common stock, you should consider carefully the risks and uncertainties described below, together with general economic and business risks and all of the other information contained in this prospectus, including our consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occur, our business, financial condition, results of operations and prospects could be harmed. In that event, the price of our common stock could decline and you could lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks described below. See "Special Note Regarding Forward-Looking Statements."

Risks Related to Our Financial Position and Capital Resources

We have incurred significant losses since our inception and anticipate that we will incur continued losses in the future.

We are a specialty pharmaceutical company with a limited operating history. To date, we have focused primarily on developing our lead product candidate, OPN-375, as well as other product candidates using our proprietary Breath Powered exhalation delivery system, or EDS, technology. Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. To date, we have generated revenue primarily from our license agreement, or the AVP-825 License Agreement, with Avanir Pharmaceuticals, Inc., or Avanir, pursuant to which we granted them the exclusive right to further develop and commercialize AVP-825 for the acute treatment of migraines in adults. We had net income of $22.6 million for the year ended December 31, 2016 and $34.3 million for the six months ended June 30, 2016 due primarily to the achievement of a development milestone under the AVP-825 License Agreement. However, we incurred net losses of $28.3 million for year ended December 31, 2015 and $16.3 million for the six months ended June 30, 2017. We incurred net losses in all other prior periods. As of June 30, 2017, we had an accumulated deficit of $174.6 million.

We expect to incur losses for the foreseeable future, and we expect these losses to increase as we:

- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize OPN-375 or any other product candidate for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed drugs;
- continue clinical development activities for OPN-375, including the U.S. Food and Drug Administration, or FDA, mandated pediatric studies, and seek regulatory approval for OPN-375 for a follow-on indication for the treatment of chronic sinusitis;
- seek to discover and develop, in-license or acquire additional products, product candidates and technology;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

We may never achieve or maintain profitability.

Our ability to become and remain profitable will depend on our ability to generate revenue. Although we may be entitled to future milestone payments and royalties under the AVP-825 License Agreement, to date we have not commercialized any of our other product candidates and will therefore depend upon our ability to successfully commercialize OPN-375, if approved, and any of our other product candidates or any other product candidates that we may in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for OPN-375 or any of our other product candidates, we do not know when any of these product candidates will generate revenue for us, if at all. Our ability to generate revenue from our current or future product candidates will depend on a number of factors, including:

- our ability to obtain regulatory approval for, and successfully commercialize, OPN-375 for the treatment of nasal polyposis;
- our ability to complete and submit a supplemental new drug application to the FDA and obtain regulatory approval for OPN-375 for the treatment of chronic sinusitis;
- our ability to complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize OPN-375 outside the United States;
- the size of the markets in the territories for which we gain regulatory approval;
- our ability to find a suitable contract sales organization to help us market and promote OPN-375, if approved;
- our ability to develop a commercial organization capable of sales, marketing and distribution for OPN-375 and any of our other product candidates for which we may obtain marketing approval;
- our ability to maintain commercially reasonable agreements with wholesalers, distributors and other third-parties in our supply chain;
- our success in establishing a commercially viable price for our products;
- our success in defending against potential generic competition and other developments in our market generally;
- our ability to manufacture commercial quantities of our products at acceptable cost levels;
- our ability to obtain coverage and adequate reimbursement from third-parties, including government payors; and
- our ability to successfully complete development activities, including the necessary clinical trials, with respect to our other product candidates.

Even if OPN-375 or any of our other product candidates is approved for commercial sale, such approved product may not gain market acceptance or achieve commercial success. If our addressable market is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or clinical practice guidelines, we may not generate significant revenue from sales of OPN-375. In addition, we would anticipate incurring significant costs associated with commercializing any approved product. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenues, we will not become profitable and may be unable to continue operations without continued funding.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain drug approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will likely require additional capital to fund our operations and, if we fail to obtain necessary financing, we may be unable to complete the commercialization of OPN-375 and the development of our other product candidates.

Our operations have consumed substantial amounts of cash. To date, we have financed our operations primarily through the sale and issuance of preferred stock and licensing revenues under the AVP-825 License Agreement and research grants. We expect to continue to spend substantial amounts to commercialize OPN-375, if approved, and to advance the clinical development of OPN-375 for the treatment of chronic sinusitis and our other product candidates. As of June 30, 2017, we had cash and cash equivalents of $58.9 million. We believe the net proceeds from this offering, together with existing cash and cash equivalents, will be sufficient to fund our operations until . During this period, we expect to launch OPN-375 in the United States, if approved, continue our clinical development plans to seek approval for OPN-375 for the treatment of chronic sinusitis and continue our early-stage development efforts with respect to our other product candidates. Our estimate of the period of time through which our financial resources will be adequate to support our operations is based on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we currently expect.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the success of our commercialization of OPN-375 for the treatment of nasal polyposis, if approved;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- our clinical development plans for OPN-375, including FDA-mandated pediatric studies and clinical trials for the follow-on indication for the treatment of chronic sinusitis;
- the outcome, timing and cost of the regulatory approval process of OPN-375 for nasal polyposis and chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- potential future licensing revenue from the AVP-825 License Agreement;
- the initiation, progress, timing, costs and results of clinical trials for our other product candidates; and
- the extent to which we in-license or acquire other products, product candidates or technologies.

We cannot be certain that additional funding will be available when needed on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts, when required or on acceptable terms, we also could be required to:

- seek strategic collaborations to assist in the commercialization of OPN-375 in the United States and other markets;
- significantly delay, scale back or discontinue the development of OPN-375 for the treatment of chronic sinusitis;
- relinquish or license on unfavorable terms our rights to our EDS technology or other product candidates that we otherwise would seek to develop or commercialize ourselves;
- delay, limit, reduce or terminate the drug development of our current or future product candidates, or seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- significantly curtail our operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We do not have any committed external source of funds other than potential milestone payments and royalties under the AVP-825 License Agreement. Until such time, if ever, as we can generate substantial revenue, we may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property.

If we raise additional funds through collaborations, or strategic alliance, marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2016, we had U.S. net operating loss, or NOL, carryforwards of approximately $11.6 million for U.S. federal income tax and state tax purposes available to offset future taxable income and U.S. federal and state research and development tax credits of $2.2 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382. The U.S. NOL carryforwards begin to expire in 2030 if not utilized. In addition, we had foreign NOLs of $80.6 million as of December 31, 2016, as a result of our operations in Norway and the United Kingdom. Such foreign NOL carryforwards do not expire but can only be used to offset profits generated in each respective country.

While a majority of our NOLs are in foreign jurisdictions and not subject to expiration, our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under Section 382, and corresponding provisions of U.S. state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change U.S. NOLs and other pre-change tax attributes, such as research and development tax credits, to offset its post-change income may be limited. We have not performed any analyses under Section 382 and cannot forecast or otherwise determine our ability to derive benefit from our various federal or state tax attribute carryforwards. As a result, if we earn net taxable income, our ability to use our pre-change U.S. NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of U.S. NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including this offering, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Foreign exchange risks and controls may affect our financial position and results of operations.

Through the operation of our subsidiaries based in the United Kingdom and Norway, we are exposed to foreign currency fluctuations and exchange rate risks. In addition to the operations of our foreign

subsidiaries, we also contract with vendors that are located outside the United States, and in some cases make payment of invoices denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements and we do not currently hedge our foreign currency exchange rate risk. In addition, because we maintain our consolidated financial statements in U.S. dollars, our financial results are vulnerable to fluctuations in the exchange rate between the U.S. dollar and foreign currencies, such as the British pound sterling, the euro, and the Norwegian krone. In preparing our consolidated financial statements, we must convert all non-U.S. dollar results to U.S. dollars, which impacts our results of operations, is reflected as a component of our stockholder's equity (deficit), and may be credited or charged to operations and reflected in other income (expense), net. The impact of changes in exchange rates has not been significant historically. However, changes in exchange rates could cause significant changes in our financial position and results of operations in the future.

Risks Related to Clinical Development and Regulatory Approval of OPN-375

We are substantially dependent on the success of our lead product candidate OPN-375, which is in a later stage of development than our other product candidates. To the extent regulatory approval of OPN-375 is delayed or not granted, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

We are focusing a significant portion of our activities and resources on our lead product candidate, OPN-375, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully develop, obtain regulatory approval for, and successfully commercialize OPN-375. The regulatory approval of OPN-375 is subject to many risks, including the risks discussed in other risk factors set forth in this prospectus, and OPN-375 may not receive marketing approval from any regulatory agency. If the results or timing of regulatory filings, the regulatory process, regulatory developments, any additional clinical trials or preclinical studies, or other activities, actions or decisions related to OPN-375 do not meet our or others' expectations, the market price of our common stock could decline significantly.

We submitted a new drug application, or NDA, for OPN-375 for the treatment of nasal polyposis in November 2016. Our NDA was subsequently accepted for filing and review by the FDA in January 2017. Under the Prescription Drug User Fee Act, or PDUFA, a decision on our NDA is anticipated in September 2017. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase 3 clinical trials or other aspects of our NDA are not sufficient for regulatory approval and may issue a complete response letter, or CRL, instead of approval. If we receive a CRL, the FDA would outline deficiencies in our NDA and may request the submission of additional information, including preclinical and clinical data. The FDA has also begun to inspect our facilities and the facilities of our third-party manufacturers, and may also inspect one or more of our clinical trial sites. If any facility or site reveals anomalies or does not otherwise have a satisfactory inspection, the FDA could delay or preclude approval of our NDA. In either case, our commercialization of OPN-375 may be delayed and we may incur additional costs and be required to devote additional resources to address the FDA's concerns. If the FDA requires us to conduct additional clinical trials or studies or requires our manufacturers to improve or change their practices, our timeline for commercialization of OPN-375 will be delayed and we will incur additional costs. Further, there can be no assurance that we will complete such studies or clinical trials or address manufacturing issues in a manner that is acceptable to the FDA.

Any delay or setback in the development or regulatory approval of OPN-375 will adversely affect our business and could cause our stock price to decline. Should our recent Phase 3 clinical development program be insufficient to support regulatory approval, we may be forced to rely on our other product candidates, which are at an earlier development stage and will require significant additional time and resources to conduct clinical development, obtain regulatory approval and proceed with commercialization. We cannot assure you that we will be able to obtain approval for OPN-375 from the FDA.

Even if the FDA were to grant approval of OPN-375, the terms of the approval may limit its commercial potential.

Even if we were to successfully obtain approval from the FDA for OPN-375 for the treatment of nasal polyposis, any such approval might significantly limit the approved indications for use or patient populations, require that black box warnings, contraindications or warnings and precautions be included on the product labeling, require expensive and time-consuming post-approval clinical trials, Risk Evaluation and Mitigation Strategy, or REMS, or surveillance as conditions of approval, or, through product labeling limit the claims that we may make, any of which may impede the successful commercialization of OPN-375. For example, intranasal steroids, or INS, such as fluticasone propionate, commonly include nasal septal perforation as a warning and precaution on their product label. Depending on the extent of any REMS requirements, our costs to commercialize OPN-375 may increase significantly and distribution restrictions could limit sales. Further, if the approval of OPN-375 contains other significant product label limitations, our ability to address our full target market will be reduced and our ability to realize the full market potential of OPN-375 will be harmed and we may have to limit our sales and marketing efforts.

Our development and commercialization strategy for OPN-375 depends, in part, on published scientific literature and the FDA's prior findings regarding the safety of approved products containing the topical steroid fluticasone propionate based on data not developed by us, but upon which the FDA may rely in reviewing our NDA.

Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FD&C Act, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an already-approved product, which is referred to as the reference listed drug, or RLD. The FDA may also require companies to perform additional clinical trials or measurements to support any differences from the RLD. Our NDA for OPN-375 relies, in part, on the FDA's previous findings of safety and published literature for Flonase and Flovent HFA, both of which contain fluticasone propionate, which is the same active pharmaceutical ingredient in OPN-375. Even though we may be able to utilize the Section 505(b)(2) pathway for potential U.S. approval for OPN-375, the FDA may require us to perform additional preclinical and clinical trials or measurements to support approval. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), if the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of OPN-375.

The approval process for combination products, such as OPN-375, may be more complex and more time consuming than if our products were to be reviewed under the jurisdiction of only one center within the FDA.

Our product candidates include products that combine drug and device constituent parts in a manner that the FDA considers to meet the definition of a "combination product" under FDA regulations. The FDA exercises significant discretion over the regulation of combination products. For OPN-375, FDA's Center for Drug Evaluation and Research, or CDER, will have primary jurisdiction for review of the NDA. However, for a drug-device combination product CDER typically consults with the Center for Devices and Radiological Health in the NDA review process, for example, to evaluate or consult on device performance data submitted by the applicant. The review of combination products often is more complex than the review of a product under the jurisdiction of only one center within the FDA.

We will need to obtain approval for any proposed names for OPN-375, and any delay associated with doing so could delay commercialization of OPN-375, and adversely impact our business.

The proprietary name we propose to use with OPN-375 in the United States must be reviewed and accepted by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA reviews any proposed product name, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any proposed proprietary product name for OPN-375, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA.

OPN-375 may become associated with undesirable adverse reactions or have other properties that could delay or prevent its regulatory approval, or limit its labeling, if approved.

Undesirable adverse reactions associated with OPN-375 could result in a restrictive label or the delay, denial or withdrawal of regulatory approval by the FDA. For example, in our clinical trials there were some instances of adverse reactions associated with local effects at the site of administration in the nasal cavity. In our two supportive open-label Phase 3 clinical trials in patients with chronic sinusitis with and without nasal polyps, a total of 12 patients experienced a total of 14 serious adverse effects, or SAEs, none of which were deemed treatment-related. In our two Phase 3 pivotal trials in patients with nasal polyposis, a total of six patients experienced a total of seven SAEs, only one of which, in a patient in the placebo group, was determined to be treatment-related. The FDA may disagree with any of the determinations regarding these SAEs.

Risks Related to Commercialization of OPN-375

We have no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Although our predecessor and subsidiary OptiNose AS commenced operations in 2000, our operations to date have been largely focused on raising capital and developing AVP-825 and OPN-375, including undertaking preclinical studies and conducting clinical trials. While we conducted the initial stages of clinical development for AVP-825, Avanir was responsible for completing the clinical development of, obtaining regulatory approval for, and initiating the commercial launch of that product under our license agreement with them. To date, we have not yet demonstrated our ability to successfully complete clinical development through the submission and attainment of marketing approvals for any product candidate, manufacture at commercial scale, or, with the exception of AVP-825, arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing drugs.

If we are unable to successfully commercialize OPN-375, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

Even if we receive regulatory approval of OPN-375 from the FDA for the treatment of nasal polyposis, our ability to successfully commercialize it will depend on many factors, including:

- our ability to manufacture commercial quantities of OPN-375 at a reasonable cost and with sufficient speed to meet commercial demand;
- our ability to engage a third-party sales organization to market and sell OPN-375;
- our success in educating physicians, patients and caregivers about the benefits, administration and use of OPN-375;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of competing products;
- the availability of coverage and adequate reimbursement for OPN-375;

- our ability to contract with wholesalers and/or specialty pharmaceutical distributors on acceptable terms;
- the effectiveness of our marketing campaigns;
- our effective use of promotional resources;
- a continued acceptable safety profile for OPN-375;
- our ability to obtain appropriate state licenses in the states in which we intend to sell OPN-375; and
- our ability to successfully defend any challenges to our intellectual property relating to OPN-375.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will be able to successfully commercialize or generate revenue from OPN-375, even if we receive regulatory approval. If we cannot do so, or are significantly delayed in doing so, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

The commercial success of OPN-375 will depend upon its acceptance by multiple stakeholders, including physicians, patients and healthcare payors.

Physicians may not prescribe OPN-375 even if it is approved by the FDA, in which case we would not generate the revenues we anticipate. The degree of market acceptance of OPN-375 will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience and ease of administration;
- pricing and cost-effectiveness;
- availability of alternative treatments and perceived advantages over such alternative treatments;
- the clinical indications for which OPN-375 is approved;
- the prevalence and severity of any AEs;
- restrictions placed on OPN-375 in connection with its approval;
- limitations or warnings contained in the FDA-approved label for OPN-375;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- consolidation among healthcare providers, which increases the impact of the loss of any relationship;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If OPN-375 is approved, but does not achieve an adequate level of acceptance by physicians, patients and healthcare payors, we may not generate sufficient revenue in order to become or remain profitable.

If third-party payors do not reimburse patients for OPN-375 or if reimbursement levels are set too low for us to sell OPN-375 at a profit, our ability to successfully commercialize OPN-375 and our results of operations will be harmed.

Our ability to commercialize OPN-375 successfully will depend in part on the extent to which coverage and adequate reimbursement for OPN-375 will be available in a timely manner from third-party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by particular third-party payors depend upon a number of factors, including each third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific condition or disease;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for OPN-375 from government authorities or other third-party payors may be a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data, including expensive pharmacoeconomic studies beyond the data required to obtain marketing approval, for the use of OPN-375 to each government authority or other third-party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement.

Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost-effective diagnosis methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for procedures and devices deemed to be experimental. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

Increasingly, third-party payors are also requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. These third-party payors could also impose price controls and other conditions that must be met by patients prior to providing coverage for use of OPN-375. For example, insurers may establish a "step-edit" system that requires a patient to first use a lower price alternative product prior to becoming eligible for reimbursement of a higher price product.

Third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and reimbursement available for OPN-375, which in turn, could negatively impact pricing. If patients are not adequately reimbursed for OPN-375, they may reduce or discontinue purchases of it, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition.

If we are unable to differentiate OPN-375 from current and future products or existing methods of treatments, our ability to successfully commercialize OPN-375 would be adversely affected.

Once approved, we initially intend to commercialize OPN-375 for the treatment of nasal polyposis and seek FDA approval for a follow-on indication of OPN-375 for the treatment of chronic sinusitis. Currently, Nasonex, marketed by Merck, is the only drug therapy approved by the FDA for the treatment of nasal polyposis. In addition, Beconase AQ, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection. We are not aware of any product approved for the treatment of chronic sinusitis. In addition to competition from Nasonex and Beconase AQ, we will also need to differentiate OPN-375 from other products and treatments identified in current clinical practice guidelines for the treatment of chronic rhinosinusitis with and without nasal polyps. Such products and treatments include the use of nasal rinses, decongestants, over-the-counter and INS products, oral steroids, antibiotics, and sinus surgery and other procedures, including functional endoscopic sinus surgery, balloon sinus dilation and steroid-releasing sinus implants. In addition, several biologic monoclonal antibodies are in clinical development for the treatment of nasal polyposis, including omalizumab, reslizumab, mepolizumab and dupilumab. If we are unable to achieve significant differentiation for OPN-375 against these other products and treatments, including on the basis of efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement, the opportunity for OPN-375 to be commercialized successfully would be adversely affected.

If the market opportunities for OPN-375 are smaller than we believe, our revenue may be adversely affected, and our business may suffer.

Our initial target market for OPN-375 will consist of ENT physicians, allergists and high-decile INS-prescribing primary care physicians that we believe treat an estimated 3.5 million U.S. patients with chronic rhinosinusitis, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. If we are able to obtain a follow-on indication of OPN-375 for the treatment of chronic sinusitis, we intend to broaden our reach and target primary care physicians that we believe treat an additional estimated 6.25 million patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps.

Our projections of both the number of people who suffer from chronic rhinosinusitis with and without nasal polyps, as well as the subset of people with these diseases who have the potential to benefit from use of OPN-375, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys we commissioned, prescription data or other market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of chronic rhinosinusitis or nasal polyposis. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for OPN-375 may be limited or may not be amenable to treatment with OPN-375, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

Clinical practice guidelines and recommendations published by various organizations could have significant influence on the use of OPN-375, if approved.

Government agencies may promulgate clinical practice guidelines directly applicable to OPN-375, if approved. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of OPN-375, if approved, or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of OPN-375, if approved.

If we are unable to enter into agreements with third parties to market and sell OPN-375, if approved, we may be unable to generate any revenue for OPN-375.

We currently have limited sales, marketing or distribution capabilities. We intend to use an outsourced contract sales organization, or CSO, to promote OPN-375, if approved, to our defined specialty audience of ENT and allergy specialists and high-decile INS-prescribing primary care physicians, although to date we have not entered into any such agreements. Any CSO that we may use may not dedicate sufficient resources to the commercialization of OPN-375 or may otherwise fail in its commercialization due to factors beyond our control. Additionally, any CSO that we may use may fail to comply with applicable legal or regulatory requirements, or may enter into agreements with other parties that have products and services that could compete with OPN-375.

In the event that we fail to successfully launch and commercialize OPN-375 through a CSO, we may also enter into a strategic collaboration with a third party. We face significant competition in seeking appropriate strategic collaborators, and these strategic collaborations can be intricate and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic collaborations because of the numerous risks and uncertainties associated with establishing strategic partnerships.

OPN-375 may become associated with undesirable adverse reactions or have other properties that could result in significant negative consequences following regulatory approval.

If OPN-375 receives FDA regulatory approval, and we or others later identify adverse events, or AEs, associated with OPN-375, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of OPN-375;
- the FDA may withdraw its approval of OPN-375 or impose restrictions on its distribution;
- the FDA may require additional warnings or contradictions in the label that could diminish the usage or otherwise limit the commercial success of OPN-375;
- we may be required to conduct additional post-marketing studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of OPN-375, if approved.

If the FDA or other applicable regulatory authorities approve generic or similar products that compete with OPN-375, it could decrease our expected sales of OPN-375.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated NDA, or ANDA. The FD&C Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA for generic substitutes. Manufacturers may be able to bring a generic product to market in a much more cost-efficient pathway than we currently anticipate. If the costs involved in bringing such a product to market are significantly less than our costs with respect to the development of OPN-375, companies that produce generic equivalents to OPN-375 may be able to offer their products at lower prices. As such, a significant percentage of any future sales of OPN-375 could be lost to any such generic products. Moreover, in addition to generic competition, we could face competition from other companies seeking approval of products that are similar to ours using the Section 505(b)(2) pathway. Such applicants may be able to rely on OPN-375, if approved, or other approved drug products or published literature to develop drug products that are similar to ours. The introduction of a drug product similar to our product candidates could expose us to increased competition, leading to a decrease in sales of OPN-375. Competition that we may face from generic or similar versions of OPN-375 could materially and adversely impact our future revenue, profitability, and cash flows.

Even if we obtain regulatory approval for OPN-375, we will still face extensive FDA regulatory requirements and may face future regulatory difficulties.

Even if we obtain regulatory approval in the United States for OPN-375, the FDA and state regulatory authorities may still impose significant restrictions on the indicated uses or marketing of OPN-375, or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. For example, we will be required by the FDA to conduct pediatric studies for OPN-375 for the treatment of nasal polyposis. Because our EDS for OPN-375 was designed for use in adult patients, we may discover that the dimensions of this EDS make it unsuitable for use in pediatric patient populations. As such, this pediatric study may also require us to undergo a costly and time-consuming development process to design and manufacture as appropriate a modified EDS to conduct these studies.

If OPN-375 is approved, we will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-marketing information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the

approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA regulations and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the United States grant similar powers to the competent authorities and impose similar obligations on companies.

In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practice, or cGMP, regulations and adherence to commitments made in the NDA. Since OPN-375 is a combination product, it is also likely that we will need to comply with some of the FDA's manufacturing regulations for devices. The FDA has discretion in determining post-approval compliance requirements for products that combine a drug substance with a delivery system device. In addition to cGMP, the FDA may require that our drug-device combination product, if approved, comply with the Quality System Regulation, or QSR, which sets forth the FDA's manufacturing quality standards for medical devices, and other applicable government regulations and corresponding foreign standards. If we, or a regulatory authority, discover previously unknown problems with OPN-375 following approval, such as AEs, of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to OPN-375 or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by foreign regulatory authorities.

If we fail to comply with applicable regulatory requirements following approval of OPN-375, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, modify or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or a pending application for marketing authorization or supplements to an NDA or to an application for marketing authorization submitted by us;
- seize our product candidate; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

If we obtain regulatory approval for OPN-375, our relationships with physicians, patients and payors in the U.S. will be subject to applicable anti-kickback, fraud and abuse laws and regulations. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.

Although we have not obtained approval for OPN-375 and begun our commercial launch for OPN-375, our current and future operations with respect to the commercialization of OPN-375 will be subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and others who may prescribe, recommend, purchase or provide OPN-375, and other parties through which we market, sell and distribute OPN-375, if approved. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws are described in greater detail in the section below under "Business — Government Regulation — Healthcare Fraud and Abuse Laws," and include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare

programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and

- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity in addition to the aforementioned potential regulatory actions. The occurrence of any event or penalty described above may inhibit our ability to commercialize OPN-375, if approved, and generate revenues which would have a material adverse effect on our business, financial condition and results of operations.

If we are able to successfully commercialize OPN-375 and if we participate in but fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we participate in the Medicaid Drug Rebate Program, and other governmental pricing programs, we will be obligated to pay certain specified rebates and report pricing information with respect to OPN-375, if approved. Pricing and rebate calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by the Centers for Medicare & Medicaid Services, or CMS, to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price, or AMP, and best price for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the Public Health Service's 340B drug pricing program, or the 340B program, and under other similar government pricing programs. These programs are described in greater detail in the section below under "Business — Government Regulation — Coverage and Reimbursement."

We will also be liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP, or best price information to the government, we may be liable for civil monetary penalties in the amount of $181,071 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, we may be liable for civil monetary penalties of up to $13,066 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP and best price data on a timely basis could result in a civil monetary penalty of $18,107 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid for OPN-375, if approved. A final regulation imposes a civil monetary penalty of up to $5,000 for each instance of knowingly and intentionally charging a 340B covered entity more than the 340B ceiling price.

Federal law requires that a company must participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program to be eligible to have its products paid for with federal funds. As part of this program, we would be obligated to make OPN-375 available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health Service, and U.S. Coast Guard). The FCP is based on the

Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the U.S. civil False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Our promotional materials, statements and training methods must comply with applicable laws and regulations, including FDA's prohibition of the promotion of unapproved, or off-label, use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's independent choice of treatment within the practice of medicine. As healthcare professionals frequently prescribe corticosteroids for the treatment of chronic nasal inflammatory diseases, such as chronic rhinosinusitis, doctors could prescribe OPN-375, if approved, for the treatment of chronic sinusitis and other chronic nasal inflammatory diseases, even though we are initially seeking regulatory approval of OPN-375 only for the treatment of nasal polyposis. If the FDA determines that our promotional materials, statements or activities constitute promotion of an off-label use, we could be required to modify our promotional materials, statements or training methods or subject us to regulatory or enforcement actions, such as the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, disgorgement of money, operating restrictions or criminal penalties. We may also be subject to actions by other governmental entities or private parties, such as the U.S. civil False Claims Act, civil whistleblower or "qui tam" actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional, materials or activities to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities. In that event, our reputation could be damaged and market adoption of OPN-375 could be impaired.

Even if we obtain FDA approval for OPN-375 in the United States, we may never obtain approval for or successfully commercialize it outside of the United States, which would limit our ability to realize its full market potential.

In order to market OPN-375 outside of the United States, we must obtain marketing authorizations and comply with numerous and varying regulatory requirements of other countries regarding quality, safety and efficacy. Clinical trials conducted in one country may not be accepted by foreign regulatory authorities, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of OPN-375 in those countries. While our management team has experience in obtaining foreign regulatory approvals at other companies, we do not have any product candidates approved for sale in any foreign jurisdiction, and we, as a company, do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market for OPN-375 will be reduced and we would not be able to realize the full market potential of OPN-375.

The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to obtain marketing approval of and commercialize OPN-375, if approved, and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of OPN-375, if approved, restrict or regulate post-approval activities and affect our ability to profitably sell OPN-375, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. These intended reforms are described in greater detail in the section below under "Business — Government Regulation — U.S. Healthcare Reform."

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of OPN-375, if approved, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Legislative changes to or regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration. The American Health Care Act of 2017, or AHCA, which would repeal and replace key portions of the Affordable Care Act was passed by the U.S. House of Representatives but remains subject to passage by the U.S. Senate. In addition, in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any

provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of OPN-375, if approved, or to successfully commercialize OPN-375, if approved.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for OPN-375, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize OPN-375.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of OPN-375 and any other product candidates that we may develop.

We currently face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and this risk will increase significantly as we commercialize OPN-375 and other product candidates that we may develop. We may face product liability claims, regardless of FDA approval for commercial manufacturing and sale as product liability claims may be brought against us by patients who have used OPN-375 in any of our clinical trials, future patients, healthcare providers or others using, administering or selling our products, if and when approved. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for OPN-375;
- injury to our reputation and significant negative media attention;
- termination of clinical trial sites or entire trial programs that we conduct in the future relating to OPN-375 or our other product candidates;
- withdrawal of clinical trial participants from any future clinical trial relating to OPN-375 or our other product candidates;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

We currently carry product liability insurance with coverage up to $5.0 million in the aggregate, with a per incident limit of $5.0 million, which may not be adequate to cover all liabilities that we may incur. Further, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to maintain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of OPN-375 or the development of our other product candidates.

Additionally, any agreements we may enter into in the future with collaborators in connection with the development or commercialization of OPN-375 or any of our other product candidates may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, several of our agreements require us to indemnify third parties and these indemnifications obligations may exceed the coverage under our product liability insurance policy. For example, the AVP-825 License Agreement provides for reciprocal indemnification obligations for each of the

parties in the event that a product liability claim arises from, among other things, one party's development, manufacture, sale or commercialization activities for AVP-825.

Risks Related to Clinical Development and Regulatory Approval of OPN-375 for the Treatment of Chronic Sinusitis and Our Other Product Candidates

The design and execution of clinical trials to support FDA-approval of OPN-375 for the treatment of chronic sinusitis is subject to substantial risk and uncertainty.

Subject to FDA approval of OPN-375 for the treatment of nasal polyposis, we intend to initiate a clinical program to support a follow-on indication of OPN-375 for the treatment of chronic sinusitis. Similar to our NDA for OPN-375 for the treatment of nasal polyposis, we believe we may also be able to use the Section 505(b)(2) pathway for potential U.S. approval for OPN-375 for the treatment of chronic sinusitis. Because there is no FDA-approved product for the treatment of chronic sinusitis, we believe there is substantial risk and uncertainty in planning and conducting adequate clinical trials to meet FDA requirements to support approval for this indication. If the clinical program required by the FDA is more costly or time-consuming than anticipated, we may decide to not pursue this follow-on indication. Additionally, if we do conduct clinical trials for this indication, OPN-375 may not demonstrate sufficient efficacy or safety to support FDA approval. If we do not obtain a follow-on indication for the treatment of chronic sinusitis, our promotion of OPN-375 will be limited to nasal polyposis, which would limit our potential sales of OPN-375.

The regulatory approval processes of the FDA are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory agency. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA may not accept our NDA filing;
- the FDA may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA;
- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may change in a manner rendering our clinical data insufficient for approval.

With the exception of our recent NDA submission for OPN-375, we have not previously submitted an NDA or any similar drug approval filing to the FDA for any product candidate, and we cannot be certain that any of our current product candidates will receive regulatory approval. If we do not receive regulatory approval for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If

the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.

Clinical trials are expensive, can take many years to complete and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our clinical trials for the follow-on indication of OPN-375 for the treatment of chronic sinusitis or our other product candidates may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for these product candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA, the FDA may not approve that product candidate and we would not be able to commercialize it, which could impair our ability to gain or maintain profitability.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including, but not limited to:

- inability to raise funding necessary to initiate or continue a clinical trial;
- delays in obtaining regulatory approval to commence a clinical trial;
- delays in reaching agreement with the FDA or foreign regulatory authorities on final trial design or the scope of the development program;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board, or IRB, approval;
- delays in recruiting suitable patients to participate in a clinical trial;
- patients' delays or failure to complete participation in a clinical trial or return for post-treatment follow-up;
- clinical sites dropping out of a clinical trial;
- time required to add new clinical sites; or
- delays by our contract manufacturing organizations, or CMOs, to produce and deliver a sufficient supply of clinical trial materials.

If clinical trials for our product candidates are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed.

We will need to identify proprietary names for our product candidates that are acceptable to FDA, and any delay associated with doing so may adversely impact our business.

Any proprietary name we propose to use with our product candidates in the United States must be reviewed and accepted by the FDA, regardless of whether we have registered it, or applied to register it, as a

trademark. The FDA reviews any proposed product name, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any proposed proprietary product name, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Our product candidates, if approved, may require REMS, which may significantly increase our costs.

Our product candidates, if approved, may require REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to healthcare professionals and restrictions on distribution and use. We cannot predict the specific scope or magnitude of REMS that may be required as part of the FDA's approval of our other product candidates. Depending on the extent of the REMS requirements, our costs to commercialize our product candidates may increase significantly and distribution restrictions could limit sales. Similar requirements may arise in countries outside of the United States.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our other product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

If we are required to conduct additional clinical trials or other studies with respect to our product candidates beyond those that we currently contemplate, or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval of any of our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval of indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for our product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

Risks Related to Our Reliance on Third Parties

If we encounter difficulties in negotiating commercial manufacturing and supply agreements with our third-party manufacturers and suppliers of OPN-375, our ability to commercialize OPN-375, if approved, would be impaired.

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources and expertise to manufacture and test, on a commercial scale, the technical performance of OPN-375 and our other product candidates. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and CMOs and suppliers who assist in the production, assembly, test, supply, storage and distribution of OPN-375 and its components in our clinical trials and FDA registration, and we control only some of the aspects of their activities. We may not be able to obtain terms that are favorable to us or enter into commercial manufacturing and supply agreements at all with each of the necessary third parties. If we are unable to enter into such agreements on commercially

reasonable terms, our ability to commercialize OPN-375, if approved, would be impaired, and our business, financial condition and results of operations would be materially adversely affected.

If we encounter issues with our contract manufacturers or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply OPN-375.

We currently depend on contract manufacturers and suppliers for OPN-375 and its components. Although we could obtain each of these components from other third-party suppliers, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for each such component, which could be costly and cause significant delays. Each of our current commercial manufacturing and supply agreements include limitations on our ability to utilize alternative manufacturers or suppliers for these components above certain specified thresholds during the terms of the agreements, which impairs our ability to prepare in advance for any future manufacturing and supply shortages or quality issues.

In addition, some of our suppliers, including our active pharmaceutical ingredient, or API, supplier and our contract manufacturers, conduct their manufacturing operations for us at a single facility. Unless and until we qualify additional facilities, we may face limitations in our ability to respond to manufacturing and supply issues. For example, if regulatory, manufacturing or other problems require one of these manufacturers or suppliers to discontinue production at their respective facility, or if the equipment used for the production of OPN-375 in these facilities is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer or supplier to provide components or API needed for OPN-375, or to manufacture OPN-375 may be significantly impaired. In the event that these parties suffer a temporary or protracted loss of its facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer or supplier, as applicable, as an alternate manufacturer or source for the respective component before any components manufactured by such manufacturer or by such supplier could be sold or used.

Any production shortfall that impairs the supply of OPN-375 or any of these components could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for OPN-375, which could adversely affect our product sales and operating results materially.

If third-party manufacturers, wholesalers and distributors fail to devote sufficient time and resources to OPN-375 or their performance is substandard, our product launch may be delayed and our costs may be higher than expected.

Our reliance on a limited number of manufacturers, wholesalers and distributors exposes us to the following risks, any of which could delay FDA approval of our product candidates and commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;
- our wholesalers and distributors could become unable to sell and deliver OPN-375 for regulatory, compliance and other reasons;
- our CMOs, wholesalers and distributors could default on their agreements with us to meet our requirements for commercialization of OPN-375;
- our CMOs, wholesalers and distributors may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell and distribute our products and we may incur additional cost; and

- if our CMOs, wholesalers and distributors were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay our commercial programs.

Our reliance on third parties reduces our control over our product candidate development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of OPN-375 and conduct required stability testing, issues may arise involving product-packaging and third-party equipment malfunctions. These issues may require refinement or resolution in order to proceed with commercial marketing of OPN-375 upon regulatory approval. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in our product or delivery devices could result in increased scrutiny by regulatory authorities, delays in our regulatory approval process, increases in our operating expenses, or failure to obtain or maintain approval for our products.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We have relied upon and plan to continue to rely upon CROs to monitor and manage data for our prospective preclinical and clinical programs. We rely on these parties for execution of our clinical trials, and we control only some of the aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with federal regulations and current Good Clinical Practices, or GCP, which are international standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, advisors and monitors. GCPs are enforced by the FDA and foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our product candidates in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat preclinical studies and clinical trials, which would increase our operating expenses and delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. For example, the FDA notified us of their inspection findings related to one of our CROs and a single clinical trial site that was part of our Phase 3 trials for OPN-375. Although we have responded, we have not yet received notice that the FDA has completed its review, nor have we received confirmation that no corrective action will be required. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons or if we receive additional FDA notices that do require corrective action, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our product candidates through clinical trials will be compromised. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain and have the full attention of our key executives and to attract, retain and motivate other qualified personnel.

We are highly dependent on the management, development, clinical, financial and business development expertise of our executive team and, in particular, the services of Peter K. Miller, our Chief Executive Officer, and Ramy A. Mahmoud, our President and Chief Operating Officer. Each of Mr. Miller and Dr. Mahmoud is employed by us at will and is permitted to terminate his employment with us at any time. We anticipate entering into new employment agreements with Mr. Miller and Dr. Mahmoud to be effective upon the consummation of this offering, but we expect that Mr. Miller and Dr. Mahmoud will continue to be employed at will. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of Mr. Miller or Dr. Mahmoud could impede the achievement of our development and commercialization objectives.

Recruiting and retaining qualified employees for our business, including scientific, technical and sales and marketing personnel, will also be critical to our success. Competition for skilled personnel in our industry is

intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in our commercialization efforts or in the performance of any future clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our research, development and commercialization objectives.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

Implementation of our development and commercialization strategies will require additional managerial, operational, sales, marketing, financial and other resources. Our current management, personnel and systems may not be adequate to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, employee turnover and reduced productivity. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of any approved product candidates;
- overseeing our preclinical studies and clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any sales and marketing personnel engaged in connection with the commercialization of any approved product;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; and
- improving our managerial, development, operational and financial systems and procedures.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. Failure to accomplish any of these activities could prevent us from successfully growing our company.

We are subject to intense competition and, if we are unable to compete effectively, our product candidates, if approved, may not reach their commercial potential.

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological change as research provides a deeper understanding of the pathology of diseases and new technologies and treatments are developed. We face competition with respect to OPN-375 from INS, oral steroids and other medical management products, and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from many different sources, including large pharmaceutical, biotechnology, specialty pharmaceutical and, to a lesser degree, medical device companies.

The key competitive factors that we expect to impact the commercial success of OPN-375 and any other product candidates we may develop are likely to be their efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement. Nasonex, marketed by Merck, is currently the only drug therapy approved by the FDA for the treatment of nasal polyposis, which is our initial target indication for OPN-375. In addition, Beconase AQ, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection. We are not aware of any drug therapy approved by the FDA or foreign regulatory agencies for the treatment of chronic sinusitis.

Even though they have not been approved for the treatment of such indications, published clinical practice guidelines do recommend the use of INS products for the treatment of chronic rhinosinusitis and nasal polyposis in an effort to maximize medical therapy prior to surgical intervention. Currently approved INS products include Rhinocort, marketed by AstraZeneca, Nasacort AQ, marketed by sanofi-aventis, Beconase AQ, Flonase, and Veramyst, each marketed by GlaxoSmithKline, Qnasl, marketed by Teva Pharmaceuticals, and Omnaris and Zetonna, each marketed by Sunovion Pharmaceuticals. Due to the limitations of current treatments, several companies are investigating the treatment of nasal polyposis with biologic monoclonal antibodies. To date, four biologic monoclonal antibodies have been studied in nasal polyposis: omalizumab, reslizumab, mepolizumab and dupilumab. Most of these INS and biologics companies, as well as other potential competitors, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval of drugs and achieving widespread market acceptance. Our competitors' drugs, or drugs they may develop in the future, may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render OPN-375 or any of our other product candidates we may develop obsolete or non-competitive before we can recover the expenses of developing and commercializing OPN-375 or any of our other product candidates. Our competitors may also obtain FDA or other regulatory approval of products more rapidly than expected or may obtain better or preferred market access by offering large rebates to payors or by other means. We may not have accurately or completely predicted the development of new and improved or low-cost surgical interventions, alternative medical therapies or other market-disrupting events. If we are unable to manufacture, distribute, stimulate demand reaching the predicted market share, overcome barriers to access or otherwise effectively commercialize the product, all of which factors may be influenced by current or future competition, then our opportunity to generate revenue from the sale of OPN-375 or any of our other product candidates, if approved, will be compromised.

Our long-term growth depends on our ability to develop and commercialize additional ENT products.

It is important to our business that we continue to build a more complete product offering within the ENT and allergy markets. We are using our proprietary EDS technology to develop new product candidates for use in the ENT and allergy markets. Developing additional product candidates is expensive and time-consuming and could divert management's attention away from the commercialization of our lead product candidate OPN-375. Even if we are successful in developing additional product candidates, the success of any new product candidates or enhancement to any existing product candidates will depend on several factors, including our ability to:

- properly identify and anticipate ENT and allergy physician and patient needs;
- develop, obtain necessary regulatory clearances or approvals, and introduce new product candidates or product enhancements in a timely manner;
- demonstrate, if required, the safety and efficacy of new product candidates with data from preclinical studies and clinical trials;
- avoid infringing upon the intellectual property rights of third parties;
- comply with all regulations relating to the marketing of new product candidates, including any new or modified EDS technologies; and
- provide adequate training to potential users of our product candidates.

If we are unsuccessful in developing and commercializing additional product candidates in other areas of the ENT and allergy markets, our ability to gain and maintain profitability may be impaired.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, which could negatively impact our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial-stage products or product candidates, businesses or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to complete technology transfers and integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities as part of the transaction. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our employees, collaborators, independent contractors, principal investigators, consultants, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from third parties and severe reputational harm.

In connection with this offering, we will adopt a Code of Business Conduct and Ethics to govern and deter such behaviors, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are

instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

The security of our information technology systems may be compromised, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

Our information technology systems may be vulnerable to physical or electronic intrusions, computer viruses or other attacks. As part of our business, we and our vendors maintain large amounts of confidential information, including non-public personal information on patients and our employees. Breaches in security could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. We expect to have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, there can be no assurance that such use or disclosure will not occur.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as private litigation and/or adverse publicity, any of which could negatively affect our operating results and business.

We may be subject to laws and regulations that address privacy and data security of patients who use our product candidates in the United States and in states in which we conduct our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information. For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. Certain of these laws and regulations are described in greater detail in the section below under "Business — Government Regulation — Healthcare Privacy Laws." Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Such an event could cause interruption of our operations. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the

extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability and damage to our reputation and the development and commercialization of our product candidates could be delayed.

We are subject to risks inherent in foreign operations.

We currently operate portions of our business through our foreign subsidiaries, including through our Norwegian subsidiary, OptiNose AS, which owns all of our intellectual property and conducts development activities, and our United Kingdom subsidiary OptiNose UK Ltd., which is party to manufacturing and supply arrangements with some of our vendors and assists on some internal development for our EDS technology. We have committed, and intend to continue to commit, resources to our international operations. We are subject to a number of risks associated with our international business operations and activities that may increase liability, costs, and require significant management attention. These risks include:

- compliance with the laws of the United States, the United Kingdom, Norway, and other countries that apply to our international operations, including import and export legislation;
- compliance with foreign data protection laws and regulations in the United Kingdom, Norway and other countries that apply to our international operations;
- the complexities and expenses of administering a business abroad;
- complications in compliance with, and unexpected changes in, tariffs, trade barriers, price and exchange controls and other foreign regulatory requirements;
- instability in economic or political conditions, including inflation, recession and actual or anticipated military conflicts, social upheaval or political uncertainty;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- uncertainties of laws and enforcement relating to the protection of intellectual property or secured technology;
- litigation in foreign court systems;
- language barriers;
- changes in tax laws and regulations in the jurisdictions in which we operate;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- difficulties staffing and managing foreign operations; and
- workforce uncertainty in countries where labor unrest is more common than in the United States;

There can be no assurance that the policies and procedures we implement to address or mitigate these risks will be successful, that our personnel will comply with them or that we will not experience these factors in the future or that they will not have a material adverse effect on our business, results of operations and financial condition.

Our corporate structure and foreign operations may have adverse tax consequences and expose us to additional tax liabilities.

All of our intellectual property, including the rights to OPN-375 and the rights under the AVP-825 License Agreement, are owned by OptiNose AS, our Norwegian subsidiary. In addition, as we plan for the commercial launch of OPN-375 we anticipate that certain commercial functions may be conducted by OptiNose UK Ltd., our United Kingdom subsidiary, or any other current or potential future foreign subsidiary.

We operate pursuant to written intercompany service and related agreements, or transfer pricing agreements. These transfer pricing agreements establish transfer prices for intellectual property licenses

production, marketing, management, technology development and other services performed by our group companies for other group companies. Transfer prices are prices that one company in a group of related companies charge to another member of the group for goods, services or the use of property. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be consistent with those between unrelated companies dealing at arm's length. Our transfer pricing arrangements are not binding on applicable tax authorities, and, if tax authorities in any country were successful in challenging our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect those revised transfer prices. A reallocation of taxable income from a lower tax jurisdiction to a higher tax jurisdiction would result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation.

If we generate sales of OPN-375 in the United States or otherwise generate any other sales or revenues, a portion of the income we generate may be allocated to one or more of our current or future foreign subsidiaries and, under current U.S. law, repatriation of any cash from our foreign subsidiaries to the United States may trigger significant adverse tax consequences. If we generate cash through our foreign operations or if the cash generated by our U.S. operations is not sufficient to fund our U.S. operations, we may face challenges applying any such cash held by our foreign subsidiaries to support the growth of our U.S. operations and any strategic opportunities in the United States. If we are forced to repatriate any foreign-held cash, we could incur a significant tax charge, and our business, operating results or financial condition could be adversely impacted.

Income earned by our foreign subsidiaries may give rise to United States corporate income tax, even if there are no distributions to the United States, to the extent that our foreign subsidiaries generate income that is subject to Subpart F of the U.S. Internal Revenue Code, or Subpart F. Subpart F income includes, for example, certain "passive" income, certain income from intercompany transactions involving our foreign subsidiaries and certain income of any foreign subsidiary which makes an "investment in U.S. property," within the meaning of Subpart F, such as holding the stock in, or making a loan to, a U.S. corporation. Any income taxable under Subpart F is currently taxable in the United States at federal corporate income tax rates of up to 35.0%, even if it is not distributed to us. We have not treated any of our foreign subsidiaries' income as being Subpart F income pursuant to available exemptions for which we believe we qualify. We may, however, be required to do so and pay taxes under Subpart F on the prior and future income of our foreign subsidiaries if we do not qualify for an available exemption.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act and other U.S. and foreign anti-corruption anti-money laundering, export control, sanctions, and other trade laws and regulations, and any determination that we violated these laws could have a material adverse effect on our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. We are also subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and possibly other anti-bribery and anti-money laundering laws in countries outside of the United States in which we conduct our activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, promising, offering, providing, soliciting, or accepting, directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector. As we commercialize OPN-375 and any of other product candidates that we may develop, we may engage with third-party manufacturers and collaborators who operate abroad and are required to obtain certain necessary permits, licenses and other regulatory approvals with respect to our business. Our activities abroad create the risk of unauthorized payments or offers of payments by employees, consultants, sales agents or distributors, even though they may not always be

subject to our control. It is our policy to implement safeguards to discourage these practices by our employees, consultants, sales agents and distributors. However, our existing safeguards and any future improvements may prove to be less than effective, and the employees, consultants, sales agents, or distributors of our company may engage in conduct for which we might be held responsible, even if we do not explicitly authorize such activities.

Noncompliance with anti-corruption, anti-money laundering, export control, sanctions, and other trade laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. Responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In addition, the U.S. government may seek to hold us liable for successor liability FCPA violations committed by companies in which we invest or that we acquire. As a general matter, enforcement actions and sanctions could harm our business, results of operations, and financial condition.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology, OPN-375 or our other product candidates, our competitors could develop and commercialize technology similar to ours, and our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. Our strategy is to seek patent protection for OPN-375, our other product candidates and their compositions, their methods of use and processes for their manufacture, and any other aspects of inventions that are commercially important to the development of our business.

The patent prosecution process is expensive and time-consuming, and we and any future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, and operating results.

The patent positions of pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be impaired.

As of June 13, 2017, we owned a total of 43 U.S. patents and 35 pending U.S. patent applications. These U.S. patents will expire between 2020 and 2030. With respect to these patent rights, we do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology and drugs, in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, inter partes reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In a patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In addition, to the extent that we have to file patent litigation in a federal court against a U.S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our EDS technology. Such a loss of patent protection could compromise our ability to pursue our business strategy.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on OPN-375, our other product candidates and our EDS technology throughout the world would be prohibitively expensive, and our intellectual property rights in

some countries outside the United States may be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the United States. For example, novel formulations of existing drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions into or within the United States or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell OPN-375 and our other product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. While our product candidates are in preclinical studies and clinical trials, we believe that the use of our product candidates in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As OPN-375 and our other product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. For instance, our use of the Section 505(b)(2) regulatory pathway for the follow-on indication of chronic sinusitis or any of our other product candidates will require us to provide a Paragraph IV certification to the NDA and patent holders of the RLD pursuant to the Hatch-Waxman Act if the RLD is covered by Orange Book-listed patents. If the NDA or patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patents, settlement of the lawsuit or a court decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product candidates may be commercialized. There can be no assurance that our product candidates do not infringe

other parties' patents or other proprietary rights and competitors or other parties may assert that we infringe their proprietary rights in any event.

There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our drug candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our commercialization efforts, delay our research and development efforts and limit our ability to continue our operations. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek to market generic versions of any of our approved products by submitting ANDAs to the FDA or new products that use our approved products as the RLD, in each case where our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with OPN-375 and any future product candidates we may develop. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. In addition, on September 16, 2011, the Leahy-Smith America Invents Act, or the AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in United States federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to claims asserting that our employees, consultants, independent contractors and advisors have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Intellectual property rights do not prevent all potential threats to competitive advantages we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage.

The following examples are illustrative:

- Others may be able to make drug and device components that are the same as or similar to OPN-375 and our other product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or any of our licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- We or any of our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- The prosecution of our pending patent applications may not result in granted patents;
- Granted patents that we own or have licensed may not cover our products or may be held not infringed, invalid or unenforceable, as a result of legal challenges by our competitors;
- With respect to granted patents that we own or have licensed, especially patents that we either acquire or in-license, if certain information was withheld from or misrepresented to the patent examiner, such patents might be held to be unenforceable;
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product;
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates;
- We may not develop additional proprietary technologies that are patentable;
- The patents of others may have an adverse effect on our business; and
- We may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our product candidates and delivery technologies, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by customarily entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific and commercial collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, our trade secrets may otherwise become known, including through a potential cybersecurity breach, or may be independently developed by competitors.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have received trademark registration for OptiNose and Breath Powered in the United States. Our trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively.

Risks Related to this Offering, Ownership of Our Common Stock and Our Status as a Public Company

There is no existing market for our common stock, and we do not know if one will develop. Even if a market does develop, the stock prices in the market may not exceed the offering price.

Prior to this offering there has been no market for shares of our common stock. Although we have applied to list our common stock on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

The price of our common stock may be volatile and you may lose all or part of your investment.

The market price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- any delay in our regulatory approval or filings for OPN-375 or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter, a request for additional information, or a CRL;
- our ability to successfully commercialize OPN-375, if approved;
- the success of competitive products or technologies;
- adverse regulatory actions with respect to our product candidates, including the failure to receive regulatory approval, or our competitors' products or product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions or divestitures, strategic collaborations, joint ventures, collaborations or capital commitments;

- the commencement, enrollment or results of planned clinical trials of our product candidates or any future clinical trials we may conduct, or any changes generally in the development status of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- the outcome of any investigations or regulatory scrutiny of our operations or litigation that may be brought against us;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated variations in our quarterly operating results;
- the number and characteristics of our efforts to in-license or acquire additional product candidates or products;
- introduction of new products or services by us or our competitors;
- failure to meet the estimates and projections of the investment community or financial guidance that we may otherwise provide to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- actual or anticipated changes in estimates as to development timelines that we may provide to the public;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general political, economic, industry and market conditions;
- investors' general perception of our company and our business;
- publication of research reports about us, our competitors or our industry, or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks stated above could have a material adverse effect on the market price of our common stock.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that the holders of a large number of shares intend to sell, substantial amounts of our common stock in the public market following this offering, the market price of our common stock could decline significantly.

After this offering, we will have outstanding shares of common stock, based on the number of shares outstanding as of , 2017, but assuming no exercise of outstanding options or warrants. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. The remaining shares will be restricted as a result of contractual lock-up agreements with the underwriters for 180 days after the date of this prospectus, as described in the "Shares Eligible for Future Sale" section of this prospectus. The representatives of the underwriters may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, release all or any portion of the securities subject to lock-up agreements. In addition, pursuant to the Second Amended and Restated Shareholders' Agreement, certain of our existing stockholders will be restricted from selling securities for a 180-day period following the effective date of the registration statement of which this prospectus is a part. Moreover, after this offering, holders of an aggregate of shares of our common stock will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

We also intend to file one or more registration statements on Form S-8 promptly following the closing of this offering to register the issuance of approximately shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

Future issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options, warrants and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock, including shares of common stock sold in this offering.

We will have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion in the application of the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. You may not agree with our decisions, and our management may not apply the net proceeds of this offering in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering in the

manner described in the "Use of Proceeds" section of this prospectus. Our failure to apply these net proceeds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development and commercialization of our product candidates. Pending their use, we intend to invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results and it could compromise our ability to develop and commercialize our product candidates, either of which could cause the price of our common stock to decline.

Our principal stockholders and management own substantially all of our stock prior to this offering and will continue to be able to exert significant control over matters subject to stockholder approval after the offering, which could prevent new investors from influencing significant corporate decisions.

Upon the closing of this offering, our executive officers, directors, beneficial owners of 5% or more of our capital stock and their respective affiliates will, in the aggregate, beneficially own approximately % of our outstanding common stock, including entities associated with Avista Capital Partners II, L.P., or Avista, our largest stockholder. In addition, Avista and TKWD Ventures LLC, or TKWD, will enter into a voting agreement effective upon the closing of this offering relating to the nomination of certain individuals to be elected as members of our board of directors. Upon the closing of this offering, we expect that Avista and TKWD and their respective affiliates will collectively hold as a group approximately % of our outstanding voting stock. As a result, these stockholders, acting together, would be able to significantly influence the outcome of all matters requiring stockholder approval, including the election of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock. For instance, under the terms of our fourth amended and restated certificate of incorporation, which will become effective immediately following the closing of this offering, neither Avista, TKWD nor any of their respective representatives on our board of directors are required to offer us any transaction opportunity of which they become aware, and they could take any such opportunity for themselves or offer it to other companies in which they have an investment, unless that opportunity is expressly offered to a person serving on our board of directors solely in his or her capacity as one of our directors. These actions might affect the prevailing market price for our common stock. In addition, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquiror than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. Such concentration of ownership control may also:

- delay, defer or prevent a change in control;
- entrench our management and/or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

We may also take actions that our other stockholders do not view as beneficial, which may adversely affect our results of operations and financial condition and cause the value of your investment to decline.

Following this offering, we will be a "controlled company" within the meaning of NASDAQ listing rules and, as a result, we will qualify for, and intend to rely on, exemptions from certain corporate governance requirements. Our stockholders will not have the same protections afforded to stockholders of companies that do not rely on exemptions from corporate governance requirements.

Upon the closing of this offering, Avista and TKWD will collectively control approximately % of our outstanding common stock. As a result, we will be a "controlled company" within the meaning of the corporate governance standards of NASDAQ. Under these rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including requirements that:

- a majority of the board of directors consist of independent directors;
- the compensation of our officers be determined or recommended to the board of directors by a compensation committee that is comprised solely of independent directors; and
- director nominees be selected or recommended to the board of directors by a majority of independent directors or a nominating committee comprised solely of independent directors.

Upon the closing of this offering, we intend to utilize these exemptions. As a result, our nominating and corporate governance committee and our compensation committee will not consist entirely of independent directors. Accordingly, you will not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of NASDAQ.

Avista is not subject to any contractual obligation to retain its interest, except that it has agreed, subject to certain exceptions, not to sell or otherwise dispose of any shares of our common stock or other capital stock or other securities exercisable or convertible therefor for a period of at least 180 days after the date of this prospectus without the prior written consent of the representatives of the underwriters in this offering. Pursuant to the Second Amended and Restated Shareholders' Agreement that will be in effect upon the closing of this offering, TKWD, along with certain of our other stockholders, will not sell any shares of our common stock until the third anniversary of the closing of this offering or until the completion of an underwritten secondary offering of our common stock in which Avista participates, whichever occurs sooner. Except for these restrictions, there can be no assurance as to the period of time during which Avista or TKWD will maintain their ownership of our common stock following the offering. As a result, there can be no assurance as to the period of time during which we will be able to avail ourselves of the controlled company exemptions.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our fourth amended and restated certificate of incorporation and our amended and restated bylaws, each of which will become effective immediately following the closing of this offering, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that will:

- permit our board of directors to issue up to million shares of preferred stock, with any rights, preferences and privileges as it may designate, which issuance could result in the loss of voting control by other stockholders;
- provide that our board of directors will be classified into three classes with staggered, three-year terms and that, subject to the rights of Avista and TKWD to remove their respective director nominees with or without cause, directors may only be removed for cause by the affirmative vote of the holders of at least a majority of the voting power of outstanding shares of our capital stock;

- subject to any director nomination rights afforded Avista and TKWD, provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- following the date that Avista and TKWD cease to hold a majority of the outstanding shares of our common stock, require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- provide that, with the exception of director nominees submitted by Avista and TKWD pursuant to our Second Amended and Restated Shareholders' Agreement, stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

- require that the amendment of certain provisions of our certificate of incorporation and bylaws relating to anti-takeover measures may only be approved by a vote of % of our outstanding common stock;

- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

- provide that special meetings of our stockholders may be called only by the chairman or vice chairman of our board of directors, our chief executive officer, a majority of our board of directors or, for so long as Avista and TKWD hold a controlling ownership interest in our common stock, by the holders of a majority of our outstanding common stock.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Under our fourth amended and restated certificate of incorporation, once Avista and TKWD collectively cease to own 10% or more of our capital stock, we will be governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, prior to the time the stockholder has become an interested stockholder, the board of directors has approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder.

These provisions of our fourth amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law could have the effect of discouraging potential acquisition proposals and delaying or preventing a change in control. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests or provide an opportunity for our stockholders to receive a premium for their shares of our common stock. These provisions could also affect the price that some investors are willing to pay for our common stock.

Our certificate of incorporation also provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our fourth amended and restated certificate of incorporation that will become effective immediately following the closing of this offering provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; any action asserting a claim

against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our fourth amended and restated certificate of incorporation also provides that the United States District Court for the District of Delaware and any appellate courts thereof will be the exclusive forum for resolving any such complaint for which subject matter jurisdiction of such claim is vested exclusively in the federal courts of the United States of America. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

We may fail to qualify for continued listing on NASDAQ which could make it more difficult for investors to sell their shares.

We have applied to list our common stock on The NASDAQ Global Market. If approved, we will need to satisfy the continued listing requirements of The NASDAQ Stock Market, LLC, or NASDAQ, for inclusion on The NASDAQ Global Market to maintain such listing, including, among other things, the maintenance of a minimum bid price of $1.00 per share and stockholders' equity of at least $10.0 million. There can be no assurance that we will be able to maintain compliance with the continued listing requirements or that our common stock will not be delisted from NASDAQ in the future. If our common stock is delisted by NASDAQ, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our shares are a "penny stock," which will require brokers trading in our shares to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

We expect that the initial public offering price will be substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted book value (deficit) of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, based upon an assumed initial public offering price of $ per share, the midpoint of the price range on the cover page of this prospectus. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase

price paid in this offering, if anything, in the event of our liquidation. Further, investors purchasing common stock in this offering will have contributed approximately % of the total amount invested by stockholders since our inception, but will own, as a result of such investment, only approximately % of the shares of common stock outstanding immediately following giving effect to this offering. Furthermore, if the underwriters exercise their option to purchase additional shares or our previously issued options and warrants to acquire common stock at prices below the initial public offering price are exercised, you will experience further dilution. For a further description of the dilution that you will incur as a result of purchasing shares in this offering, see "Dilution."

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain and you may never receive a return on your investment.

We have never declared or paid cash dividends on our capital stock, and you should not rely on an investment in our common stock to provide dividend income. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

As we operate in the pharmaceutical industry, we may be especially vulnerable to volatility in the market price of our common stock, especially to the extent that various factors affect the common stock of companies in our industry. In the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

We are an "emerging growth company" and intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we are eligible to and intend to take advantage of some of the exemptions from reporting requirements applicable to other public companies, but not to emerging growth companies, including, but not limited to, an exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act, reduced disclosure about executive compensation arrangements pursuant to the rules applicable to smaller reporting companies and no requirement to seek non-binding advisory votes on executive compensation or golden parachute arrangements. We will remain an emerging growth company until the earliest of (1) the beginning of the first fiscal year following the fifth anniversary of our initial public offering, or January 1, 2023, (2) the beginning of the first fiscal year after our annual gross revenue is $1.07 billion or more, (3) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities and (4) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700.0 million as of the end of the second quarter of that fiscal year.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended transition period and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of

such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We cannot predict if investors will find our common stock less attractive as a result of our taking advantage of these exemptions. If some investors find our common stock less attractive as a result of our choices, there may be a less active trading market for our common stock and our stock price may be more volatile. We may also be unable to raise additional capital as and when we need it.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to timely and accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

After the closing of this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, as well as the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. Commencing with our fiscal year ending December 31, 2018, we will be required, under Section 404 of the Sarbanes-Oxley Act, to include in our Form 10-K filing for that year a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of an exemption from the independent registered public accounting firm attestation requirement.

Our compliance with Section 404's requirement to furnish a report by management will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to this offering, we have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. We currently do not have an internal audit function, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with the applicable provisions of Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion, which could potentially subject us to sanctions or investigations by the Securities and Exchange Commission, or the SEC, or other regulatory authorities.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to timely and accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting once that firm begins the testing procedures over internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon consummation of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations reflect the reality that judgments can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

Prior to the consummation of this offering, we have not been subject to public company reporting obligations. We will incur significant additional legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act, the Dodd-Frank Act of 2010, the Exchange Act, as well as rules of the SEC and NASDAQ, for example, will result in significant initial costs to us as well as ongoing increases in our legal, audit and financial compliance costs, particularly after we are no longer an "emerging growth company." In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by NASDAQ and the SEC, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. Any changes that we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Our board of directors, management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, failure to comply with these rules and regulations might make it more difficult and more expensive for us to obtain director and officer liability insurance, or we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to maintain the same or similar coverage.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to obtain and maintain regulatory approval of our product candidates, including OPN-375, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our plans to commercialize our product candidates, including OPN-375, if approved;
- the size and growth potential of the markets for our product candidates, and our ability to service those markets;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the rate and degree of market acceptance of our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success, cost and timing of our product development activities, studies and clinical trials, including our plans to initiate additional clinical trials of OPN-375 in pursuit of a follow-on indication for chronic sinusitis;
- our ability to obtain funding for our operations beyond this offering;
- regulatory developments in the United States and foreign countries;
- our ability to operate our business without infringing the intellectual property rights of others;
- the performance of our third-party suppliers, manufacturers and contract sales organizations;
- the success of competing products that are or become available;
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for OPN-375 and our other product candidates and to avoid claims of infringement;
- the loss of key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our use of proceeds from this offering; and
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and need for additional financing.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The Private Securities Litigation Reform Act of 1995 and Section 27A

of the Securities Act of 1933, as amended, or the Securities Act, do not protect any forward-looking statements that we make in connection with this offering. Any forward-looking statements that we make in this prospectus speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

IMPLICATIONS OF BEING AN EMERGING GROWTH COMPANY

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earliest of:

- the beginning of the first fiscal year following the fifth anniversary of our initial public offering, or January 1, 2023;
- the beginning of the first fiscal year after our annual gross revenue is $1.07 billion or more;
- the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities; and
- the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700.0 million as of the end of the second quarter of that fiscal year.

For as long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies," including:

- presentation of only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act relating to the effectiveness of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will take advantage of these reporting exemptions until we are no longer an "emerging growth company." We may choose to take advantage of some but not all of these reduced burdens. For example, we have taken advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus, and have taken advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

The JOBS Act provides that an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

MARKET, INDUSTRY AND OTHER DATA

This prospectus contain estimates, projections and other information concerning our industry, our business and the prospective markets for our product candidates, including data regarding the estimated size of those markets, the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, physician and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. We obtained the industry, market and other data throughout this prospectus from our own internal estimates and research, as well as from industry publications and research, surveys and studies conducted by third parties on our behalf. We believe this data is accurate in all material respects as of the date of this prospectus.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. In several cases, we do not expressly refer to the sources from which this data is derived.

USE OF PROCEEDS

We estimate that we will receive net proceeds of $ million, or $ million if the underwriters exercise their option to purchase additional shares in full, from the sale of the shares of common stock offered by us in this offering, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions.

Similarly, a 1.0 million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us by $ million, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions.

We currently estimate that we will use the net proceeds of this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ million to support the planned launch of OPN-375, including investment to establish and continue to build our commercial infrastructure, supply chain, marketing and sales functions;
- approximately $ million to fund research and development efforts for OPN-375, including the initiation of FDA-mandated pediatric studies and the clinical trials necessary to seek approval for a follow-on indication of OPN-375 for the treatment of chronic sinusitis; and
- the remainder, if any, to fund working capital, research and development efforts and general corporate purposes, which may include the acquisition or licensing of products, product candidates, technologies, compounds, other assets or complementary businesses.

The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures depend on numerous factors, including regulatory approval of OPN-375 for the treatment of nasal polyposis, the progress of our clinical development efforts for OPN-375 for a follow-on indication for the treatment of chronic sinusitis and the progress of our preclinical and clinical development efforts with respect to our other product candidates. As a result, our management will have broad discretion in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the net proceeds.

Although we may use a portion of the net proceeds from this offering for the acquisition or licensing, as the case may be, of products, product candidates, technologies, compounds, other assets or complementary businesses, we have no current understandings, agreements or commitments to do so. Pending these uses, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing cash resources, will be sufficient to enable us to fund our operations through , including to support the planned launch of OPN-375, if approved. With respect to the additional research and development efforts for OPN-375, including the initiation of FDA-mandated pediatric studies and the clinical trials necessary to seek approval for a follow-on indication for the treatment of chronic sinusitis, we expect that we will require additional funds as these studies and trials

progress, the exact amounts of which will depend on the timing, design and outcome of the clinical trials and our cash position. We have based these estimates on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We may need to raise additional capital through public offerings and private placements of our equity securities, debt financings, strategic partnerships, alliances and licensing arrangements, or a combination thereof.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2017 on:

- an actual basis;
- a pro forma basis, giving effect to:
  - the automatic conversion of all our outstanding convertible preferred stock into an aggregate of 8,680,566 shares of our common stock, which will occur upon the closing of this offering; and
  - the filing of our fourth amended and restated certificate of incorporation following the closing of this offering; and
- a pro forma as adjusted basis, giving effect to the pro forma adjustments set forth above and the sale by us of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our consolidated financial statements and the related notes appearing at the end of this prospectus, the sections entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other consolidated financial information appearing elsewhere in this prospectus.

	As of June 30, 2017		
(in thousands)	Actual	Pro Forma	Pro Forma As Adjusted[1]
Cash and cash equivalents	$ 58,887	$ 58,887	
Redeemable convertible preferred stock:			
Series A Preferred Stock, par value $0.001 per share; 285,480 shares authorized, 285,480 shares issued and outstanding, actual; 285,480 shares authorized, no shares issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	5,381	—	
Series B-1 Preferred Stock, par value $0.001 per share; 35,680 shares authorized, 35,680 shares issued and outstanding, actual; 35,680 shares authorized, no shares issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	673	—	
Series B-2 Preferred Stock, par value $0.001 per share; 782,600 authorized, 782,600 shares issued and outstanding, actual; 782,600 shares authorized, no shares issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	14,760	—	
Series C Preferred Stock, par value $0.001 per share; 4,115,344 shares authorized, 4,115,344 shares issued and outstanding, actual; 4,115,344 shares authorized, no shares issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	110,840	—	

(in thousands)	As of June 30, 2017 Actual	Pro Forma	Pro Forma As Adjusted[1]
Series C-1 Preferred Stock, par value $0.001 per share; 1,656,410 shares authorized, 1,656,410 shares issued and outstanding, actual; 1,656,410 shares authorized, no shares issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	43,517	—	
Series C-2 Preferred Stock, par value $0.001 per share; 687,474 shares authorized, 687,474 shares issued and outstanding, actual; 687,474 shares authorized, no shares issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	19,951	—	
Series D Preferred Stock, par value $0.001 per share; 1,369,863 shares authorized, 1,117,578 shares issued and outstanding, actual; 1,369,863 shares authorized, no shares issued or outstanding, pro forma; no shares authorized, issued or outstanding, pro forma as adjusted	37,296	—	
Total redeemable convertible preferred stock	232,418	—	
Stockholders' (deficit) equity:			
Common stock, par value $0.001 per share; 13,067,149 shares authorized, 1,408,540 shares issued and outstanding, actual; shares authorized, 10,089,106 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	1	10	
Preferred stock, par value $0.001 per share; no shares authorized, issued or outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	
Additional paid-in capital	—	232,409	
Accumulated other comprehensive loss	(105)	(105)	
Accumulated deficit	(174,577)	(174,577)	
Total stockholders' (deficit) equity	(174,681)	57,737	
Total capitalization	$ 57,737	$ 57,737	

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the amount of each of cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization on a pro forma as adjusted basis by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. Similarly, each increase (decrease) of 1,000,000 shares offered by us would increase (decrease) the amount of each of cash and cash equivalents, total stockholders' equity (deficit) and total capitalization on a pro forma as adjusted basis by $ million, assuming the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions.

The number of shares of our common stock in the table above is based on 10,089,106 shares of common stock outstanding as of June 30, 2017, which gives effect to the pro forma transactions described above, and excludes:

- 1,523,901 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2017 at a weighted average exercise price of $18.64 per share;

- 654,624 shares of common stock issuable upon the exercise of warrants to purchase common stock outstanding as of June 30, 2017 at an exercise price of $23.56 per share; and

- 99,505 shares of common stock reserved for future issuance under our 2010 Stock Incentive Plan, as amended, as of June 30, 2017.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of June 30, 2017, our historical net tangible book value (deficit) was $(174.7) million, or $(124.02) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our liabilities and convertible preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share is our historical net tangible deficit divided by the number of shares of common stock outstanding as of June 30, 2017.

Our pro forma net tangible book value as of June 30, 2017, was $57.7 million, or $5.72 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities after giving effect to the automatic conversion of all shares of our convertible preferred stock outstanding into an aggregate of 8,680,566 shares of our common stock, which will occur upon the closing of this offering.

Our pro forma as adjusted net tangible book value as June 30, 2017, which is our pro forma net tangible book value at that date, after giving effect to the sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, would have been $ million, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to new investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of June 30, 2017	$ (124.02)	
Pro forma increase in net tangible book value (deficit) per share attributable to the automatic conversion of all outstanding shares of our preferred stock	129.74	
Pro forma net tangible book value per share as of June 30, 2017	5.72	
Increase in pro forma net tangible book value per share attributable to investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

The information discussed above is illustrative only, and the dilution information following this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by $ per share and the dilution in pro forma per share to investors participating in this offering by $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions.

Similarly, each 1,000,000 share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share after this offering by $ and decrease the dilution in pro forma per share to investors participating in this offering by $, assuming the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions. A 1,000,000 share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by $ and increase the dilution in pro forma per share to investors participating in this offering by $, assuming the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions.

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value will increase to $ per share, representing an immediate increase in pro forma as adjusted net tangible book value to existing stockholders of $ per share and an immediate decrease of dilution of $ per share to investors participating in this offering.

The following table summarizes, as of June 30, 2017, on a pro forma as adjusted basis as described above, the total number of common shares purchased from us on an as converted to common share basis, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table below shows, investors participating in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares purchased		Total consideration		
	Number	Percent	Amount (in thousands)	Percent	Average price per share
Existing stockholders before this offering	10,089,106	%	$ 185,875	%	$ 18.42
Investors participating in this offering					
Total		100%	$	100%	

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by investors participating in this offering and total consideration paid by all stockholders by $ million and , in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

Similarly, each 1,000,000 share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by investors participating in this offering and total consideration paid by all stockholders by $ million, and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming the assumed initial public offering price remains the same.

If the underwriters exercise their option to purchase additional shares in full in this offering, the number of shares of common stock held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be further increased to , or % of the total number of shares of common stock to be outstanding after this offering.

The number of shares of our common stock reflected in the discussion above is based on 10,089,106 shares of common stock outstanding as of June 30, 2017, which gives effect to the pro forma transactions described above, and excludes:

- 1,523,901 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2017 at a weighted average exercise price of $18.64 per share;
- 654,624 shares of common stock issuable upon the exercise of warrants to purchase common stock outstanding as of June 30, 2017 at an exercise price of $23.56 per share; and
- 99,505 shares of common stock reserved for future issuance under our 2010 Stock Incentive Plan, as amended, as of June 30, 2017.

To the extent that stock options are exercised, new stock options are issued under our stock incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED CONSOLIDATED FINANCIAL DATA

This section should be read together with our consolidated financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus. We derived the selected consolidated statement of operations data for the years ended December 31, 2015 and 2016 and the selected consolidated balance sheet data as of December 31, 2015 and 2016 from our audited consolidated financial statements and accompanying notes appearing elsewhere in this prospectus. We derived the selected statement of operations data for the six months ended June 30, 2016 and 2017 and the selected balance sheet data as of June 30, 2017 from our unaudited interim consolidated financial statements and accompanying notes appearing elsewhere in this prospectus. The selected consolidated financial data in this section are not intended to replace our consolidated financial statements and the related notes. The unaudited interim consolidated financial data, in management's opinion, have been prepared on the same basis as the audited consolidated financial statements and the related notes included elsewhere in this prospectus, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the information for the periods presented. Our historical results are not necessarily indicative of the results that may be expected in the future and results from our interim period may not necessarily be indicative of the results of the entire year or any future period.

(in thousands, except share and per share data)	Years Ended December 31, 2015	Years Ended December 31, 2016	Six Months Ended June 30, 2016	Six Months Ended June 30, 2017
Consolidated Statement of Operations Data:				
Licensing revenues	$ 85	$ 47,500	$ 47,500	$ —
Operating expenses:				
Research and development	22,156	15,311	8,373	8,979
Selling, general and administrative	6,006	6,869	3,296	6,661
Total operating expenses	28,162	22,180	11,669	15,640
(Loss) income from operations	(28,077)	25,320	35,831	(15,640)
Other (income) expense, net:				
Interest (income) expense	791	3,374	1,676	767
Other (income) expense	(554)	(667)	(152)	(124)
Total other (income) expense, net	237	2,707	1,524	643
Net (loss) income	(28,314)	22,613	34,307	(16,283)
Accretion of redeemable convertible preferred stock	(12,061)	(13,114)	(6,557)	(8,224)
Net (loss) income attributable to common stockholders	$ (40,375)	$ 9,499	$ 27,750	$ (24,507)
Net (loss) income per share of common stock,				
basic	$ (28.79)	$ 1.15	$ 3.35	$ (17.40)
diluted	$ (28.79)	$ 0.94	$ 2.74	$ (17.40)
Weighted average common shares outstanding,				
basic	1,402,290	1,403,900	1,402,290	1,408,540
diluted	1,402,290	1,724,513	1,717,460	1,408,540
Pro forma net income (loss) per share of common stock,				
basic (unaudited)		$ 2.73		$ (1.76)
diluted (unaudited)		$ 2.63		$ (1.76)
Pro forma weighted average common shares outstanding,				
basic (unaudited)		8,279,414		9,251,267
diluted (unaudited)		8,600,027		9,251,267

(in thousands)	As of December 31, 2015	As of December 31, 2016	As of June 30, 2017
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 15,198	$ 36,797	$ 58,887
Working capital[(1)]	8,624	34,765	54,689
Total assets	16,009	41,551	63,962
Convertible notes	14,480	15,256	—
Redeemable convertible preferred stock	155,059	168,173	232,418
Accumulated deficit	(161,252)	(151,099)	(174,577)
Total stockholders' deficit	(161,392)	(151,197)	(174,681)

(1) Working capital is calculated as current assets minus current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion summarizes the significant factors affecting the operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with "Prospectus Summary — Summary Consolidated Financial Data," "Selected Consolidated Financial Data" and the consolidated financial statements and the related notes thereto included elsewhere in this prospectus. The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and all other non-historical statements in this discussion are forward-looking statements and are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including those discussed below and elsewhere in this prospectus, particularly in the section entitled "Risk Factors."

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat, or ENT, and allergy specialists. Our lead product candidate, OPN-375, is a therapeutic utilizing our proprietary Breath Powered exhalation delivery system, or EDS, that delivers a topically-acting and potent anti-inflammatory corticosteroid for the treatment of chronic rhinosinusitis with and without nasal polyps. Chronic rhinosinusitis is a serious nasal inflammatory disease that is currently treated using therapies, such as intranasal steroids, or INS, that have significant limitations. We believe OPN-375 has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by current INS. We also believe that payors will respond favorably to OPN-375's clinical, cost, and quality-of-care profile, as compared to current and potential future costly drug therapy and surgical treatment options.

In November 2016, we submitted a new drug application, or NDA, for OPN-375 for the treatment of nasal polyposis to the U.S. Food and Drug Administration, or FDA. Subject to FDA approval, we expect to launch OPN-375 in the second quarter of 2018 with a dedicated sales force targeting a specialty prescriber base comprised of approximately 15,000 physicians in the United States. We plan to initiate additional clinical trials of OPN-375 in the second half of 2018 to seek a follow-on indication for the treatment of chronic sinusitis to broaden our market opportunity. OPN-375, if approved for the treatment of nasal polyposis, would represent the second commercial product that we have developed utilizing our EDS. Our first commercial product, indicated for the acute treatment of migraines in adults, was licensed in 2013 to Avanir Pharmaceuticals, Inc., or Avanir, and was approved by the FDA in January 2016.

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. To date, we have generated revenue primarily from our license agreement with Avanir, or the AVP-825 License Agreement, pursuant to which we granted them the exclusive right to further develop and commercialize AVP-825 for the acute treatment of migraines in adults. We have not generated any commercial product revenue to date and we do not expect to generate any additional revenue from the AVP-825 License Agreement in the near term, as future sales milestones and royalty payments are subject to the achievement of specified sales thresholds. We had net income of $22.6 million for the year ended December 31, 2016 and $34.3 million for the six months ended June 30, 2016 due primarily to the achievement of a development milestone under the AVP-825 License Agreement. However, we incurred net losses of $28.3 million for year ended December 31, 2015 and $16.3 million for the six months ended June 30, 2017. We incurred net losses in all other prior periods. As of June 30, 2017, we had an accumulated deficit of $174.6 million. We have funded our operations primarily through the sale and issuance of preferred stock, as well as licensing revenues received under the AVP-825 License Agreement. As of June 30, 2017, we had $58.9 million in cash and cash equivalents.

We expect to continue to incur substantial net losses and negative cash flows from operations for the foreseeable future as we seek regulatory approval for, and, if approved, begin to commercialize OPN-375 and from our ongoing activities.

Our results may vary depending on many factors, including our ability to obtain regulatory approval of OPN-375 for the treatment of nasal polyposis and the follow-on indication for the treatment of chronic sinusitis, to achieve market acceptance of OPN-375 among physicians, patients and third-party payors and to continue development activities for our other product candidates.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations until . However, we will need to raise additional capital in the future to further the commercialization of OPN-375 for the treatment of nasal polyposis, if approved, to further the clinical development of OPN-375 for a follow-on indication for the treatment of chronic sinusitis, and to support the development of our other product candidates. We may seek to obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received.

Financial Operations Overview

Licensing revenues

To date, we have not generated any revenues from product sales. Substantially all of our revenue to date has been derived from the AVP-825 License Agreement. We do not expect to generate significant product revenue unless and until we commercialize OPN-375, if approved, and our other product candidates.

In July 2013, we, through our wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement under which we granted an exclusive license to Avanir to further develop and commercialize AVP-825 (now marketed as Onzetra Xsail). Under the terms of the AVP-825 License Agreement, we have received $70.0 million in aggregate licensing revenues to date in connection with the initial signing and the achievement of development milestones, including a $47.5 million payment upon FDA approval of AVP-825 in the first quarter of 2016. We are eligible to receive up to an additional $50.0 million upon the achievement of annual sales milestones and tiered low double-digit royalty payments once and if net sales of the product exceed a specified cumulative threshold. We do not expect to generate any additional revenue from the AVP-825 License Agreement in the near term.

Research and development expense

Research and development expense consists substantially of costs incurred in connection with the development and pursuit of regulatory approval for OPN-375 for the treatment of nasal polyposis. We expense research and development costs as incurred. These expenses include:

- personnel expenses, including salaries, benefits and stock-based compensation expense;
- costs of funding research performed by third parties, including pursuant to agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our preclinical studies and clinical trials;
- expenses incurred under agreements with contract manufacturing organizations, or CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- consultant fees and expenses associated with outsourced professional scientific development services;
- expenses for regulatory activities, including filing fees paid to regulatory agencies and costs incurred to compile filings with the FDA;

- costs incurred to maintain, expand and protect our patent portfolio; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

We typically use our employee, consultant and infrastructure resources across our research and development programs. Although we track certain outsourced development costs by product candidate, we do not allocate personnel costs or other internal costs to specific product candidates.

We plan to incur research and development expenses for the foreseeable future as we expect to seek to continue development of OPN-375 for a follow-on indication for the treatment of chronic sinusitis and our other product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, and given the preliminary nature of our clinical trial design for OPN-375 for a follow-on indication for the treatment of chronic sinusitis and any FDA-mandated pediatric studies for OPN-375, and the early stage of our other product candidates, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in our continued development efforts.

Selling, general and administrative expense

Selling, general and administrative expense consists primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees in executive, finance, accounting, business development, legal and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation and maintenance, not otherwise included in research and development expense, as well as legal fees related to corporate matters and fees for accounting and other consulting services.

We anticipate that our general and administrative expense will increase as a result of an expanded infrastructure and an increased headcount. We anticipate higher corporate infrastructure costs including, but not limited to accounting, legal, human resources, consulting and investor relations fees, as well as increased director and officer insurance premiums, associated with becoming a public company.

Sales and marketing related expenses consist of market research and other activities to prepare for the anticipated commercialization of OPN-375, as well as salaries and related benefits for employees focused on such efforts. We anticipate an increase in headcount and expense, including in connection with the engagement of a contract sales organization, as a result of our preparation for the commercial launch of OPN-375 in the United States.

Interest (income) expense

Interest (income) expense consists of interest earned on our cash and cash equivalents held with institutional banks and interest expense related to amounts amortized and accrued under our convertible notes that were converted into preferred stock in March 2017.

Other (income) expense

Other (income) expense consists primarily of grant and other income as a result of government cost reimbursements for research and development activities over a contractually defined period, as well as foreign currency income (losses) due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

Consolidated Results of Operations

Comparison of six months ended June 30, 2016 and 2017

The following table sets forth our selected consolidated statements of operations data for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2016	2017
Licensing revenues	$ 47,500	$ —
Operating expenses:		
Research and development	8,373	8,979
Selling, general and administrative	3,296	6,661
Total operating expenses	11,669	15,640
Income (loss) from operations	35,831	(15,640)
Other (income) expense:		
Interest (income) expense	1,676	767
Other (income) expense	(152)	(124)
Total other (income) expense	1,524	643
Net income (loss)	$ 34,307	$ (16,283)

Licensing Revenues

Revenue was $47.5 million and $0 for the six months ended June 30, 2016 and 2017, respectively. Revenue earned during the six months ended June 30, 2016 was attributable to the achievement of a development milestone under the terms of the AVP-825 License Agreement as a result of FDA approval of Onzetra Xsail in January 2016.

Research and development expense

Research and development expenses were $8.4 million and $9.0 million for the six months ended June 30, 2016 and 2017, respectively. The $0.6 million increase was attributable primarily to:

- a $0.4 million increase in research and development spending in connection with collecting feedback on our clinical trial results and to prepare for our planned clinical trials for a follow-on indication for the treatment of chronic sinusitis;
- a $0.3 million increase in intellectual property expenses as a result of an increase in new patent filings;
- a $0.2 million increase in contract manufacturing expenses as a result of our preparation for the commercial launch of OPN-375, if approved, for the treatment of nasal polyposis;
- a $0.2 million increase in personnel expenses due to increases in stock-based compensation expense; and
- a $0.2 million increase in rent expense and other operating expenses in connection with our new corporate office lease.

These increases were offset primarily by:

- a $0.7 million decrease in regulatory expenses as a result of the substantial completion of our NDA submission activities for OPN-375 for the treatment of nasal polyposis.

Selling, general and administrative expense

Selling, general and administrative expenses were $3.3 million and $6.7 million for the six months ended June 30, 2016 and 2017, respectively. The $3.4 million increase was due primarily to:

- a $1.5 million increase in commercial expenses for our preparation of the commercial launch of OPN-375, if approved, for the treatment of nasal polyposis;
- a $0.7 million increase in professional fees as a result of our preparations to become a public company;
- a $0.7 million increase in personnel expenses due primarily to increased headcount;
- a $0.3 million increase in stock-based compensation expense; and
- a $0.2 million increase in rent and other operating expenses in connection with our new corporate office lease.

Interest (income) expense, net

Interest (income) expense, net, was $1.7 million and $0.8 million for the six months ended June 30, 2016 and 2017, respectively, and was related primarily to our convertible notes. The convertible notes were converted to shares of preferred stock in March 2017.

Other (income) expense, net

Other income, net, was $0.2 million and $0.1 million for the six months ended June 30, 2016 and 2017, respectively. The income in both periods was attributable primarily to grant eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary.

Comparison of the years ended December 31, 2015 and 2016

The following table sets forth our selected consolidated statements of operations data for the periods indicated (in thousands):

	Year Ended December 31,	
	2015	2016
Licensing revenues	$ 85	$ 47,500
Operating expenses:		
Research and development	22,156	15,311
Selling, general and administrative	6,006	6,869
Total operating expenses	28,162	22,180
Income (loss) from operations	(28,077)	25,320
Other (income) expense:		
Interest (income) expense	791	3,374
Other (income) expense	(554)	(667)
Total other (income) expense	237	2,707
Net income (loss)	$ (28,314)	$ 22,613

Licensing Revenues

Revenue was $0.1 million and $47.5 million for the years ended December 31, 2015 and 2016, respectively. Revenue earned during the year ended December 31, 2015 was attributable to research and development services provided in connection with the AVP-825 License Agreement. Revenue earned during the year ended December 31, 2016 was attributable to the achievement of a development milestone under the terms of the AVP-825 License Agreement as a result of FDA approval of Onzetra Xsail in January 2016.

Research and development expense

Research and development expenses were $22.2 million and $15.3 million for the years ended December 31, 2015 and 2016, respectively. The $6.9 million decrease was attributable primarily to the $10.0 million decrease in clinical development and chemistry, manufacturing and controls expenses in connection with the substantial completion of our Phase 3 program of OPN-375 for the treatment of nasal polyposis in 2015.

This decrease was offset primarily by:

- a $1.9 million increase in bonus expense;
- a $0.8 million increase in regulatory and intellectual property maintenance costs in connection with the submission of our NDA for OPN-375 for the treatment of nasal polyposis;
- a $0.3 million increase in personnel expenses; and
- a $0.1 million increase in rent and other operating expenses in connection our new corporate office lease.

Selling general and administrative expense

Selling, general and administrative expenses were $6.0 million and $6.9 million for the years ended December 31, 2015 and 2016, respectively. The $0.9 million increase was due primarily to:

- a $1.2 million increase in bonus expense;
- a $0.6 million increase in professional service expenses as a result of our preparations to become a public company and for our commercial launch of OPN-375, if approved, for the treatment of nasal polyposis;
- a $0.3 million increase in personnel expenses; and
- a $0.1 million increase in rent and other operating expenses in connection with our new corporate office lease.

These increases were offset by a $1.3 million decrease in marketing-related expenses incurred in connection with market research and commercial feasibility studies that we commissioned for OPN-375 in 2015.

Interest (income) expense, net

Interest expense, net, was $0.8 million and $3.4 million for the years ended December 31, 2015 and 2016, respectively. The $2.6 million increase was attributable primarily to the September 2015 issuance of $15.0 million in convertible notes.

Other (income) expense, net

Other income, net, was $0.6 million and $0.7 million for the years ended December 31, 2015 and 2016, respectively. The $0.1 million increase was due primarily to an increase in grant eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary.

Liquidity and Capital Resources

We have funded our operations primarily through the sale and issuance of preferred stock, as well as through licensing revenues received under the terms of the AVP-825 License Agreement. As of June 30, 2017, we had $58.9 million in cash and cash equivalents.

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. We had net income of $22.6 million for the year ended December 31, 2016 and $34.3 million for the six months ended June 30, 2016 due primarily to the achievement of a milestone under the AVP-825 License Agreement. However, we incurred net losses of $28.3 million for the year ended December 31, 2015 and $16.3 million for the six months ended June 30, 2017. We incurred net losses in all other prior periods. As of June 30, 2017, we had an accumulated deficit of $174.6 million.

Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with existing cash and cash equivalents, will be sufficient to fund our operations until , during which time, we expect to launch OPN-375 for the treatment of nasal polyposis in the United States, if approved, continue our clinical development of OPN-375 for a follow-on indication for the treatment of chronic sinusitis and continue our early-stage development efforts with respect to our other product candidates. We have based this estimate on assumptions that may prove to be incorrect and we could use our available capital resources sooner than we currently expect. We may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis. If additional funding is not secured when required, we may need to delay or curtail our operations until such funding is received.

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Year Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Net cash (used in) provided by operating activities	$ (28,714)	$ 21,720	$ 32,388	$ (13,627)
Net cash used in investing activities	(80)	(215)	(6)	(711)
Net cash provided by financing activities	19,123	55	—	36,434
Effects of exchange rates on cash and cash equivalents	(14)	39	34	(6)
Net (decrease) increase in cash and cash equivalents	$ (9,685)	$ 21,599	$ 32,416	$ 22,090

Operating activities

Cash provided by (used in) operating activities increased by $50.4 million, from $(28.7) million for the year ended December 31, 2015 to $21.7 million for the year ended December 31, 2016. The $50.4 million increase in cash provided by operating activities was attributable primarily to the net income generated from the $47.5 million of licensing revenue earned in connection with the achievement of a development milestone under the terms of the AVP-825 License Agreement resulting from FDA approval of Onzetra Xsail in January 2016.

Cash provided by (used in) operating activities decreased by $46.0 million, from $32.4 million for the six months ended June 30, 2016 to $(13.6) million for the six months ended June 30, 2017. The $46.0 million decrease in cash provided by operating activities was attributable primarily to net income generated from the $47.5 million of licensing revenue earned in connection with the achievement of a development milestone under the terms of the AVP-825 License Agreement resulting from FDA approval of Onzetra Xsail in January 2016. No revenue was generated from the AVP-825 License Agreement during the six months ended June 30, 2017.

Investing activities

Cash used in investing activities increased $0.1 million from $0.1 million for the year ended December 31, 2015 to $0.2 million for the year ended December 31, 2016. The $0.1 million increase was related to increased purchases of equipment.

Cash used in investing activities increased $0.7 million from $6,000 for the six months ended June 30, 2016 to $0.7 million for the six months ended June 30, 2017. The $0.7 million increase was related to increased purchases of equipment in connection with the preparation for the commercial launch of OPN-375.

Financing activities

Cash provided by financing activities decreased $19.0 million from $19.1 million for the year ended December 31, 2015 to $0.1 million for the year ended December 31, 2016. During 2015, we received $4.8 million in net proceeds from the sale of our Series C-1 Preferred Stock and $14.3 million in net

proceeds from the sale and issuance of our convertible promissory notes that were subsequently converted to Series C-2 Preferred Stock in March 2017. During 2016, we received $0.1 million in cash from stock option exercises.

Cash provided by financing activities increased $36.4 million from $0 for the six months ended June 30, 2016 to $36.4 million for the six months ended June 30, 2017. During 2017, we received $36.4 million in net proceeds from the sale of our Series D Preferred Stock.

Sources of capital

AVP-825 License Agreement

As described above, under the terms of the AVP-825 License Agreement, we received $70.0 million in aggregate licensing revenues to date in connection with the initial signing and the achievement of development milestones, including a $47.5 million payment upon FDA approval of AVP-825 in the first quarter of 2016. We are eligible to receive up to an additional $50.0 million upon the achievement of annual sales milestones and tiered low double-digit royalty payments once and if net sales of the product exceed a specified cumulative threshold. We do not expect to generate any additional revenue from the AVP-825 License Agreement in the near term.

Series C-1 and Series D Redeemable Convertible Preferred Stock

In July 2014, we issued and sold an aggregate of 1,419,781 shares of our Series C-1 Preferred Stock to some of our existing investors and members of our management team and board of directors at a purchase price of $21.13 per share, for aggregate consideration of $30.0 million. We subsequently sold an additional 236,629 shares of our Series C-1 Preferred Stock at a purchase price of $21.13 per share, for aggregate consideration of $5.0 million in July 2015.

In March 2017, we issued and sold an aggregate of 1,065,451 shares of our Series D Preferred Stock to new investors and some of our existing stockholders at a purchase price of $32.85 per share, for aggregate consideration of $35.0 million. In April 2017 and May 2017, we issued and sold to some of our existing stockholders an additional 52,127 shares of our Series D Preferred Stock at a purchase price of $32.85 per share, for additional aggregate consideration of $1.7 million.

In September 2015, we entered into a convertible note purchase agreement with some of our existing stockholders to borrow up to $30.0 million. We borrowed $15.0 million of the total loan amount in the form of convertible promissory notes, or the Notes, in September 2015, and retained the option to borrow a second $15.0 million tranche until March 30, 2017. In addition to front-end and back-end fees owed on the Notes, the Notes bore interest at a rate of 17.0% per annum and, if not converted prior, would mature on September 30, 2020. In March 2017, concurrently with our Series D Preferred Stock financing, the 2015 Notes (including all principal, interest and back-end fees thereon) were converted into an aggregate of 687,474 shares of our Series C-2 Preferred Stock at a conversion price of $28.40 per share.

Funding requirements

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we:

- engage a contract specialty sales force, projected to initially consist of approximately 75 sales representatives, to market OPN-375 for the treatment of nasal polyposis and build commercial infrastructure to support sales and marketing for OPN-375;
- continue clinical development activities for OPN-375, including FDA-mandated pediatric studies, and seek regulatory approval for OPN-375 for a follow-on indication of chronic sinusitis;
- hire additional staff and add operational, financial and information systems to execute our business plan;
- maintain, expand and protect our patent portfolio;
- contract to manufacture OPN-375 and our other product candidates;

- continue research and development activities for our other product candidates; and
- operate as a public company.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the success of our commercialization of OPN-375 for the treatment of nasal polyposis, if approved;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- our clinical development plans for OPN-375, including FDA-mandated pediatric studies and clinical trials for the follow-on indication for the treatment of chronic sinusitis;
- the outcome, timing and cost of the regulatory approval process of OPN-375 for nasal polyposis and chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- potential future licensing revenue from the AVP-825 License Agreement;
- the initiation, progress, timing, costs and results of clinical trials for our other product candidates; and
- the extent to which we in-license or acquire other products, product candidates or technologies.

We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements until . We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will need to raise additional capital in the future to further the commercialization of OPN-375 for the treatment of nasal polyposis, if approved, to complete the clinical development of OPN-375 for a follow-on indication for the treatment of chronic sinusitis, and to support the development of our other product candidates. If we receive regulatory approval for OPN-375 for the treatment of nasal polyposis, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected and we may need to delay or curtail our operations until such funding is received.

Contractual obligations and commitments

The following table summarizes our contractual obligations at December 31, 2016:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Operating leases[1]	$ 657	$ 193	$ —	$ —	$ 850
Long-term debt[2]	—	—	18,859	—	18,859
Total	$ 657	$ 193	$ 18,859	$ —	$ 19,709

(1) Reflects obligations pursuant to our office leases in Yardley, Pennsylvania, Oslo, Norway and Swindon, England.

(2) Reflects principal and interest obligations pursuant to the Notes that were converted into shares of our Series C-2 Preferred Stock in March 2017. Accordingly, no further amounts are payable under the Notes.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical accounting policies

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reported period. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the preparation of our consolidated financial statements.

Revenue recognition

We have generated revenue primarily through licensing arrangements, which generally contain multiple elements, or deliverables, including licenses and research and development activities we perform on behalf of the licensee. Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured.

Currently, our only source of revenue is the AVP-825 License Agreement. The AVP-825 License Agreement includes licensed rights to patented technology, non-refundable up-front license fees, research services, and regulatory and sales milestones as well as royalty payments.

For arrangements with multiple elements, we recognize revenue in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, which provides guidance for separating and allocating consideration in a multiple element arrangement. The selling prices of deliverables under an arrangement may be derived using third-party evidence, or TPE, or a best estimate of selling price, or BESP, if vendor-specific objective evidence of selling price, or VSOE, is not available. The objective of BESP is to determine the price at which we would transact a sale if each element within the AVP-825 License Agreement was sold on a standalone basis. Deliverables under the arrangement are separate units of accounting if the delivered item has value to the customer on a standalone basis and if the arrangement includes a general right of return relative to the delivered item, and delivery or performance of the undelivered item is considered probable and substantially within our control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting for our licensing arrangements, we evaluate whether the license has standalone value to the licensee based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the licensee and the availability of relevant research expertise in the marketplace. In

addition, we consider whether or not the licensee could use the license for its intended purpose without the receipt of the remaining deliverables, the value of the license was dependent on the undelivered items and the licensee or other vendors could provide the undelivered items.

Whenever we determine that an element is delivered over a period of time, revenue is recognized using either a proportional performance model, if a pattern of performance can be determined, or a straight-line model over the period of performance, which is typically the research and development term.

Development milestones may be triggered either by the results of our research efforts or by events external to it, such as regulatory approval to market a product. Consideration that is contingent upon achievement of a development milestone is recognized in its entirety as revenue in the period in which the milestone is achieved, but only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement. For a milestone to be considered substantive, the consideration earned by achieving the milestone must be commensurate with either our performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, relate solely to past performance and be reasonable relative to all deliverables and payment terms in the collaboration agreement. As of December 31, 2016, all development milestones have been achieved under the AVP-825 License Agreement.

Royalties and sales milestones are recorded as earned in accordance with the contract terms when third party sales can be reliably measured and collectability is reasonably assured.

Research and development expenses

Research and development expense consists primarily of costs incurred in connection with development and regulatory approval of our lead product candidate, OPN-375, as well as costs associated with developing commercial manufacturing capabilities for OPN-375. We expense research and development costs as incurred.

At the end of each reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the applicable research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expenses relating to these costs. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We account for stock-based compensation awards in accordance with the FASB Accounting Standards Codification, or ASC, Topic 718, *Compensation — Stock Compensation*, or ASC 718. ASC 718 requires all stock-based compensation awards to employees to be recognized as expense based on their grant date fair values. We use the Black-Scholes option pricing model to value our stock option awards and we account for forfeitures of stock option awards as they occur. For awards issued to employees, we recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Stock-based awards issued to nonemployees are revalued at each reporting period until the award vests in accordance with ASC Topic 505, *Equity*. The resulting increase or decrease in value, if any, is recognized as expense or income, respectively, during the period the related services are rendered. Expense for awards with performance conditions is estimated and adjusted on a quarterly basis based upon our assessment of the probability that the performance condition will be met. We have not issued awards where vesting is subject to market conditions; however, if we were to grant such awards in the future, recognition would be based on the derived service period.

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair value of our common stock, the expected life of the option, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in our Black-Scholes option-pricing model represent

management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions used in our Black-Scholes option-pricing model are estimated as follows:

- *Expected Term.* Due to the lack of a public market for the trading of our common stock and the lack of sufficient company-specific historical data, the expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin, or SAB, No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term of nonemployee options is equal to the contractual term.

- *Expected Volatility.* The expected volatility is based on historical volatilities of similar entities within our industry which were commensurate with the expected term assumption as described in SAB No. 107.

- *Risk-Free Interest Rate.* The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.

- *Expected Dividends.* The expected dividend yield is 0% because we have not historically paid, and do not expect for the foreseeable future to pay, a dividend on our common stock.

The following table reflects the weighted average assumptions used to estimate the fair value of options granted during the periods presented.

	Year Ended December 31, 2016	Six Months Ended June 30, 2017
Expected term (in years)	6.08	6.08
Expected volatility	74.29%	73.93%
Risk-free interest rate	2.22%	2.07%
Expected dividend yield	0%	0%
Fair value of common stock	$ 14.85	$ 14.85

No awards were granted during the year ended December 31, 2015 and the six months ended June 30, 2016.

Stock-based compensation expense was $0.6 million, $0.6 million, $0.5 million and $1.0 million for the years ended December 31, 2015 and 2016 and the six months ended June 30, 2016 and 2017, respectively. At June 30, 2017, we had $3.0 million of unamortized stock-based compensation expense related to unvested service-based stock options, which is expected to be recognized over a remaining average vesting period of 3.52 years, and $2.7 million of unamortized stock- based compensation expense related to unvested performance-based stock options, which will be recognized when the occurrence of the performance condition is deemed probable.

We expect the impact of our stock-based compensation expense for stock options granted to employees and non-employees to increase in future periods due to the potential increases in the value of our common stock and in headcount.

Valuation of common stock

All options to purchase shares of our common stock are granted with an exercise price per share equal to or greater than the fair value per share of our common stock on the date of grant, based on the information known to us on the date of grant. We have granted options to certain of our executive officers in the past several years with exercise prices per share in excess of the then estimated fair market value in order to incentivize stock appreciation. Prior to this offering, on each grant date, the fair values of the shares of common stock underlying our stock options were estimated on each grant date by our board of directors, based on information known to us at the date of grant. In order to determine the fair value of our common stock, our board of directors considered, among other things, contemporaneous valuations of our common and preferred stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid. Given the absence of a public trading market of our capital stock, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common and preferred stock, including:

- contemporaneous third-party valuations of our common stock;
- the prices, rights, preferences and privileges of our preferred stock relative to the common stock;
- our business, financial condition and results of operations, including related industry trends affecting our operations;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company, given prevailing market conditions;
- the lack of marketability of our common stock;
- the market performance of comparable publicly traded companies; and
- U.S. and global economic and capital market conditions and outlook.

After the closing of this offering, our board of directors will determine the per share fair value of our common stock based on the closing price of our common stock as reported by The NASDAQ Global Market on the date of grant.

Stock Option Grants

The following table summarizes by grant date the number of shares of common stock underlying stock options granted from January 1, 2016 through the date of this prospectus, as well as the associated per share exercise price and the estimated fair value per share of our common stock as determined by our board of directors as of the grant date:

Grant date	Number of shares subject to options granted	Exercise price per share of common stock	Estimated fair value per share of common stock	Estimated fair value per share of common stock option award
December 20, 2016[1]	100,000	$ 47.10	$ 14.85	$ 6.61
December 20, 2016	238,500	14.85	14.85	9.86
January 23, 2017	55,000	14.85	14.85	9.81
January 30, 2017	50,000	14.85	14.85	9.81
February 13, 2017	7,000	14.85	14.85	9.80
February 20, 2017	2,000	14.85	14.85	9.79
February 27, 2017	2,000	14.85	14.85	9.78
August 7, 2017	55,500	20.95	20.95	13.71

(1) Reflects an option granted to one of our executive officers with a per share exercise price in excess of the then estimated fair market value in order to incentivize stock appreciation.

Based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, the intrinsic value of vested and unvested stock options outstanding as of June 30, 2017 was $ million and $ million, respectively.

Recent accounting pronouncements

See Note 3 to our audited and unaudited consolidated financial statements beginning on page F-1 of this prospectus for a description of recent accounting pronouncements applicable to our consolidated financial statements.

Qualitative and quantitative disclosures about market risk

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes and do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

Through the operation of our subsidiaries based in the United Kingdom and Norway, we are exposed to foreign exchange rate risks. In addition to the operations of our foreign subsidiaries, we also contract with vendors that are located outside the United States, and in some cases make payment of invoices denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of June 30, 2017, we had minimal liabilities denominated in foreign currencies.

As of June 30, 2017, we had cash and cash equivalents of $58.9 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% increase in interest rates would have a significant impact on the realized value of our investments.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2015 and 2016 or the six months ended June 30, 2016 and 2017.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." As an "emerging growth company," we are electing not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

On November 7, 2016, we dismissed PricewaterhouseCoopers LLP, or PwC, as our independent auditor. The dismissal was approved by the audit committee of the Board of Directors.

The report of PwC on our consolidated financial statements as of and for the fiscal year ended December 31, 2015 did not contain any adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal year ended December 31, 2015, and the subsequent interim period through November 7, 2016, (i) there were no disagreements with PwC on any matter of accounting principles or practices,

financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to PwC's satisfaction, would have caused PwC to make reference to the subject matter of the disagreements in their report on the financial statements for such fiscal year, and (ii) there were no "reportable events," as that term is described in Item 304(a)(1)(v) of Regulation S-K.

On December 6, 2016, we engaged Ernst & Young LLP, or EY, to serve as our independent registered public accounting firm, to audit the fiscal year ended December 31, 2016, as well as to reaudit the fiscal year ended December 31, 2015, which had previously been audited by PwC. The engagement of EY has been approved by our board of directors. During the two most recent fiscal years, neither we, nor anyone acting on our behalf, consulted with EY regarding either: (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our consolidated financial statements, and no written report nor oral advice was provided by EY, or (ii) any matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K, or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

We requested that PwC furnish us with a letter addressed to the SEC stating whether it agrees with the above statements. A copy of the letter dated June 23, 2017, is filed as an exhibit to the registration statement of which this prospectus forms a part.

BUSINESS

Overview

Our Company

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat, or ENT, and allergy specialists. Our lead product candidate, OPN-375, is a therapeutic utilizing our proprietary Breath Powered exhalation delivery system, or EDS, that delivers a topically-acting and potent anti-inflammatory corticosteroid for the treatment of chronic rhinosinusitis with and without nasal polyps. Chronic rhinosinusitis is a serious nasal inflammatory disease that is currently treated using therapies, such as intranasal steroids, or INS, that have significant limitations. We believe OPN-375 has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by current INS. We also believe that payors will respond favorably to OPN-375's clinical, cost, and quality-of-care profile, as compared to current and potential future costly drug therapy and surgical treatment options.

In November 2016, we submitted a new drug application, or NDA, for OPN-375 for the treatment of nasal polyposis to the U.S. Food and Drug Administration, or FDA. Subject to FDA approval, we expect to launch OPN-375 in the second quarter of 2018 with a dedicated sales force targeting a specialty prescriber base comprised of approximately 15,000 physicians in the United States. We plan to initiate additional clinical trials of OPN-375 in the second half of 2018 to seek a follow-on indication for the treatment of chronic sinusitis to broaden our market opportunity. OPN-375, if approved for the treatment of nasal polyposis, would represent the second commercial product that we have developed utilizing our EDS. Our first commercial product, indicated for the acute treatment of migraines in adults, was licensed in 2013 to Avanir Pharmaceuticals, Inc., or Avanir, and was approved by the FDA in January 2016.

The Unmet Need

Chronic rhinosinusitis is a serious nasal inflammatory disease characterized by chronic inflammation affecting tissues high and deep in the nasal passages, including the area where the openings from the sinuses normally ventilate and drain. This disease significantly impacts the quality of life and daily functioning of an estimated 30 million adults in the United States. The U.S. healthcare system spends approximately $60 billion annually in direct costs treating patients with chronic rhinosinusitis and its associated symptoms, including an estimated $5 billion on sinus surgeries. In the United States, physicians perform over 500,000 sinus surgeries each year, and we estimate that over seven million adults have undergone sinus surgery to treat chronic rhinosinusitis with and without nasal polyps.

In medical literature and practice, chronic rhinosinusitis is commonly divided into two subgroups: chronic rhinosinusitis with nasal polyps and chronic rhinosinusitis without nasal polyps. Chronic rhinosinusitis patients with and without nasal polyps suffer from chronic inflammation of the lining of the deep nasal passages and sinuses. Patients with chronic rhinosinusitis with nasal polyps also develop non-cancerous polyps on these chronically inflamed surfaces, typically originating in the deep crevices or sinus cavities on both sides of the nose. We estimate that up to 10 million adults in the United States have chronic rhinosinusitis with nasal polyps.

Both subgroups of chronic rhinosinusitis also share the same four defining diagnostic symptoms: nasal congestion/obstruction; facial pain and pressure; rhinorrhea, or runny nose, and postnasal drip; and loss of sense of smell and taste. Additional symptoms include headaches, chronic sleep problems, fatigue, frequent episodes of acute rhinosinusitis and mood disorders. There is evidence suggesting that the harm to a sufferer's quality of life from chronic rhinosinusitis, as measured in multiple domains, such as bodily pain, social functioning and mental health, is comparable to or worse than other serious diseases, including chronic obstructive pulmonary disease, congestive heart failure and angina. As a result, many patients eventually seek surgery for symptom relief.

Although the term chronic rhinosinusitis is often used in medical literature and medical practice, the FDA does not recognize chronic rhinosinusitis as a single indication for drug development purposes. Instead, the FDA recognizes chronic sinusitis, defined as inflammation of the sinuses with a duration longer than eight weeks, and nasal polyposis, defined as non-cancerous polyps on the inflamed tissue of the nasal passages and sinuses, as separate indications for drug development purposes. For purposes of this prospectus, we use the terms chronic sinusitis and nasal polyposis when referring to FDA treatment indications and our clinical trials, and use the term chronic rhinosinusitis with and without nasal polyps when referring to disease and economic data reported in the medical literature, medical practice and our estimates of OPN-375's market opportunity.

Current Treatment Limitations

Multiple current clinical practice guidelines specify the use of INS early in the treatment algorithm for chronic rhinosinusitis with and without nasal polyps. Steroids are generally pharmacologically effective at treating inflammation. However, conventional INS, including nasal sprays and nasal aerosols, are topically-acting and unable to effectively and consistently place the steroids onto the primary site of inflammation and nasal polyp origin, high and deep in the nasal passages. These products deposit a majority of the drug in the front of the nose or on the floor of the nasal passages, reducing their effectiveness and leaving many patients without sufficient symptomatic relief. These recognized limitations cause some physicians to seek out alternative treatment regimens such as high-volume steroid nasal rinses. This approach, however, has not been well studied, is difficult to administer, can be costly and may risk systemic side effects. Physicians may also prescribe oral steroids on an episodic basis to patients who have not received sufficient symptomatic relief from INS. Oral steroids, which are often effective in reducing inflammation and nasal polyps, offer only temporary benefit and are limited by the risk of significant systemic side effects associated with both short- and long-term use.

In cases where patients remain symptomatic despite medical management, physicians often recommend various forms of sinus surgery to help restore normal sinus ventilation or drainage. The effectiveness of sinus surgery can vary significantly and many patients experience persistent or recurrent symptoms and surgery does not address the underlying cause of inflammation. In patients with nasal polyps, regrowth of the nasal polyps has been reported in as high as 60% of cases within four years. Because sinus surgery is not curative and also does not address the underlying cause of the inflammation, many patients continue to require short- and long-term courses of INS after surgery.

Our Solution

OPN-375 combines our EDS with a liquid formulation of fluticasone propionate, a well-characterized, second-generation corticosteroid. OPN-375 is designed to deliver medication into the high and deep regions of the nasal passages where both nasal polyps and inflamed and swollen membranes can obstruct normal sinus ventilation and drainage. In multiple studies utilizing advanced imaging, our EDS produced a differentiated pattern of drug delivery with significantly more drug deposited in the high and deep regions of the nasal passages, areas not well accessed by conventional INS delivery mechanisms. We believe OPN-375 has the potential to become part of the standard of care for the treatment of patients with chronic rhinosinusitis before they progress to more costly treatment alternatives. We also believe that the current treatment practice of postoperative INS use could support OPN-375's adoption as a maintenance therapy to improve outcomes following sinus surgery.

We have conducted five clinical trials evaluating over 1,500 adult patients, including two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials in adults with nasal polyposis and two supportive open-label Phase 3 clinical trials in adults with symptoms of chronic sinusitis with or without nasal polyps. In both Phase 3 pivotal clinical trials, patients treated with OPN-375 experienced statistically significant reductions of both nasal congestion/obstruction symptoms and total polyp grade, which were the co-primary endpoints. Treatment benefits were also observed in all four defining symptoms of chronic rhinosinusitis, as well as in polyp elimination, quality of life, need for sinus surgery and patient global impression of change. In addition, the magnitude of improvement for patients treated by OPN-375 in our

Phase 3 pivotal clinical trials, as measured by the Sinonasal Outcome Test-22, a validated clinical outcome assessment, was comparable to the reported benefits in third-party studies of endoscopic sinus surgery, or ESS, and balloon sinus dilation. In addition, OPN-375 had an adverse event profile generally comparable to the profile reported in similarly designed studies with conventional INS. In our supportive open-label Phase 3 clinical trials, which evaluated approximately 900 patients with symptoms of chronic sinusitis with and without nasal polyps for a period of up to one year, OPN-375 was generally well tolerated and produced results on efficacy endpoints similar to those observed in our Phase 3 pivotal clinical trials. In these supportive trials, we observed comparable symptom improvements in patients with and without nasal polyps and continuing incremental polyp reduction and symptom improvement through 12 months.

We believe OPN-375 will offer a cost-effective treatment solution to payors who are increasingly being asked to pay for multiple high-cost therapies for a variety of diseases priced at tens of thousands of dollars per year. We intend to price OPN-375 comparably to branded INS that are currently approved to treat nasal polyposis. We expect OPN-375 to be adopted by physicians at a natural point in the care pathway for use in patients with chronic rhinosinusitis with or without nasal polyps before they progress to costly surgical interventions or biologic monoclonal antibodies in development for nasal polyposis. Sinus surgery costs between $8,500 and $16,000 per procedure, and we expect that biologic monoclonal antibodies for the treatment of nasal polyposis will cost approximately $35,000 per year based on the doses being studied in nasal polyposis and the current costs per dose in other indications. We believe OPN-375 will offer a cost-effective clinical benefit to payors that will reduce the perceived need for multiple step-edits and prior authorizations, which we believe will increase the likelihood of successful commercial adoption of OPN-375.

Our U.S. Market Opportunity

If we obtain FDA approval of OPN-375 for nasal polyposis, our initial target market will consist of ENT physicians, allergists and primary care physicians in the United States that most frequently prescribe INS. This group of approximately 5,000 primary care physicians, which we refer to as high-decile INS-prescribing primary care physicians, account for approximately 25% of all INS prescriptions written by primary care physicians. We refer to these ENT physicians, allergists and high-decile INS-prescribing primary care physicians collectively as the specialty segment of our target market. We believe the approximately 15,000 physicians in this specialty segment together treat an estimated 3.5 million U.S. patients with chronic rhinosinusitis, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. We believe the total annual U.S. market opportunity for OPN-375 in this specialty segment is over $3.4 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. If we are able to obtain approval for the follow-on indication of chronic sinusitis, we intend to broaden our commercialization efforts to target additional primary care physicians that we believe treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. We refer to these additional primary care physicians as the primary care segment of our target market. We believe the total additional annual U.S. market opportunity for OPN-375 in this primary care segment is over $6.0 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. Therefore, we estimate the total annual U.S. market opportunity for the combined specialty and primary care segments is over $9.5 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps.

Intellectual Property and Barriers to Entry

OPN-375 benefits from substantial intellectual property and other technical barriers to entry, including regulatory and drug delivery complexities. Our patent portfolio for OPN-375 consists of nine issued U.S. patents expiring through 2030 and 12 U.S. patent applications that, if granted, would expire through 2034. We believe the unique features of our EDS, as well as its delivery of a topically-acting drug, will present generic and 505(b)(2) NDA competitors of OPN-375 with human factors engineering challenges specific to drug-device combination products and chemistry, manufacturing and controls challenges unique to suspension and respiratory products. We also believe that any future substitutable generic competitors would be required to conduct, among other things, non-inferiority clinical trials demonstrating equivalent

efficacy and safety outcomes to establish clinical bioequivalence to OPN-375. We believe these clinical trials would require a significant amount of time and capital investment and present clinical development uncertainties.

Our Management Team

We are led by a management team with an average of over 20 years of experience developing and commercializing products at large, multinational pharmaceutical and medical device companies, such as Johnson & Johnson, Sanofi-Aventis, Bristol Myers-Squibb, Takeda and Novartis. Our management team's experience is complemented by its expertise at growing emerging healthcare companies, such as Cephalon, Aton Pharma, NuPathe and Take Care Health System. Our team previously developed our first product using an exhalation delivery system, Onzetra Xsail. We believe the experience of our management team and our broad network of relationships with leaders within the industry and the medical community provide us with insight into product development and identification of product opportunities that benefit patients and physicians in the ENT and allergy specialty segments.

Our Growth Strategy

Our goal is to become a leading specialty pharmaceutical company dedicated to developing proprietary products that become a part of the standard of care for diseases in the ENT and allergy segments. We also plan to expand the use of our EDS into additional indications with significant unmet needs, including potential nose-to-brain drug delivery for central nervous system disorders. The key elements of our strategy are to:

- ***Commercialize OPN-375 in the ENT and allergy specialty segments in the United States.*** We plan to deploy an efficient, go-to-market commercialization model and have begun building our commercial leadership team and organization. Initially, we intend to engage a dedicated specialty sales force to promote OPN-375 to a defined prescriber base consisting of approximately 10,000 ENT and allergy specialists, as well as approximately 5,000 high-decile INS-prescribing primary care physicians. We believe these physicians treat an estimated 3.5 million chronic rhinosinusitis patients, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. We expect our sales force will initially consist of approximately 75 representatives.

- ***Pursue pipeline development of OPN-375 for chronic sinusitis to broaden our market opportunity.*** If approved, we plan to seek a follow-on indication for OPN-375 for the treatment of chronic sinusitis. We believe OPN-375 would be the first drug therapy product approved for the treatment of chronic sinusitis. Upon approval, we plan to broaden our marketing to additional primary care physicians that we believe treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. If we obtain approval for this indication, we may also direct promotional resources to an additional estimated 20 million adults who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.

- ***Develop a pipeline of additional products focused on the ENT and allergy specialty segments.*** We are evaluating the use of our EDS to deliver other drugs or drug combinations, including antibiotics, anticholinergics, antihistamines, mucolytics, leukotriene inhibitors and other medication classes, to treat diseases primarily managed by ENT and allergy specialists. We also intend to explore complementary drug, diagnostic or device technologies or products to make effective use of our commercial infrastructure. We also plan to evaluate strategic licensing, acquisition, development and commercial partnerships that could increase our commercial efficiencies.

- ***Explore business development activities for our EDS outside of the ENT and allergy segments.*** We are exploring the possibility of using our EDS to support nose-to-brain drug delivery. We are in the early stages of clinical development of OPN-300, which combines our EDS with oxytocin for the treatment of Prader-Willi syndrome and autism spectrum disorder. We are in preclinical development of OPN-021, which combines our EDS with orexin-A, for the treatment of narcolepsy or symptoms of other diseases potentially amenable to the same pharmacologic activity, such as Parkinson's disease.

We intend to evaluate business development activities to capture value through the continued development of these assets.

- ***Expand OPN-375 into international markets.*** We have begun an initial assessment of the development and commercialization of OPN-375 for markets outside the United States and plan to conduct further strategic evaluation of such markets if OPN-375 is approved in the United States. We also intend to explore strategic collaboration opportunities in Europe and the rest of the world in order to maximize the commercial potential and the availability of OPN-375 to patients.

Chronic Rhinosinusitis and Market Opportunity

Chronic Rhinosinusitis

Chronic rhinosinusitis is a serious nasal inflammatory disease significantly impacting patients' quality of life and daily functioning. Chronic rhinosinusitis, unlike allergic rhinitis, is characterized by chronic inflammation affecting tissues high and deep in the nasal passages, including the area where the openings from the sinuses normally ventilate and drain, causing symptoms that persist for a period of 8 to 12 weeks or longer. Chronic rhinosinusitis patients typically suffer from these symptoms four to six months a year, with symptoms often persisting for many years.

In medical literature and practice, chronic rhinosinusitis is commonly divided into two subgroups: chronic rhinosinusitis with nasal polyps and chronic rhinosinusitis without nasal polyps. Chronic rhinosinusitis patients with and without nasal polyps suffer from chronic inflammation of the lining of the deep nasal passages and sinuses. Patients with chronic rhinosinusitis with nasal polyps also develop non-cancerous polyps on these chronically inflamed surfaces, typically originating in the deep crevices or sinus cavities on both sides of the nose. We estimate that up to 10 million adults in the United States have chronic rhinosinusitis with nasal polyps. Both subgroups of chronic rhinosinusitis also share the same four defining diagnostic symptoms: nasal congestion/obstruction; facial pain and pressure; rhinorrhea, or runny nose, and postnasal drip; and loss of sense of smell and taste. Additional symptoms include headaches, chronic sleep problems, fatigue, frequent episodes of acute rhinosinusitis and mood disorders. There is evidence suggesting that the harm to a sufferer's quality of life from chronic rhinosinusitis, as measured in multiple domains, such as bodily pain, social functioning and mental health, is comparable to or worse than other serious diseases, including chronic obstructive pulmonary disease, congestive heart failure and angina. As a result, many patients eventually seek surgery for symptom relief.

Although the term chronic rhinosinusitis is often used in medical literature and medical practice, the FDA does not recognize chronic rhinosinusitis as a single indication for drug development purposes. Instead, the FDA recognizes chronic sinusitis, defined as inflammation of the sinuses with a duration longer than eight weeks, and nasal polyposis, defined as non-cancerous polyps on the inflamed tissue of the nasal passages and sinuses, as separate indications for drug development purposes.

The American Academy of Otolaryngology-Head and Neck Surgery estimates that approximately 30 million adults in the United States have chronic rhinosinusitis, and it is estimated that up to 10 million adults have chronic rhinosinusitis with nasal polyps. Chronic rhinosinusitis imposes a significant healthcare burden on insurers and employers. The U.S. healthcare system spends approximately $60 billion annually in direct costs treating patients with chronic rhinosinusitis and its associated symptoms, including an estimated $5 billion on sinus surgeries. In the United States, physicians perform over 500,000 sinus surgeries each year, and we estimate that over seven million adults have undergone sinus surgery to treat chronic rhinosinusitis with and without nasal polyps. Chronic rhinosinusitis has been reported to account for an aggregate of 73 million restricted activity days per year. Additionally, people with chronic rhinosinusitis have been reported to be absent from work because of this disease 6.5% of the time and to suffer a 38% loss of productivity.

Our U.S. Market Opportunity

We estimate that approximately 9.75 million chronic rhinosinusitis patients are currently being treated in physician offices in the United States. We derived this estimate from a large patient claims database that reflects actual treatment patterns of chronic rhinosinusitis over a two-year period from 2010 to 2012. We also estimate that approximately 10,000 ENT and allergy specialists, as well as approximately 5,000 high-decile INS-prescribing primary care physicians, treat approximately 36% of all chronic rhinosinusitis patients in the United States, or approximately 3.5 million patients, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. In accordance with multiple published clinical practice guidelines, physicians typically medically manage chronic rhinosinusitis patients by prescribing INS despite the fact that there are no FDA-approved products for the treatment of chronic sinusitis without nasal polyps. If we obtain FDA approval of OPN-375 for nasal polyposis, we initially intend to target approximately 15,000 physicians in the specialty segment. If we obtain the follow-on indication for chronic sinusitis, we intend to broaden our marketing outreach to additional primary care physicians that treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. We may also direct promotional resources to an additional estimated 20 million people who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.

Based on internal estimates, we believe the total annual U.S. market opportunity for OPN-375 in the specialty segment is over $3.4 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. Based on these same estimates, we believe the total additional annual U.S. market opportunity for OPN-375 in the primary care segment is over $6.0 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps. Therefore, we estimate the total annual U.S. market opportunity for the combined specialty and primary care segments is over $9.5 billion, of which approximately one-third consists of patients with chronic rhinosinusitis with nasal polyps.

Treatment Landscape

The treatment of chronic rhinosinusitis with and without nasal polyps typically begins with medical management. In cases where patients remain symptomatic despite medical management, physicians often recommend various forms of sinus surgery to help restore normal sinus ventilation and drainage. The following is a brief description of the current and potential future treatment landscape for chronic rhinosinusitis with and without nasal polyps:

Current Therapies

- ***Intranasal Steroids.*** Multiple published clinical practice guidelines generally recommend topically-acting INS as the first line of prescription therapy for the treatment of chronic rhinosinusitis with and without polyps. As a result, physicians typically prescribe INS nasal sprays or nasal aerosols despite the fact that there are no FDA-approved products for the treatment of chronic sinusitis without nasal polyps. Therefore, the majority of chronic rhinosinusitis sufferers being treated have tried INS. We estimate that physicians in the United States prescribe approximately 17 million INS prescriptions each year for the treatment of chronic rhinosinusitis. Nasonex, or mometasone furoate nasal spray, is currently the only INS approved by the FDA for the treatment of nasal polyposis. Physicians not only prescribe INS as a standalone therapy, but also typically prescribe INS following sinus surgery as some third-party clinical trials suggest that INS treatment can improve symptoms and delay symptom recurrence.

- ***Oral steroids.*** Physicians may prescribe oral steroids on an episodic basis to patients who have not received sufficient symptomatic relief from INS. Oral steroids are often effective at treating the underlying inflammation associated with the disease and reducing postoperative scarring, but the benefit is temporary. As inflammation returns, many patients resume INS therapy.

- ***Other medical management.*** Physicians commonly employ a variety of other non-surgical treatments in the medical management of chronic rhinosinusitis, including nasal saline rinses, multi-week courses of antibiotics, leukotriene antagonists, decongestants, aspirin desensitization and antifungals. The recognized limitations of drug deposition with current INS cause some physicians to seek out alternative treatment regimens, such as high doses of locally compounded liquid budesonide in high-volume nasal rinses. Chronic rhinosinusitis is one of the most common reasons for adult outpatient antibiotic use in the United States, comprised of approximately 37 million prescriptions per year.

- ***Sinus surgery and other procedures.*** Physicians generally recommend surgical treatment of chronic rhinosinusitis with and without nasal polyps only after patients fail medical management. The primary surgical alternative is ESS, which attempts to open the sinus drainage pathways while preserving as much bone and sinus tissue lining as possible. The physician typically uses rigid steel instruments and powered cutting tools to remove inflamed tissue, including any nasal polyps, and underlying bone to create a larger passage through the nasal anatomy to the sinuses. At the conclusion of the procedure, patients often have their nasal passages packed with a material that acts as a spacer to prevent surgical adhesions and control bleeding. Patients typically require one or more follow-up debridement treatments in which the physician may remove more tissue, crusting, scabs or scar tissue at the area of surgery in order to keep the sinus drainage pathway open and promote proper healing.

Several companies have developed less invasive technologies for the treatment of chronic rhinosinusitis since the introduction of ESS, such as balloon sinus dilation devices and steroid-releasing sinus implants. Balloon sinus dilation employs a high pressure inflated balloon to open blocked sinus pathways to increase ventilation and mucus drainage. Steroid-releasing sinus implants are used to hold open the surgically enlarged sinus, while releasing a steroid over a period of time in order to reduce postoperative sinus inflammation and scarring.

Potential Future Therapies

Several biologic monoclonal antibodies, some of which are already approved for other indications, are being developed for the treatment of nasal polyposis, and are believed to inhibit specific pathways of inflammation present in nasal polyps. These biologic monoclonal antibodies include omalizumab, reslizumab, mepolizumab and dupilumab.

Limitations of Therapies

The current and potential future therapies to treat patients suffering from chronic rhinosinusitis with and without nasal polyps have a number of limitations, including:

- ***Limited efficacy of INS treatments using traditional nasal sprays and nasal aerosols.*** Although steroids are generally pharmacologically effective, conventional INS, including nasal sprays and nasal aerosols, are unable to effectively and consistently place the steroids onto the primary site of inflammation and nasal polyp origin, high and deep in the nasal passages. These products deposit a majority of the drug in the front of the nose or on the floor of the nasal passages, reducing their effectiveness and leaving many patients without sufficient symptomatic relief.

- ***Short-term benefits of oral steroids outweighed by significant side effects.*** Oral steroids offer only temporary benefit and are limited by the risk of significant systemic side effects associated with both short- and long-term use. These side effects include, among others, weight gain; increased risk of infections; loss of bone mineral density; death of bone tissue; cataract formation; glaucoma; adrenal suppression; and psychiatric complications, including mania, depression, and psychosis.

- ***Varying degrees of efficacy with other medical management.*** Other non-surgical treatments have varying degrees of supporting data and efficacy. In addition, high-volume steroid nasal rinses are difficult to administer, can be costly, may risk systemic side effects due to the absorption of the steroid into the body, can be associated with fluid draining from the nose after the procedure and are difficult for patients to comply with over prolonged courses of outpatient therapy.

- ***Sinus surgery and other procedures are costly and may not be a complete solution.*** The effectiveness of sinus surgery varies significantly and many patients experience persistent or recurrent symptoms. Reports have shown that nasal polyp regrowth following surgery occurs in as high as 60% of cases within four years. Because sinus surgery is not curative and also does not address the underlying cause of the inflammation, many patients require short- and long-term courses of INS after surgery and approximately 20% of patients elect surgical revisions. Postoperative scarring and persistent inflammation are common and can compromise symptom outcomes and also negatively impact the ability of the sinuses to heal. Sinus surgery is also a costly procedure, with estimated costs ranging from $8,500 to $16,000 per procedure. While balloon sinus dilation has the ability to open sinuses in a less invasive manner, it also does not address the underlying cause of the inflammation associated with chronic rhinosinusitis and is costly. Similarly, steroid-releasing sinus implants have limited duration of anti-inflammatory effect, are costly and face reimbursement challenges.

- ***Potential future biologic monoclonal antibodies treatment may be costly, difficult to administer or have negative side effects.*** The risks and benefits associated with the use of biologic monoclonal antibodies for the treatment of nasal polyposis are not yet fully established. We expect the use of biologic monoclonal antibodies for the treatment of nasal polyposis to be costly, with estimated costs of approximately $35,000 per year based on the doses being studied in nasal polyposis and the current costs per dose in other indications. These drugs also require subcutaneous injections or intravenous administration that require frequent physician office visits. We believe the systemic nature of these treatments, which target components of the immune response, may result in more adverse side effects than treatments with topically-acting steroids.

Our Solution

OPN-375

Our lead product candidate, OPN-375, combines our EDS with a liquid formulation of fluticasone propionate, a potent, well-characterized, second-generation anti-inflammatory corticosteroid for the treatment of serious nasal diseases characterized by chronic inflammation, such as chronic rhinosinusitis. OPN-375 is designed to deliver fluticasone propionate into the high and deep regions of the nasal passages where nasal polyps or inflamed and swollen membranes can obstruct normal sinus ventilation and drainage. Our NDA for OPN-375 for the treatment of nasal polyposis was accepted for filing by the FDA in January 2017 and the FDA set a Prescription Drug User Fee Act, or PDUFA, date of September 18, 2017 for completion of its review. If approved for the treatment of nasal polyposis, we plan to initiate additional clinical trials of OPN-375 for the treatment of chronic sinusitis. We are seeking regulatory approval of OPN-375 for the treatment of nasal polyposis utilizing the FDA's 505(b)(2) NDA regulatory pathway. The 505(b)(2) regulatory pathway enables us to rely, in part, on the FDA's prior findings in the approval of Flonase and Flovent HFA, both of which contain fluticasone propionate.

If approved, we believe OPN-375 could become a part of the standard of care for the treatment of patients with chronic rhinosinusitis with and without nasal polyps before they progress to more costly treatment alternatives for the following reasons:

- ***High patient dissatisfaction with current INS treatments.*** In a market research study that we commissioned, we surveyed 438 patients with chronic sinusitis with and without nasal polyps. In this study, approximately 80% of the patients reported being frustrated with the symptom relief offered from their current INS medication and approximately 90% of the patients reported they would be interested in using a new product if it would improve symptom relief.

- ***Strong physician interest in OPN-375 product profile.*** We surveyed approximately 700 physicians, consisting of 400 ENT and allergy specialists and 300 primary care physicians that currently treat patients with chronic sinusitis with and without nasal polyps. Approximately 75% of these physicians, including both specialists and primary care physicians, agreed, in part, that INS medications do not work well in patients with chronic sinusitis due to their belief that conventional INS do not sufficiently reach the high and deep regions of the nasal passages where inflammation occurs. In addition, 70% to 80% of these physicians reported that they would "definitely" or "probably" prescribe their patients a product with a clinical profile similar to OPN-375.

- ***Fluticasone propionate is the most widely-prescribed INS in the United States.*** OPN-375 contains fluticasone propionate, a potent, well-characterized, second-generation, anti-inflammatory corticosteroid with a low bioavailability, meaning that only a small percentage of the drug is absorbed into the body. Corticosteroids provide multiple anti-inflammatory mechanisms of action and are used in forms such as pills, creams, inhalers and nasal sprays, to treat many sites of inflammation.

- ***OPN-375 was designed to overcome the limitations of current INS therapies by delivering medication high and deep in the nasal passages***. In multiple studies utilizing advanced imaging, our EDS produced a differentiated pattern of drug delivery with significantly more drug deposited at the primary site of inflammation high and deep in the nasal passages where nasal polyps or inflamed and swollen membranes produce nasal symptoms and can obstruct normal sinus ventilation and drainage.

- ***Strong clinical data demonstrating safety and efficacy.*** In two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials evaluating adult patients with nasal polyposis, we met our co-primary endpoints of statistically significant reductions of nasal congestion/obstruction symptoms and total polyp grade. OPN-375 also produced treatment benefits in all four defining symptoms of chronic rhinosinusitis, as well as in polyp elimination, quality of life, need for sinus surgery and patient global impression of change. In two supportive open-label Phase 3 clinical trials evaluating approximately 900 patients with symptoms of chronic sinusitis with and without nasal polyps for a period of up to one year, OPN-375 was generally well tolerated. In these supportive trials, we observed comparable symptom improvements in patients with and without nasal polyps and continuing incremental polyp reduction and symptom improvement through 12 months.

- ***OPN-375 is easy to use.*** In a market study that we commissioned, 98% of patients reported that OPN-375 was easy to use after four weeks of use and 93% stated the ease of use was comparable to other INS.

- ***Potential for broad payor access.*** In a market research study that we commissioned, we surveyed 26 health insurance plans representing over 150 million covered lives. Most payors reacted positively to a profile of OPN-375 with respect to its product design, mechanism of action and efficacy results based upon our clinical data. This research further suggested that market access for OPN-375 will be dependent on OPN-375's pricing. A majority of payors surveyed in our study indicated that they do not intend to actively manage INS products priced below a certain dollar threshold and many surveyed payors indicated that they would provide access without prior authorization to INS products priced within a certain dollar range. The surveyed payors reported the following potential coverage based on the OPN-375 profile: (i) no step edits on plans covering approximately 27% of commercial lives, meaning that payors would not require patients to use generic INS before seeking reimbursement for OPN-375, (ii) a single step edit on plans covering approximately 48% of commercial lives, (iii) a prior authorization requirement on plans covering approximately 10% of commercial lives and (iv) no coverage by plans covering approximately 15% of commercial lives. In addition to this market research study, we obtained formulary data for INS from various sources representing approximately 159 million covered lives. These data indicate that health insurance plans covering 84% of commercial lives do not require prior authorization in the INS category for contracted products. If approved, we intend to immediately engage payors to secure broad market access for OPN-375 in the commercial segment by targeting Tier 3 payor coverage, single step edit with no prior authorization. This level of coverage indicates that payors would require patients to use

a generic INS as a first step in treating their disease prior to the payor covering OPN-375. However, such coverage would not require the prior authorization of the payor. Tier 3 payor coverage requires a patient co-pay that is higher than that required for generics or drugs within a payor's formulary. We also intend to potentially contract with Medicare to accelerate physician adoption of OPN-375.

§ ***Cost-Effective Solution.*** We intend to price OPN-375 comparably to branded INS that are currently approved to treat nasal polyposis. We believe OPN-375 will offer a cost-effective, clinical benefit to payors that will reduce the perceived need for multiple step-edits and prior authorizations, which we believe will increase the likelihood of successful commercial adoption of OPN-375.

Our EDS

Our exhalation delivery systems enable the development of drug-device combination products intended for self-administration. We have developed both a liquid delivery system and a powder delivery system utilizing natural functional behaviors of the upper nasal airways to offer better drug deposition. These systems are designed to overcome many limitations inherent in conventional nasal spray and nasal aerosol delivery systems, most notably, enabling higher and deeper intranasal drug delivery.

Liquid EDS

The liquid EDS depicted below, which is the EDS used in OPN-375, consists of a primary drug container for the liquid drug formulation and an amber glass vial which are sealed by a crimp-fitted metering spray pump and enclosed within a proprietary liquid delivery subassembly. The nasal spray applicator, which is a component of the subassembly, is attached to the pump and extends to the top of the nosepiece of the liquid delivery subassembly. The EDS includes a flexible mouthpiece and an asymmetrically-shaped nosepiece as part of a mechanism that uses the patient's exhaled breath to naturally seal closed the soft palate and to facilitate delivery of drug to the nasal passages through the sealing nosepiece. The nosepiece is designed to create a seal with the nostril and also to expand and stent the upper part of the nasal valve, which is an important anatomical structure that is the narrowest part of the entire respiratory tract and a barrier that causes most medication delivered by conventional INS to deposit in the front part of the nose.

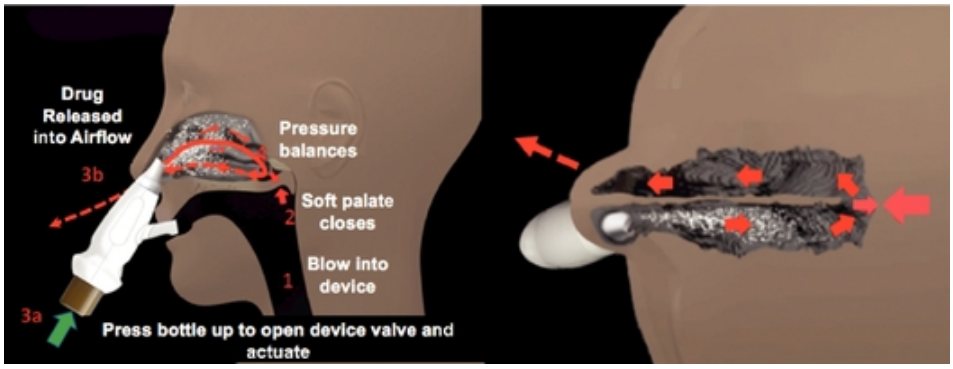
Powder EDS

The powder EDS depicted below, which is the EDS used in Onzetra Xsail, consists of a reusable device body incorporating a flexible mouthpiece to adjust to individual anatomic variations, and a white button piercing assembly to pierce the medication capsule. Disposable nosepieces are provided in a foil pouch to be inserted into the drug delivery device body. Each pre-filled nosepiece section contains a medication capsule containing a dry powder formulation and a clear release tab. The capsule is pierced by pressing and releasing the white button piercing assembly. The flexible mouthpiece and an asymmetrically-shaped nosepiece are part of the mechanism that uses the patient's exhaled breath to naturally seal closed the soft palate and to facilitate delivery of drug to the nasal passages through the sealing nosepiece. The medication capsule is intended for single dose administration and is not refillable or removable from the nosepiece.

Following drug administration, the disposable nosepiece, including the dose-expended medication capsule, is then removed and discarded.

How our EDS works

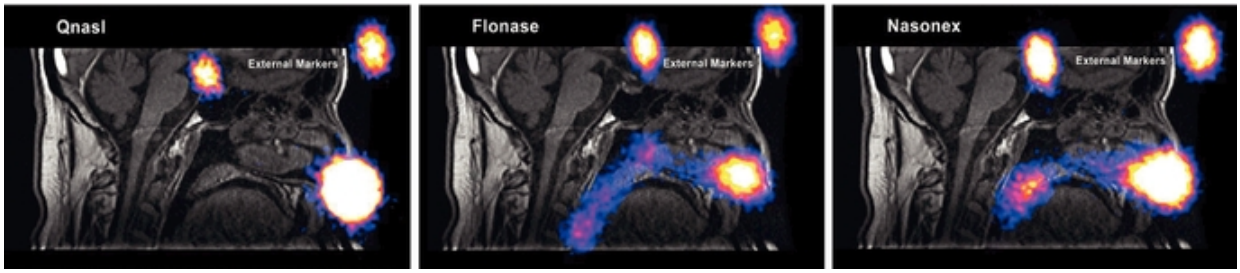
When exhaling into an EDS, the soft palate automatically elevates and creates an air-tight seal separating the nasal cavity from the throat and lungs. This natural action is the same as that which prevents air from escaping from the nose when trying to blow up a balloon or blow a trumpet. The exhaled air is then routed through the EDS which introduces medication into the air flow and then directs the air and medication through the sealing nosepiece. The positive air pressure, which is the opposite of the negative pressure produced by sniffing with ordinary nasal sprays, acts to dynamically expand the nasal valve and the narrowed nasal passages, helping to "float" the drug around obstructing anatomic barriers and fill one side of the nasal cavity. This enables high and deep deposition of medication in the nasal passages. The positive air pressure, proportional to the pressure on the other side of the soft palate, helps to open a passage between the two sides of the nasal cavity, behind the back edge of the nasal septum. The picture below illustrates this action, which allows the exhaled air pressure to escape from the opposite nostril.



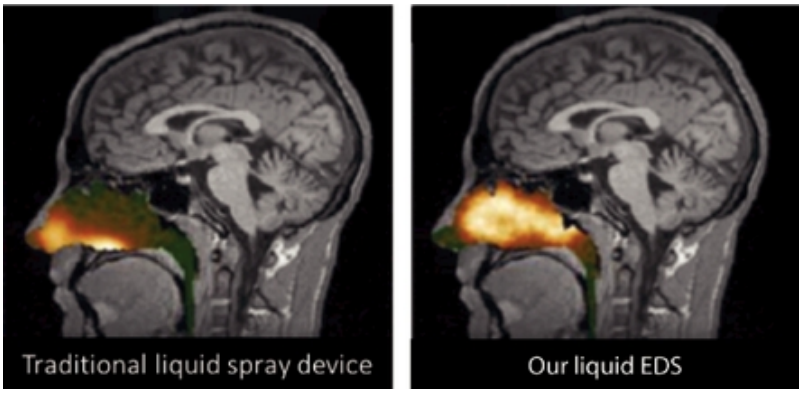
The drug delivery mechanism of our EDS is designed to overcome the drug deposition shortcomings of conventional nasal sprays and nasal aerosols. In conventional nasal sprays and nasal aerosols, the medication is inhaled or sniffed into the nose creating negative pressure within the nasal passages, which does not facilitate the expansion of the nasal valve or the nasal passages and may obstruct the drug from reaching deep into the nose where most nasal polyps and inflamed and swollen sinus membranes exist.

The pattern of drug deposition produced by conventional nasal sprays and our EDS has been evaluated in multiple studies using a combination of advanced imaging modalities to depict the regions of the nasal passages where drug is deposited after administration in human volunteers. In an open label, crossover

study conducted by a third party in nine patients with allergic rhinitis, investigators examined the nasal deposition of radio-labeled materials that allow for traceability following use of Qnasl (HFA-beclomethasone, nasal aerosol), Flonase (fluticasone propionate, nasal spray) and Nasonex (mometasone furoate monohydrate, nasal spray). In this study, gamma cameras were used to capture emitted radiation from these tracers to create two-dimensional images in a similar process to the capture of x-ray images. These gamma images were merged with magnetic resonance images, or MRI, to quantify regional deposition within the nasal passages. The images below illustrate how the pattern of drug deposition in the nasal passages produced by Qnasl, Flonase and Nasonex was concentrated in the front and lower regions of the nasal passages, as opposed to the high and deep regions of the nasal passages targeted in the treatment of chronic rhinosinusitis.

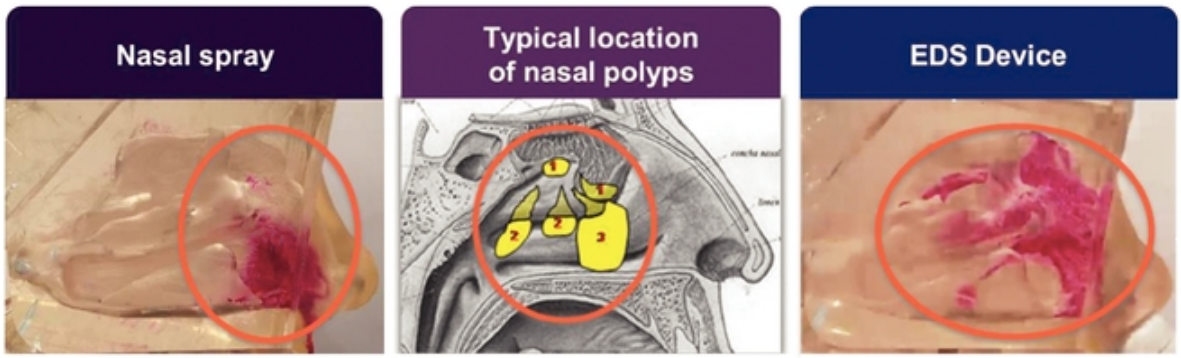


We conducted six deposition studies evaluating 53 subjects that produced approximately 250 images. As depicted in the representative figures below, our EDS produced a differentiated pattern of drug delivery with significantly more drug deposited in the high and deep regions of the nasal passages.



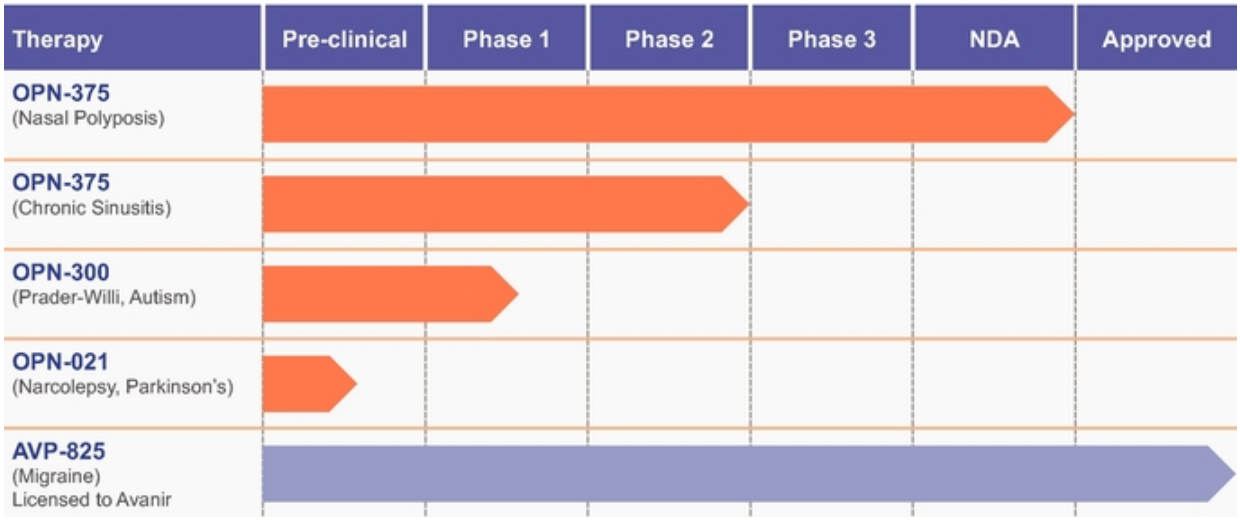
The pictures above use gamma camera image information, which was then superimposed on the corresponding MRI section. These images represent deposition in the two minutes after delivery using a traditional liquid nasal spray and a version of our liquid EDS device. Deposition with traditional liquid nasal spray was greatest in the front parts of the nose, whereas deposition with our EDS was greatest in the high and deep regions of the nose.

The pictures below illustrate how our EDS places medication higher and deeper in the nasal passages. As depicted below, although conventional nasal spray systems can reach, and therefore treat, large nasal polyps, they are not suitable for reaching nasal polyps or inflammation in the higher and deeper regions where obstruction of the sinus openings occurs.



Our EDS is also designed to address user dissatisfaction with standard nasal delivery by reducing drug drip-out from the front and back of the nose and the bad taste that often accompanies drug entering the throat. By reducing the loss of drug to non-targeted sites, such as the gastrointestinal tract by swallowing, or lungs, our EDS has the potential to improve the efficiency of drug activity and to improve tolerability by reducing off-target effects.

Our Pipeline



OPN-375 for Chronic Sinusitis

Subject to FDA approval of OPN-375 for the treatment of nasal polyposis, we plan to initiate additional clinical trials of OPN-375 in the second half of 2018 to seek a follow-on indication for the treatment of chronic sinusitis. We believe OPN-375 would be the first drug therapy product approved for the treatment of chronic sinusitis. Upon approval, we intend to broaden our commercialization efforts to target primary care physicians that we believe treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. If we obtain approval for this indication, we may also direct promotional resources to an additional estimated 20 million adults who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.

Other Product Candidates

Although our initial focus is to prioritize the development of OPN-375 in the ENT and allergy specialty segments, we have applied our EDS to other product candidates in our pipeline across a broad range of disease areas. By placing drug high and deep in the nose, in regions where cranial nerves connect directly with the brain, we believe it may be possible to deliver medications directly into the brain and avoid the difficulties of getting drug past the blood-brain barrier. This may enable treatment of brain diseases using small or large molecules that otherwise do not readily enter the nervous system.

OPN-300

We have engaged in early clinical development activities for OPN-300, which combines our EDS with oxytocin. Oxytocin is a small, naturally occurring peptide currently used to stimulate lactation in breastfeeding women. Oxytocin acts as a neurotransmitter in the brain and has recently been considered a potential novel treatment alternative in several brain disorders due to a growing body of evidence of its critical role in social cognition and behavior. Because oxytocin is a peptide with poor oral bioavailability, nasal administration with our EDS may allow for improved delivery. With standard liquid nasal spray delivery, only a small amount of the drug reaches systemic circulation. It is estimated that less than 0.01% of oxytocin in the blood enters the brain across the blood-brain barrier.

OPN-300 is being developed to target two orphan indications: Prader-Willi syndrome, a rare genetic disorder that is the leading genetic cause of obesity; and autism spectrum disorder. We conducted a Phase 1 clinical trial in late 2013 using OPN-300 in healthy volunteers. In that trial, a low dose of oxytocin delivered using our EDS produced a statistically significantly greater social-cognitive effect as measured with functional magnetic resonance imaging, performance on cognitive tests, and physiological markers, than intravenous administration of the same active ingredient that produced blood levels that were not statistically different. We believe this clinical trial supports the possibility of direct nose-to-brain activity of medication delivered using our EDS. We recently completed a second pilot clinical trial of OPN-300 in adult male patients with autism spectrum disorder. In that trial, adult men with autism spectrum disorder receiving nasal oxytocin showed statistically significant differences in interpretation of facial expressions. We are preparing for additional clinical development activities in pursuit of an indication for Prader-Willi syndrome.

OPN-021

We are in preclinical development of OPN-021, which combines our EDS with orexin-A, also known as hypocretin-A, a peptide that acts as a neurotransmitter in the brain. OPN-021 is being developed for the treatment of narcolepsy or symptoms of other diseases potentially amenable to the same pharmacologic activity, such as Parkinson's disease. Narcolepsy is a chronic neurodegenerative disease caused by a deficiency of orexin-producing neurons in the lateral hypothalamus region of the brain. It is clinically characterized by excessive daytime sleepiness, sudden and uncontrollable muscle weakness or paralysis and by intrusions into wakefulness of physiological aspects of rapid eye movement sleep. We are in the process of developing the formulation for OPN-021 and are planning to initiate a Phase 1 clinical trial when a suitable formulation is prepared.

Other

We are evaluating the use of our EDS to deliver other drugs or drug combinations, including antibiotics, anticholinergics, antihistamines, mucolytics, leukotriene inhibitors and other medication classes used to treat diseases primarily managed by ENT and allergy specialists. We have also identified several other product candidates with the potential to leverage our EDS to create clinically differentiated drug treatments for indications such as central nervous system disorders and pain. We will continue to evaluate opportunities to develop product candidates indicated for markets outside of our ENT and allergy focus through business development activities.

Our Commercial Strategy

We are implementing our commercial strategy for OPN-375 to focus on the following three phases of penetrating the chronic rhinosinusitis markets and become part of the standard of care treatment:

- ***Efficient entry in the ENT and allergy specialty segments:*** We are initially planning to deploy an efficient, specialty-focused, go-to-market commercialization model to launch OPN-375. Initially, we intend to engage a dedicated specialty sales force to promote OPN-375 to a defined prescriber base consisting of approximately 10,000 ENT and allergy specialists comprised of approximately 6,400 offices, as well as approximately 5,000 high-decile INS-prescribing primary care physicians. We believe these physicians treat an estimated 3.5 million chronic rhinosinusitis patients, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps. We expect our sales force will initially consist of approximately 75 representatives.

- ***Facilitate broader adoption:*** If OPN-375 is approved to treat nasal polyposis, we intend to pursue a follow-on indication of chronic sinusitis. Upon approval for the follow-on indication, we intend to broaden our commercialization efforts to target primary care physicians that we believe treat an additional estimated 6.25 million U.S. patients with chronic rhinosinusitis, an estimated one-third of whom have chronic rhinosinusitis with nasal polyps. We may target these physicians through a commercial partnership.

- ***Activate patient demand:*** If we obtain approval for this indication, we may also direct promotional resources to an additional estimated 20 million U.S. people who are not regularly under the care of physicians for this disease using programs such as direct-to-consumer and direct-to-patient promotion.

We intend to efficiently launch into the ENT and allergy segments following approval of OPN-375 by utilizing the following strategies:

- ***Define a clear patient type for OPN-375.*** We intend to focus on moderate-to-severely symptomatic patients who have not achieved satisfactory results with currently available INS.

- ***Establish a compelling brand position in the medical continuum of care.*** In an effort to establish our brand position within the continuum of care, we intend to, among other things, educate physicians, payors and patients on OPN-375's unique mechanism of action and differentiated efficacy profile.

- ***Develop a meaningful payor-friendly value proposition.*** We intend to establish a meaningful value proposition for physicians, payors and patients by highlighting the potential for OPN-375 to reduce or delay the need for surgical intervention, reduce antibiotic prescribing and increase patient satisfaction with treatment outcomes.

- ***Drive awareness, adoption and access.*** If approved, we intend to immediately engage with physicians and payors to educate both constituencies about OPN-375 and its benefits, with the goal of securing broad market access by the time of launch in the second quarter of 2018.

    - **Physicians:** We intend to utilize a contract clinical nurse educator team to target ENT and allergy specialists to (i) increase awareness about OPN-375 within our specialty audience, (ii) familiarize healthcare professionals on the proper administration of OPN-375, (iii) identify patients who will be ready to initiate therapy with OPN-375 when available and (iv) enroll physicians and patients in programs designed to support demand for OPN-375.

    - **Payors:** We intend to engage with payors prior to launch with the objective of securing broad market access in the commercial segment by targeting Tier 3 payor coverage, single step edit with no prior authorization. Specifically, we plan to target pharmaceutical benefit managers, national plans and regional plans representing, in the aggregate, up to approximately 160 million of the estimated 191 million U.S. covered commercial lives.

    - **Patients:** We plan to build a patient and physician support infrastructure in an effort to accelerate physician adoption and reduce the risk of patient abandonment during the fulfillment process. We expect that this infrastructure may include (i) patient samples, (ii) a

co-pay assistance program to enable enrollment at the pharmacy for patients who have commercial coverage, (iii) a sample voucher program, (iv) savings cards for cash payors, (v) reimbursement support programs for the retail channel, (vi) a "specialized" distribution channel to assist patients with the complexities of the payor landscape and (vii) a patient assistance program to provide access to OPN-375 to people who have no or inadequate insurance.

OPN-375 Clinical Development

Overview

We have evaluated OPN-375 in the following five clinical trials comprised of over 1,500 patients:

- two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials designed to compare the safety and efficacy of OPN-375 to a placebo EDS in adults with bilateral nasal polyposis, which we refer to as NAVIGATE I and NAVIGATE II or collectively, our pivotal clinical trials;
- two open-label Phase 3 clinical trials to evaluate the safety of OPN-375 in adults with symptoms of chronic sinusitis with or without nasal polyps, which we refer to as EXHANCE-3 and EXHANCE-12 or collectively, our supportive clinical trials; and
- one Phase 1, open-label, randomized, single-dose, bioavailability study to compare the bioavailability of fluticasone propionate from OPN-375 to Flonase and Flovent HFA in healthy patients and patients with mild-to-moderate asthma.

Clinical Trial Highlights

Our Phase 3 clinical development program included a population of patients generally reflective of our intended patient population, with approximately 90% having previously tried currently available INS and almost one-third having previously undergone sinus surgery. Key results from our Phase 3 clinical trial program include:

- In our pivotal clinical trials, OPN-375 produced statistically significant benefits on both of the co-primary endpoints: a reduction of nasal congestion/obstruction symptoms at week 4 and a reduction in total polyp grade at week 16.
- Patients with nasal polyps generally experienced greater improvements in symptoms and reductions in polyp grade with longer duration of use.
- In our pivotal clinical trials, approximately 16% of patients treated with OPN-375 had nasal polyps eliminated in at least one nostril after 16 weeks of treatment, and approximately 27% had nasal polyps eliminated in at least one nostril after an additional eight weeks of treatment. In our supportive clinical trials, we observed complete response rates in at least one nostril of 48% of patients in EXHANCE-3 and 47.1% of patients in EXHANCE-12.
- In our pivotal clinical trials, OPN-375 produced improvement across all four defining symptoms of chronic rhinosinusitis.
- Over 85% of patients receiving OPN-375 across our pivotal clinical trials reported improvement, and approximately two-thirds reported being "much" or "very much" improved, compared to approximately one-third of patients in the placebo EDS group. In our supportive clinical trials, approximately 70% of patients with symptoms of chronic sinusitis, both with and without nasal polyps, reported that they were "much" or "very much" improved after treatment with OPN-375.
- On a Sinonasal Outcome Test-22, the improvement with the 186- and 372-microgram, or mcg, doses of OPN-375 was superior to the placebo EDS in both NAVIGATE I and NAVIGATE II. The magnitude of improvement associated with treatment with OPN-375 was approximately 20 points. Although cross-trial comparisons have significant limitations and must be interpreted with caution, in a previous third-party study evaluating a large cohort (n=1468) of patients who were underwent sinus surgery, the degree of change on this outcome measure was approximately 18 points.

- After 12 months of treatment with OPN-375 in our supportive clinical trials, at least 50% of patients had a Sinonasal Outcome Test-22 score that was at or below 9.3, which is the average score that has been reported for healthy individuals.

- OPN-375 was well tolerated and had an adverse event profile generally similar to that observed in several comparably designed third party studies, including those of mometasone furoate in nasal polyposis patients and of fluticasone propionate formulations in polyposis and allergic rhinitis patients.

Phase 3 Pivotal Clinical Trials (NAVIGATE I and NAVIGATE II)

We have conducted two independent but comparable randomized double-blinded, placebo controlled Phase 3 clinical trials to examine the safety and efficacy of OPN-375 versus a placebo EDS in adults with bilateral nasal polyposis and moderate nasal congestion/obstruction. These clinical trials, which we refer to as NAVIGATE I and NAVIGATE II, also provided dose-ranging information to support the selection of clinically appropriate dose(s) for commercialization of OPN-375 and served as pivotal clinical trials in our NDA for the treatment of adults with nasal polyposis. These pivotal clinical trials were conducted in the United States, Canada, South Africa and several European countries.

Study Design

Each pivotal clinical trial included a single-blind EDS-placebo lead-in and a placebo EDS control group, a multi-center, multi-national study population to increase generalizability, an assessment of the efficacy of multiple doses (93, 186 or 372 mcg twice daily) over a 16-week period and experts in nasal endoscopy to assess objective efficacy outcomes and adverse events, or AEs, in all patients. We have elected not to pursue FDA approval for the 93-mcg dose. Patients who completed the double-blinded phase of the pivotal clinical trials were allowed to continue in an open-label extension phase in which all patients received 372 mcg of OPN-375 twice daily for up to eight additional weeks. All patients and investigators remained blinded to the original treatment during the open-label phase, allowing for a comparison of as-randomized initial treatments through the end of the open-label extension phase at week 24. We treated a total of 646 adults across both pivotal clinical trials with 568 adults completing the open-label extension phase.

Each of NAVIGATE I and NAVIGATE II had co-primary endpoints of (i) change in subjective nasal congestion/obstruction symptoms from baseline to week 4 and (ii) change in objectively-measured total (bilateral) nasal polyp grade from baseline to week 16. The severity of nasal symptoms was recorded by patients in an electronic diary immediately before dosing in the morning (AM) and evening (PM), and was measured using 7-day average instantaneous AM diary scores. Total (bilateral) nasal polyp grading was assessed with nasoendoscopy and is based on polyp protrusion past certain anatomical landmarks. These grading assessments were performed at screening (baseline) and at weeks 4, 8, 12, 16 (which was the end of the double-blinded phase) and 24 (which was the end of the open-label phase) using a 0 to 3 point scale for each nostril, with 0 representing no polyps and 3 representing severe polyposis. The scores for each nostril were summed to yield a range of 0 to 6 for both nostrils.

These trials also evaluated several secondary endpoints, including the impact of OPN-375 treatment on surgical eligibility and changes in the Sinonasal Outcome Test-22 score, which considers the core defining signs and symptoms of nasal polyposis and the impact on functioning, quality of life and sleep. We also conducted a complete response analysis to evaluate the percentage of patients with a recorded nasal polyp grade of zero on at least one side of the nasal cavity.

Efficacy Results

The 186- and 372-mcg treatment groups achieved statistically significant reductions in the primary assessments of congestion severity at week 4 and reductions in polyp grade at week 16 relative to a placebo EDS. In NAVIGATE I, the differences from the placebo EDS generally increased with each increasing dose of OPN-375 for both co-primary endpoints, meaning that administering higher doses to a patient led to a greater decrease in nasal congestion/obstruction symptoms and bilateral nasal polyp grade. In NAVIGATE II, the 186-mcg group achieved the largest numerical reduction in the primary assessment of congestion

symptom severity, and the 372-mcg group achieved the largest numerical reduction in the primary assessment of polyp grade. On average, patients in both pivotal clinical trials had moderate nasal polyposis (with an average bilateral score of approximately 3.9) at baseline. Patients treated with 372 mcg had the largest mean change in polyp grade in each pivotal clinical trial, with decreases in grade after 16 weeks of 1.1 and 1.4 in NAVIGATE I and NAVIGATE II, respectively. There was also a consistent decrease in average polyp grade over time through 24 weeks.

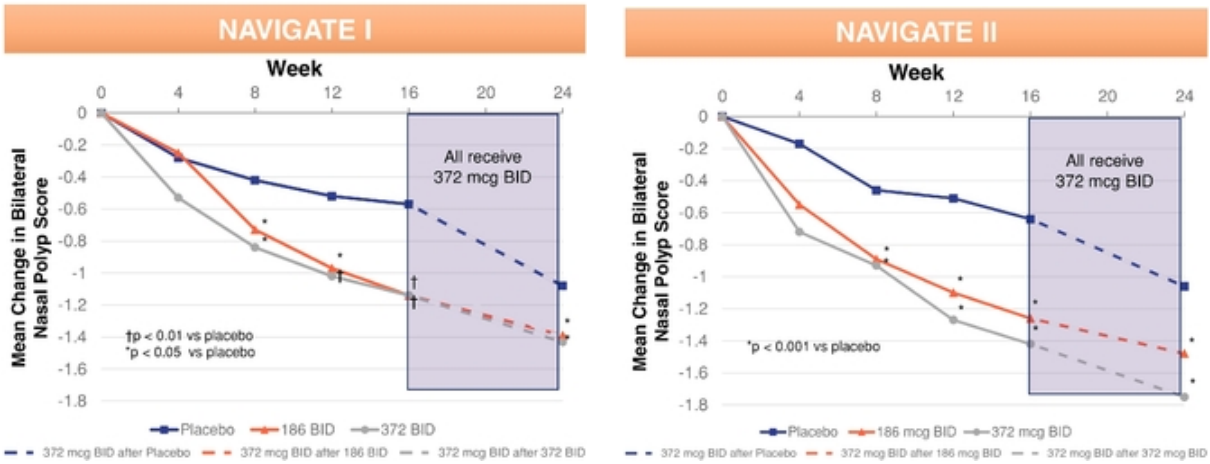
The following table summarizes the mean change in congestion scores in each of the pivotal clinical trials:

Mean Changes from Baseline in AM Congestion Score After 4 Weeks of Treatment in Adult Patients with Nasal Polyposis

				Difference from Placebo EDS		
Treatment	N	Baseline Score (Standard Deviation)	Mean (Standard Error) Change from Baseline	Mean	95% confidence interval	p-value[1]
NAVIGATE I						
OPN-375 372 mcg	79	2.29 (0.44)	–0.62 (0.08)	–0.38	–0.57, –0.19	<0.001
OPN-375 186 mcg	80	2.24 (0.42)	–0.54 (0.08)	–0.30	–0.48, –0.11	0.002
Placebo EDS	82	2.31 (0.41)	–0.24 (0.07)			
NAVIGATE II						
OPN-375 372 mcg	82	2.25 (0.42)	–0.62 (0.07)	–0.38	–0.58, –0.18	<0.001
OPN-375 186 mcg	80	2.20 (0.37)	–0.68 (0.07)	–0.45	–0.65, –0.25	<0.001
Placebo EDS	79	2.29 (0.43)	–0.24 (0.07)			

(1) The p-value, or probability value, is a measure of statistical significance reflecting the likelihood that an observed result occurred by chance.

The following charts summarize the mean change in bilateral nasal polyps score in each of the pivotal clinical trials:



In addition to the co-primary efficacy endpoints described above, we also assessed a number of secondary endpoints in the pivotal clinical trials, including the following:

§ *Sinonasal Outcome Test-22.* In a Sinonasal Outcome Test-22, which broadly assesses the impact of nasal polyposis on certain outcomes, including the symptoms of nasal polyposis, functioning and quality of life, the change observed with the 186- and 372-mcg doses of OPN-375 was superior to

the placebo EDS in both of the pivotal clinical trials. The magnitude of improvement associated with treatment with OPN-375 was approximately 20 points.

§ *Quality of Sleep.* A positive impact of OPN-375 on sleep was shown for the 372-mcg dose in both pivotal clinical trials through the "Sleep" sub-scale of the Sinonasal Outcome Test-22 and, in NAVIGATE II, a positive effect was further shown across a number of the sub-scales of the MOS-Sleep-R, a validated set of measures commonly used in clinical studies to assess changes in sleep quality.

§ *Defining Symptoms.* The 186- and 372-mcg treatment groups, in pooled data for NAVIGATE I and NAVIGATE II, achieved statistically significant improvement in all four of the core defining symptoms of nasal polyposis at the end of the double-blinded phase.

§ *Patient Global Impression of Change.* Patient global impression of change is a summary measure of treatment benefit from the perspective of the patient measuring their perception of improvement or worsening of their condition. At the end of the double-blinded phase, the percentage of patients who were improved was substantially higher with OPN-375 compared with the placebo EDS. Of the patients receiving 186 or 372 mcg of OPN-375, 86% reported improvement combined across both pivotal clinical trials, and 65.9% reported being "much" or "very much" improved. A post-hoc analysis of a subgroup of patients in the NAVIGATE I and II trials who were using a marketed INS at the time of study entry showed similar results, with 65% of patients treated with 186 or 372 mcg of OPN-375 reporting being "much" or "very much improved" after 16 weeks of treatment compared with 28% of patients treated with the placebo EDS.

§ *Need for Surgery.* Surgical eligibility was assessed using standardized criteria defined prior to trial initiation. Surgery was not necessarily planned or pending for these patients. The proportion of patients considered eligible for surgery among the 186-mcg and 372-mcg dose groups combined across both pivotal trials was reduced by 54% after 16 weeks of treatment with OPN-375 versus 36% with the EDS-placebo group and was reduced by approximately 64% after the additional eight weeks of active treatment with the 372-mcg dose.

§ *Complete Response Analysis.* The polyp grading scale is neither linear nor a direct measure of polyp mass, making it difficult to interpret mean change scores. Therefore, we also performed a complete response analysis to evaluate the percentage of patients who had nasal polyps eliminated on at least one side of the nasal passages. The percentage of patients who had nasal polyps eliminated on at least one side of the nasal passages at the end of the double-blinded phase was 14.1% in the 186- and 372-mcg dose groups combined across both pivotal clinical trials, compared to 7.8% of placebo EDS recipients. By the end of 24 weeks, after all patients received up to an additional eight weeks of active treatment with the 372-mcg dose, the complete response rate was 17.3% in patients previously treated with the placebo EDS compared to 26.2% in patients who previously received OPN-375 across the 186- and 372-mcg dose groups in both pivotal clinical trials.

Safety Results

OPN-375 was generally well tolerated across the 186- and 372-mcg dose groups in NAVIGATE I and NAVIGATE II. The most commonly reported AEs in the active treatment groups in the pivotal clinical trials, which are shown in the table below, were associated with local effects at the site of administration in the nasal passages or associated with the underlying disease. Most local AEs were not spontaneously reported but were identified as a result of active monitoring of all patients at scheduled intervals by endoscopic nasal examination at each visit. The majority of these AEs were reported to be mild and were observed to resolve with continued use of OPN-375. A total of six patients in the pivotal clinical trials experienced a total of seven serious adverse events, or SAEs, only one of which, in a patient in the placebo group, was determined to be treatment-related. A total of 2.2% of patients in all treatment groups in the pivotal clinical trials discontinued treatment during the double-blinded phase because of adverse reactions. The rate of withdrawal due to adverse reactions among patients receiving OPN-375 (1.6%) in the pivotal clinical trials was lower than the rate among patients receiving the placebo EDS (3.7%).

Summary of Adverse Events with OPN-375 Reported in ³ 3% of Patients with Nasal Polyposis and More Common Than Placebo EDS in Phase 3 Pivotal Clinical Trials

Adverse Event	Placebo EDS (N = 161) n (%)	OPN-375 186 mcg (N = 160) n (%)	OPN-375 372 mcg (N = 161) n (%)
Patients with at least one AE	80 (49.7)	84 (52.5)	96 (59.6)
Epistaxis	10 (6.2)	35 (21.9)	37 (23.0)
Nasal mucosal bleeding identified by nasal endoscopy	6 (3.8)	29 (18.2)	35 (21.7)
Epistaxis identified other than by nasal endoscopy	4 (2.5)	19 (11.9)	16 (9.9)
Nasal septum ulceration	3 (1.9)	11 (6.9)	12 (7.5)
Nasopharyngitis	8 (5.0)	3 (1.9)	12 (7.5)
Nasal mucosal disorder (erythema or ulceration not at the nasal septum)	8 (5.0)	15 (9.4)	11 (6.8)
Nasal congestion	6 (3.7)	7 (4.4)	9 (5.6)
Acute sinusitis	6 (3.7)	7 (4.4)	8 (5.0)
Nasal septum disorder (erythema)	3 (1.9)	6 (3.8)	7 (4.3)
Headache	5 (3.1)	8 (5.0)	6 (3.7)
Pharyngitis	2 (1.2)	2 (1.3)	5 (3.1)

N = number of patients; n = number of patients in subset.

Phase 3 Open-Label Clinical Trials (EXHANCE-3 and EXHANCE-12)

We also conducted two supportive, open-label Phase 3 clinical trials in adults with symptoms of chronic sinusitis with or without nasal polyps. The supportive clinical trials, which we refer to as EXHANCE-3 and EXHANCE-12, were conducted in the United States with a primary objective to assess the safety of twice-daily intranasal administration of the 372 mcg dose of OPN-375 in an expanded number of patients and over an extended period of time. We also assessed a variety of objective and subjective efficacy parameters, including an assessment of each patient's symptoms and functioning and qualification for surgical intervention.

Study Design

Eligibility for enrollment, endpoint and study design were similar in EXHANCE-3 and EXHANCE-12 with the exception of duration (3 months in the case of EXHANCE-3 and 12 months in the case of EXHANCE-12). Across both supportive clinical trials, a total of 898 adults were treated, including 762 adults with chronic sinusitis without nasal polyps and 136 adults with symptoms of chronic sinusitis with nasal polyps.

Safety Results

OPN-375 was generally well tolerated. As shown in the table below, 59.2% of patients in the supportive clinical trials experienced at least one treatment-emergent AE, with the most common being similar to those in the OPN-375 treatment groups of the pivotal clinical trials. The most common AEs were local (in the nose) and not systemic. Most AEs were mild and resolved with continued use of OPN-375. A total of 12 patients experienced a total of 14 SAEs in the supportive clinical trials, none of which were deemed treatment-related. Approximately 80% of patients completed the supportive clinical trials, with approximately 5% discontinuing due to an AE and 1% discontinuing for lack of efficacy.

Summary of Adverse Events Reported in ³ 3% of Patients in EXHANCE 3 AND EXHANCE 12

Adverse Event	OPN-375 372 mcg (N = 898) n (%)
Patients with at least 1 Adverse Event	532 (59.2)
Epistaxis	164 (18.3)
Epistaxis identified other than by nasal endoscopy	73 (8.1)
Nasal mucosal bleeding identified by nasal endoscopy[a]	124 (14.4)
Nasal mucosal disorder (erythema or ulceration not at the nasal septum)	109 (12.1)
Nasal septum disorder (erythema)	71 (7.9)
Nasal septum ulceration	53 (5.9)
Acute sinusitis	48 (5.3)
Upper respiratory tract infection	46 (5.1)
Headache	44 (4.9)
Nasal congestion	34 (3.8)
Cough	27 (3.0)

a = Some patients had both a spontaneously reported epistaxis AE and a nasal examination epistaxis finding.

Efficacy Results

Efficacy was also measured in EXHANCE-3 and EXHANCE-12. Key efficacy results from EXHANCE-3 and EXHANCE-12 included:

- On the Lund-Mackay scale, which is an endoscopic objective assessment of disease in the nasal passages, scores for edema, nasal discharge and nasal polyps decreased through up to 12 months of treatment, with similar benefits observed in patients who did or did not have nasal polyps at baseline. Among those patients entering the clinical trials with endoscopic evidence of edema within the nasal cavity, approximately 35% with polyps and 53% without polyps in EXHANCE-3 and 50% with polyps and 56% without polyps in EXHANCE-12 no longer had observable edema by the end of the study.

- Patients with nasal polyps experienced improvement in nasal polyp grades. As observed in the pivotal clinical trials, mean nasal polyp grading scale scores improved more with longer durations of treatment. In addition, the percentage of nasal polyp patients with a polyp grade of 0 on at least one side of the nose was 47.1% in EXHANCE-12 and 48.0% in EXHANCE-3 by the end of their participation in the study.

- Mean total Sinonasal Outcome Test-22 scores improved throughout both supportive clinical trials. After 12 months of treatment with OPN-375 in our supportive clinical trials, at least 50% of patients had a score that was at or below 9.3, which is the average score that has been reported for healthy individuals.

Phase 1 Bioavailability Clinical Trial

We performed a Phase 1, open-label, randomized, single-dose, bioavailability clinical trial of OPN-375 and Flonase in healthy patients and OPN-375 and Flovent HFA in patients with mild-to-moderate asthma. We conducted the Phase 1 clinical trial to establish a bridge between OPN-375, which consists of our fluticasone propionate formulation combined with our EDS, and Flonase and Flovent HFA, the reference listed drugs for our NDA. We chose fluticasone propionate in part because it has limited absorption into the body. In our NDA, we relied in part on the FDA's previous findings of safety for Flonase and Flovent HFA, including non-clinical toxicology findings and findings of systemic safety risks related to hypothalamic-pituitary-adrenal, or HPA, axis suppression, which is a known side effect of corticosteroids. To do so, we

were required to establish that the systemic exposure, or the amount of drug absorbed into the body, to fluticasone propionate following use of OPN-375 did not exceed the exposure produced by Flovent HFA.

Study Design

Part one of the clinical trial was a three-way, three-treatment, three-sequence crossover study in healthy patients in which patients were randomized to a sequence containing the following treatments: 186 mcg (1 × 93 mcg to each nostril) of OPN-375; 372 mcg (2 × 93 mcg to each nostril) of OPN-375; and 400 mcg (4 × 50 mcg to each nostril) of Flonase. The primary objective of part one was to assess and compare the systemic exposure of a single dose of 186 mcg and 372 mcg of OPN-375 with 400 mcg of Flonase in healthy patients. If one or both of the test doses resulted in a systemic exposure that was at least 125% of that of Flonase, then part two was to be conducted. Part two of the clinical trial was a two-way, two-treatment, two-sequence crossover study in mild-to-moderate asthmatic patients in which patients were randomized to a sequence containing the following: 372 mcg (4 × 93 mcg) of OPN-375 and 440 mcg (2 × 220 mcg) of Flovent HFA. The primary objective of part two was to assess and compare the systemic exposure produced by a single dose of 372 mcg of OPN-375 with 440 mcg of Flovent HFA in mild-to-moderate asthmatic patients. A total of 112 adults were examined across both parts of the clinical trial.

Results

In part one of the clinical trial, peak and total exposure to fluticasone propionate was higher following 372 mcg of OPN-375 compared to 400 mcg of Flonase. Peak exposure to fluticasone propionate was also higher for 186 mcg of OPN-375 than 400 mcg of Flonase, but total exposure was higher for 400 mcg of Flonase than 186 mcg of OPN-375. In part two of the clinical trial, doses of 372 mcg of OPN-375 produced systemic exposure substantially lower than that of 440 mcg of Flovent HFA. In particular, peak plasma of the drug, or C_{max}, and the total amount of absorption, known as the area under the curve from time 0 to infinity, or AUC0-∞, were approximately 37% and 50% lower following administration of 372 mcg of OPN-375 relative to 440 mcg of Flovent HFA, respectively. We believe these results support our use of Flonase and Flovent HFA as referenced listed drugs in our NDA for OPN-375.

Regulatory Exclusivity and Barriers to Entry

OPN-375 benefits from substantial intellectual property and regulatory barriers to entry, including the following:

- ***Strong patent protection.*** Our OPN-375 patent portfolio consists of nine issued U.S. patents expiring through 2030 and 12 U.S. patent applications that, if granted, would expire through 2034. We rely primarily on the protections afforded by device and method of use patents. Our issued U.S. patents and patent applications for OPN-375 are based on our EDS, including the combination of this technology with fluticasone propionate.

- ***Complex drug-delivery system.*** We believe the unique features of our EDS, as well as its delivery of a topical-acting corticosteroid, affords us significant protection against generic competition, as well as against a potential 505(b)(2) NDA, that seeks to reference OPN-375 in order to obtain approval for a therapeutically equivalent, substitutable competitor product. OPN-375, utilizing our proprietary EDS, presents human factors engineering complexities for drug-device combination products and chemistry, manufacturing and controls challenges unique to suspension and respiratory products. Any future substitutable generic entrant will need to have considerable combination product know-how to develop and validate a substitutable drug delivery device or technology to compete with our EDS.

- ***Clinical and regulatory complexity.*** We have conducted a clinical development program comprised of over 1,500 patients to support our NDA for OPN-375 to treat nasal polyposis, including human factors studies and Phase 3 clinical trial assessments evaluating and validating the use of our EDS. As with other drugs that primarily have local activity, we believe the regulatory pathway for products seeking approval as substitutable generic equivalents to OPN-375 will be more complex and costly than the pharmacokinetic studies generally required for systemically-acting medications. We believe current FDA guidance for substitutable INS generally requires the demonstration of "clinical

bioequivalence," which has caused developers to conduct non-inferiority clinical trials. Clinical trials in nasal polyposis are different from those that have been performed to support approval of generic INS for allergic rhinitis. We believe potential generic competitors to OPN-375 must not only demonstrate efficacy versus placebo, but must also show equivalent efficacy and safety outcomes to establish clinical bioequivalence to OPN-375, requiring a significant amount of time and capital investment and presenting clinical development uncertainties.

§ ***Three-year regulatory exclusivity.*** We have requested, and believe OPN-375 may be eligible for, three-year regulatory exclusivity. If granted, this exclusivity means that we will be afforded at least three years in which to market our product free of generic or 505(b)(2) competition post-NDA approval.

Intellectual Property

We strive to protect our proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our product candidates and technologies that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, as well as know-how, trademarks, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We internally developed our intellectual property related to our EDS, AVP-825 and our product candidates, including OPN-375. We have sought and intend to continue to seek appropriate patent protection for our product candidates, as well as other proprietary technologies and their uses by filing patent applications in the United States and selected other countries.

Patents

As of June 13, 2017, we owned a total of 43 U.S. patents and 35 pending U.S. patent applications. These U.S. patents will expire between 2020 and 2030. These U.S. patent applications, subject to issuance, would be projected to expire between 2020 and 2035, with potential patent term adjustments that would extend the patent term. In addition to our U.S. intellectual property, we also own 185 foreign issued patents, which will expire between 2020 and 2033 and 132 foreign patent applications, which will expire between 2020 and 2035, subject to issuance.

Our OPN-375 patent portfolio consists of nine issued U.S. patents and 12 pending U.S. patent applications. Our issued U.S. patent portfolio consists of device and method of use patents expiring between 2020 and 2030. Our pending patent applications in the United States, subject to issuance, would be projected to expire between 2022 and 2034, with potential patent term adjustments that would extend the patent term.

If OPN-375 is approved, certain of our patents and patent applications, if granted, will be published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated NDA, or ANDA, or a 505(b)(2) NDA. If any of these potential generic competitors claim that their product will not infringe OPN-375's listed patents, or that such patents are invalid, then they must send notice to us once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. We may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification, which would automatically prevent the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

The rest of our patent portfolio largely relates to patents and applications owned by us and directed to AVP-825 and other product candidates, including OPN-300 and OPN-021.

Trade Secrets and Other Proprietary Information

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants and other advisors to execute confidentiality agreements upon the

commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions. Further, we generally require confidentiality agreements from business partners and other third parties that receive our confidential information.

Trademarks

We also rely on trademarks and trade designs to develop and maintain our competitive position. We have received trademark registration for OptiNose and Breath Powered in the United States.

AVP-825 License Agreement

In July 2013, we, through our wholly-owned subsidiary, OptiNose AS, entered into a license agreement, or the AVP-825 License Agreement, with Avanir pursuant to which we granted an exclusive license to Avanir to further develop and commercialize AVP-825, a combination of our EDS with a lose-dose sumatriptan powder, for the acute treatment of migraines in adults, in the United States, Canada and Mexico, which we refer to collectively as the Licensed Territory. AVP-825 was approved by the FDA in January 2016 for the acute treatment of migraines in adults and became commercially available in May 2016 under the brand name Onzetra Xsail.

We have received $70.0 million in aggregate licensing revenues to date, consisting of an up-front fee of $20.0 million received in 2013, a $2.5 million payment received in June 2014 upon the achievement of a development milestone and a $47.5 million payment received in February 2016 upon FDA approval of AVP-825. We are eligible to receive up to an additional $50.0 million upon the achievement of annual sales milestones and tiered low double-digit royalty payments once and if net sales of the product exceed a specified cumulative threshold.

Unless earlier terminated in accordance its terms, the AVP-825 License Agreement, including the royalty payments, will remain in effect on a country-by-country basis in the Licensed Territory until the commercial launch of a generic product in such country, at which time the AVP-825 License Agreement, including the royalty payments, will expire as to that particular country. In the United States, which to date is the only jurisdiction in the Licensed Territory in which AVP-825 has been approved for marketing, the commercial launch of a generic version of AVP-825 can occur as soon as the FDA grants marketing approval to a product as a generic to AVP-825. Avanir may terminate the AVP-825 License Agreement in its sole discretion upon prior written notice to us as described in the agreement. We may terminate the AVP-825 License Agreement if Avanir commences any legal or administrative proceeding to revoke or challenge the validity of certain of the intellectual property we licensed to Avanir pursuant to the AVP-825 License Agreement. In addition, the AVP-825 License Agreement provides for customary termination rights in the event of a breach of the AVP-825 License Agreement by the other party.

Manufacturing and Distribution

Manufacturing

We currently contract with third parties for the manufacture, testing and storage of our product candidates. In our experience, contract manufacturers, or CMOs, are generally cost-efficient and reliable and therefore we currently have no plans to build our own clinical or commercial manufacturing capabilities. Because we rely on CMOs, we employ personnel with extensive technical, manufacturing, analytical and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions. Manufacturing is subject to extensive regulations that

impose various procedural and documentation requirements, and which govern record-keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Our systems and our contractors are required to comply with these regulations, and we assess this compliance regularly through monitoring of performance and a formal audit program. To date, our third-party manufacturers have met our manufacturing requirements for clinical trials.

We have entered into supply agreements with a number of CMOs for the commercial manufacture and supply of OPN-375:

- In July 2017, we entered into a supply agreement with Hovione Inter Ltd, or Hovione, for the supply of fluticasone propionate, the active pharmaceutical ingredient included in the liquid suspension formulation. This agreement has a term of five years from commercial launch of OPN-375, subject to earlier termination or extension in accordance with the terms of the agreement. Either we or Hovione may terminate the agreement prior to that date for uncured material breach or insolvency of the other party. We may also terminate the agreement in the event Hovione, among other things, (i) loses any required FDA approval rendering it unable to fulfill its contractual obligations, (ii) is engaged in felonious or fraudulent activities or (iii) does not submit a Corrective and Preventive Action plan to the FDA within a specified period of time of being notified of deficiencies in Hovione's facility.

- In August 2017, we entered into a manufacture and supply agreement with Contract Pharmaceuticals Limited Canada, or CPL, for the formulation and assembly of the finished drug product during the fill/pack operation. This agreement has a term of five years from the date on which we provide a purchase order for validation batches to CPL, subject to earlier termination or extension in accordance with the terms of the agreement. Either we or CPL may terminate the agreement prior to that date by mutual consent or for uncured material breach by or insolvency of the other party. We may also terminate the agreement if, among other things, any intellectual property of any third party is reasonably alleged by a third party to be infringed, misappropriated or otherwise violated by the manufacture, import, use, sale or distribution of OPN-375 or if any regulatory authority requires us to cease production of the sale of OPN-375.

We expect that our third-party manufacturers will be capable of providing sufficient quantities of OPN-375, if approved, to meet anticipated commercial demands.

Distribution

We plan to establish a distribution channel in the United States for the commercialization of OPN-375, if approved. We expect to sell OPN-375, if approved, to wholesale pharmaceutical distributors, who, in turn, will sell OPN-375 to pharmacies, hospitals and other customers. We expect to use a third-party logistics provider for key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing and accounts receivable management.

Competition

Our industry is highly competitive and subject to rapid and significant technological change as research provides a deeper understanding of the pathology of diseases and new technologies and treatments are developed. We believe our scientific knowledge, technology, and development capabilities provide us with substantial competitive advantages, but we face potential competition from multiple sources, including large pharmaceutical, biotechnology, specialty pharmaceutical and, to a lesser degree, medical device companies.

OPN-375, if approved, will compete primarily with INS, oral steroids and other medical management products, including locally compounded liquid budesonide in high-volume nasal rinses. OPN-375, if approved, will also compete with surgical procedures, balloon sinus dilation products and steroid-releasing sinus implants. Key competitive factors affecting the commercial success of OPN-375 and any other product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement.

The only INS on the market indicated for the treatment of nasal polyposis is Nasonex, which is marketed by Merck & Co., Inc. In addition, Beconase AQ, which is an INS marketed by GlaxoSmithKline, is indicated for the prophylaxis of nasal polyps after surgical resection. There are no products approved for the treatment of chronic rhinosinusitis without nasal polyps. There are two categories of INS: first-generation INS products, which include Rhinocort, Nasacort AQ and Qnasl; and second-generation INS products, which include Flonase, Veramyst, Omnaris and Zetonna. The primary difference between first- and second-generation INS products is that first-generation INS are absorbed into the blood to a greater extent than second-generation INS, with systemic bioavailability ranging from 10% to 50% compared to a systemic bioavailability with fluticasone propionate, a second-generation INS, of less than 2%. Many of the most widely-prescribed INS products are available in generic form and some, such as Flonase, are available over-the-counter.

Several companies are also currently developing biologic monoclonal antibodies for the treatment of nasal polyposis. These biologic monoclonal antibodies, which inhibit specific pathways of inflammation present in nasal polyps, include omalizumab, reslizumab, mepolizumab and dupilumab. Omalizumab has been studied in investigator-initiated Phase 2 clinical trials. GlaxoSmithKline has studied mepolizumab in a sponsor-initiated Phase 2 clinical trial and plans to begin enrolling patients in a Phase 3 clinical trial later this year with study completion anticipated in 2019. Dupilumab has been studied in a sponsor-initiated Phase 2 clinical trial and Sanofi is currently investigating it in two Phase 3 clinical trials that are enrolling patients and expected to be completed in the second half of 2018. If these biologic monoclonal antibodies are successfully developed and approved for marketing, they could represent significant competition for OPN-375.

Government Regulation

As a pharmaceutical company that operates in the United States, we are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act, or the FD&C Act, and FDA's implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, advertising and promotion of our product candidates. Although the discussion below focuses on regulation in the United States, because that is currently our primary focus, we anticipate seeking approval for, and marketing, our products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences.

Development and Approval

Under the FD&C Act, FDA approval of an NDA is required before any new drug can be marketed in the United States. NDAs require extensive studies and submission of a large amount of data by the applicant.

Preclinical Testing. Before testing any compound in human patients in the United States, a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice, or GLP, regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Application. Human clinical trials in the United States cannot commence until an investigational new drug, or IND, application is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA. Once human clinical trials have commenced, the FDA may stop a clinical trial by placing it on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board, or IRB. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of AEs. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e.g., http://clinicaltrials.gov). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human patients, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs.

- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

NDA Submission and Review. The FD&C Act provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FD&C Act is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of preclinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate.

Section 505(b)(2) of the FD&C Act provides an alternate regulatory pathway to obtain FDA approval for new formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the reference listed drug, or RLD, and submit its own product-specific data — which may include data from preclinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the RLD. We submitted an NDA for OPN-375 to the FDA in November 2016 through the Section 505(b)(2) regulatory approval pathway, with Flonase and Flovent HFA as the RLDs. Flonase and Flovent HFA contain fluticasone propionate, which is also used in OPN-375.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually has followed such recommendations.

Our product candidates include products that combine drug and device components in a manner that the FDA considers to meet the definition of a "combination product" under FDA regulations. The FDA exercises significant discretion over the regulation of combination products, including the discretion to require separate marketing applications for the drug and device components in a combination product. For our product candidate OPN-375, FDA's Center for Drug Evaluation and Research, or CDER, will have primary jurisdiction for review of the NDA, and both the drug and device will be reviewed under one marketing application. However, for a drug-device combination product CDER typically consults with the Center for Devices and Radiological Health in the NDA review process.

The FDA may determine that a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practice, or cGMP, requirements and adequate to assure consistent production of the product within required specifications.

Once an NDA submission has been accepted for filing — which occurs, if at all, within 60 days after submission of the NDA — the FDA's goal for a non-priority review of an NDA is ten months. The review process can be and often is significantly extended, however, by FDA requests for additional information, studies, or clarification. After review of an NDA, the FDA may decide to not approve the application or may issue a complete response letter outlining the deficiencies in the submission. The complete response letter also may request additional information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor.

Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the

availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as "Phase 4" or "post-marketing" studies.

Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

Post-Approval Regulation

Once approved, products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials if new safety information develops.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

It is also likely that we will need to comply with some of FDA's manufacturing regulations for devices. FDA has discretion in determining post-approval compliance requirements for products that combine a drug substance with a delivery system device. In addition to cGMP, FDA may require that our drug-device combination product, if approved, comply with the Quality System Regulation, or QSR, which sets forth the FDA's manufacturing quality standards for medical devices.

Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and not described in the product's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human

Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug.

Other Requirements. NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the RLD. Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

505(b)(2) NDAs. As discussed above, if a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under section 505(b)(2) of the FD&C Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on the FDA's finding that the RLD is safe and effective, and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Regulatory Exclusivities. The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a "new chemical entity," or NCE — generally meaning that the active moiety has never before been approved in any drug — there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains new clinical data, derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office, or PTO, in consultation with the FDA, reviews and approves the application for patent term restoration. When any of our products is approved, we intend to seek patent term restoration for an applicable patent when it is appropriate.

Other Exclusivities

Pediatric Exclusivity. Section 505A of the FD&C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or *Orange Book* listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. We may seek orphan drug designation and exclusivity for OPN-300, which we are developing for the treatment of Prader-Willi syndrome and autism spectrum disorder.

U.S. Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, which we refer to together as the Affordable Care Act, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law

substantially changes the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service's 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Details of the changes to the Medicaid Drug Rebate program and the 340B program are discussed under the risk factor "*If we are able to successfully commercialize OPN-375 and if we participate in but fail to comply with our reporting and payment obligations under the Medicaid drug rebate program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects*" in the "Risk Factors" section of this prospectus.

Some states have elected not to expand their Medicaid programs to individuals with an income of up to 133% of the federal poverty level, as is permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products for which we receive regulatory approval, business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the Affordable Care Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has announced delays in the implementation of key provisions of the Affordable Care Act.

Moreover, legislative changes to or regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration. The American Health Care Act of 2017, or AHCA, which would repeal and replace key portions of the Affordable Care Act was passed by the U.S. House of Representatives but remains subject to passage by the U.S. Senate. In addition, in January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. We expect that the Affordable Care Act, as currently enacted or as it may be amended or replaced in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of products for which we receive regulatory approval or to successfully commercialize our product candidates, if approved.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government healthcare programs such as Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third-party payors determine which drugs they will cover and the amount of reimbursement they will provide for a covered drug. In the U.S., there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

In order to secure coverage and reimbursement for our products, if approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our product candidates may not be considered medically necessary or cost-effective by payors. Further, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. The Centers for Medicare and Medicaid Services, or CMS, surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates.

Participation in the Medicaid Drug Rebate program would require us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount is recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. The terms of our participation in the program would impose a requirement for us to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision.

Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of AMP and the Medicaid rebate amount under the Affordable Care Act or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations.

In the U.S. Medicare program, outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C.

Coverage and reimbursement for covered outpatient drugs under Part D are not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and

therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques.

The availability of coverage under Medicare Part D may increase demand for products for which we receive marketing approval. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program could decrease the coverage and price that we receive for any approved products and could seriously harm our business.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we expect to participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, we would be obligated to make our "innovator" drugs available for procurement on an FSS contract and charge a price to four federal agencies — the VA, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard — that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. We also expect to participate in the Tricare Retail Pharmacy program, under which we would pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. Civil monetary penalties can be applied if a manufacturer is found to have knowingly submitted any false price information to the government or fails to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate the manufacturer's Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for the manufacturer's covered outpatient drugs. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal Civil False Claims Act.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs, and reform government program reimbursement methodologies for drug products.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. If Congress does not take action in the future to modify these sequestrations, Medicare Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment legislation could have a similar effect.

Further, the Affordable Care Act may reduce the profitability of drug products. It expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, increased the minimum Medicaid rebate due for most innovator drugs, and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid drug rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $4.0 billion in 2017, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The Affordable Care Act also expanded the Public Health Service's 340B program to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

Legislative changes to and regulatory changes under the Affordable Care Act remain possible in the 115th U.S. Congress and under the Trump Administration, as discussed above under the heading "U.S. Healthcare Reform." In addition, there likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to contain healthcare costs. Thus, even if we obtain favorable coverage and reimbursement status for any products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additional information regarding these programs is discussed under the risk factor "*If we are able to successfully commercialize OPN-375 and if we participate in but fail to comply with our reporting and payment obligations under the Medicaid drug rebate program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects*" in the "Risk Factors" section of this prospectus.

Healthcare Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, our business will be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third-party reimbursement becomes available for one or more of our products. These laws include, but are not limited to, anti-kickback and false claims statutes.

The federal Anti-kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. The Affordable Care Act amended federal law to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceuticals, including certain discounts, or engaging such individuals as consultants, speakers or advisors, may be subject to scrutiny if

they do not fit squarely within the exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Arrangements that implicate the Anti-Kickback Statute and do not fit within an exception or safe harbor are reviewed on a case-by-case basis to determine whether, based on the facts and circumstances, they violate the statute.

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Actions under the federal civil False Claims Act may be brought by private individuals known as qui tam relators in the name of the government. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal civil False Claims Act for, among other things, providing free product to customers with the expectation that the customers would bill federal programs for the product, inflating prices reported to private price publication services which are used to set drug payment rates under government healthcare programs, and other interactions with prescribers and other customers including interactions that may have affected customers' billing or coding practices on claims submitted to the federal government. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. Federal enforcement agencies also have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which we refer to collectively as HIPAA, also created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.

The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the previous calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to

challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

Healthcare Privacy Laws

We may be subject to laws and regulations covering data privacy and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under HIPAA.

Foreign Corrupt Practices Act

In addition, the U.S. Foreign Corrupt Practices Act prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity.

Our Corporate Information

We were incorporated in May 2010. Our predecessor entity OptiNose AS was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became our subsidiary as part of an internal reorganization.

Employees

As of August 1, 2017, we had a total of 33 full-time employees (including three in the United Kingdom and one in Norway) and three part-time employees. We have no collective bargaining agreements with our employees and none are represented by labor unions. We consider our current relations with our employees to be good.

Properties

Our principal office is located in Yardley, Pennsylvania, where we lease approximately 20,500 square feet of office space pursuant to a lease that expires in March 2018. We also lease facilities in Ewing, New Jersey, Oslo, Norway and Swindon, England. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space will be readily available on commercially reasonable terms.

Legal Proceedings

We are not currently a party to any legal proceedings.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our current executive officers and directors, including their ages as of August 1, 2017:

Name	Age	Position(s)
Executive Officers		
Peter K. Miller	55	Chief Executive Officer and Director
Ramy A. Mahmoud, M.D.,M.P.H.	52	President and Chief Operating Officer
Thomas E. Gibbs	46	Chief Commercial Officer
Keith A. Goldan	46	Chief Financial Officer
Michael F. Marino	41	Chief Legal Officer and Corporate Secretary
Non-Management Directors		
Larry G. Pickering	74	Chairman of our Board of Directors
Klaas de Boer	52	Director
Per Gisle Djupesland, M.D., Ph.D.	61	Director
William F. Doyle	55	Director
Patrick O'Neill	68	Director
Sriram Venkataraman	45	Director
Joshua A. Tamaroff	32	Director

Executive Officers

Peter K. Miller has served as our Chief Executive Officer since 2010 and as a member of our board of directors since 2008. From June 2004 to May 2007, Mr. Miller was Co-Founder, Chief Executive Officer and President of Take Care Health Systems Inc., a company that introduced medical clinics inside Walgreens retail pharmacies, and from May 2007 to May 2010, served as Vice President of Walgreen Co.'s Health and Wellness Division following its acquisition of Take Care Health Systems. Prior to co-founding Take Care Health Systems, Mr. Miller spent more than 15 years at Johnson & Johnson, a multinational medical devices, pharmaceutical and consumer packaged goods manufacturer, serving in a variety of marketing and general management roles that included Worldwide President of Johnson & Johnson — Merck Consumer Pharmaceuticals and President of Janssen Pharmaceutical. Mr. Miller has served as a member of the board of directors of Actua Corporation, a publicly-held SaaS technology company, since 2010. Mr. Miller holds a B.S. in Economics from Trinity College and an M.B.A. from the Kellogg School of Management at Northwestern University. Our board of directors believes that Mr. Miller's perspective and history as our Chief Executive Officer, as well as his executive, operational and commercial expertise, qualify him to serve on our board of directors.

Ramy A. Mahmoud, M.D., M.P.H. has served as our President and Chief Operating Officer since 2010. Prior to joining us, Dr. Mahmoud spent 14 years at Johnson & Johnson, where he served as Chief Medical Officer and a member of the Global Management Board of the Ethicon group of companies. During his tenure at Johnson & Johnson, he also held senior roles in the pharmaceutical sector. Dr. Mahmoud served for 10 years on active duty in the U.S. Army and an additional 10 years in the Army Reserves, achieving the rank of Lieutenant Colonel. During his military service, Dr. Mahmoud held various patient care, research, and academic positions, culminating in his position as the head of the Department of Epidemiology at the Walter Reed Army Institute of Research. He has published more than 50 peer-reviewed papers and textbook chapters, and has served as a scientific reviewer for a number of journals and textbooks. Dr. Mahmoud earned a Master of Healthcare Management and Policy degree from the Harvard School of Public Health and an M.D. from the University of Miami. He has earned board certification in both Public Health/Preventive Medicine and in Internal Medicine.

Thomas E. Gibbs has served as our Chief Commercial Officer since September 2016. From December 2015 to September 2016, Mr. Gibbs served as the Senior Vice President, Head of the General Medicines Business Unit for the United States at Takeda Pharmaceutical Company Limited, a global pharmaceutical company. From March 2015 to December 2015, Mr. Gibbs served as Chief Commercial Officer for the U.S. and E.U. commercial organizations of Vanda Pharmaceuticals, Inc., a global biopharmaceutical company. From January 2010 to March 2015, Mr. Gibbs held a series of commercial leadership roles with increasing responsibility at Bristol-Myers Squibb, a pharmaceutical company, including Vice President of Worldwide Commercial Operations. From June 2006 to January 2010, Mr. Gibbs worked at Novartis Vaccines & Diagnostics, Inc., a vaccines manufacturer, where he held multiple commercial leadership roles including serving as Vice President of U.S. Sales from November 2007 to January 2010. Mr. Gibbs holds a B.S. in Economics and an M.B.A. from The Wharton School at the University of Pennsylvania.

Keith A. Goldan has served as our Chief Financial Officer since January 2017. From March 2015 to January 2017, Mr. Goldan served as Senior Vice President, Chief Financial Officer and Treasurer of Fibrocell Science, Inc., a publicly-held gene therapy company, and also served as its Corporate Secretary from March 2015 to June 2015. From March 2014 to March 2015, Mr. Goldan served as a financial and operational consultant to companies in the pharmaceutical industry. From November 2008 to March 2014, Mr. Goldan served as Senior Vice President and Chief Financial Officer of NuPathe Inc., a specialty pharmaceutical company that was acquired by Teva Pharmaceutical Industries Ltd. Mr. Goldan previously served as Chief Financial Officer and a member of the board of directors of PuriCore plc, a medical technology company listed on the London Stock Exchange. Earlier in his career, Mr. Goldan served as Vice President and Chief Financial Officer of Biosyn, Inc., a specialty pharmaceutical company, and in a variety of roles with ViroPharma and the Healthcare & Life Sciences Practice of KPMG. Mr. Goldan earned a B.S. in Finance from the Robert H. Smith School of Business at the University of Maryland and an M.B.A. from The Wharton School at the University of Pennsylvania.

Michael F. Marino has served as our Chief Legal Officer and Corporate Secretary since January 2017. From June 2015 to January 2017, Mr. Marino served as Senior Vice President, General Counsel and Corporate Secretary of Fibrocell Science, Inc., a publicly-held gene therapy company. From March 2014 to June 2015, Mr. Marino served as a legal consultant in the life sciences industry. From October 2010 to March 2014, Mr. Marino served as Senior Vice President, General Counsel and Corporate Secretary of NuPathe Inc., a specialty pharmaceutical company that was acquired by Teva Pharmaceutical Industries Ltd. Mr. Marino was previously an attorney at the law firms of Morgan, Lewis & Bockius LLP and WilmerHale LLP. Mr. Marino earned a B.S. in Accountancy from Villanova University and a J.D. from Boston College Law School.

Non-Management Directors

Larry G. Pickering has served as a director of our company since 2010. From January 2008 to September 2012, Mr. Pickering served as Chairman of the board of directors of Lantheus Medical Imaging, Inc., a medical imaging company with public securities. Previously, he served as Chairman of DLJMB Global Healthcare Partners, an investment firm. Mr. Pickering had a 32-year career in healthcare with Johnson & Johnson, where he served as President of Ortho Dermatology, President of Janssen Pharmaceuticals and Chairman of Janssen North America, Company Group Chairman, Worldwide OTC, Chairman of Johnson & Johnson Development Corporation and a Corporate Officer. Mr. Pickering retired from Johnson & Johnson in 2005. He holds a B.B.A. from the University of Missouri. Our board of directors believes that Mr. Pickering's extensive senior management experience in the pharmaceutical industry qualifies him for service on our board of directors.

Klaas de Boer has served as a director of our company since 2010. Mr. de Boer has served as the Managing Partner of Entrepreneurs Fund Management LP, a venture capital fund, since 2008. From 2001 to 2006, Mr. de Boer served as the Managing Director of Tsjukemar Ltd., a venture capital consulting firm. Mr. de Boer previously served as a consultant at the firms of McKinsey & Company and Vanenburg Group. Mr. de Boer holds an M.S. from Delft University of Technology and an M.B.A. from INSEAD. Our board of directors

believes that Mr. de Boer's business experience, including service on the board of directors of a number of life sciences companies, qualifies him to serve on our board of directors.

Per Gisle Djupesland, M.D., Ph.D. has served as a director of our company since 2010. Dr. Djupesland is a practicing ear, nose and throat doctor and has served as the Chief Scientific Officer of OptiNose AS since 2000. Earlier in his career, he acted as the project manager of a large scale vaccination trial in the Norwegian Armed Forces in which 55,000 conscripts were vaccinated with a new vaccine against Meningococcus B developed by the National Institute of Public Health in Norway. He has worked with HIV/AIDS epidemiology at the Institute of Public Health in Norway. Dr. Djupesland currently serves as the chairman of the board of directors of IKOS Invest AS, Ikos Subsidiary AS and Nesensia AS, and serves as a member of the board of directors of OptiNose UK Ltd. and OptiNose AS, having served as the chairman of the board of directors of OptiNose AS from 2000 to 2010. Dr. Djupesland received both his Ph.D. and M.D. from The University of Oslo, Faculty of Medicine and has been a Research Fellow at The University of Toronto. Our board of directors believes that Dr. Djupesland's perspective and business experience as the founder of OptiNose AS and an inventor of our EDS, coupled with his extensive scientific acumen in the field of rhinology, qualifies him to serve on our board of directors.

William F. Doyle has served as a director of our company since 2010. Mr. Doyle is the Executive Chairman of Novocure Ltd., a commercial stage oncology company; and the Executive Chairman of Blink Health Ltd., a private technology company providing Americans with affordable access to prescription medications. Since 2003, Mr. Doyle has been the managing partner of WFD Ventures LLC, a private venture capital firm he co-founded, and from 2014 to 2016 he was a member of the investment team of Pershing Square Capital Management L.P., a private investment firm. Previously, Mr. Doyle served as a member of Johnson & Johnson's Medical Devices and Diagnostics Group Operating Committee and was vice president, Licensing and Acquisitions. While at Johnson & Johnson, Mr. Doyle was also chairman of the Medical Devices Research and Development Council and worldwide president of Biosense-Webster, Inc. Earlier in his career, Mr. Doyle was a management consultant in the healthcare group of McKinsey & Company. In addition to serving as chairman of Novocure, within the past five years, Mr. Doyle served as director of Zoetis, Inc., an animal medicine and vaccine company. Mr. Doyle holds an S.B. in materials science and engineering from the Massachusetts Institute of Technology and an M.B.A. from Harvard Business School. Our board of directors believes that Mr. Doyle's expertise in medical device commercialization and his significant experience in the advanced technology and healthcare industries as an entrepreneur, executive, management consultant and investor, qualifies him to serve on our board of directors.

Patrick O'Neill has served as a director of our company since 2010. Since 2008, Dr. O'Neill has served as an Industry Advisor for Avista Capital Partners, or Avista. From 1976 until his retirement in 2006, he served in a number of management roles in research and development and business development at Johnson & Johnson, including leadership positions in Johnson & Johnson's pharmaceutical business, its Medical Devices and Diagnostics Group, and its surgical and interventional cardiology/radiology business units. Following his retirement from Johnson & Johnson, he served as Executive in Residence at New Enterprise Associates, a venture capital firm, from 2006 to 2007. Dr. O'Neill holds a B.S. in Pharmacy and a Ph.D. in Pharmacology from The Ohio State University. Dr. O'Neill is a member of the board of directors of Zest Anchors, Inc. Within the past five years, he has served as a director of Lantheus Holdings, Inc., a publicly-held medical imaging company. Our board of directors believes that Dr. O'Neill's experience in the pharmaceutical industry, including his participation in the development of pharmaceutical products, provides valuable insight into strategic business decisions and qualifies him to serve on our board of directors.

Sriram Venkataraman has served as a director of our company since 2010. He is also a Partner of Avista, having joined in 2007. Prior to joining Avista, Mr. Venkataraman was a Vice President in the Healthcare Investment Banking group at Credit Suisse Group AG having worked there from 2001 to 2007. Previously, he worked at GE Healthcare (formerly known as GE Medical Systems) from 1996 to 1999.

Mr. Venkataraman holds an M.S. in Electrical Engineering from the University of Illinois, Urbana-Champaign and an M.B.A. from The Wharton School at the University of Pennsylvania. He currently serves as a director of Osmotica Holdings S.C.Sp, National Spine & Pain Centers Holdings, LLC, and Zest Anchors, Inc. Mr. Venkataraman previously served as a director of AngioDynamics Inc. and Lantheus Holdings Inc. Our board of directors believes that Mr. Venkataraman's experience in the healthcare industry, his strong finance and management background, and his experience serving as a director of private and public companies qualifies him to serve on our board of directors.

Joshua A. Tamaroff has served as a director of our company since March 2017. Mr. Tamaroff joined Avista in 2009 and serves as a Vice President. Prior to joining Avista, Mr. Tamaroff worked as an Analyst in the leveraged finance group at Lehman Brothers and Barclays Capital. Mr. Tamaroff currently serves as a director of InvestorPlace Media, IWCO Direct and WideOpenWest, Inc. Mr. Tamaroff received a B.S. from Cornell University and a M.B.A. from The Wharton School at the University of Pennsylvania, where he was a Palmer Scholar. Our board of directors believes that Mr. Tamaroff's private equity investment and company oversight experience and background with respect to acquisitions, debt financings and equity financings qualifies him to serve on our board of directors.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of eight members. Immediately following the closing of this offering, our fourth amended and restated certificate of incorporation and amended and restated bylaws will provide that our board of directors will consist of a number of directors, not less than three nor more than twelve, to be fixed exclusively by resolution of our board of directors.

In accordance with our fourth amended and restated certificate of incorporation which will be effective immediately following the closing of this offering, our board of directors will be divided into three classes. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The class I directors will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2018;
- The class II directors will be will be , and , and their terms will expire at the annual meeting of stockholders to be held in 2019; and
- The class III directors will be will be and , and their terms will expire at the annual meeting of stockholders to be held in 2020.

Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Director Independence and Controlled Company Exemptions

Upon the closing of this offering, Avista Capital Partners, or Avista, and TKWD Ventures LLC, or TKWD, will collectively beneficially own a controlling interest in us. We intend to avail ourselves of the controlled company exemptions under the NASDAQ listing rules. As a controlled company, we will not be required to have a majority of "independent directors" on our board of directors as defined under NASDAQ listing rules or to have a compensation committee or a board committee performing the board nominating function composed entirely of independent directors. Since we intend to avail ourselves of the "controlled company" exemption under the NASDAQ listing rules, neither our nominating and corporate governance committee nor our compensation committee will be composed entirely of independent directors. The "controlled company" exemption does not modify the independence requirements for the audit committee, and we intend to comply with the requirements of Rule 10A-3 of the Exchange Act and the NASDAQ listing rules, which

rules require that our audit committee be composed of at least three members, a majority of whom will be independent within 90 days of the date of this prospectus, and all of whom will be independent within one year of the date of this prospectus. Similarly, once we are no longer a "controlled company," we must comply with the independent board committee requirements as they relate to the compensation committee and the nominating and corporate governance committee, on the same phase-in schedule as set forth above, with the trigger date being the date we are no longer a "controlled company" as opposed to our initial public offering date. Additionally, we will have 12 months from the date we cease to be a "controlled company" to have a majority of independent directors on our board of directors.

No director will be deemed to be independent unless our board of directors determines that the director has no relationship which would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Our board of directors has determined that Messrs. , and are independent as defined under the NASDAQ listing rules. Of these independent directors, our board of directors has determined that: (i) Messrs. , and , who will comprise our audit committee; (ii) Messrs. , and , who will comprise our compensation committee; and (iii) Messrs. , and , who will comprise our nominating and corporate governance committee, each satisfy the independence standards for those committees established by the applicable rules and regulations of the SEC and the NASDAQ listing rules.

Second Amended and Restated Shareholders' Agreement

In connection with this offering, we expect to enter into an amendment to our Second Amended and Restated Shareholders' Agreement, or the Shareholders' Agreement. The Shareholders' Agreement will provide, among other things, that each of Avista and TKWD will have the rights to nominate:

- for Avista, (i) two directors to our board of directors for so long as Avista owns % or more of our then-outstanding shares of common stock, and (ii) one director to our board of directors for so long as Avista owns less than % but 7.5% or more of our then-outstanding shares of common stock; and
- for TKWD, one director to our board of directors for so long as TKWD owns 7.5% or more of our outstanding shares of common stock.

The initial Avista nominees will be Messrs. Venkataraman and Tamaroff. The initial TKWD nominee will be Mr. Doyle. We will be required to take all necessary action to ensure the composition of our board of directors as set forth above. See "Certain Relationships and Related Party Transactions — Second Amended and Restated Shareholders' Agreement."

Board Leadership Structure

Our board of directors is currently chaired by Mr. Pickering. As a general policy, our board of directors believes that separation of the positions of chairman and chief executive officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including adopting guidelines and

policies to govern the process by which risk assessment and management is undertaken. While our board of directors maintains the ultimate oversight responsibility for the risk management process, its committees oversee risk in certain specified areas. For example:

- Our audit committee oversees management of financial reporting, compliance and litigation risks, including risks related to our insurance, information technology, human resources and regulatory matters, as well as the steps management has taken to monitor and control such exposures.
- Our compensation committee is responsible for overseeing the management of risks relating to our executive compensation policies, plans and arrangements and the extent to which those policies or practices increase or decrease risks for our company.
- Our nominating and corporate governance committee manages risks associated with the independence of our board of directors, potential conflicts of interest and the effectiveness of our board of directors.

Board Committees

Our board of directors has established, or will establish prior to the closing of this offering, an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee will operate under a charter approved by our board of directors and will be available on our website, www.optinose.com, under the "Investor Relations" section, upon the effective date of the registration statement of which this prospectus is a part. The information contained in, or that can be accessed through, our website is not part of this prospectus.

Audit Committee

Upon the closing of this offering, our audit committee will consist of , and and will be chaired by . The primary purpose of our audit committee is to assist our board of directors by providing oversight of our financial management, independent auditor and financial reporting procedures, as well as such other matters as directed by our board of directors or the audit committee charter that will be effective upon the effective date of the registration statement of which this prospectus is a part. Among other things, the audit committee's responsibilities include:

- appointing, retaining, compensating, overseeing, evaluating, and, when appropriate, terminating our independent registered public accounting firm;
- approving in advance all audit services and non-audit services to be provided to us by our independent auditor;
- discussing with management and our independent registered public accounting firm our annual and quarterly consolidated financial statements and related disclosures;
- reviewing with management its assessment of our internal control over financial reporting and disclosure controls and procedures;
- reviewing our Code of Business Conduct and Ethics and recommending any changes to our board of directors;
- overseeing our risk assessment and risk management processes;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and ratifying all related party transactions, based on the standards set forth in our related party transactions policy; and
- preparing and approving the audit committee report required to be included in our annual proxy statement.

Our audit committee will review related party transactions for potential conflicts of interests in accordance with our related party transactions policy. See "Certain Relationships and Related Party Transactions — Policies and Procedures for Transactions with Related Persons."

Our board of directors has determined that each of the members of the audit committee satisfy the financial literacy and sophistication requirements of the SEC and the listing rules of The NASDAQ Stock Market, LLC, or NASDAQ. In addition, our board of directors has determined that qualifies as an audit committee financial expert, as defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities Act.

Both our independent registered public accounting firm and management periodically will meet privately with our audit committee.

Compensation Committee

Upon the closing of this offering, our compensation committee will consist of , and , and will be chaired by . The primary purpose of our compensation committee is to review the performance and development of our management in achieving corporate goals and objectives and assure that our executive officers, including our chief executive officer, or CEO, are compensated effectively in a manner consistent with our strategy, competitive practice and stockholder interests, as well as such other matters as directed by our board of directors or the compensation committee charter that will be effective upon the effective date of the registration statement of which this prospectus is a part. Among other things, the compensation committee's responsibilities include:

- annually reviewing and recommending to our board of directors for approval the corporate goals and objectives applicable to the compensation of our CEO and other executive officers and evaluating at least annually our CEO's and other executive officers' performance in light of those goals and objectives;
- determining and approving our CEO's and other executive officers' compensation level, including salary, cash, equity-based incentive awards and any personal benefits;
- administering, or where appropriate, overseeing the administration of, executive and equity compensation plans and such other compensation and benefit plans that are adopted by us from time to time;
- establishing policies and making recommendations to our board of directors regarding director compensation;
- determining stock ownership guidelines for our CEO and other executive officers and monitoring compliance with such guidelines, if deemed advisable by our board of directors or the compensation committee; and
- overseeing risks and exposures associated with executive compensation plans and arrangements.

Nominating and Corporate Governance Committee

Upon the closing of this offering, our nominating and corporate governance committee will consist of , and , and will be chaired by . Specific responsibilities of our nominating and corporate governance committee include:

- assessing the need for new directors and developing and submitting to our board of directors for its adoption a list of selection criteria for new directors to serve on our board of directors;
- identifying, reviewing and evaluating candidates, including candidates submitted by stockholders, for election to our board of directors and recommending to our board of directors (i) nominees to fill vacancies or new positions on our board of directors and (ii) the slate of nominees to stand for election by our stockholders at each annual meeting of stockholders;
- developing, recommending, overseeing the implementation of and monitoring compliance with, our corporate governance guidelines, and periodically reviewing and recommending any necessary or appropriate changes to our corporate governance guidelines;

- annually recommending to our board of directors (i) the assignment of directors to serve on each committee; (ii) the chairperson of each committee and (iii) the chairperson of our board of directors or lead independent director, as appropriate;
- reviewing the adequacy of our certificate of incorporation and bylaws and recommending to our board of directors, as conditions dictate, amendments for consideration by the stockholders;
- implementing policies with respect to risk oversight, assessment and management of risk associated with the independence of our board of directors, potential conflicts of interest and the effectiveness of our board of directors; and
- such other matters as directed by our board of directors or the nominating and corporate governance committee charter that will be effective upon the effective date of the registration statement of which this prospectus is a part.

Code of Business Conduct and Ethics

Upon the closing of this offering, our board of directors will adopt a Code of Business Conduct and Ethics applicable to all of our employees, executive officers and directors. The Code of Business Conduct and Ethics will cover fundamental ethical and compliance-related principles and practices such as accurate accounting records and financial reporting, avoiding conflicts of interest, the protection and use of our property and information and compliance with legal and regulatory requirements. The Code of Business Conduct and Ethics will be available on our website at www.optinose.com upon the listing of our common stock on The NASDAQ Global Market. The audit committee of our board of directors will be responsible for overseeing the Code of Business Conduct and Ethics and must approve any waivers of the Code of Business Conduct and Ethics for employees, executive officers or directors. Disclosure regarding any amendments to the Code of Business Conduct and Ethics, or any waivers of its requirements, will be disclosed on our website. The information contained in, or that can be accessed through, our website is not part of this prospectus.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has served as one of our officers or employees at any time. None of our executive officers serve as a member of the compensation committee of any other company that has an executive officer serving as a member of our board of directors. None of our executive officers serve as a member of the board of directors of any other company that has an executive officer serving as a member of our compensation committee.

Limitation on Liability and Indemnification Matters

Our fourth amended and restated certificate of incorporation and our amended and restated bylaws, each of which will be effective immediately following the closing of this offering, limits our directors' liability to the fullest extent permitted under Delaware General Corporation Law, or the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Delaware law and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses, including attorneys' fees and disbursements, in advance of the final disposition of the proceeding.

We have also entered, or intend to enter, into separate indemnification agreements with our directors and executive officers. Subject to specified exemptions, these agreements, among other things, require us to indemnify our directors and executive officers for related expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or an executive officer in any action or proceeding arising out of his or her services as one of our directors or officers or any other company or enterprise to which the person provides services at our request.

We believe that these provisions in our fourth amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

The limitation of liability and indemnification provisions in our fourth amended and restated certificate of incorporation and amended bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the year ended December 31, 2016, which consists of our principal executive officer and our two other most highly compensated executive officers, are:

- Peter K. Miller, our Chief Executive Officer;
- Ramy A. Mahmoud, our President and Chief Operating Officer; and
- Thomas E. Gibbs, our Chief Commercial Officer.

Summary Compensation Table

The following table provides information regarding the compensation awarded to, earned by or paid to our named executive officers for the year ended December 31, 2016.

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1]	Non-Equity Incentive Compensation[2]	All Other Compensation ($)[3]	Total ($)
Peter K. Miller *Chief Executive Officer*	2016	488,283	246,590	630,552	715	1,366,140
Ramy A. Mahmoud *President and Chief Operating Officer*	2016	412,463	—	433,514	12,038	858,015
Thomas E. Gibbs[4] *Chief Commercial Officer*	2016	110,817	1,154,164	47,554	197	1,312,732

(1) The amounts in this column represent the aggregate grant date fair value of the options granted during calendar year 2016. The grant date fair value of the options was computed in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the executive in connection with his option awards. The assumptions made in valuing the option awards reported in this column are described in Note 11 to our consolidated financial statements included in this prospectus.

(2) The amounts in this column represent performance bonuses earned by the named executive officers in the calendar year 2016 based upon the achievement of pre-established performance objectives. See "— Non-Equity Incentive Plan Compensation" below.

(3) Represents the dollar value of life insurance premiums paid by us for the benefit of the named executive officer.

(4) Mr. Gibbs's employment as our Chief Commercial Officer commenced on September 15, 2016.

Employment Agreements

We have employment or letter agreements with each of our named executive officers. The following is a summary of the material terms of each agreement. For complete terms, please see the respective agreements attached as exhibits to the registration statement of which this prospectus forms a part.

Peter K. Miller

On May 27, 2010, we entered into an employment agreement with Mr. Miller. The agreement provides for an initial three-year employment term with automatic renewals for successive one-year periods, unless we provide Mr. Miller with written notice of non-renewal at least 90 days prior to the end of the applicable expiration date. The agreement provides for a base salary to be reviewed annually by our board of directors, or a committee thereof, for potential increases. For calendar year 2016, Mr. Miller received a base salary at the rate of $465,629 per year through July 31, 2016, and at the rate of $520,000 per year from August 1, 2016 through December 31, 2016. Effective as of January 1, 2017, Mr. Miller's base salary was increased to $535,600 per year. Mr. Miller is entitled to receive certain termination benefits under his agreement,

which are described below in the section entitled "*Potential Payments Upon a Termination or Change in Control*."

Ramy A. Mahmoud

On June 18, 2010, we entered into a letter agreement with Dr. Mahmoud. The agreement provides for a base salary to be reviewed annually by our board of directors, or a committee thereof. For calendar year 2016, Dr. Mahmoud received a base salary at the rate of $403,508 per year through July 31, 2016, and at the rate of $425,000 per year from August 1, 2016 through December 31, 2016. Effective as of January 1, 2017, Dr. Mahmoud's base salary was increased to $437,750 per year. The agreement also provides that we will pay the premiums for a term life insurance policy for Dr. Mahmoud that has a death benefit equal to approximately $3.0 million. Dr. Mahmoud is entitled to receive certain termination benefits under his agreement, which are described below in the section entitled "*Potential Payments Upon a Termination or Change in Control*."

Thomas E. Gibbs

On September 15, 2016, we entered into a letter agreement with Mr. Gibbs. The agreement provides for a base salary to be reviewed periodically by the Chief Executive Officer, President and Chief Operating Officer, or our board of directors, or a committee thereof. For the calendar year 2016, Mr. Gibbs received a base salary at a rate of $375,000. Effective January 1, 2017, Mr. Gibbs's base salary was increased to $386,250. Mr. Gibbs is entitled to receive certain termination benefits under his agreement, which are described below in the section entitled "*Potential Payments Upon a Termination or Change in Control*."

Non-Equity Incentive Plan Compensation

Each of our named executive officers are eligible to receive an annual performance bonus based on the achievement of corporate objectives as determined by our board of directors or a committee thereof. Each officer is assigned a target bonus expressed as a percentage of his base salary. Actual bonus payments may be higher or lower than the target bonus amount, as determined by our board of directors, or a committee thereof. The target bonus amounts for 2016 for Mr. Miller, Dr. Mahmoud and Mr. Gibbs were 60%, 50% and 45%, respectively. Mr. Gibbs's target bonus amount was prorated for the portion of 2016 during which he was employed by us. For 2016, Mr. Miller, Dr. Mahmoud and Mr. Gibbs earned annual performance bonuses based on the achievement of corporate objectives, consisting primarily of the submission of our NDA for OPN-375 and progress with respect to pre-commercialization activities, in the amounts of $297,960, $202,938 and $47,554, respectively.

In addition, Mr. Miller and Dr. Mahmoud were also eligible to receive a performance bonus relating to the clinical development progress of OPN-375 and the receipt of licensing revenue under the AVP-825 License Agreement. Based on the achievement of these objectives, Mr. Miller and Dr. Mahmoud earned bonuses in the amount of $332,592 and $230,576, respectively.

Actual bonus amounts paid with respect to 2016 are reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

Equity Incentive Plan Compensation

We maintain the OptiNose, Inc. 2010 Stock Incentive Plan, as amended, or the 2010 Plan, which became effective on May 27, 2010, in order to enhance our and our affiliates' ability to attract and retain highly qualified officers, directors, key employees and other persons, and to motivate such persons to serve us and our affiliates and to expend maximum effort to improve our business results and earnings, by providing to such persons an opportunity to acquire or increase a direct proprietary interest in our operations and future success.

Shares Subject to the 2010 Plan

The number of shares of our common stock available for issuance under the 2010 Plan is 1,637,356, of which 1,212,356 shares are collectively designated as the "General Option Pool" and 425,000 shares are

collectively designated as the "Success Option Pool." The options granted in our Success Option Pool were granted to our named executive officers, and have been designated for grant at a per share price of $47.10, which exceeds the estimated fair market value of our prior stock valuations, in order to incentivize stock appreciation. As of June 30, 2017, service-based options to purchase 771,876 shares of our common stock were outstanding at a weighted average exercise price of $9.81, and performance-based options to purchase 752,025 shares of our common stock were outstanding at a weighted average exercise price of $27.70. As of June 30, 2017, 99,505 shares remained available for grant under the 2010 Plan.

If the number of outstanding shares of our common stock is increased or decreased, or the shares are changed or exchanged for a different number or kind of shares or our other securities, on account of any recapitalization, reclassification, stock split, reverse stock split, combination of shares, exchange of shares, stock dividend or other distribution payable in capital stock, or other increase or decrease in such shares effected without the receipt of consideration by us, then the number and kind of shares for which grants of options may be made under the 2010 Plan will be adjusted proportionately and accordingly by our compensation committee. In addition, the number and kind of shares for which awards are outstanding, as well as the exercise price of outstanding options, will be adjusted proportionately and accordingly by our compensation committee.

If any shares covered by an award are not purchased or are forfeited or expire, or if any award otherwise terminates without delivery of any shares subject to the award or is settled in cash in lieu of shares, then the number of shares counted against the aggregate number of shares available for issuance under the 2010 Plan with respect to such award will, to the extent of any such forfeiture, termination or expiration, again be available for issuance under the 2010 Plan. If the exercise price of any option is satisfied by tendering shares to us, then only the number of shares issued net of the shares tendered will be deemed delivered for purposes of determining the maximum number of shares available for delivery under the 2010 Plan.

Awards

The 2010 Plan provides for the grant of awards of stock options and restricted stock. Stock options granted under the 2010 Plan may be nonqualified stock options or incentive stock options within the meaning of Section 422 of the Internal Revenue Code.

Award Eligibility

Awards under the 2010 Plan may be made to our or any of our affiliates' employees, officers and directors, as well as to consultants and advisors currently providing services to us or any of our affiliates.

Plan Administration

The 2010 Plan is administered by our compensation committee. Our compensation committee has full power and authority to take all actions and to make all determinations required or provided for under the 2010 Plan, any award or any award agreement, including, without limitation, to designate eligible persons to receive awards under the plan, each of whom is referred to as a Grantee, determine the type or types of awards to be made to each Grantee, determine the number of shares of our common stock to be subject to each award, establish the terms and conditions of each award, prescribe the form of each award agreement evidencing an award, and amend, modify or supplement the terms of any outstanding award. Our compensation committee, in its sole discretion, may provide for the accelerated vesting of, or lapse of restrictions on, awards at any time.

Change of Control

Our compensation committee has the discretion to determine the effect of a "change of control" of us, as defined in the 2010 Plan, on any outstanding awards. In connection with a change of control, our compensation committee may elect, in its sole discretion, to:

- cancel any outstanding awards and pay or deliver to the holder of the award an amount in cash or securities having a value equal to the product of the number of shares subject to the award, or the Grant Shares, multiplied by the amount, if any, by which the formula or fixed price per share paid to holders of our common stock pursuant to such transaction exceeds the exercise price applicable to such Grant Shares;

- provide for the assumption or continuation of outstanding options, or for the substitution for such awards for new common stock options relating to the stock of a successor entity, or a parent or subsidiary of such entity, with appropriate adjustments as to the number of shares and exercise prices, such that the awards will continue in the manner and under the terms so provided;

- cancel any outstanding awards that are unvested, or any unvested portion of such awards, without payment to the holders of such awards; or

- cancel any outstanding awards to the extent the exercise price applicable to the Grant Shares issuable under such awards is greater than the formula or fixed price per share paid to the holders of shares of our common stock pursuant to such transaction, with or without payment to the holder of such awards.

The term "change of control" is generally defined under the 2010 Plan to include:

- a liquidation, dissolution or winding up or bankruptcy of us, whether voluntary or involuntary;

- any acquisition or exclusive license, or grant, sale or transfer of a license to all or a substantial part of the our assets or intellectual property, or any combination of licenses having the same effect, in a single transaction or series of related transactions, by us or any of our subsidiaries of all or substantially all of the assets or intellectual property of us and our subsidiaries taken as a whole or the sale or disposition, whether by merger, exclusive license, or otherwise, of one or more of our subsidiaries if substantially all of the assets or intellectual property of us and our subsidiaries taken as a whole are held by such subsidiary or subsidiaries;

- any acquisition of us by another corporation or entity by consolidation, merger, share exchange or other reorganization or combination in which the shares of our capital stock outstanding immediately prior to such transaction represent, immediately after such transaction, securities representing less than 50% of our voting power or other entity surviving such transaction; or

- any acquisition of our capital stock by a single person or entity or group of affiliated persons or entities, other than an acquisition of stock from us in a bona fide equity financing the purpose of which is solely to raise capital for general corporate purposes, which results in such person or entity or group holding securities representing more than 50% of our voting power.

Plan Amendment and Termination

Our board of directors may amend, suspend or terminate the 2010 Plan at any time, provided that if our board of directors determines that the rights of a Grantee with respect to an award granted prior to such amendment, suspension or termination may be materially impaired, the consent of such Grantee will be required or the terms of his or her award will continue to be governed by the 2010 Plan without giving effect to any such amendment. An amendment to the 2010 Plan will be contingent upon approval of our stockholders to the extent required by applicable law, regulations or rules, our fourth amended and restated certificate of incorporation, which will be in effect immediately following the closing of this offering, or any agreement between us and our stockholders. The 2010 Plan will terminate automatically on May 27, 2020, unless earlier terminated by our board of directors.

Option Awards Granted During Fiscal Year 2016

On December 20, 2016, we granted stock options to Messrs. Miller and Gibbs for 25,000 shares and 50,000 shares, respectively, with an exercise price of $14.85 per share, which was equal to the fair value of our common stock on the date of grant. Subject to the executive's continued employment on each applicable vesting date, 25% of the shares underlying these options will vest on September 1, 2017 for Mr. Miller and September 15, 2017 for Mr. Gibbs, with the remainder vesting in equal monthly installments thereafter through September 1, 2020 in the case of Mr. Miller and September 15, 2020 in the case of Mr. Gibbs. The vesting of these options is subject to acceleration upon a change of control of our company.

On December 20, 2016, we granted an additional stock option to Mr. Gibbs to purchase 100,000 shares of our common stock at an exercise price of $47.10 per share, which were granted from our "Success Option Pool." Subject to his continued employment on each applicable vesting date, 25% of the shares underlying this option will vest on September 15, 2017, with the remainder vesting in three annual installments thereafter through September 15, 2020. In addition to this time-based vesting, this option will only be exercisable by Mr. Gibbs in the event of a change of control, as defined in the 2010 Plan, or upon the completion of an initial public offering.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding equity awards for each of our named executive officers as of December 31, 2016, all of which are stock options. All stock options granted to our named executive officers were made pursuant to the 2010 Plan.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Price ($)	Option Expiration Date
Peter K. Miller	214,651(1)	—	60,102(2)	4.70	02/11/21
	6,313	3,156(3)	3,156(2)	8.80	03/11/24
	—	—	200,000(4)	47.10	04/07/24
	—	25,000(5)	—	14.85	12/20/26
Ramy A. Mahmoud	103,032(6)	—	34,344(2)	4.70	02/11/21
	20,000	10,000(3)	10,000(2)	8.80	03/11/24
	—	—	100,000(4)	47.10	04/07/24
Thomas E. Gibbs	—	50,000(5)	—	14.85	12/20/2026
	—	—	100,000(7)	47.10	12/20/2026

(1) In 2014, Mr. Miller transferred for no consideration a portion of this option covering 105,000 shares to a trust the beneficiaries of which are Mr. Miller and his spouse.

(2) These options were granted on February 11, 2011 and March 11, 2014 and 50% of these options vested in January 2017 upon the FDA's acceptance of the NDA for OPN-375. The remaining options will vest upon FDA approval for OPN-375 for the treatment of nasal polyposis.

(3) These options were granted on March 11, 2014 and will vest on each of the first four anniversaries of the vesting starting date (March 10, 2014).

(4) These options were granted on April 7, 2014 and will vest 25% on each of the first four anniversaries of the vesting start date (April 7, 2014). Vested options under this grant are exercisable only immediately prior to, and contingent upon, the consummation of a "change of control," as defined in the 2010 Plan, or upon or after the consummation of an initial public offering.

(5) These options were granted on December 20, 2016 and will vest 25% on the first anniversary of the vesting start date (September 1, 2016 for Mr. Miller and September 15, 2016 for Mr. Gibbs), and 2.0833% (approximately 1/48th of such shares), for each subsequent full calendar month that the executive remains employed with us or one of our affiliates, with the vesting date occurring on the first day following such subsequent full calendar month.

(6) In 2014, Dr. Mahmoud transferred for no consideration a portion of this option covering 34,344 shares to a trust the beneficiary of which is Dr. Mahmoud's spouse.

(7) These options were granted on December 20, 2016 and will vest 25% of the shares subject to the option on each of the first four anniversaries of the vesting start date (September 15, 2016). Vested options under this grant are exercisable only immediately prior to, and contingent upon, the consummation of a "change of control," as defined in the 2010 Plan, or upon or after the consummation of an initial public offering.

Retirement Benefits

401(k) Plan

We currently maintain a defined contribution 401(k) retirement plan for all of our employees in the United States, including our named executive officers, or the 401(k) Plan. Employees are eligible to participate in the 401(k) Plan on the first month following their date of hire. Under the terms of the 401(k) Plan, participating employees may defer up to 100% of their pre-tax salary provided such deferral is not in excess of the applicable statutory limits. We do not currently match employee contributions to the 401(k) Plan and employee contributions vest immediately.

Potential Payments Upon a Termination or Change in Control

Peter K. Miller

Pursuant to his employment agreement with us, if Mr. Miller's employment is terminated by us without "cause," as defined in the agreement, then Mr. Miller will be entitled to receive the following termination benefits, subject to his execution and non-revocation of a release of claims:

- 12 months of base salary continuation; and
- 12 months of continued participation in our standard group medical, vision and dental plans on substantially the same terms as such benefits are provided to employees during such period.

Mr. Miller's employment agreement contains restrictive covenants relating to non-disclosure of confidential information, non-disparagement, assignment of inventions, non-competition that runs for 12 months following his termination of employment for any reason, non-solicitation of customers and suppliers covenants that run for 12 months following his termination of employment for any reason, and non-solicitation of employees that runs for 24 months following his termination of employment for any reason.

The stock options granted to Mr. Miller on February 11, 2011 and March 11, 2014, which are set forth above in the "*Outstanding Equity Awards at Fiscal Year End* " table, may be subject to accelerated vesting upon a change in control, subject to his continued employment on the date of the change in control. The time-based options will become fully vested upon a change in control. The performance-based options may be subject to accelerated vesting based on the achievement of accelerated vesting targets that are based on certain cumulative cash proceeds received.

The stock options granted to Mr. Miller on April 7, 2014 from our Success Option Pool, which are set forth above in the "*Outstanding Equity Awards at Fiscal Year End* " table, will become fully vested upon a change in control, subject to his continued employment on the date of the change in control.

The stock options granted to Mr. Miller on December 20, 2016, which are set forth in the above "*Outstanding Equity Awards at Fiscal Year End* " table, will vest 25% immediately prior to a change in control that occurs prior to the first anniversary of the vesting start date of the options (September 1, 2016), subject to his continued employment on the date of such change in control. The remaining options will vest 2.0833% (approximately 1/48th of such shares) for each subsequent full calendar month that he remains employed by us or our affiliates, with the vesting date occurring on the first day following such subsequent full calendar month.

Ramy A. Mahmoud

Pursuant to his letter agreement with us, if Dr. Mahmoud's employment is terminated by us without "cause," as defined in the agreement, then Dr. Mahmoud will be entitled to receive the following termination benefits, subject to his execution and non-revocation of a release of claims:

- six months of base salary continuation; and
- six months of continued participation in our standard group medical, vision and dental plans on substantially the same terms as such benefits are provided to employees during such period.

Dr. Mahmoud's letter agreement contains restrictive covenants relating to non-disclosure of confidential information, non-disparagement, assignment of inventions, non-competition that runs for six months following his termination of employment for any reason, and non-solicitation of employees, customers and suppliers that run for six months following his termination of employment for any reason.

The stock options granted to Dr. Mahmoud on February 11, 2011 and March 11, 2014, which are set forth above in the "*Outstanding Equity Awards at Fiscal Year End* " table, may be subject to accelerated vesting upon a change in control, subject to his continued employment on the date of the change in control. The time-based options will become fully vested upon a change in control. The performance-based options may be subject to accelerated vesting based on the achievement of accelerated vesting targets that are based on certain cumulative cash proceeds received.

The stock options granted to Dr. Mahmoud on April 7, 2014 from our Success Option Pool, which are set forth above in the "*Outstanding Equity Awards at Fiscal Year End* " table, will become fully vested upon a change in control, subject to his continued employment on the date of the change in control.

Thomas E. Gibbs

Pursuant to his letter agreement with us, if Mr. Gibbs' employment is terminated by us without "cause," as defined in the agreement, then Mr. Gibbs will be entitled to receive the following termination benefits, subject to his execution and non-revocation of a release of claims:

- three months of base salary continuation; and
- three months of continued participation in our standard group medical, vision and dental plans on substantially the same terms as such benefits are provided to employees during such period.

Mr. Gibbs' letter agreement contains restrictive covenants relating to non-disclosure of confidential information, non-disparagement, assignment of inventions, non-competition that runs for six months following his termination of employment for any reason, and non-solicitation of employees, customers and suppliers that run for six months following his termination of employment for any reason.

The stock options granted to Mr. Gibbs on December 20, 2016 from our Success Option Pool, which are set forth above in the "*Outstanding Equity Awards at Fiscal Year End* " table, will become fully vested upon a change in control, subject to his continued employment on the date of the change in control.

The stock options granted to Mr. Gibbs on December 20, 2016 from our General Bonus Pool, which are set forth in the above "*Outstanding Equity Awards at Fiscal Year End* " table, will vest 25% immediately prior to a change in control that occurs prior to the first anniversary of the vesting start date of the options (September 15, 2016), subject to his continued employment on the date of such change in control. The

remaining options will vest 2.0833% (approximately 1/48th of such shares) for each subsequent full calendar month that he remains employed by us or our affiliates, with the vesting date occurring on the first day following such subsequent full calendar month.

Compensation of Non-Management Directors

For the year ended December 31, 2016, other than as set forth below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-management members of our board of directors. Peter K. Miller, our Chief Executive Officer, did not receive any compensation for his service as a member of our board of directors during 2016. Mr. Miller's compensation for service as an employee for fiscal year 2016 is presented above in the "Summary Compensation Table." With the exception of Mr. Pickering, whom we paid a retainer in connection with his service as chairman of our board of directors, we did not maintain any standard fee arrangements for the non-management members of our board of directors for their service as a director in 2016.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Larry G. Pickering	50,000	123,295(2)	—	173,295
Klaas de Boer	—	—	—	—
Per Gisle Djupesland(3)	—	98,636(4)	175,359	273,995
William F. Doyle	—	—	—	—
Patrick O'Neill	—	—	—	—
Sriram Venkataraman	—	—	—	—
Joshua A. Tamaroff	—	—	—	—

(1) The amounts in this column represent the full grant date fair value for awards granted during 2016, all of which were in the form of stock options. The grant date fair value of the options was computed in accordance with ASC Topic 718, *Compensation — Stock Compensation*. These amounts do not necessarily correspond to the actual value that may be realized by the director in connection with his option awards. The assumptions made in valuing the option awards reported in this column are described in Note 11 to our consolidated financial statements included in this prospectus.

(2) These options vest 25% on the first anniversary of the vesting start date (September 1, 2016) and 2.0833% (approximately 1/48th of such shares) for each subsequent full calendar month that Mr. Pickering provides service to us or one of our affiliates, with the vesting date occurring on the first day following such subsequent full calendar month.

(3) Reflects compensation earned by Dr. Djupesland in connection with his service as the Chief Scientific Officer of OptiNose AS. The amount reflected was paid in Norwegian Kroner and converted into U.S. dollars at the average exchange rate for the period of 8.3936kr per U.S. dollar.

(4) These options vest 25% on the first anniversary of the vesting start date (September 1, 2016) and 2.0833% (approximately 1/48th of such shares) for each subsequent full calendar month that Dr. Djupesland provides service to us or one of our affiliates, with the vesting date occurring on the first day following such subsequent full calendar month.

As of December 31, 2016, Mr. Pickering and Drs. O'Neill and Djupesland owned options to purchase 27,500, 15,000 and 10,000 shares of our common stock, respectively. None of our other non-management directors held any options to purchase shares of our common stock as of December 31, 2016.

Our board of directors intends to adopt a non-management director compensation policy following the closing of this offering.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2014 to which we have been a party in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or beneficial owners of more than 5% of our capital stock, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements that are described under "Executive and Director Compensation."

Convertible Preferred Stock Financings

In July 2014, we issued an aggregate of 1,419,781 shares of our Series C-1 Preferred Stock at a purchase price of $21.13 per share, for aggregate consideration of $30.0 million. In July 2015, we issued an additional 236,629 shares of our Series C-1 Preferred Stock at a purchase price of $21.13 per share, for aggregate consideration of $5.0 million.

In March 2017, we issued an aggregate of 1,065,451 shares of our Series D Preferred Stock at a purchase price of $32.85 per share, for aggregate consideration of $35.0 million. In April 2017 and May 2017, we issued an additional 52,127 shares of our Series D Preferred Stock at a purchase price of $32.85 per share, for aggregate consideration of $1.7 million.

In connection with the Series C-1 Preferred Stock financing in July 2015, we reimbursed Avista Capital Partners, or Avista, for $6,600 in legal fees incurred by them and an aggregate of $149,999 in funding fees incurred by Avista and the other Series C-1 Preferred Stock investors. In connection with the Series D Preferred Stock financing, we reimbursed Avista and Fidelity Investments, or Fidelity, for $36,360 and $45,076, respectively, in legal fees incurred by them.

The table below sets forth the number of shares of our Series C-1 and Series D Preferred Stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members. Each share of our convertible preferred stock in the table below will automatically convert into one share of our common stock upon the closing of this offering.

Participants[1]	Shares of Series C-1 Preferred Stock	Series C-1 Convertible Preferred Stock Aggregate Purchase ($)	Shares of Series D Preferred Stock	Series D Convertible Preferred Stock Aggregate Purchase ($)
Avista Capital Partners[2]	1,161,662	24,545,918	304,416	10,000,066
Entrepreneurs Fund LP[3]	113,842	2,405,481	45,662	1,499,997
Ikos Invest AS[4]	104,635	2,210,938	—	—
Larry G. Pickering[5]	20,715	437,708	—	—
Patrick O'Neill[6]	1,456	30,765	393	12,910
TKWD Ventures LLC[7]	190,440	4,023,997	—	—
Peter K. Miller[8]	16,564	349,997	—	—
Ramy A. Mahmoud[9]	16,564	349,997	—	—
Fidelity Investments	—	—	761,035	25,000,000
William F. Doyle[7]	1,142	24,130	334	10,972

(1) Additional details regarding these stockholders and their equity holdings are provided in "Principal Stockholders."

(2) Mr. Venkataraman and Mr. Tamaroff, members of our board of directors, are affiliated with Avista Capital Partners II, LP, Avista Capital Partners (Offshore) II, LP and Avista Capital Partners (Offshore) II-A, LP.

(3) Mr. de Boer, a member of our board of directors, is affiliated with Entrepreneurs Fund LP.

(4) Dr. Djupesland, a member of our board of directors, is affiliated with Ikos Invest AS.

(5) Mr. Pickering is the chairman of our board of directors.

(6) Dr. O'Neill is a member of our board of directors.

(7) Mr. Doyle, a member of our board of directors, is affiliated with TKWD Ventures LLC.

(8) Mr. Miller is our Chief Executive Officer and a member of our board of directors.

(9) Dr. Mahmoud is our President and Chief Operating Officer.

2015 Convertible Note Financing

In September 2015, we sold and issued an aggregate principal amount of $15.0 million of senior secured convertible notes, or the 2015 Notes. Under the terms of the 2015 Notes, we were required to pay an aggregate of $450,000 in front-end fees and $450,000 plus interest in back-end fees.

In connection with the Series D Preferred Stock financing described above, we entered into a Note Conversion Agreement with the holders of the 2015 Notes pursuant to which all of the 2015 Notes, including all principal, accrued interest and back-end fee amounts, were converted into an aggregate of 687,474 shares of our Series C-2 Preferred Stock at a conversion price of $28.40 per share.

The table below sets forth the amount of 2015 Notes purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members, as well as the number of shares of Series C-2 Preferred Stock acquired by each such entity upon conversion of the 2015 Notes. Each share of our Series C-2 Preferred Stock in the table below will automatically convert into one share of our common stock upon the closing of this offering.

Participants[1]	Principal Amount of Notes Purchased ($)	Front-end Fees Paid by Us ($)	Back-end Fees ($)	Convertible Note Value at Conversion ($)	Shares of Series C-2 Preferred Stock Issued Upon Conversion
Ikos Invest AS[2]	75,000	2,250	2,844	97,635	3,437
Entrepreneurs Fund General Partner Limited[3]	1,511,075	45,332	57,295	1,967,123	69,256
Peter K. Miller[4]	66,042	1,981	2,504	85,973	3,026
Ramy A. Mahmoud[5]	35,175	1,055	1,334	45,791	1,612
Avista Capital Partners[6]	10,902,112	327,063	413,371	14,192,413	499,670
Larry G. Pickering[7]	219,639	6,589	8,328	285,927	10,066
TKWD Ventures LLC[8]	2,019,167	60,575	76,560	2,628,559	92,543
William F. Doyle[8]	10,340	310	392	13,461	473

(1) Additional details regarding these stockholders and their equity holdings are provided in "Principal Stockholders."

(2) Dr. Djupesland, a member of our board of directors, is affiliated with Ikos Invest AS.

(3) Mr. de Boer, a member of our board of directors, is affiliated with Entrepreneurs Fund LP.

(4) Mr. Miller is our Chief Executive Officer and a member of our board of directors.

(5) Dr. Mahmoud is our President and Chief Operating Officer.

(6) Mr. Venkataraman and Mr. Tamaroff, members of our board of directors, are affiliated with Avista Capital Partners II, LP, Avista Capital Partners (Offshore) II, LP and Avista Capital Partners (Offshore) II-A, LP.

(7) Mr. Pickering is a member of our board of directors.

(8) Mr. Doyle, a member of our board of directors, is affiliated with TKWD Ventures LLC.

Second Amended and Restated Registration Rights Agreement

In connection with our Series D Preferred Stock financing in March 2017, we entered into the Second Amended and Restated Registration Rights Agreement, or the Registration Rights Agreement, with the holders of our Series B-1 Preferred Stock, Series B-2 Preferred Stock, Series C Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock and Series D Preferred Stock. We expect to amend the Registration Rights Agreement in connection with this offering. For a description of the registration rights that we expect to be in place upon the closing of this offering, see "Description of Capital Stock — Registration Rights."

Second Amended and Restated Shareholders' Agreement

In connection with our Series D Preferred Stock financing in March 2017, we entered into the Second Amended and Restated Shareholders' Agreement, or the Shareholders' Agreement, with certain of our stockholders, including Avista, TWKD, Fidelity, Entrepreneurs' Fund, and certain members of our senior management team and board of directors. We expect to amend the Shareholders' Agreement in connection with this offering, which amendment will provide for, among other things:

- Avista's right to nominate (i) two directors to our board of directors for so long as it owns % or more of our then-outstanding shares of common stock, and (ii) one director to our board of directors for so long as it owns less than % but 7.5% or more of our then-outstanding shares of common stock;
- TKWD's right to nominate one director to our board of directors so long as it owns 7.5% or more of our then-outstanding shares of common stock;
- restrictions on our ability to appoint or dismiss our chief executive officer without obtaining the prior written consent of Avista, until the earlier of (i) such time that Avista holds less than % of the outstanding shares of our common stock and (ii) , 201 ;
- restrictions on our ability to license, acquire or divest any assets for consideration having a fair market value in excess of $ million without obtaining the prior written consent of Avista, until the earlier of (i) such time that Avista holds less than % of the outstanding shares of our common stock and (ii) , 201 ;
- restrictions on the ability of management and certain of our stockholders to sell securities until the earlier of (i) , 201 and (ii) the completion of an underwritten secondary offering of our common stock in which Avista participates;
- contractual lock-up obligations for certain of our stockholders upon the filing of a registration statement in connection with an underwritten offering;
- confidentiality obligations with respect to our proprietary information and the proprietary information of our stockholders; and
- a requirement that we maintain directors' and officers' insurance on behalf of all of our and our subsidiaries' current and former officers and directors.

Employment of Certain Related Persons

John Pickering, the son of Larry Pickering, the chairman of our board of directors, is an employee of our company. During the years ended December 31, 2014, 2015 and 2016, we paid John Pickering $243,531, $247,045 and $389,097, respectively, in cash compensation, consisting of his base salary and, with respect to 2016, an annual bonus. John Pickering's current annual base salary for 2017 is $267,180. He also received a bonus in 2017 of $61,932. On March 11, 2014, our board of directors granted John Pickering a stock option to purchase 3,500 shares of our common stock. The grant date fair value of this stock option was $24,420.

Helena Djupesland, the spouse of Per Gisle Djupesland, a member of the OptiNose AS board of directors, is the Co-Chief Executive Officer and a director of OptiNose AS, our Norwegian subsidiary. During the years ended December 31, 2014, 2015 and 2016, we paid Ms. Djupesland total cash compensation of $258,245, $201,552 and $193,736, respectively. Ms. Djupesland's current annual base salary for 2017 is $192,789. She also received a bonus in 2017 of $17,213. The amounts reflected were based in Norwegian kroner and converted into U.S. dollars at an average exchange rate of 6.2969kr, 8.0681kr, and 8.3936kr per U.S. dollar for the years ended December 31, 2014, 2015 and 2016, respectively, and an average exchange rate of 8.4348kr per U.S. dollar for the period from January 1, 2017 to July 28, 2017.

Each of John Pickering and Helena Djupesland participate in our general welfare and benefit plans.

Indemnification Agreements

We have entered, or intend to enter, into indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our fourth amended and restated certificate of incorporation and our amended and restated bylaws, each of which will become effective immediately following the closing of this offering. These indemnification agreements provide our directors and executive officers with contractual rights to indemnification and, in some cases, expense advancement in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request. For more information regarding these indemnification agreements, see "Management — Limitations on Liability and Indemnification Matters."

Policies and Procedures for Transactions with Related Persons

Effective upon the closing of this offering, our board of directors has adopted a related party transactions policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related party transactions. Pursuant to this policy, we will review all transactions with a dollar value in excess of $120,000 involving us in which any of our executive officers, directors, director nominees or holders of more than 5% of our capital stock, or any affiliate or member of their immediate family, is a participant.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, members of management or our directors must present information regarding the proposed related party transaction to our audit committee or, where review by our audit committee would be inappropriate due to a conflict of interest, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, all of the parties, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management's recommendation. In considering whether to approve any proposed related party transactions, our audit committee or another independent body of our board of directors will take into account the relevant available facts and circumstances, including:

- the materiality and character of the related person's interest in the transaction;
- the commercial reasonableness of the terms of the transaction;
- the benefit and perceived benefit, or lack thereof, to us;
- the opportunity costs of alternate transactions; and
- the actual or apparent conflicts of interest of the related person.

All of the transactions described in this section were entered into prior to the adoption of this policy. Although we have not had a written policy for the review and approval of transactions with related persons,

our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to a director's or officer's relationship or interest in the agreement or transaction were disclosed to our board of directors. Our board of directors took this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all our stockholders.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information relating to the beneficial ownership of our common stock as of August 1, 2017 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable. Common stock subject to options or warrants that are currently exercisable or exercisable within 60 days of August 1, 2017, are deemed to be outstanding and to be beneficially owned by the person holding the options or warrants for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Percentage ownership of our common stock "Before Offering" in the table below is based on 10,089,106 shares of common stock, which includes (a) 1,408,540 shares of common stock issued and outstanding as of August 1, 2017 and (b) 8,680,566 shares of our common stock issuable upon the automatic conversion of all outstanding shares of our convertible preferred stock upon the closing of this offering. Percentage ownership of our common stock "After Offering" in the table gives effect to the issuance of shares of our common stock in this offering, and assumes no exercise of the underwriters' option to purchase additional shares.

Name and address of beneficial owner[1]	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
5% or greater stockholders:			
Avista Capital Partners II, LP[2]	5,937,887	58.85%	
TKWD Ventures LLC[3]	1,558,748	14.70	
Entrepreneurs Fund LP[4]	1,017,354	10.02	
Entities affiliated with Ikos Invest AS[5]	884,292	8.72	
Entities affiliated with Fidelity Management & Research Company[6]	761,035	7.54	
Directors and executive officers:			
Peter K. Miller[7]	294,547	2.85	
Ramy A. Mahmoud[8]	168,380	1.64	
Thomas E. Gibbs[9]	12,500	*	
Keith A. Goldan	—	—	
Michael F. Marino	—	—	
Larry G. Pickering[10]	131,619	1.30	
Klaas de Boer	—	—	
Per Gisle Djupesland[5]	884,292	8.72	
William F. Doyle[3][11]	1,568,912	14.79	
Patrick O'Neill[12]	22,663	*	
Sriram Venkataraman[2]	5,937,887	58.85	
Joshua A. Tamaroff[13]	—	—	
All executive officers and directors as a group (12 persons)[14]	9,020,800	81.16	

* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Unless otherwise indicated, the address of each of the individuals and entities named below is c/o OptiNose, Inc., 1020 Stony Hill Road, Suite 300, Yardley, PA 19067.

(2) Consists of (a) 34,825 shares of common stock held by Avista Capital Partners II, LP, (b) 11,437 shares of common stock held by Avista Capital Partners (Offshore) II, LP, (c) 2,775 shares of common stock held by Avista Capital Partners (Offshore) II-A, LP, (d) 4,182,127 shares of common stock issuable upon conversion of convertible preferred stock held by Avista Capital Partners II, LP, (e) 1,373,354 shares of common stock issuable upon conversion of convertible preferred stock held by Avista Capital Partners (Offshore) II, LP, and (f) 333,369 shares of common stock issuable upon conversion of convertible preferred stock held by Avista Capital Partners (Offshore) II-A, LP. Avista Capital Partners II GP, LLC ultimately exercises voting and investment power over the shares of held by Avista Capital Partners II, L.P., Avista Capital Partners (Offshore) II, L.P., and Avista Capital Partners (Offshore) II-A, L.P. Voting and disposition decisions at Avista Capital Partners II GP, LLC with respect to such shares are made by an investment committee, the members of which are Thompson Dean, Steven Webster, David Burgstahler and Sriram Venkataraman, a member of our board of directors. Each of the members of the investment committee disclaims beneficial ownership of these securities except to the extent of any pecuniary interest therein. The address for each of these individuals and entities is 65 East 55th Street, 18th Floor, New York, NY 10022.

(3) Includes (a) 1,043,368 shares of common stock issuable upon conversion of convertible preferred stock, and (b) 515,380 shares of common stock subject to warrants that are exercisable within 60 days of August 1, 2017. WFD Ventures LLC is the general partner of TKWD Ventures LLC and may be deemed to have sole voting and investment power over the shares held by TKWD Ventures LLC. William F. Doyle, a member of our board of directors, is a managing member of WFD Ventures LLC, and in his capacity as such, may be deemed to exercise shared voting and investment power over the shares held by TKWD Ventures LLC. Mr. Doyle disclaims beneficial ownership in such securities, except to the extent of his pecuniary interest therein. The address for each of these individuals and entities is c/o WFD Ventures LLC, 152 West 57th Street, 10th Floor, New York, NY 10019.

(4) Consists of (a) 364,590 shares of common stock, (b) 584,220 shares of common stock issuable upon conversion of convertible preferred stock, and (c) 68,544 shares of common stock subject to warrants that are exercisable within 60 days of August 1, 2017. Entrepreneurs Fund General Partner Limited, or EF GP, is the general partner of Entrepreneurs Fund LP,

or EF LP, and may be deemed to have sole voting and investment power over the shares held by EF LP. Colin Dow and Paul Bradshaw are managing directors of EF GP, and in theirs capacity as such, may be deemed to exercise shared voting and investment power over the shares held by EF LP. Mr. de Boer, a member of our board of directors is the Managing Partner of Entrepreneurs Fund Management LLP, an affiliate of EF GP and EF LP, through common control. Neither Mr. de Boer nor Entrepreneurs Fund Management LLP has voting or investment power over EF GP or EF LP. The address for each of these individuals and entities is 2nd Floor, Windward House, La Route de la Liberation, Se. Heller, Jersey JE2 3BQ, The Channel Islands.

(5) Consists of (a) 712,000 shares of common stock held by Ikos Subsidiary AS, (b) 118,355 shares of common stock issuable upon conversion of convertible preferred stock held by Ikos Subsidiary AS (c) 3,437 shares of common stock issuable upon conversion of convertible preferred stock held by Ikos Invest AS, (d) 20,000 shares of our common stock subject to warrants held by Ikos Subsidiary AS that are exercisable within 60 days of August 1, 2017, and (e) 30,500 shares of our common stock subject to options held by Ikos Invest AS that are exercisable within 60 days of August 1, 2017. Per Gisle Djupesland, a member of our board of directors, and Helena Djupesland are directors of Ikos Invest AS and its wholly-owned subsidiary Ikos Subsidiary AS, and as such they have shared voting and investment power over the shares held by Ikos Invest AS and Ikos Subsidiary AS. The address for each of Dr. and Ms. Djupesland and these entities is Lybekkveien 5C, 0772, Oslo, Norway.

(6) Consists of (a) 343,700 shares of common stock issuable upon conversion of convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, (b) 174,300 shares of common stock issuable upon conversion of convertible preferred stock held by Fidelity Growth Company Commingled Pool, (c) 132,335 shares of common stock issuable upon conversion of convertible preferred stock held by Fidelity Securities Fund: Fidelity OTC Portfolio, (d) 104,500 shares of common stock issuable upon conversion of convertible preferred stock held by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, and (e) 6,200 shares of common stock issuable upon conversion of convertible preferred stock held by Fidelity OTC Commingled Pool. These accounts are managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Vice Chairman, the Chief Executive Officer and the President of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act, or the Fidelity Funds advised by Fidelity Management & Research Company, or FMR Co, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Board of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Board of Trustees. The address for Fidelity Securities Fund: Fidelity OTC Portfolio is The Northern Trust Company, Attn: Trade Securities Processing, C-1N, 801 South Canal Street, Chicago, IL 60607. The address for Fidelity Growth Company Commingled Pool is Mag & Co., c/o Brown Brothers Harriman & Co., Attn: Corporate Actions /Vault, 140 Broadway, New York, NY. The address for Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund is BNY Mellon, Attn: Stacey Wolfe, 525 William Penn Place, Rm. 0400, Pittsburgh, PA 152590. The address for Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund is State Street Bank & Trust, PO Box 5756, Boston, Massachusetts 02206. The address for Fidelity OTC Commingled Pool is Mag & Co., c/o Brown Brothers Harriman & Co., Attn: Corporate Actions /Vault, 140 Broadway, New York, NY 10005.

(7) Consists of (a) 34,125 shares of common stock issuable upon conversion of convertible preferred stock, (b) 155,422 shares of common stock subject to options that are exercisable within 60 days of August 1, 2017, and (c) 105,000 shares of common stock subject to options held by the Deed of Trust of Peter K. Miller, dated October 13, 2014 that are exercisable within 60 days of August 1, 2017.

(8) Consists of (a) 18,176 shares of common stock issuable upon conversion of convertible preferred stock, (b) 115,860 shares of common stock subject to options that are exercisable within 60 days of August 1, 2017, and (c) 34,344 shares of common stock subject to options held by The Ramy Mahmoud 2014 Trust for Cynthia Mahmoud that are exercisable within 60 days of August 1, 2017.

(9) Consists of 12,500 shares of common stock subject to options that are exercisable within 60 days of August 1, 2017.

(10) Consists of (a) 113,494 shares of common stock issuable upon conversion of convertible preferred stock, and (b) 18,125 shares of common stock subject to options that are exercisable within 60 days of August 1, 2017.

(11) Includes (a) 6,512 shares of common stock issuable upon conversion of convertible preferred stock, and (b) 3,652 shares of common stock subject to warrants that are exercisable within 60 days of August 1, 2017.

(12) Consists of (a) 7,663 shares of common stock issuable upon conversion of convertible preferred stock, and (b) 15,000 shares of common stock subject to options that are exercisable within 60 days of August 1, 2017.

(13) Excludes shares held by Avista Capital Partners II, LP, Avista Capital Partners (Offshore) II, LP and Avista Capital Partners (Offshore) II-A, LP. The address for Mr. Tamaroff is c/o Avista Capital Partners, 65 E. 55th Street, 18th Floor, New York, NY 10022.

(14) Consists of (a) 761,037 shares of common stock, (b) 7,233,980 shares of common stock issuable upon conversion of convertible preferred stock, (c) 539,032 shares of common stock subject to warrants that are exercisable within 60 days of August 1, 2017, and (d) 486,751 shares of common stock subject to options that are exercisable within 60 days of August 1, 2017.

DESCRIPTION OF CAPITAL STOCK

The following is a summary of the rights of our common and preferred stock and some of the provisions of our fourth amended and restated certificate of incorporation and amended and restated bylaws, each of which will become effective immediately following the closing of this offering, and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our fourth amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

General

Immediately following the closing of this offering and the filing of our fourth amended and restated certificate of incorporation, our authorized capital stock will consist of shares, of which will be designated as common stock with a par value of $0.001 per share and of which will be designated as preferred stock with a par value of $0.001 per share.

Common Stock

Outstanding Shares

As of June 30, 2017, there would have been 10,089,106 shares of common stock outstanding, held by 36 stockholders of record, after giving effect to the automatic conversion of all preferred stock outstanding as of June 30, 2017.

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, other than election of directors, which shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election of such director. In addition, the affirmative vote of the holders of at least % of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our fourth amended and restated certificate of incorporation, such as the provisions relating to director liability, amending our bylaws or changing the Court of Chancery of the State of Delaware and United States District Court for the District of Delaware and any appellate courts thereof from being the sole and exclusive forums for certain actions brought by our stockholders against us or our directors, officers or employees.

Under our fourth amended and restated certificate of incorporation and amended and restated bylaws, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to the preferences that may be applicable to any outstanding preferred stock, holders of our common stock shall be entitled to receive ratably any dividends that may be declared by our board of directors out of funds legally available for that purpose.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock shall be entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any outstanding preferred stock.

No Preemptive or Similar Rights

Our common stock shall not be entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions. The rights, preferences and privileges of the holders of common stock are subject

to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Convertible Preferred Stock

Upon the closing of this offering, all outstanding shares of our preferred stock will be automatically converted into an aggregate of 8,680,566 shares of common stock. Under our fourth amended and restated certificate of incorporation that will be in effect immediately following the closing of this offering, our board of directors will have the authority, subject to limitations prescribed by Delaware law, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations and restrictions. Our board of directors also can increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock. We have no current plan to issue any shares of preferred stock.

Stock Options

As of June 30, 2017, we had outstanding options to purchase 1,523,901 shares of our common stock at a weighted-average exercise price of $18.64 per share, pursuant to the 2010 Plan. For additional information regarding the terms of this plan, see "Executive and Director Compensation — Equity Incentive Plan Compensation."

Warrants

In June 2010, we issued common stock warrants to certain of our stockholders, including Ikos Invest AS, Entrepreneurs Fund LP and TKWD Ventures LLC, which were immediately exercisable for an aggregate of 654,624 shares of our common stock at an exercise price of $23.56 per share. These warrants remain outstanding as of June 30, 2017. The holders of these warrants may exercise the warrants, at their election, in cash, by cashless exercise or by a combination of these two methods. The shares underlying the warrants are considered registrable securities for purposes of the Registration Rights Agreement. Each warrant expires on November 1, 2020 if not earlier exercised.

Registration Rights

Pursuant to the Registration Rights Agreement, certain holders of shares of our common stock have registration rights and certain holders of our warrants and shares of our preferred stock have registration rights with respect to the shares of common stock issuable upon exercise or conversion, as applicable, as further described below. After registration of these shares of common stock pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. The registration rights will terminate with respect to each stockholder on the date on which such stockholder can sell all of its registrable shares without limitation during a three-month period without registration pursuant to Rule 144 of the Securities Act or another similar exemption under the Securities Act. See "Shares Eligible for Future Sale — Rule 144."

Demand Registration Rights

Pursuant to the Registration Rights Agreement, at any time beginning 180 days following the closing of this offering, certain holders of registrable shares who are party to the Registration Rights Agreement have the right to demand that we file a Form S-1 registration statement for the registration of their shares of common stock, including shares of common stock to be issued in connection with the automatic conversion of all outstanding shares of our preferred stock upon the closing of this offering. These registration rights are subject to specified conditions and limitations, including a minimum expected aggregate gross proceeds of $20.0 million, the number of registration demands and the right of a managing underwriter to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to effect the registration as expeditiously as possible. An aggregate of shares of common stock will be entitled to these demand registration rights upon the closing of this offering. We are not obligated to file a registration statement pursuant to this provision on more than one occasion, unless such registration statement was not declared effective by the SEC.

Registration on Form S-3

In addition, subject to specified limitations set forth in the Registration Rights Agreement, at any time after we become eligible to file a registration statement on Form S-3, holders of at least 20% of the registrable securities then outstanding may request that we register their registrable securities on a registration statement on Form S-3 for purposes of a public offering if the total amount of registrable securities registered have an aggregate offering price of at least $20.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period. An aggregate of shares of common stock will be entitled to these demand registration rights upon the closing of this offering.

Piggyback Registration Rights

At any time after the closing of this offering, if we propose to file a registration statement to register any of our securities under the Securities Act, either for our own account or for the account of any of our stockholders, other than pursuant to the demand registration rights described above, the holders of our registrable securities are entitled to notice of registration and, subject to specified exceptions, we will be required upon the holders' request to use our best efforts to include their then-held registrable securities in the registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances. In addition, in connection with an underwritten secondary offering requested by Avista, certain members of our management will have the right to participate on a pro rata basis. An aggregate of shares of common stock will be entitled to these piggyback registration rights. These piggyback registration rights do not apply to this offering.

Other Provisions

We will pay all registration expenses, other than underwriting discounts and commissions and transfer taxes, if any, attributable to the sale of the registrable securities related to any registration effected pursuant to the Registration Rights Agreement. Unless a registration has been revoked by the holders, we are also required to pay the fees and expenses of one counsel for the holders of registrable securities designated by the holder of a majority of registrable securities being registered, as well as the fees and expenses of counsel for Avista. The Registration Rights Agreement contains customary cross-indemnification provisions pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

Delaware Anti-Takeover Law and Provisions of Our Certificate of Incorporation and Bylaws

Delaware Anti-Takeover Law

Our fourth amended and restated certificate of incorporation that will be effective immediately following the closing of this offering provides that we will be subject to Section 203 of the Delaware General Corporation Law, or Section 203, once Avista and TKWD cease to beneficially own 10% of more of our outstanding shares of common stock. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/_{3}\%$ of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Certificate of Incorporation and Bylaws

Provisions of our fourth amended and restated certificate of incorporation and our amended and restated bylaws, each of which will be in effect immediately following the closing of this offering, may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our fourth amended and restated certificate of incorporation and our amended and restated bylaws will:

- permit our board of directors to issue up to million shares of preferred stock, with any rights, preferences and privileges as it may designate, which issuance could result in the loss of voting control by other stockholders;

- § provide that our board of directors will be classified into three classes with staggered, three-year terms and that, subject to the rights of Avista and TKWD to remove their respective director nominees with or without cause, directors may only be removed for cause by the affirmative vote of the holders of at least a majority of the voting power of outstanding shares of our capital stock;

- § subject to any director nomination rights afforded Avista and TKWD, provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- § following the date that Avista and TKWD cease to hold a majority of the outstanding shares of our common stock, require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- § provide that, with the exception of director nominees submitted by Avista and TKWD under our Shareholders' Agreement, stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

- § require that the amendment of certain provisions of our certificate of incorporation and bylaws relating to anti-takeover measures may only be approved by a vote of % of our outstanding common stock;

- § not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and

- § provide that special meetings of our stockholders may be called only by the chairman or vice chairman of our board of directors, our chief executive officer, a majority of our board of directors or, for so long as Avista and TKWD hold a controlling ownership interest of our common stock, by the holders of a majority of our outstanding shares of common stock.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our fourth amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware, or the United States District Court for the District of Delaware and any appellate courts thereof where subject matter jurisdiction is vested exclusively in the federal courts of the United States of America, will be the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our fourth amended and restated certificate of incorporation or our amended and restated bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our restated certificate to be inapplicable or unenforceable in such action.

NASDAQ Global Market Listing

We have applied to list our common stock on The NASDAQ Global Market under the symbol " ."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is . The transfer agent's address is

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market after this offering, or the perception that these sales could occur, could adversely affect prevailing market prices for our common stock. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of June 30, 2017, upon the closing of this offering, shares of common stock will be outstanding, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into 8,680,566 shares of common stock upon the closing of this offering and the issuance by us of shares of common stock in this offering, but assuming no exercise of the underwriters' option to purchase additional shares. All of the shares sold in this offering will be freely tradable unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act or purchased by existing stockholders and their affiliated entities that are subject to lock-up agreements. The remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws, lock-up agreements or the Shareholders' Agreement. Other than shares subject to trading restrictions under the Shareholders' Agreement, these remaining shares will generally become available for sale in the public market as follows:

- restricted shares will be eligible for immediate sale upon the closing of this offering; and
- restricted shares will be eligible for sale upon expiration of lock-up agreements 180 days after the date of this offering, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Rule 144

In general, pursuant to Rule 144 under the Securities Act, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours at any time during the three months preceding a sale and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours at any time during the three months preceding a sale and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately following the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Rule 701

Pursuant to Rule 701 under the Securities Act, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock incentive plans may be resold by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and
- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

As of June 30, 2017, options to purchase a total of 1,523,901 shares of common stock were outstanding. Of the total number of shares of our common stock issuable under these options, substantially all are subject to contractual lock-up agreements with us or the underwriters described below under "Underwriting" and will become eligible for sale in accordance with Rule 701 at the expiration of those agreements.

Lock-up Agreements

We, along with our directors, executive officers and substantially all of our other securityholders, have agreed with the underwriters that for a period of 180 days after the date of this prospectus, or the restricted period, subject to specified exceptions, we and they will not sell, offer to sell, contract to sell or lend, effect any short sale or establish or increase any put equivalent position or liquidate or decrease any call equivalent position, pledge, hypothecate, grant any security interest in or in any other way transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock. Upon expiration of the restricted period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See "— Registration Rights" below and "Description of Capital Stock — Registration Rights."

After this offering, certain of our employees, including our executive officers and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements described above.

Registration Rights

Upon the closing of this offering, the holders of shares of common stock or their transferees will be entitled to various rights with respect to registration of these shares under the Securities Act, subject to the lock-up arrangement described above. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of the registration. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See "Description of Capital Stock — Registration Rights" for additional information.

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under the 2010 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to vesting restrictions, Rule 144 volume limitations for affiliates and the lock-up agreements described above, if applicable.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a general discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined herein) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. All prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock. In general, a non-U.S. holder means a beneficial owner of our common stock (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (1) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing U.S. Treasury Regulations promulgated thereunder, published administrative pronouncements and rulings of the U.S. Internal Revenue Service, or the IRS, and judicial decisions, all as in effect as of the date of this prospectus. These authorities are subject to change and to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus.

We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any alternative minimum, Medicare contribution, estate or gift tax consequences, or any aspects of U.S. state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as holders that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below), corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, banks, financial institutions, insurance companies, brokers, dealers or traders in securities, commodities or currencies, tax-qualified retirement plans, holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation, holders holding our common stock as part of a hedge, straddle or other risk reduction strategy, conversion transaction or other integrated investment, holders deemed to sell our common stock under the constructive sale provisions of the Code, controlled foreign corporations, passive foreign investment companies and certain former U.S. citizens or long-term residents.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as partnerships for U.S. federal income tax purposes) or persons that hold their common stock through partnerships. If a partnership, including any entity or arrangement treated as a partnership for U.S. federal income tax purposes, holds shares of our common stock, the U.S. federal income tax treatment of a partner in such partnership will generally depend upon the status of the partner and the activities of

the partnership. Such partners and partnerships should consult their tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock.

There can be no assurance that a court or the IRS will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income tax consequences to a non-U.S. holder of the purchase, ownership or disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's adjusted tax basis in the common stock. Any remaining excess will be treated as capital gain from the sale or exchange of such common stock, subject to the tax treatment described below in "Gain on Sale, Exchange or Other Disposition of Our Common Stock." Any such distribution will also be subject to the discussion below under the heading "Foreign Accounts."

Dividends paid to a non-U.S. holder will generally be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

To claim a reduction or exemption from withholding, a non-U.S. holder of our common stock generally will be required to provide (a) a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements to claim the benefit of an applicable income tax treaty between the United States and such holder's country of residence, or (b) a properly executed IRS Form W-8ECI stating that dividends are not subject to withholding because they are effectively connected with such non-U.S. holder's conduct of a trade or business within the United States. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a U.S. trade or business of the non-U.S. holder and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained in the United States by such non-U.S. holder, in which case the non-U.S. holder generally will be taxed at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States); or

- our common stock constitutes a U.S. real property interest because we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation." Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. Even if we are or become a U.S. real property holding corporation, provided that our common stock is regularly traded, as defined by applicable U.S. Treasury Regulations, on an established securities market, our common stock will be treated as a U.S. real property interest only with respect to a non-U.S. holder that holds more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are a U.S. real property holding corporation and either our common stock is not regularly traded on an established securities market or a non-U.S. holder holds, or is treated as holding, more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, such non-U.S. holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply. If we are a U.S. real property holding corporation and our common stock is not regularly traded on an established securities market, a non-U.S. holder's proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a U.S. real property holding corporation. No assurance can be provided that our common stock is or will in the future be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the dividends on our common stock paid to such holder and the tax withheld, if any, with respect to such dividends. Non-U.S. holders will have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. A non-U.S. holder generally will not be subject to U.S. backup withholding with respect to payments of dividends on our common stock if it certifies its non-U.S. status by providing a valid IRS Form W-8BEN or W-8BEN-E (or successor form) or W-8ECI, or otherwise establishes an

exemption; provided we do not have actual knowledge or reason to know such non-U.S. holder is a U.S. person, as defined in the Code. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder may be allowed as a credit against the non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise qualifies for an exemption from these rules. A U.S. federal withholding tax of 30% also applies to dividends and will apply to the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity (as defined in the Code), unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity, or otherwise qualifies for an exemption from these rules. The withholding provisions described above currently apply to dividends paid on our common stock and will generally apply with respect to gross proceeds of a sale or other disposition of our common stock on or after January 1, 2019.

If withholding is imposed under FATCA on a payment related to our common stock, a beneficial owner that is not a foreign financial institution and that otherwise would not be subject to withholding (or that otherwise would be entitled to a reduced rate of withholding) generally may obtain a refund from the IRS by filing a U.S. federal income tax return (which may entail significant administrative burden). An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, OWNING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2017, among us and Jefferies LLC and Piper Jaffray & Co., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
Piper Jaffray & Co.	
BMO Capital Markets Corp.	
RBC Capital Markets, LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the closing of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such

amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We have also agreed to reimburse the underwriters for certain expenses, including an amount not to exceed $ in connection with the clearance of this offering with the Financial Industry Regulatory Authority, or FINRA, as set forth in the underwriting agreement. In accordance with FINRA Rule 5110, the reimbursement of these fees is deemed underwriting compensation for this offering.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We have applied to have our common stock approved for listing on The NASDAQ Global Market under the trading symbol " ."

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Exchange Act,
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially,
- enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of shares of our common stock, or of options or warrants to shares of our common stock, or securities or rights exchangeable or exercisable for or convertible into shares of our common stock,
- make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any shares of our common stock, or of options or warrants to shares of our common stock, or securities or rights exchangeable or exercisable for or convertible into shares of our common stock, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of .

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

may, in its sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

The foregoing restrictions shall not apply to issuances of common stock or grants of stock options, restricted stock or other incentive compensation pursuant to the terms of certain stock plans or arrangements described herein.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of

the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those shares being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Canada

Resale Restrictions

The distribution of shares in Canada is being made only in the provinces of Ontario, Québec, Manitoba, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

Representations of Canadian Purchasers

By purchasing shares in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106—Prospectus Exemptions,
- the purchaser is a "permitted client" as defined in National Instrument 31-103—Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

Conflicts of Interest

Canadian purchasers are hereby notified that certain of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the offering memorandum (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of shares should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares in their particular circumstances and about the eligibility of the shares for investment by the purchaser under relevant Canadian legislation.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each referred to herein as a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, referred to herein as the Relevant Implementation Date, no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and any offer of the shares of our common stock is directed only at investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (1) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the

SFA, (2) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (3) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

- to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;

- where no consideration is given for the transfer; or

- where the transfer is by operation of law.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to us, the offering, or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (1) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the Order, and/or (2) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated. Each such person is referred to herein as a Relevant Person.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Hogan Lovells US LLP, Philadelphia, Pennsylvania. Certain legal matters relating to this offering will be passed upon for the underwriters by Cooley LLP, New York, New York.

EXPERTS

The consolidated financial statements of OptiNose, Inc. at December 31, 2015 and 2016, and for the years then ended, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of our common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at OptiNose, Inc., 1020 Stony Hill Road, Suite 300, Yardley, PA 19067, or by calling (267) 364-3500.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.optinose.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

OptiNose, Inc.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Audited Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2015 and 2016	F-3
Consolidated Statements of Operations for the years ended December 31, 2015 and 2016	F-4
Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2015 and 2016	F-5
Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit for the years ended December 31, 2015 and 2016	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2016	F-7
Notes to Consolidated Financial Statements	F-8
Unaudited Interim Consolidated Financial Statements	
Consolidated Balance Sheets as of December 31, 2016 and June 30, 2017	F-30
Consolidated Statements of Operations for the six months ended June 30, 2016 and 2017	F-31
Consolidated Statements of Comprehensive Income (Loss) for the six months ended June 30, 2016 and 2017	F-32
Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' (Deficit) Equity for the six months ended June 30, 2017	F-33
Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2017	F-34
Notes to Unaudited Interim Consolidated Financial Statements	F-35

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of OptiNose, Inc.

We have audited the accompanying consolidated balance sheets of OptiNose, Inc. as of December 31, 2015 and 2016, and the related consolidated statements of operations, comprehensive income (loss), redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of OptiNose, Inc. at December 31, 2015 and 2016, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania

June 23, 2017

OptiNose, Inc.
Consolidated Balance Sheets
As of December 2015 and 2016
(in thousands, except share and per share data)

	December 31, 2015	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 15,198	$ 36,797
Grants and other receivables	448	384
Deposits and other current assets	171	3,494
Total current assets	15,817	40,675
Property and equipment, net	191	323
Deposits and other assets — long-term	1	553
Total assets	$ 16,009	$ 41,551
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,506	$ 3,369
Accrued expenses	3,646	2,541
Deferred other income	41	—
Total current liabilities	7,193	5,910
Convertible notes payable, net	14,480	15,256
Accrued interest	669	3,409
Total liabilities	22,342	24,575
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock, $0.001 par value:		
Series A, 285,480 shares authorized, issued and outstanding at December 31, 2015 and 2016 (liquidation value of $5,381 at December 31, 2016)	5,381	5,381
Series B-1, 35,680 shares authorized, issued and outstanding at December 31, 2015 and 2016 (liquidation value of $673 at December 31, 2016)	673	673
Series B-2, 782,600 shares authorized, issued and outstanding at December 31, 2015 and 2016 (liquidation value of $14,760 at December 31, 2016)	14,760	14,760
Series C, 4,115,344 shares authorized, issued and outstanding at December 31, 2015 and 2016 (liquidation value of $106,724 at December 31, 2016)	96,168	105,738
Series C-1, 1,656,410 shares authorized, issued and outstanding at December 31, 2015 and 2016 (liquidation value of $41,843 at December 31, 2016)	38,077	41,621
Total redeemable convertible preferred stock	155,059	168,173
Stockholders' deficit:		
Common stock, $0.001 par value; 10,624,486 shares authorized; 1,402,290 and 1,408,540 shares issued and outstanding at December 31, 2015 and 2016, respectively	1	1
Additional paid-in capital	—	—
Accumulated deficit	(161,252)	(151,099)
Accumulated other comprehensive loss	(141)	(99)
Total stockholders' deficit	(161,392)	(151,197)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 16,009	$ 41,551

See accompanying notes to consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Operations
For the years ended December 31, 2015 and 2016
(in thousands, except share and per share data)

	Years Ended December 31,	
	2015	2016
Licensing revenues	$ 85	$ 47,500
Operating expenses:		
Research and development	22,156	15,311
Selling, general and administrative	6,006	6,869
Total operating expenses	28,162	22,180
(Loss) income from operations	(28,077)	25,320
Other (income) expense:		
Grant and other income	(643)	(727)
Interest income	(28)	(143)
Interest expense	819	3,517
Foreign currency losses	89	60
Net (loss) income	(28,314)	22,613
Deemed dividend	9,992	11,005
Accretion to redemption value	2,069	2,109
Net (loss) income attributable to common stockholders	$ (40,375)	$ 9,499
Net (loss) income per share of common stock,		
basic	$ (28.79)	$ 1.15
diluted	$ (28.79)	$ 0.94
Weighted average common shares outstanding,		
basic	1,402,290	1,403,900
diluted	1,402,290	1,724,513
Pro forma net income per share of common stock,		
basic (unaudited)		$ 2.73
diluted (unaudited)		$ 2.63
Pro forma weighted average common shares outstanding,		
basic (unaudited)		8,279,414
diluted (unaudited)		8,600,027

See accompanying notes to consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Comprehensive Income and Loss
For the years ended December 31, 2015 and 2016
(in thousands)

	Years Ended December 31,	
	2015	2016
Net (loss) income	$ (28,314)	$ 22,613
Other comprehensive (loss) income:		
Foreign currency translation adjustment	(13)	42
Comprehensive (loss) income	$ (28,327)	$ 22,655

See accompanying notes to consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit
For the years ended December 31, 2015 and 2016
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Stockholders' Deficit					
			Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at January 1, 2015	6,638,885	$ 138,160	1,402,290	$ 1	$ —	$ (121,465)	$ (128)	$ (121,592)
Stock compensation expense	—	—	—	—	588	—	—	588
Sale of Series C-1 preferred stock	236,629	4,838	—	—	—	—	—	—
Accretion of Series C & Series C-1 preferred stock to redemption value	—	2,069	—	—	(588)	(1,481)	—	(2,069)
Accretion of Series C & Series C-1 preferred stock in lieu of 8% dividend	—	9,992	—	—	—	(9,992)	—	(9,992)
Foreign currency translation adjustment	—	—	—	—	—	—	(13)	(13)
Net loss	—	—	—	—	—	(28,314)	—	(28,314)
Balance at December 31, 2015	6,875,514	155,059	1,402,290	1	—	(161,252)	(141)	(161,392)
Stock compensation expense	—	—	—	—	599	—	—	599
Exercise of common stock options	—	—	6,250	—	55	—	—	55
Accretion of Series C & Series C-1 preferred stock to redemption value	—	2,109	—	—	(654)	(1,455)	—	(2,109)
Accretion of Series C & Series C-1 preferred stock in lieu of 8% dividend	—	11,005	—	—	—	(11,005)	—	(11,005)
Foreign currency translation adjustment	—	—	—	—	—		42	42
Net income	—	—	—	—	—	22,613	—	22,613
Balance at December 31, 2016	6,875,514	$ 168,173	1,408,540	$ 1	$ —	$ (151,099)	$ (99)	$ (151,197)

See accompanying notes to consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Cash Flows
For the years ended December 31, 2015 and 2016
(in thousands)

	Years Ended December 31,	
	2015	2016
Operating activities:		
Net (loss) income	$ (28,314)	$ 22,613
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation	75	83
Stock-based compensation	588	599
Amortization of debt discount and issuance costs	195	776
Changes in operating assets and liabilities:		
Grants and other receivables	144	65
Deposits and other assets	1,504	(3,888)
Accounts payable	450	(130)
Accrued expenses	(3,814)	(1,097)
Accrued interest	669	2,740
Deferred other income	(211)	(41)
Cash (used in) provided by operating activities	(28,714)	21,720
Investing activities:		
Purchases of property and equipment	(80)	(215)
Cash used in investing activities	(80)	(215)
Financing activities:		
Proceeds from the sale of Series C-1 preferred stock	5,000	—
Cash paid for issuance costs of Series C-1 preferred stock	(162)	—
Proceeds from the exercise of stock options	—	55
Proceeds from issuance of convertible notes payable, net	14,285	—
Cash provided by financing activities	19,123	55
Effects of exchange rate changes on cash and cash equivalents	(14)	39
Net (decrease) increase in cash and cash equivalents	(9,685)	21,599
Cash and cash equivalents at beginning of year	24,883	15,198
Cash and cash equivalents at end of year	$ 15,198	$ 36,797
Supplemental disclosure of noncash financing activities:		
Deemed dividend	$ 9,992	$ 11,005
Accretion to redemption value	$ 2,069	$ 2,109

See accompanying notes to consolidated financial statements

1. Organization and Description of Business

OptiNose, Inc. (the Company) was incorporated in Delaware in May 2010 (inception) and its facilities are located in Yardley, Pennsylvania, Oslo, Norway and Swindon, England. The Company's predecessor entity OptiNose AS was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became a wholly-owned subsidiary of the Company as part of an internal reorganization.

The Company is a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. The Company's lead product candidate, OPN-375, is a therapeutic utilizing our proprietary Breath Powered exhalation delivery system (EDS) that delivers a topically-acting and potent anti-inflammatory corticosteroid for the treatment of chronic rhinosinusitis with and without nasal polyps. The Company's new drug application (NDA) for OPN-375 was accepted for filing and review by the U.S. Food and Drug Administration (FDA) in January 2017.

2. Liquidity

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio and conducting pre-clinical studies and clinical trials. The Company has not generated any revenue from product sales. As of December 31, 2016, the Company had cash and cash equivalents of $36,797. In addition, in March 2017 through May 2017, the Company completed the sale of 1,117,578 shares of Series D preferred stock at a per share purchase price of $32.85, resulting in gross proceeds to the Company of $36,712 (Note 14). The Company will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of the Company's planned development and commercialization activities. If additional funding is not secured when required, the Company may need to delay or curtail its operations until such funding is received. The Company is subject to a number of risks similar to other life sciences companies, including, but not limited to, successful development and commercialization of its drug candidates, raising additional capital, the development of new technological innovations by its competitors, protection of proprietary technology and market acceptance of the Company's products.

3. Basis of Presentation and Summary of Significant Accounting Policies

The accompanying consolidated financial statements have been prepared in conformity with United States (US) generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

Principles of consolidation

The consolidated financial statements include the accounts of OptiNose, Inc. and its wholly-owned subsidiaries, OptiNose US, Inc., OptiNose AS and OptiNose UK Ltd. All inter-company balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

of expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.

Cash and cash equivalents

All highly liquid investments purchased with an original maturity date of three months or less at the date of purchase are considered to be cash equivalents. The Company generally invests its cash in deposits with high credit quality financial institutions. Additionally, the Company performs periodic evaluations of the relative credit standing of these financial institutions.

The Company maintains its cash and cash equivalent balances at foreign and domestic financial institutions. Bank deposits with Norwegian banks are insured up to approximately 2,000 Norwegian krone by the Norwegian Banks' Guaranty Fund. Bank deposits with US banks are insured up to $250 by the Federal Deposits Insurance Corporation. The Company had uninsured cash balances of $14,254 and $35,866 at December 31, 2015 and 2016, respectively.

Fair value of financial instruments

The Company measures certain assets and liabilities at fair value, which is defined as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The FASB accounting guidance outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company uses quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of the inputs as follows:

- Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 — Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.
- Level 3 — Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

At December 31, 2015 and 2016, the Company's financial instruments included cash and cash equivalents, grants receivable, accounts payable and accrued expenses. The carrying amounts reported in the Company's financial statements for these instruments approximates their respective fair values because of the short-term nature of these instruments. At December 31, 2015 and 2016, there were no financial assets or liabilities measured at fair value on a recurring basis.

The Company's financial instruments also included convertible debt at December 31, 2015 and 2016 (Note 8).

Property and equipment

Property and equipment is recorded at cost. Significant additions or improvements are capitalized, and expenditures for repairs and maintenance are charged to expense as incurred. Gains and losses on disposal

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

of assets are included in the consolidated statements of comprehensive loss. Depreciation is calculated on a straight-line basis over the estimated useful lives of the respective assets.

The estimated useful lives of equipment are as follows:

Computer equipment	3 years
Software	3 years
Machinery & production equipment	5 - 10 years
Furniture & fixtures	3 - 5 years
Leasehold improvements	Shorter of lease term or useful life

Long lived assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell. The Company has not recognized any impairment or disposition of long-lived assets.

Deposits and other assets

Deposits and other current assets consist primarily of payments made in advance to outsourced mold development manufacturers and equipment suppliers, as well as a receivable due from the U.S. Food and Drug Administration (FDA) related to a Prescription Drug User Fee Act (PDUFA) New Drug Application (NDA) fee that was refunded to the Company in March 2017.

Throughout 2016, the Company made upfront payments to outsourced mold development manufacturers and equipment suppliers for molds and equipment that are expected to be used for commercial production of OPN-375, should FDA approval be obtained for the product candidate. The Company expects to take delivery of this equipment at various points in 2017. For equipment received prior to FDA approval, the Company expects to record the equipment as a component of research and development expense if there is no alternative future use of the equipment without FDA approval, and accordingly, deposits made through December 31, 2016 for which there is currently not an alternative future use have been recorded as short term deposits. Conversely, deposits on equipment that were determined to have an alternative future use will be capitalized as fixed assets when received and therefore are classified in long-term deposits at December 31, 2016.

Convertible debt

The Company analyzes its convertible debt instruments for embedded derivatives that may require bifurcation from the host and accounted for as derivatives. At the inception of each instrument, the Company performs an analysis of the embedded features requiring bifurcation and may elect, if eligible, to account for the entire debt instrument at fair value. If elected, any changes in fair value are recognized in the accompanying statements of operations and comprehensive loss until the instrument is settled. The Company has not elected to account for its convertible debt at fair value.

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

Revenue recognition

The Company's revenues are generated primarily through licensing arrangements, which generally contain multiple elements, or deliverables, including licenses and research and development activities to be performed by the Company on behalf of the licensee. Revenues are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured.

Currently the Company's revenues are generated pursuant to the terms of a single license agreement (the AVP-825 License Agreement) with Avanir Pharmaceuticals, Inc. (Avanir) (Note 7). The AVP-825 License Agreement includes licensed rights to patented technology, non-refundable up-front license fees, research services, and regulatory and sales milestones as well as royalty payments.

For arrangements with multiple elements, the Company recognizes revenue in accordance with the FASB ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, which provides guidance for separating and allocating consideration in a multiple element arrangement. The selling prices of deliverables under an arrangement may be derived using third-party evidence (TPE), or a best estimate of selling price (BESP), if vendor-specific objective evidence of selling price (VSOE) is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the License Agreement was sold on a standalone basis. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, and delivery or performance of the undelivered item is considered probable and substantially within the Company's control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting for the Company's collaborations, the Company evaluated whether the AVP-825 License Agreement has standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, the Company considers whether or not (i) the collaborator could use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license was dependent on the undelivered items and (iii) the collaborator or other vendors could provide the undelivered items.

Whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional performance model, if a pattern of performance can be determined, or a straight-line model over the period of performance, which is typically the research and development term.

Development milestones may be triggered either by the results of the Company's research efforts or by events external to it, such as regulatory approval to market a product. Consideration that is contingent upon achievement of a development milestone is recognized in its entirety as revenue in the period in which the

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

milestone is achieved, but only if the consideration earned from the achievement of a milestone meets all the criteria for the milestone to be considered substantive at the inception of the arrangement. For a milestone to be considered substantive, the consideration earned by achieving the milestone must (i) be commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) relate solely to past performance and (iii) be reasonable relative to all deliverables and payment terms in the AVP-825 License Agreement. As of December 31, 2016, all development milestones have been achieved.

Royalties and sales milestones are recorded as earned in accordance with the contract terms when third party sales can be reliably measured and collectability is reasonably assured.

Grant income

Government grants are agreements that provide cost reimbursement for certain research and development activities over a contractually defined period. Income from government grants is recognized in the period in which related costs are incurred, provided that the conditions under which government grants were provided have been met and only perfunctory obligations are outstanding. Grant income received in excess of costs incurred is recognized as deferred other income.

Research and development

Research and development costs are expensed as incurred. Research and development costs consist primarily of device development, clinical trial related costs, and regulatory related costs. The Company enters into agreements with contract research organizations (CROs) to facilitate, coordinate and perform agreed upon research and development activities for the Company's clinical trials. These CRO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical trial milestones. The Company prepays certain CRO fees whereby the prepayments are recorded as a current or non-current prepaid asset and are amortized into research and development expense over the period of time the contracted research and development services were performed. The Company's CRO contracts generally also included other fees such as project management and pass through fees whereby the Company expenses these costs as incurred, using the Company's best estimate. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs, and other miscellaneous costs. Pass through fees incurred are based on the amount of work completed for the clinical trials and are monitored through reporting provided by the Company's CROs.

Stock-based compensation

The Company measures and recognizes compensation expense for all stock options awarded to employees and nonemployees based on the estimated fair value of the awards on the respective grant dates. The Company uses the Black-Scholes option pricing model to value its stock option awards. The Company recognized compensation expense for time-based awards on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The Company recognized compensation expense for performance based awards when the performance condition is probable of achievement. Stock-based awards issued to nonemployees are revalued at each reporting period until the award vests. The Company accounts for forfeitures of stock option awards as they occur.

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

Estimating the fair value of options requires the input of subjective assumptions, including the estimated fair value of the Company's common stock, the expected life of the options, stock price volatility, the risk-free interest rate and expected dividends. The assumptions used in the Company's Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective.

Dividends

Dividends on redeemable convertible preferred stock are accreted through a charge to additional paid-in-capital, if available, or to retained earnings (accumulated deficit).

Income taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities and the expected benefits of net operating loss carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the period in which temporary differences are expected to be settled, is reflected in the Company's financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. As of December 31, 2015 and 2016, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

Net income (loss) per common share

For the year ended December 31, 2016, the Company used the two-class method to compute net income (loss) per common share because the Company has issued securities (redeemable convertible preferred stock) that entitle the holder to participate in dividends and earnings of the Company. Under this method, net income is reduced by any dividends earned and the accretion of redeemable convertible preferred stock to its redemption value during the period. The remaining earnings (undistributed earnings) are allocated to common stock and each series of redeemable convertible preferred stock to the extent that each preferred security may share in earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the redeemable convertible preferred stock have no obligation to fund losses.

Diluted net income (loss) per common share is computed under the two-class method by using the weighted-average number of shares of common stock outstanding, plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options, warrants, and convertible debt. In addition, the Company analyzes the potential dilutive effect of the outstanding redeemable convertible preferred stock and convertible debt under the "if-converted" method when calculating diluted earnings per share, in which it is assumed that the outstanding redeemable convertible preferred stock or convertible debt converts into common stock at the beginning of the period or when

(in thousands, except share and per share data)

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

issued if later. The Company reports the more dilutive of the approaches (two class or "if-converted") as their diluted net income per share during the period.

For the year ended December 31, 2015, in which the Company reported a net loss, there was no dilutive effect under either the two-class or "if-converted" method. For the year ended December 31, 2016, the Company presented diluted net income per common share using the two-class method, which was more dilutive than the "if-converted" method.

Automatically upon the closing of a qualified initial public offering, all of the Company's outstanding redeemable convertible preferred stock will convert into common stock. In the accompanying consolidated statements of operations, unaudited pro forma basic and diluted net income (loss) per share of common stock has been prepared to give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock as if this proposed initial public offering had occurred on the later of the beginning of the reporting period or the issuance date of the redeemable convertible preferred stock. Accordingly, the unaudited pro forma net income (loss) attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net income (loss) per share of common stock excludes the effects of accretion on convertible preferred stock.

The following table sets forth the computation of basic and diluted net income (loss) per share for the periods indicated:

	Years Ended December 31,	
	2015	2016
Basic net (loss) income per common share calculation:		
Net (loss) income attributable to common stockholders	$ (40,375)	$ 9,499
Less: undistributed earnings to participating securities	—	(7,884)
Net (loss) income attributable to common stockholders — basic	(40,375)	1,615
Weighted average common shares outstanding — basic	1,402,290	1,403,900
Net (loss) income per share of common stock — basic	$ (28.79)	$ 1.15
Diluted net (loss) income per common share calculation:		
Net (loss) income attributable to common stockholders	$ (40,375)	$ 9,499
Less: undistributed earnings to participating securities	—	(7,884)
Net (loss) income attributable to common stockholders — diluted	(40,375)	1,615
Weighted average common shares outstanding — basic	1,402,290	1,403,900
Stock options	—	320,613
Weighted average common shares outstanding — diluted	1,402,290	1,724,513
Net (loss) income per share of common stock — diluted	$ (28.79)	$ 0.94

(in thousands, except share and per share data)

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

Diluted net income (loss) per common share for the years presented do not reflect the following potential common shares, as the effect would be antidilutive:

	Years Ended December 31,	
	2015	2016
Stock options	1,181,901	812,387
Common stock warrants	654,624	654,624
Convertible preferred stock	6,875,514	6,875,514
Convertible debt	653,930	663,985
Total	9,365,969	9,006,510

Foreign currency translation and transactions

Operations in non-US entities are recorded in the functional currency of each entity. For financial reporting purposes, the functional currency of an entity is determined by a review of the source of an entity's most predominant cash flows. The results of operations for any non-US dollar functional currency entities are translated from functional currencies into US dollars using the average currency rate during each month. Assets and liabilities are translated using currency rates at the end of the period. Adjustments resulting from translating the financial statements of our foreign entities that use their local currency as the functional currency into US dollars are reflected as a component of other comprehensive income (loss).

Foreign currency transaction losses resulting from exchange rate fluctuations on transactions denominated in a currency other than the functional currency totaled $89 and $60 in 2015 and 2016 respectively.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company globally manages its business within one reportable segment. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance. At December 31, 2015 and 2016, all of the Company's revenues were derived from the AVP-825 License Agreement with Avanir, which was entered into by the Company's wholly owned subsidiary, OptiNose AS. Long-lived assets located outside of the United States were de minimis as of December 31, 2015 and 2016.

Recent accounting pronouncements

On March 30, 2016, the FASB issued ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for employee share-based payment transactions including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The guidance is applicable to public business entities for fiscal years beginning after December 15, 2016 and interim periods within those years. The Company early adopted this guidance effective December 31, 2016, and there was no material impact on its results of operations, financial positions, or cash flows.

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The FASB issued the update to require the recognition of lease assets and liabilities on the balance sheet of lessees. The standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within such fiscal years. The ASU requires a modified retrospective transition method with the option to elect a package of practical expedients. Early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. The new guidance simplifies the presentation of deferred income taxes by requiring that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 applies to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this ASU. For public entities, ASU 2015-17 is effective for financial statements issued for annual periods beginning after December 15, 2016, with earlier application permitted. The Company early adopted this guidance effective December 31, 2016, and there was no impact on the Company's financial position.

In April 2015, the FASB issued ASU No. 2015-03, *Interest — Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. This newly issued accounting standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct reduction from the carrying amount of that debt liability. Retrospective application is required. The amendments in this standard are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The Company adopted this guidance effective December 31, 2016, and accordingly, all deferred issuance costs are reflected as a reduction of the outstanding debt balances as of December 31, 2015 and 2016 in the consolidated balance sheets.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard is effective in the first annual period ending after December 15, 2016. Early application is permitted. The Company adopted this guidance during 2016 and there was no impact on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will replace numerous requirements in US GAAP, including industry-specific requirements. This guidance provides a five step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. This statement requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgments made when applying the guidance. The guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods within that reporting period. An entity can elect to apply the

(in thousands, except share and per share data)

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented — referred to as the full retrospective method or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings — referred to as the modified retrospective method.

The Company has not yet completed its final review of the impact of this guidance including the new disclosure requirements, as it is continuing to evaluate the impacts of adoption and the implementation approach to be used. The Company plans to adopt the new standard effective January 1, 2018. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its current conclusions.

4. Deposits and Other Assets

Deposits and other assets consisted of the following:

	December 31, 2015	December 31, 2016
Short-term		
Receivable due from the FDA	$ —	$ 2,038
Deposits on equipment	—	1,201
Other	171	255
Total short-term deposits and other assets	171	3,494
Long-term		
Deposits on equipment	$ —	$ 499
Other	1	54
Total long-term deposits and other assets	1	553
	$ 172	$ 4,047

5. Property and Equipment

Property and equipment, net, consisted of:

	December 31, 2015	December 31, 2016
Computer equipment and software	$ 208	$ 293
Furniture and fixtures	72	121
Machinery and equipment	203	255
Leasehold improvements	—	28
	483	697
Less: accumulated depreciation	(292)	(374)
	$ 191	$ 323

Depreciation expense was $75 and $83 for the years ended December 31, 2015 and 2016, respectively.

(in thousands, except share and per share data)

6. Accrued Expenses

Accrued expenses consisted of:

	December 31,	
	2015	2016
Research and development expenses	$ 3,352	$ 736
Selling, general and administrative expenses	221	290
Bonus expense	—	1,390
Other	73	125
	$ 3,646	$ 2,541

7. AVP-825 License Agreement

In July 2013, the Company's wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement with Avanir for the exclusive right to sell AVP-825 (now marketed as Onzetra® Xsail®), a product combining a low-dose powder form of sumatriptan with the Company's technology platform, for the acute treatment of migraines in adults and any follow-on products under development that consist of a formulation that contains triptans as the sole active ingredient. Through December 31, 2016, under the terms of the AVP-825 License Agreement, the Company received aggregate cash payments of $70,000 upon the achievement of certain development milestones. Under the terms of the License Agreement, the Company is eligible to receive up to $50,000 upon the achievement of sales milestones as well as tiered low double-digit royalty payments on net sales in the US, Canada and Mexico after such cumulative sales exceed a specified threshold.

The Company determined that there were two deliverables under the AVP-825 License Agreement: (i) the license which was delivered in July 2013 and (ii) its obligation to provide certain research and development services in execution of the development plan and to share equally in certain qualified third party development costs through FDA approval. The Company concluded that the license had standalone value to Avanir and was separable from the research and development services, given Avanir has significant research capabilities in the field.

As a result, the license and research services qualify as separate units of accounting and the value of the license and the value of the research services were separately valued based upon the estimated selling price of each deliverable. The value attributable to the license was recognized up-front upon delivery of the license and the values attributable to the research services were deferred and recognized over the period in which the related services were to be delivered based upon a percentage of costs incurred in each respective reporting period. The estimated selling price of each deliverable was determined using the BESP. The BESP reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold on a stand-alone basis.

In conjunction with the AVP-825 License Agreement, the Company recognized $85 and $47,500 as licensing revenue for the years ended December 31, 2015 and 2016, respectively. The $47,500 of license

(in thousands, except share and per share data)

7. AVP-825 License Agreement (Continued)

revenues in 2016 related to the FDA approval milestone, which was achieved in January 2016 and was received in cash in February 2016.

8. Convertible Notes

At December 31, 2015 and 2016, the Company's convertible notes payable, net, balance was as follows:

	December 31, 2015	December 31, 2016
Face amount	$ 15,000	$ 15,000
Front end fees	(375)	(75)
Debt issuance costs	(220)	(44)
Back end fees	75	375
Convertible notes payable, net	$ 14,480	$ 15,256

On September 30, 2015, the Company entered into a Senior Secured Convertible Note Purchase Agreement (Notes) with various existing shareholders. The Notes provided the Company with up to $30,000 in capital available in two separate tranches. The first tranche of $15,000 closed on September 30, 2015. The second tranche of up to $15,000 was available to the Company until March 30, 2017. The Notes bore an annual interest rate of 17% and were scheduled to mature on September 30, 2020. The Notes also bore front end fees of $450, which were paid at issuance, and back end fees of $450 plus interest that were to be paid at maturity. The Notes may be repaid at any time in $100 increments, did not contain any prepayment penalties and were secured by assets of OptiNose Inc. and OptiNose US, Inc. At the option of the majority purchaser of the Notes after March 30, 2017 or prior to March 30, 2017 if an event of default had occurred or was continuing under the Notes, all note principal along with any accrued interest and back end fees thereon, could be converted into Series C-2 shares of preferred stock at a conversion price based upon a Company valuation equal to the lower of fair market value and $300,000.

As of December 31, 2015, the fair value of the Notes approximated its carrying value given the proximity of the issuance date of the Notes to the year-end balance sheet date. As of December 31, 2016, the fair value of the Notes was $21,814, which was estimated based upon the as-converted value of the Notes as of December 31, 2016. The Company developed its own assumptions that did not have observable inputs or available market data to support the estimated fair value of its convertible notes. Due to the nature of these inputs, they were considered Level 3 fair value measurements.

The Company recorded $819 and $3,517 in interest expense during the years ended December 31, 2015 and 2016, respectively, in conjunction with the Notes. Total coupon interest on the Notes and back end fees was $669 and $2,740 during the years ended December 31, 2015 and 2016, respectively. The front end fees of $450 were recorded as debt discount at issuance and are being amortized to interest expense over the 18 month loan conversion period. During the years ended December 31, 2015 and 2016, the Company recorded a total of $75 and $300 of interest expense related to the front end fees. Additionally,

(in thousands, except share and per share data)

8. Convertible Notes (Continued)

back end fees of $450 were also being amortized to interest expense over the 18 month loan conversion period of which $75 and $300 was recorded as interest expense and as an increase in the carrying amount of the Notes in the years ended December 31, 2015 and 2016, respectively. The Company also incurred $265 in debt issuance costs during the year ended December 31, 2015, which were also being amortized to interest expense over the 18 month loan conversion period.

In connection with the Company's Series D financing in March 2017 (Note 14), the Notes and associated accrued interest and back fees thereon totaling $19,527 converted into 687,474 shares of Series C-2 Preferred Stock as a per share conversion price of approximately $28.40.

9. Commitments and Contingencies

Leases

The Company leases office space under three operating leases. In October 2016, the Company entered into new leases for its corporate headquarters in the US and its office in Norway. Rent expense is recognized as incurred.

The following is a schedule of future minimum annual payments at December 31, 2016 under non-cancelable operating lease agreements:

For the years ending December 31:	
2017	$ 657
2018	178
2019	15
Total future minimum lease payments at December 31, 2016	$ 850

Rent expense under these operating leases was approximately $312 and $407 for the years ended December 31, 2015 and 2016, respectively.

Employment agreements

The Company has entered into employment contracts with its officers and certain employees that provide for severance and continuation of benefits in the event of termination of employment by the Company without cause. In addition, in the event of termination of employment following a change in control, the vesting of certain equity awards may be accelerated.

Litigation

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding.

Retirement plans

For U.S. employees, the Company maintains a defined contribution 401(k) retirement plan, which covers all employees. Employees are eligible on the first of the month following their date of hire. Under the

(in thousands, except share and per share data)

9. Commitments and Contingencies (Continued)

401(k) plan, participating employees may defer up to 100% of their pre-tax salary but not more than statutory limits. There is currently no employer matching of employee contributions and employee contributions vest immediately.

For Norway and UK employees, the Company maintains defined contribution pension plans which meet statutory requirements of those jurisdictions. The Company incurred costs of approximately $24 related to the pension plans in each of the years ended December 31, 2015 and 2016.

10. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock (Preferred Stock) consisted of the following:

Class	Authorized	Issued and Outstanding	Balance as of December 31, 2015	Balance as of December 31, 2016	Liquidation value at December 31, 2016
Series A	285,480	285,480	$ 5,381	$ 5,381	$ 5,381
Series B-1	35,680	35,680	673	673	673
Series B-2	782,600	782,600	14,760	14,760	14,760
Series C	4,115,344	4,115,344	96,168	105,738	106,724
Series C-1	1,656,410	1,656,410	38,077	41,621	41,843
	6,875,514	6,875,514	$ 155,059	$ 168,173	$ 169,381

In July 2015, the Company's existing investors and members of management purchased 236,629 Series C-1 shares for $21.13 per share for gross proceeds of $5,000. The Company paid a 3% funding fee upon receipt of the 2015 proceeds as well as certain issuance costs which totaled $162.

Certain provisions of the outstanding Preferred Stock are as follows:

- *Conversion:* Each share of Preferred Stock is convertible, at the option of the holder, into shares of common stock, on a one-to-one basis, subject to adjustment for certain events. The conversion price may be adjusted to prevent dilution of the Preferred Stock.

  The Preferred Stock is also mandatorily convertible upon the closing of an initial public offering or by a written election by a supermajority of the various classes of preferred stockholders.

- *Dividends:* All classes of Preferred Stock participate in any dividends with common stockholders on an as-converted basis.

- *Liquidation:* In the event of the liquidation, dissolution, or winding up of the affairs of the Company (a Liquidity Event), the holders of Preferred Stock are entitled to receive a liquidation preference prior to any payment to the holders of Common Stock (Series C-1 and Series C Preferred Stock ranking pari passu to each other and senior to the Series A, Series B-1 and Series B-2 Preferred Stock).

  Each share of Series C and Series C-1 carries an 8% minimum compounded annual return for purposes of calculating their respective liquidation preference. This minimum compounded annual

(in thousands, except share and per share data)

10. Redeemable Convertible Preferred Stock (Continued)

return is treated as a deemed dividend under GAAP. The liquidation preference for each share of Series C and Series C-1 Preferred Stock is equal to $17.20 and $21.13 (plus any declared and unpaid dividends), respectively, plus the greater of (i) its minimum compounded annual return or (ii) participation on an as converted basis in any proceeds to be distributed to holders of preferred stock or common stock after payment in full of all preferential amounts. The liquidation preference for each share of Series A, Series B-1, and Series B-2 Preferred Stock is $18.85, $18.85, and $18.86 (plus any declared and unpaid dividends), respectively. Additionally, the (i) sale or exclusive license by the Company of all or substantially all of the assets or intellectual property of the Company (whether by merger, exclusive license or otherwise), (ii) merger, consolidation, share exchange or other reorganization or combination in which the shares of capital stock of the Company immediately prior to such transaction represent, immediately after such transaction, securities representing less than 50% of the voting power of the Company or other entity surviving such transaction, or (iii) acquisition by a single person, entity or affiliated group of more than 50% of the Company's voting power, shall, unless the holders of Preferred Stock representing a supermajority elect otherwise, be regarded as a Liquidity Event.

§ *Redemption:* At the election of a majority of the Series C and Series C-1 stockholders, all classes of Preferred Stock are redeemable at any time after June 7, 2017 (subsequently extended to March 24, 2020. See Note 14). Due to this redemption feature, the Company's Preferred Stock has been classified within temporary equity on the consolidated balance sheets at December 31, 2015 and 2016.

11. Stock-based Compensation

The Company issues stock-based awards pursuant to its 2010 Stock Incentive Plan, as amended (the Plan). As of December 31, 2015 and 2016, 1,217,356 and 1,637,356 shares of the Company's common stock were authorized to be issued under the Plan, respectively. The amount, terms of grants, and exercisability provisions are determined and set by the Company's board of directors. The Company measures employee stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. Stock-based awards issued to nonemployees are revalued until the award vests. The Company recorded stock-based compensation expense in the following expense categories of its accompanying consolidated statements of operations for the years ended December 31, 2015 and 2016:

	2015	2016
Research and development	$ 354	$ 362
Selling, general and administrative	234	237
	$ 588	$ 599

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying common stock at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. There were no options granted

(in thousands, except share and per share data)

11. Stock-based Compensation (Continued)

during the year ended December 31, 2015. The fair value of each grant of options during the year ended December 31, 2016 was determined using the methods and assumptions discussed below.

- The expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data. The expected term of nonemployee options is equal to the contractual term.

- The expected volatility is based on historical volatilities of similar entities within the Company's industry which were commensurate with the expected term assumption as described in SAB No. 107.

- The risk-free interest rate is based on the interest rate payable on US Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.

- The expected dividend yield is 0% because the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend on its common stock.

- As the Company's common stock has not historically been publicly traded, its board of directors periodically estimated the fair value of the Company's common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

For the year ended December 31, 2016, the grant date fair value of all option grants was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

Risk free interest rate		2.22%
Expected term (in years)		6.08
Expected volatility		74.29%
Annual dividend yield		0.00%
Fair value of common stock	$	14.85

(in thousands, except share and per share data)

11. Stock-based Compensation (Continued)

Service-based stock options

Options issued under the Plan generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the board of directors. Vesting generally occurs over a period of not greater than four years. The following table summarizes the activity related to service-based stock option grants to employees and nonemployees for the years ended December 31, 2015 and 2016:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Balance at January 1, 2015	423,626	$ 5.58	6.83
Granted	—		
Exercised	—		
Forfeited	—		
Outstanding at December 31, 2015	423,626	5.58	5.83
Granted	238,500	14.85	
Exercised	(3,125)	8.80	
Forfeited	(3,125)	8.80	
Outstanding at December 31, 2016	655,876	$ 8.92	6.67
Exercisable at December 31, 2016	376,538	$ 5.18	4.57
Vested and expected to vest at December 31, 2016	655,876	$ 8.92	6.67

During the years ended December 31, 2015 and 2016, stock based compensation expense includes $155 and $166, respectively, related to awards that vested during the period. As of December 31, 2016, the unrecognized compensation cost related to unvested service-based stock options expected to vest was $2,490. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 3.74 years. The total aggregate intrinsic value of service-based options exercised during the year ended December 31, 2016 was $20. The aggregate intrinsic value of service-based options outstanding and service-based options exercisable as of December 31, 2016 was $3,891 and $3,644, respectively. Service-based options granted during the year ended December 31, 2016 had grant date weighted average fair values of $9.86 per option.

Performance-based stock options

The Company has issued performance-based stock options under the Plan which generally have a ten-year life from the date of grant and may vest upon the achievement of certain milestones in connection with the Company's development programs. Additionally, the Company has issued options in excess of the fair market value of common shares on the issuance date that are only exercisable upon a change in control or upon or after an initial public offering. Compensation expense for performance-based stock options is only recognized when management determines it is probable that the awards will vest.

(in thousands, except share and per share data)

11. Stock-based Compensation (Continued)

The following table summarizes the activity related to performance-based stock option grants to employees and nonemployees for the years ended December 31, 2015 and 2016:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Balance at January 1, 2015	758,275	$ 27.54	8.21
Granted	—		
Exercised	—		
Forfeited	—		
Outstanding at December 31, 2015	758,275	27.54	7.21
Granted	100,000	47.10	
Exercised	(3,125)	8.80	
Forfeited	(103,125)	45.94	
Outstanding at December 31, 2016	752,025	$ 27.70	6.55
Exercisable at December 31, 2016	176,013	$ 5.65	4.97

During the years ended December 31, 2015 and 2016, stock based compensation expense includes $433 related to performance awards that either vested or were deemed probable of vesting during the period. As of December 31, 2016, there was $3,121 of unrecognized compensation cost related to unvested performance-based stock options that will vest and be expensed when the occurrence of the performance condition is deemed probable. The total aggregate intrinsic value of performance-based options exercised during the year ended December 31, 2016 was $20. The aggregate intrinsic value of performance-based options outstanding and performance-based options exercisable as of December 31, 2016, was $3,238 and $1,619, respectively. Performance-based options granted during the year ended December 31, 2016 had grant date weighted average fair values of $6.61 per option.

Common stock warrants

The Company also has 654,624 common stock warrants outstanding with an exercise price of $23.56 per share that expire in 2020.

(in thousands, except share and per share data)

12. Income Taxes

Income (loss) before income tax expense was as follows:

	December 31,	
	2015	2016
Domestic operations	$ (1,366)	$ (4,967)
Foreign operations	(26,948)	27,580
Income (loss) before provision for income taxes	$ (28,314)	$ 22,613

A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements was as follows:

	December 31,	
	2015	2016
Income tax expense at statutory rate	35.00%	35.00%
Permanent items	(0.02)	0.04
Foreign rate differential	(9.52)	(12.24)
State taxes, net of federal benefit	0.31	(1.40)
Increase (decrease) in tax reserves	—	—
Change in valuation allowance	(25.77)	(21.40)
Effective income tax rate	0.00%	0.00%

(in thousands, except share and per share data)

12. Income Taxes (Continued)

The principal components of the Company's deferred tax assets and liabilities were as follows:

	December 31,	
	2015	2016
Deferred tax assets:		
Accrued expenses and other	$ 10	$ 539
Interest expense	149	677
Stock compensation	864	1,092
Research and development	2,183	2,183
Net operating losses	28,430	22,695
Total deferred tax assets	31,636	27,186
Deferred tax liabilities:		
Fixed assets	(8)	(46)
Total deferred tax liabilities	(8)	(46)
Less: valuation allowance	(31,628)	(27,140)
Total net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2016, the Company had foreign net operating loss (NOL) carry forwards of $80,570 from its operations in Norway and the UK, which are available to reduce future foreign taxable income. As of December 31, 2016, the Company had US federal and state NOLs of $11,574. These domestic NOL carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%. This could limit the amount of NOLs that the Company can utilize annually to offset future domestic taxable income or tax liabilities, if any. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. These federal and state NOLs will begin to expire in 2030 through 2036.

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against its deferred tax assets at December 31, 2015 and 2016, respectively, because the Company's management has determined that is it more likely than not that these assets will not be fully realized. The Company experienced a net change in valuation allowance of $4,488 for the year ended December 31, 2016.

At December 31, 2016, no provision has been made for US federal and state income taxes of foreign earnings due to the history of foreign losses. However, the Company expects that the future earnings, if

12. Income Taxes (Continued)

any, of its foreign subsidiaries will be reinvested indefinitely. Upon becoming profitable, if ever, distribution of these earnings, in the form of dividends or otherwise, may result in the Company falling subject to US income taxes and foreign withholding taxes. The determination of the amount of unrecognized deferred US income tax and foreign withholding tax liabilities on these future earnings, if any, is not practicable because of the complexities with the hypothetical calculations.

The Company files income tax returns in Norway, the UK, the US, and various states within the US. In the normal course of business, the Company is subject to examination by federal, state and foreign jurisdictions, where applicable. The Company's tax years in the US are still open under statute from inception to present. All open years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods.

The Company's policy is to record interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2015 and 2016, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations.

13. Related-party transactions

Convertible debt

All of the Company's convertible debt (see Note 8) is held by the Company's holders of convertible Preferred Stock.

14. Subsequent Events

In March 2017, the Company was refunded $2,038 from the FDA, which was recorded as a receivable within deposits and other current assets as of December 31, 2016.

In March through May 2017, the Company completed the sale of 1,117,578 shares of Series D Preferred Stock at a per share purchase price of $32.85, resulting in gross proceeds to the Company of $36,712 (the Series D Financing). In connection with the Series D Financing, the Company's existing convertible notes and associated accrued interest and back end fees thereon totaling $19,527 converted into 687,474 shares of Series C-2 Preferred Stock at a per share conversion price of approximately $28.40.

Certain provisions of the Series D Preferred Stock are as follows:

- *Conversion:* Each Series D share is convertible, at the option of the holder, into shares of common stock, on a one-to-one basis, subject to adjustment for certain events. The shares are also mandatorily convertible upon (i) the closing of a firm commitment underwritten public offering resulting in the listing of the Company's common stock on a nationally recognized stock exchange or securities market, or (ii) by the election of holders representing at least a majority of the issued and outstanding Series D shares.

- *Redemption:* At the election of the holders of a majority of the Series C Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock and Series D Preferred Stock at any time after March 24, 2020, all of the outstanding shares of Series D Preferred Stock (and the Company's other Preferred Stock) shall be redeemed by the Company for its minimum liquidation preference (including any declared and unpaid dividends).

14. Subsequent Events (Continued)

- *Dividends:* The Series D Preferred Stock shall participate in any dividends with common stockholders on an as converted basis with the Company's other outstanding Preferred Stock.

- *Liquidation:* The Series D Preferred Stock ranks senior to the Series B Preferred Stock, Series A Preferred Stock and common stock as to liquidation preference and is pari passu to the Series C Preferred Stock, Series C-1 Preferred Stock and Series C-2 Preferred Stock. The Series D Preferred Stock carries an 8% minimum compounded annual return. In the event of a liquidation, dissolution or winding up of the affairs of the Company, each share of Series D Preferred Stock shall be entitled to a liquidation preference equal to $32.85 per share (including any declared and unpaid dividends), plus the greater of (i) its minimum compounded annual return, or (ii) its participation on an as converted basis in any proceeds to be distributed to holders of Preferred Stock or common stock after payment in full of all preferential amounts.

The key provisions of the Series C-2 Preferred Stock are as follows:

- *Conversion:* Each Series C-2 share is convertible, at the option of the holder, into shares of common stock, on a one-to-one basis, subject to adjustment for certain events. The shares are also mandatorily convertible upon (i) the closing of a firm commitment underwritten public offering resulting in the listing of the Company's common stock on a nationally recognized stock exchange or securities market, or (ii) by the election of holders representing at least 75% of the issued and outstanding shares of Preferred Stock (other than Series D shares).

- *Redemption:* At the election of the holders of a majority of the Series C Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock and Series D Preferred Stock at any time after March 24, 2020, all of the outstanding shares of Series C-2 Preferred Stock (and Company's other Preferred Stock) shall be redeemed by the Company for its minimum liquidation preference (including any declared and unpaid dividends).

- *Dividends:* The Series C-2 Preferred Stock shall participate in any dividends with common stockholders on an as converted basis with the Company's other outstanding Preferred Stock.

- *Liquidation:* The Series C-2 Preferred Stock ranks senior to the Series B Preferred Stock, Series A Preferred Stock and common stock as to liquidation preference and is pari passu to the Series C Preferred Stock, Series C-1 Preferred Stock and Series D Preferred Stock. The Series C-2 Preferred Stock carries an 8% minimum compounded annual return. In the event of a liquidation, dissolution or winding up of the affairs of the Company, each share of Series C-2 Preferred Stock shall be entitled to a liquidation preference equal to $28.40 per share (including any declared and unpaid dividends), plus the greater of (i) its minimum compounded annual return, or (ii) participate on an as converted basis in any proceeds to be distributed to holders of Preferred Stock or common stock after payment in full of all preferential amounts.

In conjunction with the Series D financing, the number of authorized shares of common stock was increased from 10,624,486 to 13,067,149 and the number of authorized shares of Preferred Stock was increased from 6,875,514 to 8,932,851, of which 1,369,863 shares were designated as Series D shares and 687,474 shares were designated as Series C-2 shares. Also, the redemption date for all classes of the Company's Preferred Stock was extended to March 24, 2020 and the terms upon which all classes of Preferred Stock would mandatorily convert into common stock in connection with an underwritten public offering were revised to align with the terms of the Series C-2 Preferred Stock.

OptiNose, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2016	June 30, 2017 (unaudited)	Pro Forma June 30, 2017 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 36,797	$ 58,887	$ 58,887
Grants and other receivables	384	219	219
Deposits and other current assets	3,494	1,808	1,808
Total current assets	40,675	60,914	60,914
Property and equipment, net	323	1,142	1,142
Deferred offering costs	—	1,567	1,567
Deposits and other assets — long-term	553	339	339
Total assets	$ 41,551	$ 63,962	$ 63,962
Liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity			
Current liabilities:			
Accounts payable	$ 3,369	$ 2,311	$ 2,311
Accrued expenses	2,541	3,781	3,781
Deferred other income	—	133	133
Total current liabilities	5,910	6,225	6,225
Convertible notes payable, net	15,256	—	—
Accrued interest	3,409	—	—
Total liabilities	24,575	6,225	6,225
Redeemable convertible preferred stock, $0.001 par value:			
Series A, 285,480 shares authorized, issued and outstanding actual (liquidation value of $5,381 at June 30, 2017)	5,381	5,381	—
Series B-1, 35,680 shares authorized, issued and outstanding actual (liquidation value of $673 at June 30, 2017)	673	673	—
Series B-2, 782,600 shares authorized, issued and outstanding actual (liquidation value of $14,760 at June 30, 2017)	14,760	14,760	—
Series C, 4,115,344 shares authorized, issued and outstanding actual (liquidation value of $110,993 at June 30, 2017)	105,738	110,840	—
Series C-1, 1,656,410 shares authorized, issued and outstanding actual (liquidation value of $43,517 at June 30, 2017)	41,621	43,517	—
Series C-2, 0 and 687,474 shares authorized, issued and outstanding at December 31, 2016 and June 30, 2017, respectively, actual (liquidation value of $19,951 at June 30, 2017)	—	19,951	—
Series D, 0 and 1,369,863 shares authorized at December 31, 2016 and June 30, 2017, respectively, 0 and 1,117,578 shares issued and outstanding December 31, 2016 and June 30, 2017,respectively, actual (liquidation value of $37,496 at June 30, 2017)	—	37,296	—
Total redeemable convertible preferred stock	168,173	232,418	—
Stockholders' (deficit) equity:			
Common stock, $0.001 par value; 10,624,486 and 13,067,149 shares authorized at December 31, 2016 and June 30, 2017, respectively; 1,408,540 shares issued and outstanding at December 31, 2016 and June 30, 2017, actual; 10,089,106 shares issued and outstanding pro forma June 30, 2017	1	1	10
Additional paid-in capital	—	—	232,409
Accumulated deficit	(151,099)	(174,577)	(174,577)
Accumulated other comprehensive loss	(99)	(105)	(105)
Total stockholders' (deficit) equity	(151,197)	(174,681)	57,737
Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity	$ 41,551	$ 63,962	$ 63,962

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Operations
For the six months ended June 30, 2016 and 2017
(in thousands, except share and per share data)
(Unaudited)

	Six Months Ended June 30,	
	2016	2017
Licensing revenues	$ 47,500	$ —
Operating expenses:		
Research and development	8,373	8,979
Selling, general and administrative	3,296	6,661
Total operating expenses	11,669	15,640
Income (loss) from operations	35,831	(15,640)
Other (income) expense:		
Grant and other income	(166)	(93)
Interest income	(71)	(95)
Interest expense	1,747	862
Foreign currency losses (gains)	14	(31)
Net income (loss)	$ 34,307	$ (16,283)
Deemed dividend	5,502	7,150
Accretion to redemption value	1,055	1,074
Net income (loss) attributable to common stockholders	$ 27,750	$ (24,507)
Net income (loss) per share of common stock		
basic	$ 3.35	$ (17.40)
diluted	$ 2.74	$ (17.40)
Weighted average common shares outstanding		
basic	1,402,290	1,408,540
diluted	1,717,460	1,408,540
Pro forma net loss per share of common stock — basic and diluted		$ (1.76)
Pro forma weighted average common shares outstanding — basic and diluted		9,251,267

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Comprehensive Income and Loss
For the six months ended June 30, 2016 and 2017
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2016	2017
Net income (loss)	$ 34,307	$ (16,283)
Other comprehensive income (loss):		
Foreign currency translation adjustment	29	(6)
Comprehensive income (loss)	$ 34,336	$ (16,289)

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit
For the six Months Ended June 30, 2017
(Unaudited)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Stockholders' Deficit					
			Common Stock		Additional Paid -in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2016	6,875,514	$ 168,173	1,408,540	$ 1	$ —	$ (151,099)	$ (99)	$ (151,197)
Conversion of convertible debt to Series C-2 preferred stock	687,474	19,527	—	—	—	—	—	—
Sale of Series D preferred stock, net of issuance costs	1,117,578	36,494	—	—	—	—	—	—
Stock compensation expense	—	—	—	—	1,029	—	—	1,029
Accretion of Series C, Series C-1 & Series D preferred stock to redemption value	—	1,074	—	—	(1,029)	(45)	—	(1,074)
Accretion of Series C, Series C-1, Series C-2 & Series D preferred stock in lieu of 8% dividend	—	7,150	—	—	—	(7,150)	—	(7,150)
Foreign currency translation adjustment	—	—	—	—	—	—	(6)	(6)
Net loss	—	—	—	—	—	(16,283)	—	(16,283)
Balance at June 30, 2017	8,680,566	$ 232,418	1,408,540	$ 1	$ —	$ (174,577)	$ (105)	$ (174,681)

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Cash Flows
For the six months ended June 30, 2016 and 2017
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2016	2017
Operating activities:		
Net income (loss)	$ 34,307	$ (16,283)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	39	66
Stock-based compensation	505	1,029
Amortization of debt discount and issuance costs	388	194
Changes in operating assets and liabilities:		
Grants and other receivables	(63)	165
Deposits and other assets	(966)	1,900
Accounts payable	(1,462)	(1,683)
Accrued expenses	(1,800)	184
Accrued interest	1,359	668
Deferred other income	81	133
Cash provided by (used in) operating activities	32,388	(13,627)
Investing activities:		
Purchases of property and equipment	(6)	(711)
Cash used in investing activities	(6)	(711)
Financing activities:		
Proceeds from the sale of Series D preferred stock	—	36,712
Cash paid for financing costs	—	(278)
Cash provided by financing activities	—	36,434
Effects of exchange rate changes on cash and cash equivalents	34	(6)
Net increase in cash and cash equivalents	32,416	22,090
Cash and cash equivalents at beginning of period	15,198	36,797
Cash and cash equivalents at end of period	$ 47,614	$ 58,887
Supplemental disclosure of noncash financing activities:		
Deemed dividend	$ 5,502	$ 7,150
Accretion to redemption value	$ 1,055	$ 1,074
Deferred offering costs within accounts payable and accrued expenses	$ —	$ 1,507
Conversion of convertible notes payable and accrued interest into Series C-2 preferred stock	$ —	$ 19,527

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.

Notes to Unaudited Interim Consolidated Financial Statements

For the six months ended June 30, 2016 and 2017

(in thousands, except share and per share data)

1. Organization and Description of Business

OptiNose, Inc. (the Company) was incorporated in Delaware in May 2010 (inception) and its facilities are located in Yardley, Pennsylvania, Ewing, New Jersey, Oslo, Norway and Swindon, England. The Company's predecessor entity OptiNose AS was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became a wholly-owned subsidiary of the Company as part of an internal reorganization.

The Company is a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. The Company's lead product candidate, OPN-375, is a therapeutic utilizing its proprietary Breath Powered exhalation delivery system (EDS) that delivers a topically-acting and potent anti-inflammatory corticosteroid for the treatment of chronic rhinosinusitis with and without nasal polyps. The Company's new drug application (NDA) for OPN-375 was accepted for filing and review by the U.S. Food and Drug Administration (FDA) in January 2017.

2. Liquidity

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio and conducting preclinical studies and clinical trials. The Company has not generated any revenue from product sales. As of June 30, 2017, the Company had cash and cash equivalents of $58,887. During the six months ended June 30, 2017, the Company sold 1,117,578 shares of Series D preferred stock, which resulted in gross proceeds to the Company of $36,712 (Note 9).

The Company will need to secure additional funding in the future, from one or more equity or debt financings, collaborations, or other sources, in order to carry out all of the Company's planned development and commercial activities. If additional funding is not secured when required, the Company may need to delay or curtail its operations until such funding is received. The Company is subject to a number of risks similar to other life sciences companies, including, but not limited to, successful discovery and development of its drug candidates, raising additional capital, the development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products.

3. Basis of Presentation and Summary of Significant Accounting Policies

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with United States (US) generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2017 and its results of operations and cash flows for the six months ended June 30, 2016 and 2017. Operating results for the six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2016.

Principles of consolidation

The unaudited interim consolidated financial statements include the accounts of OptiNose, Inc. and its wholly-owned subsidiaries, OptiNose US, Inc., OptiNose AS and OptiNose UK Ltd. All inter-company balances and transactions have been eliminated in consolidation.

Unaudited pro forma financial information

Immediately prior to the closing of a qualified initial public offering, all of the Company's outstanding redeemable convertible preferred stock will automatically convert into common stock. The accompanying unaudited pro forma consolidated balance sheet as of June 30, 2017 assumes the conversion of all outstanding redeemable convertible preferred stock as of June 30, 2017, into an aggregate of 8,680,566 shares of common stock. In the accompanying unaudited interim consolidated statements of operations, unaudited pro forma basic and diluted net income (loss) per share of common stock has been prepared to give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock as if this proposed initial public offering had occurred on the later of the beginning of the reporting period or the issuance date of the redeemable convertible preferred stock. Accordingly, the unaudited pro forma net income (loss) attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net income (loss) per share of common stock excludes the effects of accretion on convertible preferred stock.

Use of estimates

The preparation of the unaudited interim consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited interim consolidated financial statements and reported amounts of expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited interim consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined to be necessary.

Fair value of financial instruments

At December 31, 2016 and June 30, 2017, the Company's financial instruments included cash and cash equivalents, grants receivable, accounts payable and accrued expenses. The carrying amounts reported in the Company's financial statements for these instruments approximates their respective fair values because of the short-term nature of these instruments. At December 31, 2016 and June 30, 2017, there were no financial assets or liabilities measured at fair value on a recurring basis.

The Company's financial instruments also included convertible debt at December 31, 2016 (Note 8).

Deposits and other assets

Deposits and other assets consist primarily of payments made in advance to outsourced mold development manufacturers and equipment suppliers, as well as a receivable due from the FDA at December 31, 2016

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

related to a Prescription Drug User Fee Act (PDUFA) NDA fee that the FDA refunded to the Company in March 2017.

Throughout 2016 and 2017, the Company made upfront payments to outsourced mold development manufacturers and equipment suppliers for molds and equipment that are expected to be used for commercial production of the OPN-375 product should FDA approval be obtained for the product candidate. The Company expects to receive this equipment at various points in 2017. For equipment received prior to FDA approval, the Company expects to record the equipment as a component of research and development expense if there is no alternative future use of the equipment without FDA approval, and accordingly, deposits made through June 30, 2017 for which there is currently not an alternative future use have been recorded as short term deposits. Conversely, deposits on equipment that were determined to have an alternative future use will be capitalized as fixed assets when received and therefore are classified in long-term deposits at June 30, 2017.

Deferred offering costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated, at which time these costs are netted against the proceeds from the equity financing. Should the equity financing no longer be considered probable of being consummated, all deferred offering costs will be charged to operating expenses in the consolidated statements of operations.

Net income (loss) per common share

For the six month period ended June 30, 2016, the Company used the two-class method to compute net income (loss) per common share because the Company has issued securities (redeemable convertible preferred stock) that entitle the holder to participate in dividends and earnings of the Company. Under this method, net income is reduced by the amount any dividends earned and the accretion of redeemable convertible preferred stock to its redemption value during the period. The remaining earnings (undistributed earnings) are allocated to common stock and each series of redeemable convertible preferred stock to the extent that each preferred security may share in earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the redeemable convertible preferred stock have no obligation to fund losses.

Diluted net income (loss) per common share is computed under the two-class method by using the weighted-average number of shares of common stock outstanding, plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options, warrants, and convertible debt. In addition, the Company analyzes the potential dilutive effect of the outstanding redeemable convertible preferred stock and convertible debt under the "if-converted" method when calculating diluted earnings per share, in which it is assumed that the outstanding redeemable convertible preferred stock or convertible debt converts into common stock at the beginning of the period or when issued if later. The Company reports the more dilutive of the approaches (two class or "if-converted") as their diluted net income per share during the period.

(in thousands, except share and per share data)

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

For the six months ended June 30, 2017 in which the Company reported a net loss, there is no dilutive effect under either the two-class or "if-converted" method. For the six months ended June 30, 2016, the Company presented diluted net income per common share using the two-class method, which was more dilutive than the "if-converted" method.

The following table sets forth the computation of basic and diluted net income (loss) per share for the periods indicated:

	Six Months Ended June 30,	
	2016	2017
Basic net income (loss) per common share calculation:		
Net income (loss) attributable to common stockholders	$ 27,750	$ (24,507)
Less: undistributed earnings to participating securities	(23,049)	—
Net income (loss) attributable to common stockholders — basic	4,701	(24,507)
Weighted average common shares outstanding — basic	1,402,290	1,408,540
Net income (loss) per share of common stock — basic	$ 3.35	$ (17.40)
Diluted net income (loss) per common share calculation:		
Net income (loss) attributable to common stockholders	$ 27,750	$ (24,507)
Less: undistributed earnings to participating securities	(23,049)	—
Net income (loss) attributable to common stockholders — diluted	4,701	(24,507)
Weighted average common shares outstanding — basic	1,402,290	1,408,540
Stock options	315,170	—
Weighted average common shares outstanding — diluted	1,717,460	1,408,540
Net income (loss) per share of common stock — diluted	$ 2.74	$ (17.40)

Diluted net income (loss) per common share for the periods presented do not reflect the following potential common shares, as the effect would be antidilutive:

	Six Months Ended June 30,	
	2016	2017
Stock options	580,137	1,523,901
Common stock warrants	654,624	654,624
Convertible debt	590,870	—
Convertible preferred stock	6,875,514	8,680,566
Total	8,701,145	10,859,091

3. Basis of Presentation and Summary of Significant Accounting Policies (Continued)

Recent accounting pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which will replace numerous requirements in US GAAP, including industry-specific requirements. This guidance provides a five-step model to be applied to all contracts with customers, with an underlying principle that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The new standard also defines accounting for certain costs related to origination and fulfillment of contracts with customers, including whether such costs should be capitalized. This statement requires extensive quantitative and qualitative disclosures covering the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including disclosures on significant judgements made when applying the guidance and assets recognized from costs incurred to obtain or fulfill a contract. The guidance is effective for annual reporting periods beginning after December 15, 2017, and interim periods within that reporting period. An entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented — referred to as the full retrospective method or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings — referred to as the modified retrospective method.

The Company is currently in process of assessing the impact that ASU 2014-09 will have on its financial statements and related disclosures. To date, the Company has derived its revenues from a single licensing agreement with Avanir (the AVP-825 License Agreement). The consideration the Company has received to date includes an upfront payment, research and development funding and development milestone payments. Additionally, the Company is eligible to receive sales milestone payments and royalties in the future once product sales exceed a certain threshold. The Company plans to analyze the performance obligations under the AVP-825 License Agreement, and the consideration received to date and that the Company may receive in the future, as part of its analysis of the impact of ASU 2014-09 on this arrangement.

Significant assessment and implementation matters to be addressed prior to adopting ASU 2014-09 include completing the Company's review of the AVP-825 License Agreement, as well as any other customer arrangements that the Company enters into prior to the adoption date, confirming its method of adoption, determining the impact the new accounting standard will have on its financial statements and related disclosures and updating, as needed, its business processes, systems and controls required to comply with ASU 2014-09 upon its effective date of January 1, 2018. The Company will make updates to its quarterly and year-end disclosures, with a focus on implementation status updates related to the impact ASU 2014-09 will have on its financial statements and related footnotes. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its current conclusions.

The Company plans to adopt the new standard effective January 1, 2018 using the modified retrospective approach.

(in thousands, except share and per share data)

4. Deposits and Other Assets

Deposits and other assets consisted of the following:

	December 31, 2016	June 30, 2017
Short-term		
Receivable due from the FDA	$ 2,038	$ —
Deposits on equipment	1,201	1,399
Other	255	409
Total short-term deposits and other assets	$ 3,494	$ 1,808
Long-term		
Deposits on equipment	$ 499	$ 336
Other	54	3
Total long-term deposits and other assets	553	339
	$ 4,047	$ 2,147

5. Property and Equipment

Property and equipment, net, consisted of:

	December 31, 2016	June 30, 2017
Computer equipment and software	$ 293	$ 374
Furniture and fixtures	121	121
Machinery and equipment	255	1,059
Leasehold improvements	28	28
	697	1,582
Less: accumulated depreciation	(374)	(440)
	$ 323	$ 1,142

Depreciation expense was $39 and $66 for six months ended June 30, 2016 and 2017, respectively.

(in thousands, except share and per share data)

6. Accrued Expenses

Accrued expenses consisted of:

	December 31, 2016	June 30, 2017
Research and development expenses	$ 736	$ 655
Selling, general and administrative expenses	290	1,610
Bonus expense	1,390	1,240
Other	125	276
	$ 2,541	$ 3,781

7. AVP-825 License Agreement

In July 2013, the Company's wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement with Avanir for the exclusive right to sell AVP-825 (now marketed as Onzetra® Xsail®), a product combining a low-dose powder form of sumatriptan with its technology platform, for the acute treatment of migraines in adults and any follow-on products under development that consist of a formulation that contains triptans as the sole active ingredient. Through December 31, 2016, under the terms of the AVP-825 License Agreement, the Company received aggregate cash payments of $70,000 in connection with the initial signing and upon the achievement of certain development milestones. Under the terms of the License Agreement, the Company is eligible to receive up to $50,000 upon the achievement of sales milestones as well as tiered low double-digit royalty payments on net sales in the US, Canada and Mexico after such cumulative sales exceed a certain threshold.

In conjunction with the AVP-825 License Agreement, the Company recognized $47,500 as licensing revenue during the six months ended June 30, 2016. The revenue was related to the achievement of the FDA approval milestone in January 2016. The Company did not recognize any licensing revenue during the six months ended June 30, 2017.

8. Convertible Notes

At December 31, 2016 and June 30, 2017, the Company's convertible notes payable, net, balance was as follows:

	December 31, 2016	June 30, 2017
Face amount	$ 15,000	$ —
Front end fees	(75)	—
Debt issuance costs	(44)	—
Back end fees	375	—
Convertible notes payable, net	$ 15,256	$ —

8. Convertible Notes (Continued)

On September 30, 2015, the Company entered into a Senior Secured Convertible Note Purchase Agreement (Notes) with various existing shareholders. The Notes provided the Company with up to $30,000 in capital available in two separate tranches. The first tranche of $15,000 closed on September 30, 2015. The second tranche of up to $15,000 was available to the Company until March 30, 2017. The Notes bore an annual interest rate of 17% and were scheduled to mature on September 30, 2020 if not otherwise converted to Series C-2 shares. The Notes also bore front end fees of $450, which were paid at issuance, and back end fees of $450 plus interest that was to be paid at maturity. The Notes could be repaid at any time in $100 increments, did not contain any prepayment penalties and were secured by assets of OptiNose Inc. and OptiNose US, Inc. At the option of the majority purchaser of the Notes after March 30, 2017, or prior to March 30, 2017 if an event of default occurred or was continuing under the Notes, all note principal along with any accrued interest and back end fees thereon, could be converted into Series C-2 shares of preferred stock at a conversion price based upon a Company valuation equal to the lower of fair market value and $300,000.

The Company recorded $1,747 and $862 in interest expense during the six months ended June 30, 2016 and 2017, respectively, in conjunction with the Notes. Total coupon interest on the Notes and back end fees was $1,359 and $668 during the six months ended June 30, 2016 and 2017, respectively. The front end fees of $450 were recorded as debt discount at issuance and are being amortized to interest expense over the 18 month loan conversion period. During the six month periods ended June 30, 2016 and 2017, the Company recorded a total of $150 and $75 of interest expense, respectively, related to the front end fees. Additionally, back end fees of $450 are also being amortized to interest expense over the 18 month loan conversion period of which $150 and $75 has been recorded as interest expense and as an increase in the carrying amount of the Notes during the six months ended June 30, 2016 and 2017, respectively. The Company also incurred $265 in debt issuance costs during the year ended December 31, 2015 which are also being amortized to interest expense over the 18 month loan conversion period.

As of December 31, 2016, the fair value of the Notes was $21,814, which was estimated based on the as converted value of the Notes as of that date.

On March 24, 2017, in connection with the Series D Financing, the Notes and associated accrued interest and back end fees thereon totaling $19,527 converted into 687,474 shares of Series C-2 preferred stock at a per share conversion price of approximately $28.40.

(in thousands, except share and per share data)

9. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock (Preferred Stock) consisted of the following:

Class	Authorized	Issued and Outstanding	Balance as of December 31, 2016	Balance as of June 30, 2017	Liquidation value at June 30, 2017
Series A	285,480	285,480	$ 5,381	$ 5,381	$ 5,381
Series B-1	35,680	35,680	673	673	673
Series B-2	782,600	782,600	14,760	14,760	14,760
Series C	4,115,344	4,115,344	105,738	110,840	110,993
Series C-1	1,656,410	1,656,410	41,621	43,517	43,517
Series C-2	687,474	687,474	—	19,951	19,951
Series D	1,369,863	1,117,578	—	37,296	37,496
	8,932,851	8,680,566	$ 168,173	$ 232,418	$ 232,771

During the six months ended June 30, 2017, the Company sold 1,117,578 shares of Series D Preferred Stock at a per share purchase price of $32.85, resulting in gross proceeds to the Company of $36,712 (the Series D Financing). In connection with the Series D Financing, the Company's existing convertible notes and associated accrued interest and back end fees thereon totaling $19,527 converted into 687,474 shares of Series C-2 Preferred Stock at a per share conversion price of approximately $28.40 (Note 8).

In conjunction with the Series D financing, the number of authorized shares of common stock was increased from 10,624,486 to 13,067,149 and the number of authorized shares of preferred stock was increased from 6,875,514 to 8,932,851, of which 1,369,863 shares were designated as Series D shares and 687,474 shares were designated as Series C-2 shares. Also, the redemption date for all classes of the Company's preferred stock was extended to March 24, 2020 and the terms upon which all classes of Preferred Stock would mandatorily convert into common stock in connection with an underwritten public offering were revised to align with the terms of the Series C-2 preferred stock.

Certain provisions of the outstanding Preferred Stock are as follows:

§ *Conversion:* Each share of Series A, Series B, Series C, Series C-1 and Series C-2 Preferred Stock is convertible, at the option of the holder, into shares of common stock, on a one-to-one basis, subject to adjustment for certain events. The Series A, Series B, Series C, Series C-1 and Series C-2 Preferred Stock is also mandatorily convertible upon (i) the closing of a firm commitment underwritten public offering resulting in the listing of the Company's common stock on a nationally recognized stock exchange or securities market, or (ii) by the election of holders representing at least 75% of the issued and outstanding shares of Preferred Stock (other than Series D Preferred Stock).

Each share of Series D Preferred Stock is convertible, at the option of the holder, into shares of common stock, on a one-to-one basis, subject to adjustment for certain events. The Series D Preferred Stock is also mandatorily convertible upon (i) the closing of a firm commitment underwritten public offering resulting in the listing of the Company's common stock on a nationally

9. Redeemable Convertible Preferred Stock (Continued)

recognized stock exchange or securities market, or (ii) by the election of holders representing at least a majority of the issued and outstanding Series D Preferred Stock.

§ *Dividends:* All classes of Preferred Stock participate in any dividends with common stockholders on an as-converted basis.

§ *Liquidation:* In the event of the liquidation, dissolution, or winding up of the affairs of the Company (a Liquidity Event), the holders of Preferred Stock are entitled to receive a liquidation preference prior to any payment to the holders Common Stock (with the right of Series D, Series C-2, Series C-1 and Series C Preferred Stock ranking pari passu to each other and senior to the Series A, Series B-1 and Series B-2 Preferred Stock).

Each share of Series C, Series C-1, Series C-2 and Series D Preferred Stock carries an 8% minimum compounded annual return for purposes of calculating their respective liquidation preference. This minimum compounded annual return is treated as a deemed dividend under GAAP. The liquidation preference for each share of Series C, Series C-1, Series C-2 and Series D Preferred Stock is equal to $17.20, $21.13, $28.40 and $32.85 (plus any declared and unpaid dividends), respectively, plus the greater of (i) its minimum compounded annual return or (ii) participation on an as converted basis in any proceeds to be distributed to holders of preferred stock or common stock after payment in full of all preferential amounts. The liquidation preference for each share of Series A, Series B-1, and Series B-2 Preferred Stock is $18.85, $18.85, and $18.86 (plus any declared and unpaid dividends), respectively.

Additionally, the (i) sale or exclusive license by the Company of all or substantially all of the assets or intellectual property of the Company (whether by merger, exclusive license or otherwise), (ii) merger, consolidation, share exchange or other reorganization or combination in which the shares of capital stock of the Company immediately prior to such transaction represent, immediately after such transaction, securities representing less than 50% of the voting power of the Company or other entity surviving such transaction, or (iii) acquisition by a single person, entity or affiliated group of more than 50% of the Company's voting power, shall, unless otherwise the holders of (x) Preferred Stock representing a Supermajority and (y) a majority of Series D Stock elect otherwise, be regarded as a Liquidity Event.

§ *Redemption:* At the election of a majority of the Series C and Series C-1, Series C-2 and Series D stockholders, all classes of Preferred Stock are redeemable at any time after March 24, 2020. Due to this redemption feature, the Company's Preferred Stock has been classified within temporary equity on the consolidated balance sheets at December 31, 2016 and June 30, 2017.

10. Stock-based Compensation

The Company issues stock-based awards pursuant to its 2010 Stock Incentive Plan, as amended (Plan). As of June 30, 2017, 1,637,356 shares of the Company's common stock were authorized to be issued under the Plan, and 99,505 shares were reserved for future issuance under the Plan. The amount, terms of grants, and exercisability provisions are determined and set by the Company's board of directors. The Company measures employee stock-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. Stock-based awards issued to nonemployees are revalued until the award vests. The Company recorded stock-based compensation expense in the

(in thousands, except share and per share data)

10. Stock-based Compensation (Continued)

following expense categories of its accompanying consolidated statements of operations for the six months ended June 30, 2016 and 2017:

	2016	2017
Research and development	$ 298	$ 508
General and administrative	207	521
	$ 505	$ 1,029

Service-based stock options

Options issued under the Plan generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the board of directors. Vesting generally occurs over a period of not greater than four years. The following table summarizes the activity related to service-based stock option grants to employees and nonemployees for the six months ended June 30, 2017:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2016	655,876	8.92	6.67
Granted	116,000	14.85	
Exercised	—		
Forfeited	—		
Outstanding at June 30, 2017	771,876	$ 9.81	6.69
Exercisable at June 30, 2017	396,332	$ 5.36	4.18
Vested and expected to vest at June 30, 2017	771,876	$ 9.81	6.69

During the six months ended June 30, 2017, the Board approved the grant of time-based options to purchase 116,000 shares of common stock to employees that generally vest over four years. The options had an estimated weighted average grant date fair value of $9.81. The grant date fair value of each option grant was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

Risk free interest rate	2.07%
Expected term (in years)	6.08
Expected volatility	73.93%
Annual dividend yield	0.00%
Fair value of common stock	$ 14.85

(in thousands, except share and per share data)

10. Stock-based Compensation (Continued)

At June 30, 2017, the unrecognized compensation cost related to unvested service-based stock options expected to vest was $3,043. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 3.52 years.

Performance-based stock options

The Company has issued performance-based stock options under the Plan which generally have a ten-year life from the date of grant and may vest upon the achievement of certain milestones in connection with the Company's development programs. Additionally, the Company has issued options in excess of the fair market value of common shares on the issuance date that are only exercisable upon a change in control or upon or after an initial public offering. Compensation expense for performance-based stock options is only recognized when management determines it is probable that the awards will vest.

The following table summarizes the activity related to performance-based stock option grants to employees and nonemployees for the six months ended June 30, 2017:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2016	752,025	$ 27.70	6.55
Granted	—		
Exercised	—		
Forfeited	—		
Outstanding at June 30, 2017	752,025	$ 27.70	6.06
Exercisable at June 30, 2017	264,019	$ 5.65	4.47

As of June 30, 2017, there was $2,700 of unrecognized compensation cost related to unvested performance-based stock options that will vest and be expensed when the occurrence of the performance condition is deemed probable.

Common stock warrants

The Company also has 654,624 common stock warrants outstanding with an exercise price of $23.56 per share that expire in 2020.

11. Related-party transactions

Debt and equity transactions

All of the Company's convertible debt (see Note 8) was with the Company's holders of convertible preferred stock.

Shares

Common Stock

Preliminary Prospectus

Jefferies **Piper Jaffray** **BMO Capital Markets** **RBC Capital Markets**

, 2017

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than the underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and The NASDAQ Global Market initial listing fee.

Item	Amount Paid or to be Paid
SEC registration fee	$ *
FINRA filing fee	*
NASDAQ Global Market initial listing fee	25,000
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. Our fourth amended and restated certificate of incorporation and amended and restated bylaws, each of which will become effective

immediately following the closing of this offering, provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our fourth amended and restated certificate of incorporation, which will become effective immediately following the closing of this offering, includes such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

As permitted by the Delaware General Corporation Law, we have entered into, or intend to enter into, indemnification agreements with our directors and executive officers. These agreements, among other things, will require us to indemnify each director and officer to the fullest extent permitted by law and advance expenses to each indemnitee in connection with any proceeding in which indemnification is available.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, or otherwise.

The form of underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification by the underwriters named in this registration statement of our executive officers, directors and us, and by us of the underwriters named in this registration statement, for certain liabilities, including liabilities arising under the Securities Act, in connection with matters specifically provided in writing for inclusion in this registration statement.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding securities issued by us since January 1, 2014 that were not registered under the Securities Act. Also included is the consideration, if any, received by us for such securities, and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(a) Issuances of Capital Stock

1. In July 2014, we issued and sold an aggregate of 1,419,781 shares of our Series C-1 Preferred Stock to certain of our existing investors and members of our management team and board of directors at a purchase price of $21.13 per share, for aggregate consideration of $30.0 million.

2. In July 2015, we issued and sold to our existing Series C-1 Preferred Stock holders an additional 236,629 shares of Series C-1 Preferred Stock at a purchase price of $21.13 per share, for aggregate consideration of $5.0 million.

3. In March 2017, we issued and sold an aggregate of 1,065,451 shares of our Series D Preferred Stock to certain new and existing investors at a purchase price of $32.85 per share, for aggregate consideration of $35.0 million.

4. In April 2017 and May 2017, we issued and sold to certain of our existing stockholders an additional 52,127 shares of Series D Preferred Stock at a purchase price of $32.85 per share, for aggregate consideration of $1.7 million.

(b) Convertible Notes

1. In September 2015, we issued and sold convertible notes in the aggregate principal amount of $15.0 million. In March 2017, concurrently with our Series D Preferred Stock financing, the notes were converted into an aggregate of 687,474 shares of our Series C-2 Preferred Stock at a conversion price of approximately $28.40 per share.

(c) Stock Option Grants

1. On March 11, 2014, we granted stock options to purchase a total of 98,222 shares of common stock at an exercise price of $8.80 per share to 11 employees pursuant to our 2010 Stock Incentive Plan, as amended, or the 2010 Plan.

2. On March 11, 2014, we granted stock options to purchase a total of 52,625 shares of common stock at an exercise price of $8.80 per share to two executive officers pursuant to our 2010 Plan.

3. On April 7, 2014, we granted stock options to purchase a total of 300,000 shares of common stock at an exercise price of $47.10 per share to two executive officers pursuant to our 2010 Plan.

4. On April 21, 2014, we granted a stock option to purchase a total of 7,500 shares of common stock at an exercise price of $8.80 per share to one employee pursuant to our 2010 Plan.

5. On April 21, 2014, we granted a stock option to purchase 12,500 shares of common stock at an exercise price of $8.80 per share to one executive officer pursuant to our 2010 Plan.

6. On April 21, 2014, we granted a stock option to purchase 100,000 shares of common stock at an exercise price of $47.10 per share to one executive officer pursuant to our 2010 Plan.

7. On July 30, 2014, we granted a stock option to purchase 5,000 shares of common stock at an exercise price of $8.80 per share to one employee pursuant to our 2010 Plan.

8. On December 20, 2016, we granted stock options to purchase a total of 141,000 shares of common stock at an exercise price of $14.85 per share to eight employees pursuant to our 2010 Plan.

9. On December 20, 2016, we granted stock options to purchase a total of 97,500 shares of our common stock at an exercise price of $14.85 to two executive officers and two directors pursuant to our 2010 Plan.

10. On December 20, 2016, we granted a stock option to purchase 100,000 shares of common stock at an exercise price of $47.10 per share to one executive officer pursuant to our 2010 Plan.

11. On January 23, 2017, we granted a stock option to purchase a total of 55,000 shares of common stock at an exercise price of $14.85 per share to one executive officer pursuant to our 2010 Plan.

12. On January 30, 2017, we granted stock options to purchase a total of 50,000 shares of common stock at an exercise price of $14.85 per share to one executive officer pursuant to our 2010 Plan.

13. On February 13, 2017, we granted stock options to purchase a total of 7,000 shares of common stock at an exercise price of $14.85 per share to two employees pursuant to our 2010 Plan.

14. On February 20, 2017, we granted a stock option to purchase 2,000 shares of common stock at an exercise price of $14.85 per share to one employee pursuant to our 2010 Plan.

15. On February 27, 2017, we granted a stock option to purchase 2,000 shares of common stock at an exercise price of $14.85 per share to one employee pursuant to our 2010 Plan.

16. On August 7, 2017, we granted stock options to purchase a total of 55,500 shares of common stock at an exercise price of $20.95 per share to nine employees pursuant to our 2010 Plan.

The offers, sales and issuances of the securities described in paragraphs (a) and (b) above were exempt from registration under the Securities Act in reliance on Regulation D of the Securities Act.

With respect to the shares of Series C-2 Preferred Stock issued upon conversion of the convertible notes in March 2017 described in paragraph (b), the issuance of such shares was exempt from registration under Section 3(a)(9) of the Securities Act.

The grants of stock described in paragraph (c) above to our executive officers and directors were exempt from registration under Section 4(a)(2) of the Securities Act as transactions not involving any public offering. The remaining grants of stock options described in paragraph (c) above were exempt from registration under the Securities Act in reliance on Rule 701 as offers and sales of securities under written compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

All purchasers of securities in transactions exempt from registration pursuant to Regulation D described above represented to us in connection with their purchase that they were accredited investors, as defined in Rule 501 under the Securities Act, and were acquiring the securities for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from the registration requirements of the Securities Act.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. The certificates representing the issued securities described in this Item 15 included appropriate legends setting forth that the applicable securities have not been registered and reciting the applicable restrictions on transfer. There were no underwriters employed in connection with any of the transactions set forth in this Item 15.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

The list of exhibits is set forth under "Index to Exhibits" at the end of this registration statement and is incorporated by reference herein.

(b) Financial Statement Schedules

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Borough of Yardley, Commonwealth of Pennsylvania, on the day of , 2017.

OPTINOSE, INC.

By: _____

Name: Peter K. Miller
Title: *Chief Executive Officer*

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter K. Miller and Keith A. Goldan, as his true and lawful attorney-in-fact and agent, with the full power of substitution, for him and in his name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
_____ Peter K. Miller	Chief Executive Officer and Director (Principal Executive Officer)	, 2017
_____ Keith A. Goldan	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	, 2017
_____ Larry G. Pickering	Chairman of the Board of Directors	, 2017
_____ Sriram Venkataraman	Director	, 2017

Signature	Title	Date
_____ William F. Doyle	Director	, 2017
_____ Klaas de Boer	Director	, 2017
_____ Per Gisle Djupesland	Director	, 2017
_____ Patrick O'Neill	Director	, 2017
_____ Joshua A. Tamaroff	Director	, 2017

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
1.1#	Form of Underwriting Agreement.
2.1*	Exchange Agreement, dated as of June 7, 2010, by and among the Registrant, OptiNose AS and the other signatories thereto (the Registrant hereby agrees to furnish supplementally a copy of any omitted schedules to the SEC upon request).
3.1*	Third Amended and Restated Certificate of Incorporation, as currently in effect.
3.2*	By-Laws, as currently in effect.
3.3*	Amendment No. 1 to the By-Laws, as currently in effect, dated March 24, 2017.
3.4#	Form of Fourth Amended and Restated Certificate of Incorporation, to be effective immediately following the closing of this offering.
3.5#	Form of Amended and Restated Bylaws, to be in effect immediately following closing of this offering.
4.1#	Form of Common Stock Certificate.
4.2*	Second Amended and Restated Registration Rights Agreement, dated March 24, 2017, by and among the Registrant and certain of its stockholders.
4.3*	Second Amended and Restated Shareholders' Agreement, dated March 24, 2017, by and among the Registrant and certain of its stockholders.
4.4*	Form of Warrant issued by the Registrant on June 7, 2010.
5.1#	Opinion of Hogan Lovells US LLP.
10.1#+	Form of Indemnification Agreement.
10.2*+	Employment Agreement, dated as of May 27, 2010, by and between the Registrant and Peter K. Miller.
10.3*+	Letter Agreement, dated as of June 18, 2010, by and between the Registrant and Ramy A. Mahmoud.
10.4*+	Letter Agreement, dated as of September 15, 2016, by and between OptiNose US, Inc. and Thomas E. Gibbs.
10.5*+	Letter Agreement, dated as of January 13, 2017, by and between OptiNose US, Inc. and Keith A. Goldan.
10.6*+	Letter Agreement, dated as of January 13, 2017, by and between OptiNose US, Inc. and Michael F. Marino.
10.7#+	2010 Stock Incentive Plan, as amended.
10.8#+	Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan (Relating to Success Pool Grants).
10.9#+	Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan (Relating to Option Pool Grants).
10.10#+	Form of Non-Qualified Stock Option Agreement Granted Under the 2010 Stock Incentive Plan.

Exhibit Number	Exhibit Description
10.11†	License Agreement, dated as of July 1, 2013, by and between OptiNose AS and Avanir Pharmaceuticals, Inc.
10.12*†	First Amendment of License Agreement, dated as of April 25, 2014, by and between OptiNose US, Inc. and Avanir Pharmaceuticals, Inc.
10.13*†	Amendment to License Agreement, dated as of August 6, 2015, by and between OptiNose AS and Avanir Pharmaceuticals, Inc.
10.14†	Supply Agreement, dated July 1, 2017, by and between Hovione Inter Ltd and OptiNose US, Inc., OptiNose UK, Ltd and OptiNose AS.
10.15†	Manufacture and Supply Agreement, dated as of August 18, 2017, by and among OptiNose US, Inc., OptiNose UK Ltd. and OptiNose AS and Contract Pharmaceuticals Limited Canada.
16.1*	Letter of PricewaterhouseCoopers LLP as to change in accountant, dated June 23, 2017.
21.1*	List of Subsidiaries of the Registrant.
23.1#	Consent of Ernst &Young LLP, independent registered public accounting firm.
23.2#	Consent of Hogan Lovells US LLP (included in Exhibit 5.1).
24.1#	Power of Attorney (included on signature page).

* Previously filed.

\# To be filed by amendment.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

\+ Indicates management contract or compensatory plan.

Exhibit 10.11

Execution Copy

LICENSE AGREEMENT

between

OPTINOSE AS

and
AVANIR PHARMACEUTICALS, INC.

LICENSE AGREEMENT

This **LICENSE AGREEMENT** (the "**Agreement**") is entered into on July 1, 2013 (the "**Effective Date**") between **OptiNose AS**, a Norwegian corporation, company registration number 982483131, with its principal place of business at Austliveien 1, 0751 Oslo, Norway, and its postal address at Pb 288 Roa, 0702 Oslo, Norway ("**OptiNose**"), and **Avanir Pharmaceuticals, Inc.,** a Delaware corporation, with offices at 20 Enterprise, Suite 200, Aliso Viejo, CA 92656, U.S.A. ("**Avanir**"). OptiNose and Avanir are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, OptiNose is a pharmaceutical company with expertise in improving the delivery of pharmaceutical products through the nasal cavity through the research and development of nasal delivery devices;

WHEREAS, Avanir is a pharmaceutical company having the capability to develop, obtain regulatory approval for, manufacture, distribute, market and sell such products;

WHEREAS, OptiNose has developed a breath-powered nasal delivery device for the delivery of, among other products, powder formulations of a triptan, and owns certain patents, know-how and other intellectual property related to such product;

WHEREAS, Avanir desires to obtain an exclusive license to such patents, know-how and other intellectual property in order to develop further and commercialize the Product in the Licensed Territory (each, as defined below), and OptiNose desires to grant such license to Avanir, all on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE I
DEFINITIONS; INTERPRETATION

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1.

1.1 **"Affiliate"** means, with respect to a particular Party, a person, corporation, or other business entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party, as the case may be. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means: (a) to possess, directly or indirectly, the affirmative power to direct or cause the direction of the management and policies of such person, corporation, or other business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect ownership of fifty percent (50%) or more of the voting share capital of such person, corporation or other business entity.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.2 **"Annual Net Sales"** means the total Net Sales of Products sold by Avanir, its Affiliates and/or sublicensees in the Licensed Territory for each twelve (12) consecutive month period commencing with the first day of the calendar month in which the First Commercial Sale occurs or the anniversary of such date, as applicable.

1.3 **"Commercially Reasonable Efforts"** means the level of efforts and resources consistent with the efforts and resources expended by [***].

1.4 **"Confidential Information"** means, with respect to a Party, all Information of such Party or its Affiliates that is provided to the other Party or its Affiliate pursuant to this Agreement. All Information disclosed by either Party or its Affiliates to the other Party or its Affiliates pursuant to the Confidential Disclosure Agreement between the Parties dated September 20, 2012 (the "**Confidentiality Agreement**"), shall be deemed to have been disclosed under this Agreement on a going-forward basis and shall be subject to the terms of Article 12 from and after the Effective Date.

1.5 **"Contract Year"** means each twelve (12) consecutive month period beginning with the first day of the calendar month in which the First Commercial Sale occurs, or the anniversary of such date, as applicable.

1.6 **"Control"** means, with respect to any material, Information, or intellectual property right, that a Party or its Affiliate owns or has a license to such material, Information, or intellectual property right, and has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to

such material, Information, or intellectual property right on the terms and conditions set forth herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would first be required hereunder to grant to the other Party such access, license or sublicense.

1.7 **"Device"** means a nasal device used for the delivery of pharmaceutical products in a powder or liquid formulation and that is covered by an OptiNose Patent listed on Exhibit 1.28.

1.8 **"Device Improvement"** means any discoveries or inventions, whether or not patentable, developed by [***] in exercising its rights or performing its obligations under this Agreement, to the extent [***].

1.9 **"FDA"** means the U.S. Food and Drug Administration, or its successor.

1.10 **"FD&C Act"** means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

1.11 **"First Commercial Sale"** shall mean the date of the first sale for end use or consumption of the first Product in any country of the Licensed Territory.

1.12 **"Fiscal Quarter"** means a consecutive three (3) calendar month period during a Fiscal Year starting on either October 1, January 1, April 1 or July 1, as the case may be.

1.13 **"Fiscal Year"** means each consecutive twelve (12) month period commencing on October 1 of each calendar year and ending on September 30 of the calendar year thereafter.

1.14 **"Generic Product"** means a product that: (a) has been deemed by the FDA to be [***] to the Product by virtue of [***] or any other product that has been deemed by the FDA (or other applicable Governmental Authority in a particular country of the Licensed Territory) to be [***] and (b) [***].

1.15 **"Governmental Authority"** means any federal, state, local, municipal or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal), including any Regulatory Authority.

1.16 **"Head to Head Trial"** means the OPN-SUM-MIG-3302 Phase III clinical trial for the Product ongoing as of the Effective Date, under the protocol entitled, "*Efficacy and Safety of 20 mg Sumatriptan Powered*

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Delivered Intranasaly with the Bi-Directional Device compared with 100 mg Sumatriptan Tablets in Adults with Acute Migraine with or without Aura."

1.17 **"IND"** means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated hereunder; or (b) an equivalent application to a Regulatory Authority in any jurisdiction outside the U.S., the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.18 **"Information"** means any data, results, technology, business information, financial information and other proprietary information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), Regulatory Materials, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, research, preclinical and clinical test data (including original patient report forms, investigator reports, clinical protocols, statistical analyses, expert opinions and reports)), manufacturing data (including analytical and quality control data, stability data, other study data and procedures and other chemistry, manufacturing and control (CMC) data), safety or other adverse reaction files and complaint files, presentations and papers from academic meetings or market research, in each case, together with all supporting data and raw source data; provided, however, Information shall exclude any and all patient specific and other similar data to the extent such exclusion is required by applicable privacy laws (in which case such Information shall be treated confidentially in accordance with applicable privacy laws).

1.19 **"Lawful Entry"** means the commercial launch of a Generic Product following Regulatory Approval of such Generic Product; provided that, (i) such commercial launch or other availability of the Generic Product is not [***], or (ii) [***]; and provided further that in each of (i) and (ii), such Generic Product [***].

1.20 **"Laws"** means all laws, statutes, rules, regulations, and ordinances of any multi-national, federal, state, local or municipal subdivision, including laws and regulations promulgated by Regulatory Authorities relating to the development, manufacture, testing and/or commercialization of pharmaceutical products.

1.21 **"Licensed Territory"** means the United States, Canada and Mexico.

1.22 **"Marketing Approval Application"** or "**MAA"** means an NDA submitted to (and the submission of which has been accepted for substantive review by) the FDA in the United States or a corresponding application for approval to sell a Product that has been submitted to (and the submission of which has been accepted for substantive review by) a Regulatory Authority in any other jurisdiction.

1.23 **"NDA"** means a New Drug Application (or its equivalent), as defined in the FD&C Act.

1.24 **"Net Sales"** means the gross amounts invoiced by Avanir, its Affiliates and/or sublicensees, as the case may be, for sales of Products to Third Party customers, less reasonable and customary deductions for the following items incurred, allowed, paid or accrued, as determined in accordance with

generally accepted accounting principles in the United States ("**GAAP**"), applied on a consistent basis by Avanir, its Affiliate or sublicensee, as applicable:

(a) [***];

(b) [***];

(c) [***]; and

(d) [***].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Notwithstanding the foregoing, [***]. If a sale or other disposition with respect to Products is not at arm's length, then the Net Sales from such sale or other disposition shall be [***].

1.25 **"OptiNose Additional Intellectual Property"** means, subject to Section 9.7, any industrial designs, works of authorship, and copyrights Controlled by OptiNose or any of its Affiliates as of the Effective Date or during the Term that are necessary or reasonably useful for the research, development, use, manufacture, sale or other commercialization of the Product or Device.

1.26 **"OptiNose IP"** means, collectively, the OptiNose Patents, OptiNose Know-How, OptiNose Trademarks, and OptiNose Additional Intellectual Property.

1.27 **"OptiNose Know-How"** means, subject to Section 9.7, all Information (including trade secrets) Controlled by OptiNose or any of its Affiliates as of the Effective Date or during the Term necessary or reasonably useful for the research, development, use, manufacture, sale or other commercialization of the Device or a Product. OptiNose shall, within [***] of the Effective Date, provide Avanir with a schedule listing material, tangible OptiNose Know-How. For clarity, OptiNose Know-How shall include all Device Improvements other than Device Improvements covered by or claimed in an OptiNose Patent.

1.28 **"OptiNose Patent"** means, subject to Section 9.7, all Patents Controlled by, OptiNose or any of its Affiliates as of the Effective Date or during the Term that cover or claim a Product and/or Device, including those Patents listed on Exhibit 1.28, together with all divisionals, substitutions, registrations, re-examinations, additions, continuations, continuations-in-part, reissues, renewals and Patent Term Extensions of or to any of the foregoing. For clarity, OptiNose Patents shall include any Patents Controlled by OptiNose or any of its Affiliates that cover or claim a Device Improvement.

1.29 **"OptiNose Trademarks"** means, subject to Section 9.7, any, whether domestic or foreign, trademarks, service marks, and trade names Controlled by OptiNose or any of its Affiliates as of the Effective Date or during the Term that are used (or required to be used) in connection with the Device or a Product in the Licensed Territory, including those trademarks, service marks and trade names listed on Exhibit 1.29 (the "**Existing OptiNose Trademarks**").

1.30 **"Out-of-Pocket Expenses"** means amounts paid by a Party (or its Affiliate) to Third Party vendors or contractors, for services or materials provided by them directly in their performance of activities reflected in the Development Plan, to the extent the amounts paid for such services or materials are specified in Exhibit 4.5(a) attached to this Agreement. For clarity, Out-of-Pocket Expenses do not include payments for salaries or benefits, facilities, utilities, general office supplies, insurance, information technology, and other general administrative costs of a Party or its Affiliate.

1.31 **[***]**

1.32 **[***]**

1.33 **"Patent Term Extension"** means any term extensions, supplementary protection certificates, and equivalents thereof offering patent or patent-like protection beyond the initial term with respect to any issued Patents.

1.34 **"Patents"** means, whether domestic or foreign: (a) any patent applications, issued patents, utility models and designs and inventor's certificates; and (b) all divisionals, substitutions, registrations, re-examinations, additions, continuations, continuations-in-part, reissues, renewals and Patent Term Extensions of or to any of the foregoing.

1.35 **"Product(s)"** means any products or product candidates developed by or under the authority of a Party or any of its Affiliates as of the Effective Date or during the Term consisting of a formulation that contains as its sole active ingredient a compound within the class of compounds known as triptans, including any salt,

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

polymorphic or amorphous form of such a compound, that is delivered in a nasal delivery device; [***]. For purposes of the foregoing, the class of compounds known as triptans includes the compounds known as of the Effective Date as the following: Sumatriptan, [***]. Solely for the purposes of clause (i) of Section 2.3(a), a "Product" shall also include products or product candidates consisting of [***].

1.36 **"Product Complaint"** means any written, oral or electronic expression of dissatisfaction regarding a Product, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

1.37 **"Regulatory Approval"** means all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary for the development, manufacture, marketing, import or sale of a Product in a given country or regulatory jurisdiction.

1.38 **"Regulatory Authority"** means the FDA or any applicable Governmental Authority in a jurisdiction outside the United States with similar regulatory authority in such jurisdiction.

1.39 **"Regulatory Exclusivity"** means any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority or other Governmental Authority in the Licensed Territory, other than an issued and unexpired Patent, including any regulatory data protection exclusivity.

1.40 **"Regulatory Materials"** means all INDs, Marketing Approval Applications, Regulatory Approvals, applications for pricing approvals and other regulatory applications, submissions, notifications, communications, correspondence, and/or filings made to, received from or otherwise conducted with a Regulatory Authority (including minutes of meeting with Regulatory Authorities and any Product package insert) that are necessary or reasonably useful in connection with, or otherwise pertain specifically to, the development, manufacture, marketing, sale or other commercialization of the Product in the Licensed Territory.

1.41 **"Successful Completion of the Head to Head Trial"** means that pursuant to the statistical analysis plan determined pursuant to Section 4.3(a) at least one of the criteria set forth below in items (i) through (iv) has been satisfied and item (v) has been satisfied:

(i) [***]

(ii) [***]

(iii) [***]

(iv) [***]

(v) [***]

1.42 **"Third Party"** means any person, corporation or other business entity, other than OptiNose or Avanir or their respective Affiliates.

1.43 **"United States"** or "**U.S.**" means the United States of America and its possessions and territories, including Puerto Rico.

1.44 **"Valid Claim"** means an issued and unexpired claim of Patent, or a claim of a pending patent application, included in the OptiNose Patents within the Licensed Territory that: (a) has not been held unpatentable, invalid or unenforceable by a court or other Governmental Authority of competent jurisdiction in a decision from which no appeal can be or has been taken; and (b) which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise. Notwithstanding the foregoing, if a claim of a pending patent application within the OptiNose Patents has not issued as a claim of a patent within [***] after the filing date from which such claim takes priority, such claim shall not be a Valid Claim for the purposes of this Agreement,

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

unless and until such claim issues as a claim of an issued patent (from and after which time the same shall be deemed a Valid Claim subject to (a) and (b) above).

1.45 **"Wind-Down Period"** means the period commencing on the termination of this Agreement in its entirety and ending [***] thereafter.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.46 **Additional Definitions**. Each of the following terms shall have the meaning described in the corresponding Section of this Agreement indicated below:

Term	Section
Acquiring Entities	9.7
Acquisition	9.7
Avanir Assumed Patent	9.2(b)
Avanir Indemnitees	11.1
Avanir Trademarks	9.6
[***]	[***]
Claims	11.1

Committee	3.4
Consultants	Exhibit 4.5(b)
Cost Sharing Commencement Date	Exhibit 4.5(b)
Current Clinical Studies and Activities	4.3(a)
[***]	[***]
Debarred Person	10.3(l)
Development Milestone	8.2(a)
Development Plan	4.1(a)
Development Plan Budget	Exhibit 4.5(b)
Device-Specific Regulatory Materials	5.4(b)
[***]	[***]
Escalation Notice	3.6
HSR Act	10.2(p)
HSR Rules	10.2(p)
Indemnified Party	11.3
Indemnifying Party	11.3
Infringement	9.3(a)
Infringer	9.3(a)
JAMS	14.3(b)
Joint Development Committee / JDC	3.2(a)
Joint Development Costs	Exhibit 4.5(b)
Joint Intellectual Property Committee / JIPC	3.3
Joint Steering Committee / JSC	3.1(a)
Liabilities	11.1
OptiNose Indemnitees	11.2
OptiNose Style Guide	6.3
Patent Challenge	13.2(b)
Product Launch Plan	6.2(a)
Prosecution and Maintenance	9.2(c)
Royalty	8.3(a)
Royalty Report	8.3(b)(i)
Royalty Term	8.3(d)
Rules	14.3(b)
Sales Milestone	8.2(b)
Supply Agreement	7.4
Supply Transition Date	7.1
Supply Transition Period	2.1(b)
Supply Transition Plan	7.1
Tax residence Certificate	8.4(b)
Term	13.1
Third Party Agreements	10.3(a)
Third Party Infringement Actions	9.4

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.47 **Interpretation**.

Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless the context clearly requires otherwise, whenever used in this Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation," whether or not such additional words are written; (ii) the word "or" shall have its inclusive meaning of "and/or" except when paired as "either/or"; (iii) the word "day" or "quarter" or "year" means a calendar day or calendar quarter or calendar year; (iv) the word "notice" shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other communications contemplated under this Agreement; (v) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement (including the Exhibits hereto); (vi) provisions that require that a Party, the Parties or a Committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter or otherwise; (vii) words of any gender include the other gender; (viii) words using the singular or plural number also include the plural or singular number, respectively; (ix) the word "will" shall be construed to have the same meaning and effect as the word "shall;" and (x) references to any specific Law, article, section or other division thereof, shall be deemed to include the then current amendments thereto or any replacement thereof.

ARTICLE II
LICENSES AND TECHNOLOGY TRANSFER

2.1 **License to Avanir under OptiNose IP.**

(a) **Exclusive Product License**. Subject to Section 2.1(b) below and the other terms and conditions of this Agreement, OptiNose hereby grants Avanir an exclusive (even as to OptiNose) license to and under the OptiNose Know-How, the OptiNose Patents, the OptiNose Trademarks and the OptiNose Additional Intellectual Property: (i) to use, sell, offer for sale, have sold and import the Product in the Licensed Territory; and (ii) to make or have made the Product anywhere in the world solely for such permitted use, sale, offer for sale and importation in the Licensed Territory; provided that Avanir shall [***].

(b) **Retained Rights**. Notwithstanding Section 2.1(a) above, but subject to Section 2.3 below, OptiNose retains rights under the OptiNose IP to use, make, have made, sell, have sold, import or otherwise export products (including the Product) in the Licensed Territory for uses other than the prevention, treatment and/or palliation of, or other applications relating to, [***] or [***]. For the avoidance of doubt, but subject to Section 2.3 below: (i) the foregoing retention of rights includes OptiNose's rights to use, make, have made, sell, have sold, import, or otherwise exploit products for the prevention, treatment and/or palliation of, or other applications relating to [***] so long as such products are not a Product; and (ii) subject to the manufacturing rights granted by OptiNose to Avanir pursuant to Section 2.1(a)(ii) above, nothing in this Agreement shall limit (or be construed to limit) OptiNose's rights to freely exploit any OptiNose IP or other intellectual or proprietary rights Controlled by OptiNose or its Affiliates or the Product outside the Licensed Territory, including to make or have made the Product anywhere in the world solely to exploit the Product outside of the Licensed Territory (or from the Effective Date until the Supply Transition Date ("**Supply Transition Period**"), for the purposes of using Product in the Licensed Territory in accordance with the Development Plan under this Agreement).

(c) **Sublicense Rights**. Subject to the terms and conditions of this Section 2.1(c), Avanir shall have the right to grant and authorize sublicenses to its Affiliates and any Third Party under the rights granted in Section 2.1(a) above, without the consent of OptiNose; provided that with respect to each such sublicense under the OptiNose IP granted by Avanir to a Third Party: (i) such sublicense shall be in writing and shall refer to this Agreement and shall be subject and subordinate to this Agreement; (ii) a copy of such sublicense shall be provided to OptiNose following the execution thereof; provided that confidential terms may be redacted to the extent such terms are not necessary to determine compliance with this Agreement or to determine the rights granted under any OptiNose IP; and (iii) [***]. In addition, such Third Party sublicensee shall: (A) [***]; (B) [***]; (C) [***]; (D) [***]; and (E) [***]. Avanir shall use reasonable efforts to enforce the provisions of its agreements with

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

sublicensees incorporating the requirements set forth in the foregoing clauses (A) through (E). For the avoidance of doubt, any co-promotion agreement or similar agreement pursuant to which Avanir's counterparty is compensated by Avanir for its activities and does not receive any revenues from sales of Product directly from the purchasers thereof shall not be deemed a sublicense pursuant to this Section 2.1(c) (and conversely any co-promotion agreement or similar agreement pursuant to which Avanir's counterparty does receive any revenues from sales of Product directly from the purchasers thereof shall be deemed a sublicense); provided that any such agreement between Avanir or its Affiliate with respect to co-promotion or other similar arrangement involving the Product shall comply with the terms of clauses (A) through (E) of this Section 2.1(c).

2.2 **No Implied Licenses**. Except as explicitly set forth in this Agreement, neither Party grants any license or other rights, express or implied, under its intellectual property rights or its INDs, MAAs, Regulatory Approvals or confidential and proprietary rights to the other Party, and no additional rights shall be deemed granted by implication, estoppel or otherwise. Nothing in this Agreement will grant (or be construed to grant) to Avanir or its Affiliates any right to make, have made, use, offer for sale, sell, import or otherwise exploit any product other than a Product or a Device in connection with the making, having made, use, offering for sale, selling, importing or otherwise exploiting a Product for the Licensed Territory.

2.3 **Restrictions on the Parties.**

(a) Notwithstanding any provision of this Agreement to the contrary, commencing on the Effective Date and continuing until the expiration or earlier termination of this Agreement, OptiNose agrees, on behalf of itself and its Affiliates, (i) not to[***], or (B) authorize or assist any Third Party to do any of the foregoing; and (ii) to refrain from asserting any rights of OptiNose or its Affiliates under any other Patents Controlled by OptiNose or its Affiliates, against the use, making, having made, or other permitted exploitation of a Product by or under the authority of Avanir in the Licensed Territory.

(b) Notwithstanding any provision of this Agreement to the contrary, Avanir agrees, on behalf of itself and its Affiliates, and shall use reasonable efforts to require its sublicensees, not to, directly or indirectly: (i) manufacture, use, sell, offer for sale, market, promote, import or otherwise exploit or commercialize any Product outside the Licensed Territory (except as expressly permitted by Section 2.1(a)(ii)), or (ii) authorize or assist any Third Party to do any of the foregoing.

2.4 **Transfer of OptiNose Know-How.**

(a) [***], OptiNose shall provide to Avanir [***] copies of all OptiNose Know-How that is in tangible form and that may be [***] for Avanir to develop, obtain Regulatory Approval for, and/or commercialize the Product in the Licensed Territory and to manufacture the Product in any country for use and sale in the Licensed Territory (subject to Section 2.1(a)(ii) to the extent applicable), including: (i) copies of all documentation, reports and other Information from all clinical trials and preclinical studies for the Product or the Device that have been obtained by OptiNose; (ii) copies of all Regulatory Materials pertaining to the Product in the Licensed Territory; and (iii) copies of all non-clinical, analytical and manufacturing data relating to the Product.

(b) From time-to-time throughout the Term [***], and otherwise promptly upon Avanir's reasonable request, OptiNose shall provide to Avanir copies of all OptiNose Know-How that is in tangible form and that is Controlled by OptiNose that has not previously been provided hereunder, including all additional data, documentation, reports and other Information arising out of all activities assigned to OptiNose under the Development Plan.

(c) In complying with its obligations under this Section 2.4, OptiNose shall provide the OptiNose Know-How in electronic form, to the extent the same exists in electronic form, and shall provide copies as reasonably requested. The Parties will cooperate and reasonably agree upon formats and procedures to facilitate the orderly and efficient exchange of the OptiNose Know-How, as set forth above.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(d) Upon Avanir's request and until [***], OptiNose shall reasonably cooperate with and assist Avanir as may be reasonably necessary to allow Avanir to understand the OptiNose Know-How and to utilize the OptiNose Know-How for the purposes contemplated in this Agreement.

ARTICLE III
GOVERNANCE

3.1 **Joint Steering Committee.**

(a) **Establishment**. Within [***] following the Effective Date, OptiNose and Avanir shall establish a Joint Steering Committee ("**Joint Steering Committee**" or "**JSC**") to oversee, review and coordinate the Parties' development activities with respect to the Product and Regulatory Approvals for the Product in the Licensed Territory and to provide a forum for the Parties to discuss Avanir's activities with respect to the commercialization of the Product in the Licensed Territory, subject to the provisions of this Article 3.

(b) **Duties. The JSC shall:**

(i) Review changes to the Development Plan in accordance with this Agreement;

(ii) Provide a forum for the Parties to exchange information and coordinate their respective activities regarding matters pertaining to the development and manufacture of the Product and matters pertaining to Regulatory Approval of the Product in the Licensed Territory, as provided in Article 4 below;

(iii) Until [***], provide a forum for the Parties to discuss Avanir's activities with respect to the commercialization of the Product in the Licensed Territory;

(iv) As appropriate, establish additional committees to allow for the exchange of information between the Parties relating to the commercialization of the Product in the Licensed Territory;

(v) Provide a forum for resolving matters to be decided by the JDC under this Agreement pursuant to the procedures set forth in Section 3.2 and Section 3.6 below; and

(vi) Perform such other duties as are specifically assigned to the JSC in this Agreement.

3.2 **Joint Development Committee.**

(a) Establishment. Within [***] following the Effective Date, OptiNose and Avanir shall establish a joint development committee ("**Joint Development Committee**" or "**JDC**") to oversee, review and manage the conduct of the development activities necessary to obtain Regulatory Approval for the Product in the Licensed Territory.

(b) Duties. Until [***], the JDC shall:

(i) Review and approve changes to the Development Plan in accordance with Section 4.1(b);

(ii) Subject to and within the parameters of the Development Plan, oversee and manage development and regulatory activities for the Product in the Licensed Territory;

(iii) Perform such other duties as are specifically assigned to the JDC in this Agreement or delegated to the JDC by the JSC.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.3 **Joint IP Committee**. Within [***] following the Effective Date, OptiNose and Avanir shall establish a joint intellectual property committee ("**Joint IP Committee**" or "**JIPC**") to discuss all OptiNose Patents, OptiNose Trademarks and copyright matters relating to the OptiNose IP to the extent licensed to Avanir or its Affiliates for Products and to ensure that Avanir has a reasonable opportunity to review, comment on and cooperate in determining OptiNose's strategy relating to the filing, prosecution, maintenance and enforcement of the OptiNose Patents.

3.4 **Committee Membership**. The JSC, JDC and JIPC (each, a "**Committee**") shall each be composed of an equal number of representatives from each of OptiNose and Avanir, selected by such Party. Unless the Parties otherwise agree, the exact number of representatives for each of OptiNose and Avanir shall be: (a) with respect to the JSC, three (3) representatives, at least one of whom shall be at the [***] level or above; (b) with respect to the JDC, three (3) representatives, at least one of whom shall be at the [***] level or above; and (c) with respect to the JIPC, two (2) representatives, at least one (1) of whom shall be a Juris Doctor (or an equivalent legal education in a jurisdiction outside the United States), be licensed to practice before the United States Patent & Trademark Office or the European Patent Office and have responsibility for intellectual property matters for the Party whom they represent. Either Party may replace its respective Committee representatives at any time with prior written notice to the other Party.

3.5 **Committee Meetings**. The JSC shall each meet at least once each calendar quarter, or as more or less often as otherwise agreed to by the Parties. The JDC and JIPC shall meet at least two (2) times each calendar year, or as otherwise reasonably requested by either Party to fulfill such Committee's responsibilities under this Agreement. All Committee meetings may be conducted by telephone, video-conference or in person as determined by the applicable Committee; provided that each Committee shall meet in person at least once each calendar year unless otherwise agreed by the Parties. Unless otherwise agreed by the Parties, all in-person meetings for each Committee shall be held on an alternating basis between OptiNose's U.S. facilities and Avanir's U.S. facilities. Each Party shall bear its own personnel and travel costs and expenses relating to Committee meetings. With the consent of the other Party (not to be withheld unreasonably), other representatives of a Party may attend any Committee meeting as non-voting observers.

3.6 **Committee Decision-making**. Decisions of the JSC and JDC shall each be made by [***]. In the event the JDC fails to reach [***] agreement with respect to a particular matter within its decision-making authority, then, upon request by either Avanir or OptiNose, such matter shall be referred to the JSC for resolution. In the event that the JSC fails to reach [***] agreement with respect to a particular matter within its authority within [***] of the matter first being presented to the JSC for decision, then upon written notice by one Party to the other Party specifying the matter within the authority of the JSC that is in dispute (each, an "**Escalation Notice**"), [***] to resolve such matter, by telephone or in person as mutually agreed. If, despite [***], the [***] fail to resolve such matter within [***] following the date of the Escalation Notice, then upon the written request of either Avanir or OptiNose, [***]; provided, however, that [***] in a manner that would: (i) [***], or (ii) [***].

3.7 **Scope of Governance**. Notwithstanding the creation of the JSC, JDC or JIPC, each Party shall retain the rights, powers and discretion granted to it hereunder, and no Committee shall be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. No Committee shall have the power to amend or modify this Agreement, and no decision of any Committee shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be formally decided by the JSC and JDC, as applicable, are only those specific issues that are expressly provided in this Agreement to be decided by the JSC and JDC, as applicable.

ARTICLE IV
DEVELOPMENT

4.1 **Development Plan.**

(a) **Initial Development Plan**. An initial development plan setting forth the development activities to be conducted by each Party in support of [***], and the anticipated budget and timeline therefor is

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

attached hereto as Exhibit 4.1 ("**Development Plan**"). The Development Plan shall specify the number of personnel (calculated on the basis of full-time equivalents ("**FTEs**")) that each Party (and if applicable, its Affiliates) is expected to provide in connection with the performance of such Party's and its Affiliates' responsibilities under the Development Plan and the budget for Out-of-Pocket Expenses of each Party for such development activities. Each Party shall use [***] to fulfill such FTE and other obligations in the performance of its responsibilities under the Development Plan.

(b) **Changes to a Development Plan**. The JDC shall review the Development Plan on an ongoing basis, and in no event less frequently than [***]. The JDC may adopt amendments to the then-current Development Plan (including any amendments or updates to the Development Plan as permitted under this Section 4.1(b)); provided, however, that the written approval of both Avanir and OptiNose (which approval shall not be unreasonably withheld) shall be required for any amendment to the Development Plan that: (i) would impose on OptiNose the responsibility to incur Out-Of-Pocket Expenses in connection with the development of the Product in the Licensed Territory in addition to those specified to be incurred by OptiNose in Exhibits 4.5(a) and 4.5(b) attached hereto; or (ii) OptiNose can reasonably expect would result in a delay of [***] beyond the anticipated date for [***] specified in the initial Development Plan attached to as Exhibit 4.1 (or such later date as Avanir and OptiNose mutually agree, which agreement shall not be unreasonably withheld by either Party);.

4.2 **Development Activities of Avanir**. Except as provided in Section 4.3 below, and subject to Section 4.1(b)(ii), Avanir shall have the right to control, and shall [***] conduct, clinical development and other activities required to [***]. Avanir shall carry out all such activities in the United States in accordance with the then-current Development Plan and the Out-Of-Pocket Expenses incurred by Avanir in performing such activities shall be shared by the Parties to the extent and as provided in Section 4.5 below. In addition, Avanir shall, at its expense, be responsible for the conduct of clinical trials, continuing non-clinical studies and other activities following the receipt of Regulatory Approval for the Product in each country of the Licensed Territory for the further development of the Product for use in such country. Without limiting the foregoing, such development activities shall include the performance of any post-marketing studies required by applicable Regulatory Authorities to maintain Regulatory Approvals held by Avanir (or its designee) for the Product in the Licensed Territory.

4.3 **Development Activities of OptiNose.**

(a) **Development Activities in the Licensed Territory**. Except as otherwise mutually agreed, after the Effective Date, OptiNose shall be responsible for completing the Head to Head Trial and those other clinical studies and activities listed on Exhibit 4.3 to this Agreement or assigned to OptiNose under the Development Plan (collectively, the "**Current Clinical Studies and Activities**") and the Out-of-Pocket Expenses incurred by OptiNose in performing the Current Clinical Studies and Activities shall be shared by the Parties to the extent and as provided in Section 4.5 below. Notwithstanding any other provision of this Agreement, the Parties shall not modify, in any material respect, the protocol for the Head to Head Trial in effect as of the Effective Date, unless mutually agreed (which agreement shall not be unreasonably withheld by either Party); provided further that the Parties acknowledge and agree that, promptly following the Effective Date, they shall cooperate in good faith to develop and mutually agree upon the statistical analysis plan for the Head to Head Trial. OptiNose shall [***] conduct and complete the Current Clinical Studies and Activities assigned to it in the Development Plan in accordance with the timelines specified therein and otherwise in accordance with this Agreement.

(b) **Development Activities Outside the Licensed Territory**. OptiNose agrees to keep Avanir reasonably informed regarding the clinical and other material development activities relating to Products outside the Licensed Territory by way of updates to the JSC at its meetings[***]. Without limiting the foregoing or Section 2.4 above, [***] OptiNose shall provide to Avanir copies of all protocols for clinical trials involving a Product (and a synopsis thereof) proposed to be conducted outside the Licensed Territory reasonably in advance of the date the protocol for the applicable clinical trial will be submitted to a Regulatory Authority or the date of the initiation of such trial (whichever occurs first). Avanir shall have the right to comment on such protocols to the extent the corresponding clinical trial(s) are reasonably likely to [***] impact the commercialization of the Product in the Licensed Territory and OptiNose shall [***] any such comments provided by Avanir.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.4 **Conduct of Activities**. Each Party shall conduct those activities allocated to such Party under the Development Plan in compliance in all material respects with all applicable Laws and in accordance with good scientific and clinical practices, applicable under the applicable law of the country in which such activities are conducted.

4.5 **Development Cost Sharing**. The Parties shall share [***] those Out-of-Pocket Expenses constituting Joint Development Costs set out in Exhibit 4.5(a) that are incurred under and in accordance with the Development Plan in performing development and/or regulatory activities to [***]. Each Party shall remit any necessary reimbursement payments to the other Party in furtherance of its obligations under this Section 4.5 in accordance with the procedures set forth on Exhibit 4.5(b). It is understood that Joint Development Costs shall not include [***].

4.6 **Communications Regarding Development of Product**. Each Party agrees to keep the other Party reasonably informed as to the progress of such Party's performance of the clinical and other development activities and regulatory activities assigned to such Party (or its Affiliate) under the Development Plan, by way of updates to the JDC at its meetings and as otherwise reasonably requested.

ARTICLE V
REGULATORY MATTERS

5.1 **In General**. Avanir shall [***] to obtain Regulatory Approval for the Product in the United States, Canada and Mexico.

5.2 **Assignment of Regulatory Filings**. Promptly following the Effective Date, [***], OptiNose shall assign and cause to be assigned to Avanir IND No. 110090 and all other Regulatory Material relating to the Product in the Licensed Territory. Prior to the assignment and transfer of such IND and other Regulatory Materials, OptiNose shall maintain (and/or cause to be maintained) such IND and other Regulatory Materials and shall take all reasonable actions to make available to Avanir and/or its designee the benefits of such IND and other Regulatory Materials in the Licensed Territory, to the extent required by Avanir in connection with its activities under this Agreement. The Out-Of-Pocket Expenses incurred by OptiNose in performing its obligations under this Section 5.2 shall be shared by the Parties to the extent and as provided in Section 4.5 above.

5.3 **Responsibility for Regulatory Filings**. Following the Effective Date and subject to Section 5.4, Avanir shall be responsible for and shall [***], preparing, filing, obtaining and maintaining Regulatory Approvals for the Product in the Licensed Territory. Such activity by Avanir shall be done in consultation with the JDC and to the extent applicable, subject to the provisions of Section 5.4, and through the JDC, Avanir shall consult with OptiNose in connection with Avanir's pursuit of such activities in the United States and reasonably consider comments provided by OptiNose at the meetings of the JDC with respect thereto. Avanir shall also obtain any export approvals required by the FDA to import or export the Product to any country within the Licensed Territory. The Out-Of-Pocket Expenses incurred by Avanir in connection with preparing, filing, and obtaining Regulatory Approvals for the Product in the United States under this Article 5 shall be shared by the Parties to the extent and as provided in Section 4.5 above.

5.4 **Regulatory Cooperation**. Subject to this Section 5.4, Avanir shall be responsible for liaising with and managing all interactions with Regulatory Authorities in the Licensed Territory relating to the Product, unless otherwise agreed in writing by the Parties, [***].

(a) **Involvement of OptiNose. [***]:**

(i) [***];

(ii) [***]; and

(iii) [***].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(b) **OptiNose Right to [***] Device-Specific Regulatory Materials**. To the extent the content of any Marketing Approval Application, labeling, and/or other Regulatory Materials, for the Product in the Licensed Territory pertains specifically to the Device ("**Device-Specific Regulatory Materials**"), OptiNose shall have the right to [***] such content if OptiNose [***] that such content is reasonably likely to [***]; provided that OptiNose shall not [***] and if OptiNose does [***], upon Avanir's request, OptiNose shall promptly meet with Avanir to discuss [***]; provided further that if Avanir has not received notice from OptiNose [***] to any such Device-Specific Regulatory Materials within [***] of OptiNose's receipt of the same, OptiNose's [***] and Avanir may [***].

(c) **Cooperation and Assistance**. Without limiting Section 5.4(a) and Section 5.4(b) above: (i) Avanir shall keep OptiNose reasonably informed via the JDC as to all material interactions with Regulatory Authorities in the Licensed Territory relating to the Product; and (ii) OptiNose shall provide reasonable cooperation and assistance to Avanir in the event Avanir must respond to questions from Regulatory Authorities in the Licensed Territory concerning development activities conducted by or on behalf of OptiNose or its Affiliates involving the Device or the Product; provided that the Out-of-Pocket Expenses incurred by OptiNose in providing such cooperation to respond to questions: (A) from the FDA, shall constitute Joint Development Costs that are shared by the Parties in accordance with Section 4.5 and Exhibit 4.5(b); and (B) from a Regulatory Authority in a country of the Licensed Territory outside the United States, shall be reimbursed by Avanir.

5.5 **Clinical Safety Reporting; Pharmacovigilance.**

(a) **Clinical Safety Reporting**. As between the Parties: (a) OptiNose shall be responsible for the timely reporting of all adverse drug reactions/experiences, Product quality, Product Complaints, and safety data concerning the Product to the appropriate Regulatory Authorities in the Licensed

Territory until the transfer of the IND pursuant to Section 5.2 above; and (b) Avanir shall be responsible for the timely reporting of all adverse drug reactions/experiences, Product quality, Product Complaints, and safety data concerning the Product to the appropriate Regulatory Authorities in the Licensed Territory following the transfer of the IND pursuant to Section 5.2 above.

(b) **Pharmacovigilance Agreement**. During the Term, OptiNose shall promptly report to Avanir any Information of which it becomes aware concerning any adverse event, including any Product malfunction, side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, in or involving a research patient in a clinical trial or other person involving the Product (and if required by a Regulatory Authority, the Device) and the seriousness thereof, whether or not determined to be attributable to any Product. In conjunction with this Agreement, the Parties shall enter into a pharmacovigilance agreement consistent with the ICH guidelines, including: (i) providing detailed procedures regarding the maintenance of core safety information and the exchange of safety data relating to the Product (and if required by a Regulatory Authority, the Device) within and outside the Licensed Territory within appropriate timeframes and in an appropriate format to enable each Party to meet both its expedited and periodic regulatory reporting requirements; and (ii) ensuring compliance with the reporting requirements of all applicable Regulatory Authorities within and outside the Licensed Territory.

5.6 **Inspections**. During the Term or (if longer) as otherwise required by Law, [***], OptiNose shall permit Avanir and its representatives (and those of any Regulatory Authority and/or Third Party that Avanir requests) to enter the relevant sites of OptiNose and its contractors who were involved in the development or production of any Product or the generation of any material OptiNose Know-How, including clinical trial sites and, if applicable, manufacturing sites, during normal business hours and upon reasonable advance notice, to inspect and verify the activities related to the development and/or production of Product, including compliance with applicable Laws. Upon Avanir's request, OptiNose shall, at Avanir's expense, provide assistance in connection with any such inspection. [***].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

ARTICLE VI
COMMERCIALIZATION

6.1 **In General**. Avanir (itself or through its Affiliates or respective sublicensees) shall have the sole right and responsibility to commercialize the Product in the Licensed Territory, as provided in this Article 6, including the responsibility for all medical affairs matters relating to the Product in the Licensed Territory. Avanir shall [***], following its receipt of Regulatory Approval of such Product in each jurisdiction in the Licensed Territory, including in accordance with the Product Launch Plan for the period such plan is in effect and to the extent applicable. Avanir shall conduct all commercialization activities with respect to the Product in the Licensed Territory in compliance with applicable Laws, in all material respects.

6.2 **Product Launch Plan**.

(a) **Product Launch Plan**. No later than [***] prior to the anticipated date of the First Commercial Sale of the Product in the United States, Avanir shall prepare and provide to the JSC and OptiNose preliminary Product launch plan summarizing generally Avanir's plans for pre-commercialization activities with respect to the Product in the United States, and the commercialization of the Product in the United States for the [***] ("**Product Launch Plan**"). Without limiting the foregoing, the Product Launch Plan shall provide for [***].

(b) **Updates to the Product Launch Plan**. Avanir shall finalize the Product Launch Plan [***] prior to the anticipated date of the First Commercial Sale of the Product in the United States and shall provide such updated Product Launch Plan to OptiNose and the JSC. Thereafter, from time to time prior to [***], Avanir shall update the Product Launch Plan as necessary, and shall submit any such updated Product Launch Plan to the JSC and OptiNose; provided that, [***]. OptiNose shall have the right to review and comment upon the initial Product Launch Plan, and any such amendments to such plan, and Avanir shall reasonably consider any comments provided by OptiNose with respect thereto.

6.3 **Compliance with OptiNose Style Guide**. OptiNose shall create guidelines for Device-specific marketing materials for the Product in the United States ("**OptiNose Style Guide**") which shall include guidelines for the following content contained within Product marketing materials: [***] OptiNose shall submit the OptiNose Style Guide to Avanir for Avanir's review and comment at least [***] days prior to Avanir's anticipated submission to the FDA of an NDA for a Product and OptiNose shall use reasonable efforts to incorporate any comments Avanir may have with respect to the OptiNose Style Guide. Avanir shall ensure that its promotional activities with respect to the Device shall comply with the OptiNose Style Guide unless [***] (a) would violate applicable Laws or (b) is [***] on the commercialization of the Product in a particular country of the Licensed Territory.

6.4 **Communications Regarding Commercialization of the Product**. Avanir and OptiNose each agrees to keep the other Party reasonably informed as to the progress of the material commercialization activities with respect to the Product conducted by or under the authority of such Party in such Party's territory (i.e., for Avanir in the Licensed Territory and for OptiNose, outside the Licensed Territory), by way of updates to the JSC at its meetings and as otherwise reasonably requested[***].

ARTICLE VII
MANUFACTURE AND SUPPLY

7.1 **Transfer of Manufacturing and Supply Responsibility**. Within [***] after the Effective Date, Avanir and OptiNose shall develop and reasonably agree upon a detailed plan, including technical transfer requirements, ("**Supply Transition Plan**") to transfer to Avanir (or its designee) responsibility for manufacturing and supply of the Device and Product for commercial use (including registration batches, validation batches, pre-launch quantities and launch quantities of the Product) in the Licensed Territory by Avanir, its Affiliates and/or sublicensees by no later than [***]. OptiNose shall [***] allocate appropriate resources to effect the transfer of such responsibility in an orderly and timely manner in accordance with the Supply Transition Plan and the timelines set forth therein. The Supply Transition Plan shall also include provisions for the assignment, at Avanir's request, of OptiNose's (or its Affiliates') agreements for the manufacture and/or supply of Devices and the Product for the Licensed Territory; provided that neither OptiNose nor any of its Affiliates shall not be obligated to assign to Avanir any such agreement that is [***] in connection with OptiNose's research, development or commercialization of the Product outside the Licensed Territory or of any products other than the Product; provided further that if any such

agreements will not be assigned by OptiNose (or its relevant Affiliate) to Avanir following the Supply Transition Date, OptiNose shall (and shall cause its Affiliates to) cooperate with Avanir to provide Avanir with the benefits of its arrangements with the relevant Third Party supplier relating to the manufacture and/or supply of the Product for the Licensed Territory, until such time as Avanir has established its own arrangements with respect thereto. Without limiting the foregoing, the Supply Transition Plan shall include the provision to Avanir of all OptiNose Know-How and OptiNose Additional Intellectual Property not previously disclosed by OptiNose to Avanir hereunder and that is [***] for the manufacture of the Device and Product in accordance with the licenses granted to Avanir under this Agreement.

7.2 **Activities Prior to Supply Transition Date**. Prior to the Supply Transition Date:

(a) OptiNose shall supply to Avanir, and be responsible for obtaining supply for itself of, all units of the Device and the Product necessary for the conduct of the activities under Development Plan, [***]; and

(b) OptiNose shall maintain and manage its relationships with any Third Party suppliers of the Device and/or the Product in a manner consistent with the Supply Transition Plan to reasonably facilitate the transfer to Avanir of responsibility for manufacturing and supply of the Product for commercial use in the Licensed Territory from and after the Supply Transition Date.

7.3 **Activities After Supply Transition Date.**

(a) Within [***] after the Supply Transition Date, OptiNose shall transfer to Avanir all remaining inventory of any unfinished Product work in progress or finished Products in OptiNose's possession, or held on behalf of OptiNose, other than (i) [***] and/or (ii) [***].

(b) After the Supply Transition Date, Avanir shall supply to OptiNose, and be responsible for obtaining supply for itself of, all units of the Product necessary for the conduct of activities under the Development Plan and the commercialization of the Product in the Licensed Territory.

(c) Within [***] after the Supply Transition Date, OptiNose shall cause its Affiliate to sell, convey, assign and transfer to Avanir all right, title and interest, in and to the equipment set forth on Exhibit 7.3(c) for the [***] price set forth in Exhibit 7.3(c), which amount shall be paid by Avanir to OptiNose within [***] following the transfer of such equipment becoming effective. OptiNose will execute and deliver to Avanir on the Supply Transition Date, a general assignment and bill of sale in a mutually agreeable form and such other instruments of conveyance, assignment and transfer as Avanir may reasonably request, in each case to convey to Avanir all right title and interest in and to such equipment. To the extent such equipment is in the possession of a Third Party, OptiNose shall provide notice to such Third Party of the conveyance, assignment and transfer of such equipment to Avanir and instruct such Third Party to hold and maintain such equipment solely for the benefit of Avanir after the Supply Transition Date and not use such equipment for any purpose other than as expressly requested by Avanir.

(d) On and from the Supply Transition Date, as between the Parties and subject to OptiNose's rights under Section 2.1(b) Avanir shall have the exclusive right to manufacture the Product for distribution in the Licensed Territory.

7.4 **Supply of Product and Devices to OptiNose**. After the Supply Transition Date, the Parties shall cooperate, as mutually agreed, on the supply by Avanir (or its designee) to OptiNose of [***], pursuant to a separate supply agreement ("**Supply Agreement**"). If the Parties mutually agree, OptiNose and Avanir shall negotiate in good faith the terms of such Supply Agreement, which terms shall include the pricing of such [***] and/or such [***] to be supplied by Avanir (or its designee) to OptiNose and other commercially reasonable terms and conditions for agreements of this type.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

ARTICLE VIII
COMPENSATION

8.1 **License Fee**. Within [***] after the Effective Date, in consideration of past research and development expenses, Avanir shall pay to OptiNose an upfront fee of Twenty Million Dollars ($20,000,000) in accordance with Section 8.5 below. Such upfront fee shall be non-creditable against any other payments due hereunder.

8.2 **Milestones.**

(a) **Development Milestone Payments**. Avanir shall make the following one-time milestone payments to OptiNose based on the achievement by Avanir, its Affiliate or sublicensee (or with respect to the Successful Completion of the Head to Head Trial, the achievement by OptiNose or its Affiliates) of each of the milestone events set forth below by a Product covered by a Valid Claim (each, a "**Development Milestone**") and in accordance with Section 8.2(c) below (except as expressly provided in the table below with respect to the first Development Milestone). For clarity, each milestone payment by Avanir to OptiNose under this Section 8.2(a) shall be payable only once, regardless of the number of times achieved, and in no event shall the aggregate amount to be paid by Avanir under this Section 8.2(a) exceed Forty Million Dollars ($40,000,000).

Milestone No.	Milestone Event	Milestone Payment
1	Successful Completion of the Head to Head Trial	$10,000,000, payable as follows:

		a) (a)$2,500,000, following the achievement of such Development Milestone event; and (b)$7,500,000, following receipt of the first Regulatory Approval for such a Product in the United States; provided that, the foregoing payments (i.e., a total payment of $10,000,000) shall be made at the same time if Successful Completion of the Head to Head Trial is achieved following receipt of the first Regulatory Approval for a Product in the United States.
2	Receipt of the first Regulatory Approval for such a Product in the United States	$30,000,000

(b) **Sales Milestones Payments**. Avanir shall make the following one-time sales milestone payments to OptiNose following the end of the first Contract Year in which Annual Net Sales of Products reach the specified thresholds (each, a "**Sales Milestone**") as set forth in this Section 8.2(b); [***]. Each milestone payment by Avanir to OptiNose under this Section 8.2(b) shall be payable only once, and in no event shall the aggregate amount to be paid by Avanir under this Section 8.2(b) exceed [***].

Sales Milestone	Milestone Payment
Annual Net Sales of Products exceed [***]	[***]
Annual Net Sales of Product exceed [***]	[***]
Annual Net Sales of Product exceed [***]	[***]
Annual Net Sales of Product exceed [***]	[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(c) **Reporting and Payments**. Avanir shall notify OptiNose in writing within [***] after the achievement of each Development Milestone set out in Section 8.2(a) and within [***] after the end of the [***] in which the achievement of each Sales Milestone set out in Section 8.2(b) occurs. Within (i) [***] of the achievement of the applicable Development Milestone and (ii) [***] of the end of the [***] during which the applicable Sales Milestone was achieved, Avanir shall pay OptiNose the corresponding payments due in accordance with Section 8.5 below. Except as otherwise expressly provided herein, each payment under this Section 8.2 shall be non-creditable against any other payments due hereunder.

8.3 **Royalties.**

(a) **Royalty Rates**. Subject to Section 8.3(c) below, in consideration for the rights and licenses granted to Avanir under this Agreement, Avanir shall pay to OptiNose royalties at the rates set forth below on Net Sales of Products during the Royalty Term in each country of the Licensed Territory ("**Royalty**"); [***].

Annual Net Sales of Products	Royalty Rate
For that portion of Annual Net Sales of Products less than or equal to [***]	[***]
For that portion of Annual Net Sales of Products exceeding [***] but less than or equal to [***]	[***]
For that portion of Annual Net Sales exceeding [***]	[***]

(b) **Royalty Reports and Payment.**

(i) *Royalty Reports*. Within [***] after the [***] in which the First Commercial Sale of a Product in the Licensed Territory is made by Avanir, its Affiliate or sublicensee, Avanir shall deliver to OptiNose a report (each, a "**Royalty Report**") setting out, on a country-by-country basis:

(A) gross sales of the Product in the relevant Fiscal Quarter, and the calculation of Net Sales of Product from such gross sales; and

(B) the amount of the Royalty due to OptiNose, if any, calculated in accordance with Section 8.3(a) above.

(ii) *Royalty Payment*. Simultaneously with the delivery of each such Royalty Report, Avanir shall pay to OptiNose the Royalty, if any, due to OptiNose for the [***] covered by such report, in accordance with Section 8.5 below. If no Royalty is due for such [***], Avanir shall so report.

(c) **One Royalty**. No more than one Royalty payment shall be due under this Agreement with respect to a sale of a particular Product (e.g., even if such Product is covered by multiple Valid Claims). No Royalty shall be payable under this Section 8.3 with respect to sales or other dispositions of Products for use in [***].

(d) Avanir's obligation to pay royalties under this Section 8.3 shall continue, on a country-by-country basis, with respect to sales of Product in such country of the Licensed Territory until the Lawful Entry of the first Generic Product in such country in the Licensed Territory (and the period prior to such Lawful Entry during which Avanir is obligated to pay royalties, the "**Royalty Term**"); provided however, that Avanir shall not have any obligation to pay Royalties or any other amounts with respect to sales of Products in a particular country of the Licensed Territory during any period in which a Generic Product(s) is or are commercially available. Following the expiration of the Royalty Term in a particular country, no further royalties or milestone amounts shall be payable by Avanir, its Affiliates or sublicensees with respect to that Product in such country.

8.4 **Taxes.**

(a) **Payment of Tax**. Each Party shall be solely responsible for the payment of any and all taxes levied on its income arising directly or indirectly from the efforts of the Parties under this Agreement. If applicable Laws require that taxes be deducted and withheld from a payment made by Avanir to OptiNose pursuant to this Article 8, Avanir shall (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

authority; and (iii) send evidence of the obligation together with proof of payment to OptiNose within sixty (60) days following that payment. OptiNose shall indemnify and hold harmless Avanir against any withholding tax liability (included related penalties and interest) assessed against Avanir in connection with any payments pursuant to this Article 8.

(b) **Cooperation; Tax Residence Certificate**. The Parties shall cooperate and use Commercially Reasonable Efforts to reduce the taxes attributable to the payments made hereunder. In addition, OptiNose shall provide Avanir any tax forms that may be reasonably necessary in order for Avanir not to withhold tax or to withhold tax at a reduced rate under any applicable bilateral income tax treaty, including appropriate certification from relevant revenue authorities that OptiNose is a tax resident of a jurisdiction that is a party to such income tax treaty (a "**Tax Residence Certificate**"). Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

(c) **Assessment**. Avanir or OptiNose may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by applicable law. The other Party shall reasonably cooperate with the protesting Party, at its request and expense, in any protest by providing records and such additional information as may reasonably be necessary for such Party to pursue such protest.

8.5 **Payment Method**. Unless otherwise expressly stated in this Agreement, all amounts specified in, and all payments to be made under, this Agreement shall be in United States Dollars. Unless Avanir and OptiNose otherwise agree, all payments shall be made by wire transfer of immediately available funds in U.S. Dollars into an account designated in writing by the Party to whom such payment is due. If any currency conversion shall be required in connection with the payment of any royalties or other amounts under this Agreement, such conversion shall be made by using the average of the exchange rates for the purchase and sale of United States Dollars reported by *The Wall Street Journal* on the last business day of the Fiscal Quarter to which such Royalty or other payments relate.

8.6 **Records; Audits.**

(a) Avanir shall maintain, and shall require its Affiliates and sublicensees to maintain, complete and accurate records in sufficient detail to permit OptiNose to confirm the accuracy of (i) the calculation of Net Sales, Royalties and the achievement of Sales Milestones under this Agreement, and (ii) the calculation of Joint Development Costs incurred during the Term by Avanir or its Affiliates. Upon at least [***] prior notice, Avanir shall, and shall require its Affiliates and use reasonable efforts to require its sublicensees to, make such records available during regular business hours at such Party's principal place of business for a period of [***] from the end of the Fiscal Year to which they pertain for examination, and not more than [***] each Fiscal Year, by an independent certified public accountant from a nationally recognized firm in the United States selected by OptiNose, for the sole purpose of verifying the accuracy of the financial reports furnished by Avanir pursuant to this Agreement; provided that Avanir may require such accountant(s) to enter into a customary confidentiality agreement for arrangements of such type. Such accountants shall disclose to OptiNose, with a copy to Avanir, only whether the (A) Net Sales, Royalties and other payments hereunder are correct or incorrect; (B) whether the calculation of Joint Development Costs incurred by Avanir is accurate, and the amount of discrepancy, if any, in either case; and/or (C) if it believes in good faith that Avanir is in breach of any of its payment obligations hereunder. No other information shall be provided to OptiNose. With respect to Royalties and other payments owed to OptiNose hereunder, any amounts shown to be owed but unpaid shall be paid within [***] from the accountant's report. Any amounts shown to have been overpaid shall be refunded within [***] from the accountant's report. OptiNose shall bear the full cost of such audit unless such audit discloses an underpayment of more than [***] of the amount actually owed during the applicable Fiscal Year, in which case Avanir shall reimburse OptiNose for its out-of-pocket expenses incurred for such audit. OptiNose shall hold all information disclosed to it under this Section 8.6(a) and all Royalty Reports delivered by Avanir pursuant to Section 8.3(b) as Confidential Information of Avanir.

(b) OptiNose shall, and shall require its Affiliates to, maintain complete and accurate records in sufficient detail to permit Avanir to confirm the accuracy of Joint Development Costs incurred by OptiNose under

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

this Agreement. Upon [***] prior notice, OptiNose shall, and shall require its Affiliates to, make such records shall be available during regular business hours for a period of [***] from the end of the Fiscal Year to which they pertain for examination, and not more than [***] each Fiscal Year, by an independent certified public accountant selected by Avanir from a nationally recognized firm in the United States, for the sole purpose of verifying the accuracy of the Joint Development Costs reported by OptiNose pursuant to this Agreement; provided that OptiNose may require such accountant(s) to enter into a customary confidentiality agreement for arrangements of such type. Such accountants shall disclose to Avanir, with a copy to OptiNose, only whether: (A) the calculation of Joint Development Costs incurred by Avanir, are correct or incorrect; (B) the amount of discrepancy, if any; and (C) if it believes in good faith that OptiNose is in breach of any of its payment obligations hereunder. No other information shall be provided to Avanir. In the event the audit reveals an error in the calculation of any Joint Development Costs previously reported by OptiNose, such Joint Development Costs shall be adjusted for purposes of this

Agreement. Avanir shall bear the full cost of such audit unless such audit discloses an overstatement of more than [***] of the Joint Development Costs actually incurred by OptiNose during the applicable Fiscal Year, in which case OptiNose shall reimburse Avanir for its out-of-pocket expenses incurred for such audit. Avanir shall hold all information disclosed to it under this Section 8.6(b) as Confidential Information of OptiNose.

ARTICLE IX
INTELLECTUAL PROPERTY MATTERS

9.1 **Ownership of Device Improvements and Other Intellectual Property**

(a) Inventorship of all inventions and discoveries conceived, reduced to practice, discovered or made in the performance of activities under or pursuant to this Agreement, whether or not patentable, shall be determined in accordance with U.S. patent laws, except as otherwise expressly stated in this Agreement. Authorship of all works created, and/or any other intellectual property generated, in the performance of activities under or pursuant to this Agreement shall be determined in accordance with United States copyright laws or other applicable United States intellectual property laws, except as otherwise expressly stated in this Agreement.

(b) As between Avanir and OptiNose, OptiNose shall be the owner of all Device Improvements. Avanir agrees to assign, and hereby does assign, to OptiNose all of its and its Affiliates right, title and interest in and to any Device Improvement.

(c) As between Avanir and OptiNose, ownership of all other inventions and discoveries conceived, reduced to practice, discovered or made or created during the Term of this Agreement shall be determined consistent with inventorship, as determined pursuant to Section 9.1(a).

(d) Each Party shall execute all further instruments to document, record or perfect the Party's respective ownership consistent with this Section 9.1 as reasonably requested by the other Party.

9.2 **Prosecution and Maintenance of OptiNose Patents.**

(a) **[***]**.

(b) **[***]**.

(c) **Certain Definitions**. For purposes of this Section 9.2, "**Prosecution and Maintenance**" (including variations such as "**Prosecute and Maintain**") shall mean, with respect to a Patent, preparing, filing and doing all other lawfully permitted acts to initiate an application for and further the pre-grant/pre-issuance prosecution and post-grant/post-issuance prosecution and maintenance of a Patent. Also, as used in this Section 9.2, to "abandon" a Patent shall include deciding not to initiate or continue Prosecution or Maintenance of a Patent in the United States Patent & Trademark Office or a corresponding Governmental Authority.

(d) **Cooperation**. Each Party shall cooperate with the other Party in connection with all activities relating to the Prosecution and Maintenance of the OptiNose Patents undertaken by such other Party

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

pursuant to this Section 9.2, including: (i) making available in a timely manner any documents or information such other Party reasonably requests to facilitate such other Party's Prosecution and Maintenance of the OptiNose Patents pursuant to this Section 9.2; and (ii) if and as appropriate, signing (or causing to have signed) all documents relating to the Prosecution and Maintenance of any OptiNose Patents by such other Party. Each Party shall also promptly provide to the other Party all information reasonably requested by such other Party with regard to such Party's activities pursuant to this Section 9.2, and if requested, permit such other Party to participate, at its own expense, in any opposition, interference, appeal or similar proceeding with respect to a OptiNose Patent, to the extent the same are directed to any Product, and/or manufacturing and/or use thereof, in the Licensed Territory, so long as such actions are not adverse to the Party Prosecuting and Maintaining such Patent. All information disclosed by one Party to the other pursuant to this Section 9.2 shall be subject to the terms of Article 12 (Confidentiality).

9.3 **Enforcement.**

(a) **Notice**. In the event that OptiNose or Avanir becomes aware of any actual, possible, constructive, direct, indirect, threatened or suspected infringement or misappropriation within or outside the Licensed Territory (hereinafter referred to as "**Infringement**") of any OptiNose Patent and/or OptiNose Trademark by a Third Party ("**Infringer"**), that Party shall promptly notify the other Party in writing.

(b) **[***] Initial Control of Enforcement Actions**. [***] has the first right to initiate Infringement proceedings or take other appropriate actions against an Infringer in the Licensed Territory, at its expense. If [***] exercises such right, [***] shall use [***] to enforce the OptiNose Patents and/or OptiNose Trademarks, as applicable, against an Infringer in the Licensed Territory. In any event, [***] shall notify [***] and shall reasonably consult with [***] prior to taking any steps to enforce any OptiNose Patents and/or OptiNose Trademarks, as applicable, against an Infringer in the Licensed Territory. [***] shall have the right to participate in, including joining as a party in, any enforcement action undertaken by [***] against an Infringer in the Licensed Territory, using [***] own counsel and at [***] expense, and if [***] exercises such right of joinder, [***] shall take all necessary actions to give effect to the same. For clarity, it is understood that such right of joinder is not intended to equate to a separate right by [***] to enforce the OptiNose Patents and/or OptiNose Trademarks, as applicable (subject to Section 9.3(c) below) and, in the event, [***] exercises its right to join in an enforcement action, [***] shall not [***] in such action and shall be obligated to [***] on the terms [***]

(c) **[***] Step-In Enforcement Rights**. If within [***] of notice of an Infringement in the Licensed Territory, [***] does not initiate proceedings against an Infringer, or fails to notify [***] in writing of its intent to take timely appropriate action, against an Infringer, then [***] shall be entitled to initiate Infringement proceedings or take other appropriate action against such Infringer at its own expense.

(d) **Settlement**. Subject to this Section 9.3(d), [***] shall use [***] in connection with negotiating and entering into any settlement with an Infringer not to adversely impact [***] economic interest in the Product in a manner different from [***] (and, if any, its other licensees') economic interests in any other OptiNose product. Without limiting the foregoing, [***] shall not, [***] enter into any settlement with an Infringer, or make any admissions or assert any position in such action, that would be reasonably likely to: [***].

(e) **Recovery**. Avanir and OptiNose shall recover their respective attorneys' fees and other actual out-of-pocket expenses, or proportionate percentages thereof, associated with any actions against an Infringer undertaken pursuant to this Section 9.3 or settlement thereof from any resulting recovery made by either Party. Any excess amount of such a recovery [***]. Accordingly: (i) if OptiNose is the controlling Party with respect to any actions against an Infringer, [***]; and (ii) if Avanir is the controlling Party with respect to any actions against an Infringer, [***]. Any excess amount of such a recovery [***]. Any excess amount of such a recovery [***].

(f) **Cooperation**. Without limiting Section 9.3(b), above, the Parties shall keep one another informed of the status of their respective activities regarding any action against an Infringer, including any litigation or settlement thereof concerning an Infringement. In addition, each Party shall assist one another and cooperate in any action undertaken against an Infringer pursuant to this Section 9.3 at the other's reasonable request, and at the expense of the Party conducting such action (including joining as a party plaintiff to the extent necessary or

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

requested by the other Party). Without limiting the foregoing, in connection with any litigation against an Infringer undertaken by either Party, such Party will provide the other Party with copies of all material filings at least [***] prior to filing. The Party not taking such action shall have the opportunity to review and comment on such filings, and the Party taking such action will use reasonable efforts to incorporate the other Party's comments thereon, to the extent not inconsistent with the Party taking such action's litigation and/or defense strategy.

9.4 **Third Party Infringement Claims**. If the production, sale or use of any Product in the Licensed Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent Infringement (collectively, "**Third Party Infringement Actions**") against OptiNose or Avanir or their respective Affiliates, licensees or sublicensees, such Party shall promptly notify the other Party hereto in writing. OptiNose shall have the first right, but not the obligation, to direct and control the defense of Third Party Infringement Actions and Avanir may participate in the defense and/or settlement thereof, at its own expense with counsel of its choice; provided, however, that if the Third Party Infringement Action is filed against Avanir, OptiNose shall: (i) notify Avanir of its intention to assume control of the defense and actually initiates the defense of such Third Party Infringement Action within [***] of Avanir or OptiNose first becoming aware of the same; and (ii) indemnify and hold harmless Avanir and the Avanir Indemnitees against any Liabilities arising from such Third Party Infringement Action and/or OptiNose's control of the defense thereof, [***]. Subject to this Section 9.4 above, the Party subject to such Third Party Infringement Action shall have the first right, but not the obligation, to direct and control the defense thereof; provided, however, that the other Party may participate in the defense and/or settlement thereof at its own expense with counsel of its choice. In any event, the Party that is subject to the Third Party Infringement Action (or the Party controlling the defense of the Third Party Infringement Action, as the case may be) agrees to keep the other Party hereto reasonably informed of all material developments in connection with any such Third Party Infringement Action. The Party who is subject to the Third Party Infringement Action (or the Party controlling the defense of the Third Party Infringement Action, as the case may be) shall not, [***] settle such Third Party Infringement Action, or make any admissions or assert any position in such Third Party Infringement Action, in a manner that would be reasonably likely to: [***]. The Parties shall assist one another and cooperate in any such action at the other's reasonable request.

9.5 **Regulatory Data Protection**.

(a) To the extent required or permitted by applicable Laws in the Licensed Territory, the Parties will use [***] to promptly, accurately and completely list, with the applicable Regulatory Authorities during the Term, all applicable OptiNose Patents in the Licensed Territory, and/or any Patents covering the Product in the Licensed Territory that are Controlled by Avanir, for any Product that Avanir intends, or has begun, to commercialize in the Licensed Territory and that have become the subject of Marketing Approval Application submitted to FDA or other Regulatory Authority in the Licensed Territory, such listings to include all so called "Orange Book" listings required under the Hatch-Waxman Act and all so called "Patent Register" listings as required in Canada.

(b) In connection with such listings, the Parties will meet to evaluate and identify all applicable OptiNose Patents and Patents in the Licensed Territory that are Controlled by Avanir. OptiNose will retain final decision making authority as to the listing of all applicable Patents for any Product regardless of which Party Controls such Patent.

9.6 **Trademarks**. As between the Parties, Avanir shall own all right, title and interest in and to any trademarks other than the OptiNose Trademarks adopted by Avanir specifically for use with the Product within the Licensed Territory (such trademarks excluding any trademarks, names and/or logos related to the corporate name of Avanir or any of its Affiliates, "**Avanir Trademarks**"), and shall have the right to control the registration, filing, maintenance and enforcement thereof. Avanir shall and hereby does, grant OptiNose a non-exclusive right to use the Avanir Trademarks in connection with the sale of any Product outside of the Licensed Territory. OptiNose shall not at any time do or authorize to be done any act or thing which is likely to materially impair the rights of Avanir in any Avanir Trademark, and shall not, except for the license expressly granted herein, at any time claim any right or interest in or to such marks or the registrations or applications therefor. To the extent necessary to preserve Avanir's legal rights in the Avanir Trademarks, OptiNose shall submit representative marketing materials, packaging or

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Product displaying any Avanir Trademarks to Avanir for Avanir's review and approval prior to the first use of such marketing materials, packaging or Product and prior to any subsequent change or addition to such marketing materials, packaging or Product; [***].

9.7 **Acquisition**. OptiNose shall notify Avanir in writing within [***] of the closing of any Acquisition (as defined below). During the [***] period following its receipt of such notice from OptiNose, Avanir shall have the right to [***] upon notice to OptiNose and from and after the date of such notice [***]. Notwithstanding any other provision of this Agreement, in the event of an Acquisition, such Acquisition shall not provide Avanir with a license, rights or access to, nor shall the OptiNose IP include: (a) any [***] (collectively, the "**Acquiring Entities**") prior to the Acquisition; or (b) any [***] that such Acquiring Entities subsequently [***], or [***] or [***] under this Agreement. For purposes of this Section 9.7, "**Acquisition**" shall mean: (i) a merger involving OptiNose or OptiNose, Inc., in which the shareholders of OptiNose or OptiNose, Inc., as applicable, immediately prior to such merger cease to control (as defined in Section 1.1) OptiNose or OptiNose, Inc., as applicable, after such merger; (ii) a sale of all or substantially all of the assets of OptiNose or OptiNose, Inc., to an acquiring entity; or (iii) a sale of a controlling (as defined in Section 1.1) interest in OptiNose, Inc. to an acquiring entity.

ARTICLE X
REPRESENTATIONS AND WARRANTIES

10.1 **Mutual Representations and Warranties**. OptiNose and Avanir each hereby represents, warrants, and covenants (as applicable) to the other as follows, as of the Effective Date:

(a) **Corporate Existence and Power**. It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the rights and licenses granted by it hereunder.

(b) **Authority and Binding Agreement**. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) **No Conflict; Covenant**. Neither it nor any of its Affiliates is not a party to, and during the Term it shall not enter into, any agreement that would materially prevent it from granting the rights and licenses granted to the other Party under this Agreement or performing its obligations under the Agreement and the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement or arrangement, whether written or oral, by which it is bound.

10.2 **Additional Representations, Warranties and Covenants of OptiNose**. OptiNose represents, warrants and covenants to Avanir, on behalf or itself and its Affiliates, as follows:

(a) **Title to OptiNose IP**. OptiNose Controls all right, title and interest in and to the Patents listed on Exhibit 1.28, the trademarks listed on Exhibit 1.29 and the items existing as of the Effective Date within the OptiNose Know-How. To OptiNose's knowledge as of the Effective Date, the Patents listed on Exhibit 1.28 are the only Patents Controlled by OptiNose or its Affiliates, or in which OptiNose or its Affiliates have any rights, that are necessary to research, develop, use, practice and/or commercialize the Product in the Licensed Territory and/or to manufacture the Product and/or Device anywhere in the world. As of the Effective Date, OptiNose and its Affiliates do not have any rights in any technology or intellectual property related to the Product and/or Device that are not Controlled by OptiNose. At all times during the Term, OptiNose shall Control all rights in any technology or intellectual property related to the development, manufacture and/or commercialization of the Product and/or

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Device, such that OptiNose can fulfill all of its obligations to Avanir, and Avanir can exercise its rights, under this Agreement. For clarity, the foregoing sentence shall not limit the right of OptiNose to grant licenses to any Third Party, subject to the rights of Avanir hereunder, including pursuant to Articles II and IX of this Agreement;

(b) **No Conflicting Rights**. Neither OptiNose nor any of its Affiliates has granted, nor shall they grant during the Term, any licenses or other rights in any of OptiNose Patents, OptiNose Know-How or other OptiNose IP that conflict with the rights granted to Avanir under this Agreement or would otherwise prevent Avanir from exercising its rights or performing its obligations hereunder;

(c) **No Liens on OptiNose IP**. As of the Effective Date, the OptiNose IP is free and clear of all liens, claims, security interests or other encumbrances of any kind, and neither OptiNose nor any of its Affiliates shall permit the OptiNose IP to become encumbered by any liens, claims, security interests or other encumbrances of any kind;

(d) **Non-Infringement of OptiNose Patents by Third Parties**. As of the Effective Date, to the best of OptiNose's and its Affiliates' knowledge, there are no activities by Third Parties that would constitute Infringement of any Claims of the OptiNose Patents;

(e) **Non-Infringement of Third Party Rights**. As of the Effective Date, to the best of OptiNose's and its Affiliates' knowledge, the development, manufacture, use, or sale or other commercialization of the Product and/or Device in the Licensed Territory, and the manufacture of the Product and/or Device outside the Licensed Territory, does not infringe any claim of an issued Patent or published claim of a Patent application (as if any such published claim were issued) owned by a Third Party;

(f) **Non-Claims of Third Party Rights**. As of the Effective Date, neither OptiNose nor any of its Affiliates has received any written notice, claim or demand of any Third Party that the development, manufacture, use, or sale or other commercialization of the Product and/or Device in the Licensed Territory, or the manufacture of the Product and/or Device outside the Licensed Territory, infringes or misappropriates the intellectual property rights of such Third Party;

(g) **Non-Invalidity and Non-Unenforceability**. As of the Effective Date, (i) to the best of OptiNose's and its Affiliates' knowledge, all issued OptiNose Patents are valid and enforceable; (ii) to the best of OptiNose's and its Affiliates' knowledge, none of the OptiNose Patents are subject to any pending or threatened re-examination, opposition, interference, litigation, or other post-grant proceedings; and (iii) to the best of OptiNose's and its Affiliates' knowledge, there are no acts or omissions of OptiNose or any of its Affiliates that would (A) constitute inequitable conduct, fraud or misrepresentation with respect to any Patent application included within OptiNose Patents, or (B) render any Patent within the OptiNose Patents invalid or unenforceable in whole or in part;

(h) **Non-Action or Claim**. As of the Effective Date, there are no actual or pending, and to the best of OptiNose's and its Affiliates' knowledge, no alleged or threatened, adverse actions, suits, claims, interferences, post-grant proceedings, or formal governmental investigations, or settlements or judgments, involving the Product and/or Device, and/or the OptiNose IP by or against OptiNose or any of its Affiliates in or before any Governmental Authority. In particular, to the best of OptiNose's and its Affiliates' knowledge, there is no pending or threatened product liability or patent action involving the use or administration of the Product and/or Device;

(i) **No Payments**. As of the Effective Date, there are no royalties, fees, honoraria or other payments payable by OptiNose or any of its Affiliates to any Third Party by reason of the ownership, development, use, license, sale or disposition of the OptiNose IP or the Product and/or Device, other than salaries and sales commissions paid to employees and sales agents in the ordinary course of business;

(j) **Clinical Trials**. As of the Effective Date, there are no ongoing clinical trials related to the Product in the Licensed Territory either conducted by or on behalf of OptiNose or for which OptiNose provides supply of such Product, other than the Head to Head Trial;

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(k) **Product Marks**. As of the Effective Date, there are no product-specific brands or trademarks that have been used with any Product and/or Device, are used with any Product and/or Device, or are held and intended for use with any Product and/or Device, by OptiNose or its Affiliates, other than the Existing OptiNose Trademarks listed on Exhibit 10.2(k);

(l) **No Debarment**. In the course of the development of the Device or the Product, neither OptiNose, nor any of its Affiliates, nor their permitted contractors has been or have used any employee or consultant who has been excluded or debarred by any Regulatory Authority or subject to any exclusions or sanctions by the FDA, Office of Inspector General, or any other Governmental Authority or Regulatory Authority or professional body, or, to the best of OptiNose's and its Affiliates' knowledge, was or is the subject of debarment proceedings by a Regulatory Authority ("**Debarred Person**"). OptiNose shall immediately notify Avanir in writing if it or any of its Affiliates become, or become aware that any person or entity who participated in the development or manufacture of the Product is or becomes, a Debarred Person;

(m) **No Material Misrepresentation**. OptiNose and its Affiliates have not, nor to the best of OptiNose's and its Affiliates' knowledge, has any Third Party acting under authority of OptiNose or any of its Affiliates, made an untrue statement of a material fact to any Regulatory Authority in the Licensed Territory with respect to any Product, or intentionally failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to any Product. OptiNose and its Affiliates have, and to the best of OptiNose's and its Affiliates' knowledge, such Third Parties have complied in all material respects, and shall continue to comply in all material respects, with all regulatory requirements in the Licensed Territory with respect to the Product. All Information within the OptiNose Know-How has, to the OptiNose's and its Affiliates' knowledge, been generated in material compliance with applicable Laws, including, if applicable ICH guidelines;

(n) **Disclosure**. As of the Effective Date, to the best of OptiNose's and its Affiliates' knowledge, no material data or other Information exists which has not been disclosed by OptiNose to Avanir that would demonstrate that any Product is reasonably likely not to be approvable or otherwise is material to the transactions contemplated hereby. OptiNose has not, up through and including the Effective Date, intentionally or negligently omitted to furnish Avanir with (i) any Information in its or its Affiliates' Control or possession, or of which it or any of its Affiliates is aware, concerning any of the OptiNose IP or the activities contemplated by this Agreement, which OptiNose reasonably believes in good faith would be material to a decision by a pharmaceutical company similarly situated to Avanir to enter into this Agreement and to undertake the commitments and obligations set forth herein; and/or (ii) the identity of each product under development for the treatment of headaches, including migraine headaches, by or under the authority of OptiNose or any of its Affiliates and with respect to which an IND has been submitted anywhere in the world or being commercialized by or under the authority of OptiNose or any of its Affiliates; and

(o) **Corporate Structure**. As of the Effective Date: (i) OptiNose, Inc., a Delaware corporation with its principal place of business at 1010 Stony Hill Road, Suite 375, Yardley, PA, 19067, U.S.A. is the sole shareholder of all of the issued and outstanding capital stock of OptiNose and OptiNose US, Inc., a Delaware corporation, with its principal place of business at 1010 Stony Hill Road, Suite 375, Yardley, PA, 19067, U.S.A. and (ii) OptiNose is the sole shareholder of all of the issued and outstanding capital stock of OptiNose UK Limited, a United Kingdom corporation with its principal place of business at Berkeley House, Hunts Rise, South Marston Park, Wiltshire SN3 4TG.

(p) As of the Effective Date: (i) OptiNose, Inc. is the ultimate parent of OptiNose pursuant to Section 801.1(a)(3) of the HSR Rules; and (ii) OptiNose, Inc., including all entities which it controls directly or indirectly in accordance with Section 801.1(b) of the HSR Rules, has (A) annual net sales, as defined in Section 801.11 of the HSR Rules, less than US$141.8 million and (B) total assets, as defined in Section 801.11 of the HSR Rules, valued at less than US$141.8 million. For the purpose of this Section 10.2(p): "**HSR Act**" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976; and "**HSR Rules**" means the rules, regulations, statements, and interpretations under the HSR Act, including those promulgated under 16 C.F.R. Parts 801, 802, and 803.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

10.3 **Representations, Warranties and Covenants Regarding Third Party Agreements**. OptiNose further represents, warrants and covenants to Avanir as follows:

(a) As of the Effective Date, there are no agreements between OptiNose or its Affiliates and any Third Parties (i) pursuant to which OptiNose or its Affiliate has in-licensed any OptiNose IP in the Licensed Territory, (ii) pursuant to which OptiNose or its Affiliate obtains, or has the right to obtain, supplies of Product or otherwise related to the manufacture or supply of any Product to OptiNose or its Affiliate other than those agreements listed on Exhibit 10.3 or otherwise disclosed to Avanir prior to the Effective Date in the electronic data room, or (iii) that are otherwise necessary for Avanir to exercise its rights or perform its obligations hereunder, other than those agreements listed on Exhibit 10.3 (collectively, "Third Party Agreements"); and

(b) (i) OptiNose has provided Avanir complete and correct copies of the Third Party Agreements as the same are in effect as of the Effective Date; (ii) to the best of OptiNose's and its Affiliates' knowledge, each Third Party Agreement is in full force and effect as of the Effective Date and, to the extent not transferred to Avanir under the Supply Transition Plan, OptiNose shall (or shall cause its applicable Affiliate to) use diligent efforts to maintain and enforce such Third Party Agreement in full force and effect, in each case in accordance with its terms and conditions during the Term; (iii) as of the Effective Date, no notice of default or termination has been received or given by OptiNose or its applicable Affiliate under any Third Party Agreement; (iv) as of the Effective Date, to the best of OptiNose's and each Affiliate's knowledge, there is no act or omission by OptiNose or its applicable Affiliate that would provide a right to terminate any Third Party Agreement; and (v) during the Term, neither OptiNose nor its applicable Affiliate shall terminate, amend, waive or otherwise modify (or provide consent with respect to any termination, amendment, waiver or modification of) the rights under any Third Party Agreement that OptiNose or its Affiliates continue to hold after the Supply Transition Date in any manner that diminishes the licenses or rights granted to Avanir hereunder, requires an increase in any obligation by OptiNose hereunder with respect to the OptiNose IP or the Product and/or Device, impairs Avanir's ability to perform its obligations hereunder or otherwise adversely affects Avanir's rights hereunder; in all cases, without the prior consent of Avanir (which consent shall not be unreasonably withheld, conditioned, or delayed).

(c) Maintenance and Enforcement of Third Party Agreements. In the event of any notice of breach by OptiNose or its Affiliates, as applicable, of any Third Party Agreement, OptiNose shall immediately notify Avanir in writing. In the event of any notice of breach by the other party of the applicable Third Party Agreement in a manner that will or is likely to adversely affect Avanir's rights or obligations under this Agreement, OptiNose shall immediately notify Avanir in writing.

10.4 **Additional Representations, Warranties and Covenants of Avanir:** Avanir further represents, warrants and covenants to OptiNose as follows:

(a) **No Debarment**. In the course of developing Product, neither Avanir, nor any of its Affiliates, nor their permitted contractors will knowingly use any Debarred Person. Avanir shall immediately notify OptiNose in writing if it or any of its Affiliates become aware that any person or entity who participated in the development or manufacture of the Product and/or Device is or becomes a Debarred Person; and

(b) **No Material Misrepresentation**. Avanir and its Affiliates and its sublicensee will not knowingly make any untrue statement of a material fact to any Regulatory Authority in the Licensed Territory with respect to the Product and/or Device, nor intentionally fail to disclose a material fact required to be disclosed to any Regulatory Authority with respect to any Product and/or Device. Avanir and its Affiliates will comply in all material respects with all regulatory requirements in the Licensed Territory applicable to the Product and/or Device.

ARTICLE XI
INDEMNIFICATION

11.1 **Indemnification by OptiNose**. OptiNose shall defend, indemnify, and hold Avanir and Avanir's Affiliates and their respective sublicensees and distributors and in each case, their respective officers, directors, employees, and agents (the "**Avanir Indemnitees**") harmless from and against any and all liabilities, damages,

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

expenses, and recoveries (including court costs and reasonable attorneys' fees and expenses) (collectively, "**Liabilities**") resulting from Third Party claims, suits, proceedings, actions, and demands (collectively, "**Claims**") to the extent that such Claims arise out of, are based on, or result from: (a) the development, manufacture, storage, handling, use, promotion, sale, offer for sale, importation or other commercialization of the Product by or on behalf of OptiNose or its Affiliates or their respective licensees or distributors (other than Avanir, its Affiliates and sublicensees and their respective distributors), including injury or bodily or other product liability Claims in connection therewith; (b) a material breach of any of OptiNose's representations, warranties, or obligations under the Agreement; or (c) the willful misconduct or grossly negligent acts of OptiNose, its Affiliates, or their respective licensees or distributors (other than Avanir, its Affiliates and sublicensees and their respective distributors), or in each case, their respective officers, directors, and employees. The foregoing indemnity obligation shall not apply to the extent that the Avanir Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and OptiNose's defense of the relevant Claims is prejudiced by such failure, or to the extent that any Liability arises from, is based on, or results from (i) a material breach of any of Avanir's representations, warranties, or obligations under the Agreement; or (ii) the willful misconduct or grossly negligent acts of Avanir, its Affiliates, or their respective sublicensees or distributors, or in each case, their respective officers, directors, and employees.

11.2 **Indemnification by Avanir**. Avanir shall defend, indemnify, and hold OptiNose and OptiNose's Affiliates and their officers, directors, employees, and agents (the "**OptiNose Indemnitees**") harmless from and against any and all Liabilities resulting from Claims to the extent that such Claims arise out of, are based on, or result from: (a) the development, manufacture, storage, handling, use, promotion, sale, offer for sale, and importation of the Product by or on behalf of Avanir or its Affiliates or their respective sublicensees or distributors after the Effective Date, including injury or bodily or other product liability Claims in connection therewith (but excluding any activities conducted by or on behalf of OptiNose or any of its Affiliates prior to the Effective Date or in connection with the Development Plan or the manufacture of the Product and/or Device during the Supply Transition Period); (b) a material breach of any of Avanir's representations, warranties, or obligations under the Agreement; or (c) the willful misconduct or grossly negligent acts of

Avanir, its Affiliates, or their respective sublicensees or distributors, or in each case, their respective officers, directors, and employees. The foregoing indemnity obligation shall not apply to the extent that the OptiNose Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Avanir's defense of the relevant Claims is prejudiced by such failure, or to the extent that any Liability arises from, is based on, or results from: (i) a material breach of any of OptiNose's representations, warranties, or obligations under the Agreement; or (ii) the willful misconduct or grossly negligent acts of OptiNose, its Affiliates, or their respective licensees or distributors, or in each case, their respective officers, directors, and employees.

11.3 **Indemnification Procedures**. The Party claiming indemnity under this Article 11 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim or engage in any actions or make any statements that would adversely affect the defense or settlement of such Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money for which the Indemnified Party will be held fully harmless against. Additionally, so long as the Indemnifying Party is defending the Claim in good faith, the Indemnified Party shall not settle any such Claim or engage in any actions or make any statements that would adversely affect the defense or settlement of such Claim without the prior written consent of the Indemnifying Party, not to be unreasonably withheld.

11.4 **Limitation of Liability**. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 OR SECTION 11.2, OR DAMAGES AVAILABLE FOR (I) A PARTY'S BREACH OF [***], (II) AVANIR'S BREACH OF ITS OBLIGATIONS UNDER [***] OR OPTINOSE'S BREACH OF ITS OBLIGATIONS UNDER [***] OR (III) EITHER PARTY'S BREACH OF ITS OBLIGATIONS UNDER [***] OR OPTINOSE'S BREACH OF ITS OBLIGATIONS UNDER [***].

11.5 **Insurance**. Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which such Party has indemnification obligations under Section 11.1 or Section 11.2, and which insurance shall be primary in the event such Party is an Indemnifying Party with respect to a Claim. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11 or that the maintenance of such insurance shall not be construed to relieve either Party of its other obligations under this Agreement. Each Party shall provide the other with written evidence of such insurance, including any policy limits, upon request. Avanir shall provide OptiNose with written notice at least [***] prior to the cancellation, non-renewal or material change in any product liability insurance policy held by it, and OptiNose shall provide Avanir with written notice at least [***] prior to the cancellation, non-renewal or material change in any general commercial insurance policy held by it. Avanir shall require each sublicensee to maintain insurance consistent with the requirements of this Section 11.5.

ARTICLE XII
CONFIDENTIALITY

12.1 **Confidentiality**. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, during the Term and for a period of [***] thereafter (but with respect to any trade secrets, for such period of time as long as such information remains a trade secret), each Party agrees that it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement, any Confidential Information furnished to it by the other Party pursuant to this Agreement. The confidentiality and non-use obligations set forth above shall not apply with respect to any portion of the other Party's Confidential Information that the receiving Party can demonstrate with written evidence:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure by the disclosing Party;

(c) becomes generally available to the public or otherwise part of the public domain after its disclosure by the disclosing Party, other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement;

(d) is disclosed to the receiving Party or its Affiliate on a non-confidential basis by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the disclosing Party; or

(e) is independently discovered or developed by employees or contractors of the receiving Party or its Affiliate without access to and/or use of or reference to the other Party's Confidential Information.

12.2 **Authorized Disclosure**. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) exercising its or its Affiliates' rights under this Agreement, including in the case of Avanir, for the purpose of developing the Product, seeking, obtaining and maintaining Regulatory Approvals (including complying with the requirement of Governmental Authorities with respect to filing for, obtaining and maintaining Regulatory Approval of the Product) and manufacturing or commercializing the Product;

(b) Prosecuting or Maintaining Patents in accordance with Section 9.2;

(c) prosecuting or defending litigation or any arbitration proceedings as contemplated by this Agreement;

(d) complying with applicable Laws, including regulations promulgated by security exchanges, court order or administrative subpoenas or orders or otherwise submitting information to tax or other Governmental Authorities;

(e) disclosure to its or its Affiliates' employees, agents, consultants, contractors, licensees, sublicensees or others on a need-to-know basis, provided that in each case the recipient of such Confidential Information are bound by written obligations of confidentiality and non-use at least as restrictive in scope as those set forth in this Article 12 prior to any such disclosure; and

(f) in communication with existing and potential investors, consultants, advisors (including financial advisors, lawyers and accountants) and others on a need to know basis in order to further the purposes of this Agreement; provided that in connection with such disclosure, the disclosing Party shall inform each disclosee of the confidential nature of such Confidential Information and use reasonable efforts to cause each disclosee to treat such Confidential Information as confidential.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clause (d) of this Section 12.2, it shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order or confidential treatment limiting or preventing the required disclosure, and disclose only the minimum information necessary for such disclosure; provided that such Confidential Information disclosed accordingly shall only lose its confidentiality protection for purposes of such disclosure.

12.3 **Terms of Agreement**. Each of the Parties agrees [***], except [***]. [***] the Parties shall agree upon a mutual press release to announce the execution of this Agreement, a draft of which is attached as Exhibit 12.3, together with a corresponding Question & Answer outline for use in responding to inquiries about the Agreement; [***].

12.4 **Publication of Product Information**. Until [***], prior to its publishing, publicly presenting and/or submitting for written or oral publication a manuscript, abstract or the like that includes data generated by or under the authority of either Party in the performance of activities under the Development Plan that has not previously been published, such Party shall provide the other Party a copy thereof for its review and approval, such approval not to be unreasonably withheld, delayed, or conditioned.

12.5 **Equitable Relief**. Each Party acknowledges that its breach of this Article 12 may cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall have the right to seek, in addition to any other remedies it may have under this Agreement or otherwise, preliminary or permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article 12 by such Party.

ARTICLE XIII
TERM AND TERMINATION

13.1 **Term**. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall expire on a country by country basis upon the Lawful Entry of a Generic Product in a country in the Licensed Territory (the "**Term**"). Upon such expiration in a particular country of the Licensed Territory, the license granted to Avanir in such country of the Licensed Territory under Section 2.1 shall become a non-exclusive, fully paid-up, irrevocable and perpetual license.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

13.2 **Unilateral Termination**.

(a) **By Avanir**. Avanir shall have the right to terminate this Agreement in its entirety for any or no reason upon [***] prior written notice to OptiNose referencing this Section 13.2 at any time after [***] the Effective Date.

(b) **By OptiNose**. OptiNose shall have the right to terminate this Agreement, in the event that (i) Avanir or its Affiliates commences any Patent Challenge against OptiNose or procures or assists a Third Party to commence a Patent Challenge; or (ii) any sublicensee or co-promotion partner of Avanir with respect to the Product commences any such Patent Challenge, and within [***] following the commencement thereof, such Patent Challenge is not withdrawn or Avanir does not terminate its sublicense or co-promotion agreement with such party who commenced such Patent Challenge. For purposes of this Section 13.2(b), a "**Patent Challenge**" means any legal or administrative proceeding to revoke or challenge the validity of any of the OptiNose Patents, other than (i) a counterclaim [***], or (ii) a declaratory action proceeding [***].

13.3 **Termination for Breach**. Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if the other Party materially breaches its obligations under this Agreement and, after receiving written notice referencing this Section 13.3 and identifying such material breach in reasonable detail, fails to cure such breach within [***] from the date of such notice; *provided that* if the Party alleged to be in breach disputes such breach, in good faith, by written notice to the other Party within [***] following receipt of the notice of breach, then the non-breaching Party shall not have the right to terminate this Agreement pursuant to this Section 13.3 unless and until it has been determined in accordance with

Article 14 below that this Agreement, was materially breached, and the breaching Party fails to comply with its obligations hereunder within [***] after such determination. [***].

13.4 **OptiNose Rights upon Early Termination of the Agreement**. Upon the early termination of this Agreement in its entirety by either Party under Section 13.2 or Section 13.3 above, all licenses granted to Avanir under Section 2.1 shall terminate (it being understood that Avanir may continue to exercise such licenses on a non-exclusive basis after the effective date of any such termination to the extent necessary for Avanir to fulfill its obligations under this Section 13.4) and the following shall apply:

(a) **Regulatory Materials**. To the extent not prohibited by applicable Laws, Avanir shall promptly transfer and assign to OptiNose, in all events during the Wind-Down Period, all Regulatory Materials and Regulatory Approvals for the Product in the Licensed Territory;

(b) **Avanir License**. In the event this Agreement is terminated by Avanir pursuant to Section 13.2(a) or by OptiNose pursuant to Section 13.2(b) or Section 13.3 (but not if this Agreement is terminated by Avanir pursuant to Section 13.3), Avanir hereby grants to OptiNose, a [***] license (including the right to grant and authorize sublicenses) under any [***] Controlled by Avanir or its Affiliates (or its sublicensees) [***] for OptiNose to assume development and/or commercialization in the Licensed Territory of the Product then being marketed by Avanir, in each case solely (i) to develop, use, sell, offer for sale, have sold, import and otherwise commercialize such Product in the Licensed Territory or (ii) to make or have made such Product anywhere in the world; provided that OptiNose agrees not to exercise its rights under such license unless and until this Agreement is terminated by Avanir in accordance with [***] or by OptiNose in accordance with [***]. In the event of any such termination of this Agreement after [***], in consideration of the license granted under this Section 13.4(b), OptiNose shall pay to Avanir a royalty of [***] of the Net Sales of the Product by OptiNose, its Affiliates and (sub)licensees of the Product until such time as the aggregate royalties so paid by OptiNose to Avanir hereunder equal [***]. For such purposes, the provisions of Sections 1.21, 8.3(b), 8.3(c) and 8.3(d), 8.4, and 8.6(a), shall apply *mutatis mutandis*.

(c) **Transition Assistance**. In the event this Agreement is terminated by Avanir pursuant to Section 13.2(a) or by OptiNose pursuant to Section 13.2(b) or Section 13.3 (but not if this Agreement is terminated by Avanir pursuant to Section 13.3), during the Wind-Down Period, Avanir shall [***] provide such assistance as may be [***] by OptiNose or its designee, to transfer and/or transition over to OptiNose all then-existing

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

commercial contractual arrangements that are necessary for OptiNose to commence or continue developing, manufacturing or commercializing the Product then being marketed by Avanir, its Affiliates or sublicensees, in the Licensed Territory, including transferring, upon request of OptiNose, any agreements or arrangements with Third Party suppliers or vendors to develop, manufacture, supply, distribute or sell or otherwise commercialize such Product in the Licensed Territory. To the extent that any contract between Avanir and a Third Party is not assignable to OptiNose, then Avanir shall reasonably cooperate with OptiNose to arrange to continue to provide such services for a reasonable time after termination, but in no event longer than the Wind-Down Period. In the event that the Agreement is terminated by OptiNose in accordance with Section 13.2(b) or Section 13.3, Avanir shall provide the assistance described in this Section 13.4(c) [***]; and

(d) **Remaining Inventories; Capital Equipment**. OptiNose shall have the right to purchase from Avanir (i) any and all of the inventory of such Product held by Avanir as of the effective date of such termination at a price equal to the actual cost of Avanir to acquire or manufacture such inventory, plus reasonable and actual Third Party shipping and handling fees (or in the case of Avanir's termination of this Agreement pursuant to Section 13.3, at a price equal to [***], and (ii) any capital equipment specific to the Product owned by Avanir at [***]. Promptly after the effective date of such termination, Avanir shall submit to OptiNose a detailed list of its remaining inventory of such Product and such Product-specific capital equipment. OptiNose shall notify Avanir whether OptiNose elects to exercise its rights under this Section 13.4(d) within [***] after receiving the notice from Avanir reporting such inventory and capital equipment as of the effective date of such termination. If OptiNose does not exercise such right, then subject to Article 8 hereof, Avanir shall have the right to sell or otherwise dispose of the Product-specific capital equipment at any time and to sell any such remaining inventory over a period of no greater than the Wind-Down Period, provided that Avanir shall continue to pay Royalties on such sales of inventory in accordance with Section 8.3.

(e) **Sublicenses**. Any contracts with sublicensees of the Product in the Licensed Territory engaged by Avanir, other than Avanir's Affiliates, shall [***]. In the event [***], then the rights of such sublicensees shall [***]. Avanir shall ensure that its Affiliates and such sublicensees (if not assigned to OptiNose pursuant to this Section 13.4(e)) shall [***].

13.5 **Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by OptiNose, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any non-U.S. equivalent thereof (including Norwegian bankruptcy law, if and to the extent the same is applicable), licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Avanir, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any such non-U.S. equivalent thereof. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against OptiNose or OptiNose, Inc. under the U.S. Bankruptcy Code or any applicable non-U.S. equivalent thereof (including, under Norwegian bankruptcy law, if and to the extent the same is applicable), Avanir shall have the right to retain any and all rights licensed to it hereunder, to the maximum extent permitted by Law (such as under Sections 365(n)(1) and 365(n)(2) of the U.S. Bankruptcy Code or any such non-U.S. equivalent thereof), subject to any royalties due to OptiNose as specified hereunder, and be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Avanir's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by Avanir, unless OptiNose (or OptiNose, Inc.) elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by OptiNose (or OptiNose, Inc.) upon written request therefor by Avanir.

13.6 **Survival**. Upon expiration or termination of this Agreement in its entirety for any reason, this Agreement shall, except as otherwise provided herein, be of no further force and effect and neither Party shall have any further liability hereunder. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration; provided that [***]. Notwithstanding anything to the contrary, the following provisions shall survive any termination or expiration of this Agreement in its entirety for the period of time specified: Articles [***] and Sections [***].

13.7 **Nonexclusive Remedy**. Exercise of any right of termination afforded to either Party under this Agreement: (a) shall not prejudice any other legal rights or remedies either Party have against the other in respect of any breach of the terms and conditions of this Agreement; and (b) shall be without any obligation or liability arising from such termination other than such obligations expressly arising from such termination.

ARTICLE XIV
DISPUTE RESOLUTION

14.1 **Disputes**. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to arbitration or litigation. To accomplish this objective, and except for any Committee disputes which shall be resolved in accordance with the procedures set forth in Section 3.6 above, the Parties agree to follow the procedures set forth in this Article 14 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, including any subsequent amendments, or the validity, enforceability, construction, performance or breach hereof (and including the applicability of this Section 14.1 to any such controversy or claim), if and when a dispute arises under this Agreement.

14.2 **Initial Escalation**. Except for any Committee disputes which shall be resolved in accordance with the procedures set forth in Section 3.6 above and except as permitted under Section 14.4 and Section 14.5, with respect to all other disputes arising between the Parties under this Agreement, including with respect to the interpretation, performance under, enforcement, termination or invalidity of this Agreement, if the Parties are unable to resolve such dispute within fifteen (15) days after such dispute is first identified by either Avanir or OptiNose in writing to the other, either Party shall have the right to refer such dispute to the [***] of Avanir and OptiNose for attempted resolution by written notice to the other Party referencing the particular dispute and this Section 14.2. In such case, the [***] (or an authorized representative designated by a Party's [***]) shall have good faith negotiations within [***] after such notice is received, including, if requested by either Avanir or OptiNose, at least one (1) in person meeting of the [***] (or their respective authorized representatives) within [***] after such notice is received. If the [***] (or their respective authorized representatives) should resolve such dispute, a memorandum setting forth their agreement will be prepared and signed by both Avanir and OptiNose if requested by either Party. In all events, the Parties shall cooperate in an effort to limit the issues for consideration in such manner as narrowly as reasonably practicable in order to resolve the dispute.

14.3 **Binding Arbitration**. If the [***] (or their respective authorized representatives) are not able to resolve such dispute referred to them under Section 14.2 pertaining to the interpretation, performance under, enforcement, termination or invalidity of this Agreement, within such [***] period, such dispute shall be resolved through final, binding and non-appealable arbitration, which arbitration may be initiated by either Avanir or OptiNose by written notice to the other Party referencing the particular dispute and this Section 14.3 at any time after the conclusion of such [***] period, on the following basis:

(a) The place of arbitration shall be Orange County, CA, U.S.A., if such arbitration is initiated by OptiNose and Philadelphia, PA, U.S.A., if such arbitration is initiated by Avanir. All arbitration proceedings and communications shall be in English.

(b) The arbitration shall be conducted by the Judicial Arbitration and Mediation Services, Inc. (or any successor entity thereto) ("JAMS") under its rules of arbitration then in effect ("Rules") and, to the extent not inconsistent with the Rules, the Federal Arbitration Act, in each case, except as modified in this Agreement.

(c) The arbitration shall be conducted by a single arbitrator who is mutually agreed to by the Parties and is (i) significantly experienced with Delaware law; and (ii) has senior management and or legal/judicial experience. If the Parties are unable to agree upon the selection of an arbitrator within [***], then the arbitrator shall be selected in accordance with the Rules; provided however, that no potential arbitrator shall be appointed unless he or she has agreed in writing to abide and be bound by the provisions in this Article 14. The arbitrator shall engage

any independent experts with experience in the subject matter of the dispute as reasonably necessary to advise the arbitrator.

(d) Time is of the essence in the initiation and completion of the arbitration, and the Parties and the arbitrator shall use all reasonable efforts to complete any such arbitration (including receiving the final award from such arbitrator) within [***] from the issuance of notice of a referral of any such dispute to arbitration. The arbitrator shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time which the Parties must expend for discovery; provided that the arbitrator shall permit such discovery as he or she deems necessary to permit an equitable resolution of the dispute.

(e) Unless clearly erroneous or arbitrary and capricious, the Parties agree that the decision of the arbitrator shall be the sole, exclusive and binding remedy between them regarding the dispute presented to the arbitrator. Notwithstanding Section 15.13 below, any decision of the arbitrator may be entered in a court of competent jurisdiction for judicial recognition of the decision and an order of enforcement, including, for the avoidance of doubt, a court of competent jurisdiction located outside the United States.

(f) Disputes or claims subject to arbitration pursuant to this Section 14.3 include disputes or claims regarding the applicability of this Section 14.3 or the validity of this Agreement (but excluding disputes or claims under Section 14.3(h) or Section 14.4).

(g) The arbitrator's decision shall include the Parties' relative responsibilities with respect to the expenses of the arbitration, including each Party's responsibility regarding the cost of the arbitration filing and hearing fees, the cost of any independent expert retained by the arbitrator, and the cost of the arbitrator and administrative fees of JAMS. Except as specifically provided in the foregoing sentence, each Party shall bear its own costs and attorneys' and witnesses' fees and associated costs and expenses.

(h) Pending the selection of the arbitrator or pending the arbitrator's determination of the merits of any dispute, either Party may seek appropriate interim or provisional relief from any court of competent jurisdiction, as provided in Section 15.13 below, as necessary to protect the rights or property of that Party.

(i) The arbitration proceedings and the decision of the arbitrator shall not be made public without the joint consent of the Parties and each Party shall maintain the confidentiality of such proceedings and decision unless the Parties otherwise agrees in writing; provided that either Party may make such disclosures as are permitted for Confidential Information of the other Party under Article 12 above.

(j) In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable statute of limitations; provided that such limitation shall be tolled as of the date a Party notifies the other Party of such dispute, controversy or claim pursuant to this Article 14.

14.4 **Patent and Trademark Dispute Resolution**. Any dispute, controversy or claim relating to the scope, validity, enforceability or Infringement of any Patent covering the manufacture, use, sale, import or other exploitation of the Product, or any trademark rights relating to the Product, shall be submitted to a court of competent jurisdiction as provided in Section 15.13.

ARTICLE XV
MISCELLANEOUS

15.1 **Entire Agreement; Amendment**. This Agreement, including the Exhibits hereto, which are incorporated by reference herein, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach,

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

prior to the Effective Date, by the other Party of its obligations pursuant to the Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 **Force Majeure**. A Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party referencing this Section 15.2. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the affected Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances).

15.3 **Notices**. Any notice required or permitted to be given under this Agreement shall be in English in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes: (a) when received, if hand-delivered or sent by a reputable international courier service; or (b) upon receipt as evidenced by the date on the return receipt, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested; or (c) when transmitted by facsimile (complete transmission confirmed) or as a PDF attachment to an email (with response email confirming receipt) and followed with a copy by first class certified or registered airmail, postage prepaid, return receipt requested.

If to OptiNose or OptiNose, Inc.:

OptiNose AS
Pb 288 Roa, 0702
Oslo
NORWAY
Attn: Chief Executive Office
Email: [***]

With a copy to:

OptiNose, Inc.
1010 Stony Hill Road, Suite 375
Yardley, Pennsylvania 19067
U.S.A.
Attn: Chief Executive Officer
Email: [***]

With a copy (which shall not constitute notice) to:

Hogan Lovells US LLP
100 International Drive, Suite 2000

Baltimore, Maryland 21202
U.S.A.
Attn: Asher M. Rubin
Email: [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

If to Avanir:

Avanir Pharmaceuticals, Inc.
20 Enterprise, Suite 200
Aliso Viejo, CA 92656
U.S.A.
Attn: Vice President Legal Affairs
Phone: +1 (949) 389-6700
Fax: +1 (949) 389-6701
Email: [***]

and

Avanir Pharmaceuticals, Inc.
20 Enterprise, Suite 200
Aliso Viejo, CA 92656
U.S.A.
Attn: Senior Vice President and Chief Business Officer
Phone: +1 (949) 389-6700
Fax: +1 (949) 389-6701
Email: [***]

With a copy (which shall not constitute notice) to:

Wilson Sonsini Goodrich & Rosati PC
650 Page Mill Road
Palo Alto, California 94304-1050
U.S.A.
Attn: Kenneth A. Clark, Esq.
Miranda Biven, Esq.
Email: [***]

15.4 **No Strict Construction; Headings**. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

15.5 **Assignment**. Except as permitted under Section 15.6, neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that (a) a Party may make such an assignment or transfer of this Agreement in its entirety, without the other Party's consent, to any Affiliate; (b) Avanir may make such assignment or transfer of this Agreement in its entirety, without OptiNose's consent, to a successor to substantially all of the assets or business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or any other transaction; and (c) OptiNose may make such assignment or transfer of this Agreement in its entirety, without Avanir's consent, to a successor to substantially all of the assets or business of OptiNose AS and OptiNose, Inc., whether in a merger, sale of stock, sale of assets or any other transaction . Any such assignment or transfer to an Affiliate or a permitted successor or assignee of rights and/or obligations hereunder shall be subject to such Affiliate or permitted successor or assignee and the assigning Party(ies) providing written notice to the other Party, and the expressly assuming performance by the permitted successor or assignee of such rights and/or obligations. Any permitted assignment or transfer shall be binding on the permitted successors of the assigning Party. OptiNose shall not assign any OptiNose IP to any entity other than an entity to whom OptiNose also assigns this Agreement in its entirety in accordance with the terms of

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

this Section 15.5. Any assignment, transfer or attempted assignment or transfer by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

15.6 **Performance by Affiliates**. Each Party may discharge any obligations and exercise any rights hereunder through any of its Affiliates without the other's consent, provided that each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance, and in the case of OptiNose, upon Avanir's reasonable request, OptiNose shall notify Avanir of the identity of the Affiliate and the activities or obligations hereunder that will be, or are being,

performed by such Affiliate. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

15.7 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary in order to carry out the express purposes and intent of this Agreement.

15.8 **Severability**. If any one or more of the provisions of this Agreement is held to be invalid, illegal, or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provisions shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid, illegal, or unenforceable provision with a valid, legal, and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.9 **No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver referencing this Agreement and the particular matter and particular period of time for which the waiver is given.

15.10 **Independent Contractors**. Avanir (on the one hand) and OptiNose (on the other hand) shall act solely as independent contractors, and nothing in this Agreement shall be construed to give Avanir (on the one hand) or OptiNose (on the other hand)the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

15.11 **No Third Party Beneficiaries**. None of the provisions of this Agreement shall be for the benefit of, or enforceable by, any Third Party, including any creditor of either Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

15.12 **English Language; Governing Law**. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the Laws of the State of Delaware, U.S.A., without giving effect to any choice of law principles that would require the application of the Laws of a different jurisdiction, except for disputes governed by Section 14.4 where federal law governing intellectual property rights controls. The U.N. Convention on the Sale of Goods shall not apply to this Agreement.

15.13 **Exclusive Jurisdiction**. Subject to Article 14 above, each of the Parties (i) irrevocably consents to the exclusive jurisdiction and venue in the Delaware Court of Chancery within the State of Delaware (or, if the Delaware Court of Chancery declines to accept jurisdiction over a particular matter, any court of the United States located in the State of Delaware, or, if any such court of the United States located in the State of Delaware declines to accept jurisdiction over a particular matter, any state court located in the State of Delaware) and (ii) agrees that process shall be served upon such Party in the manner set forth in Section 15.3 above, and that service in such manner shall constitute valid and sufficient service of process. Each Party waives and covenants not to assert or

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

plead any objection that such Party might otherwise have to such jurisdiction, venue, and process. Subject to Article 14 above, each Party hereby agrees not to commence any legal proceedings relating to or arising out of this Agreement or the transactions contemplated hereby in any jurisdiction or courts other than as provided herein.

15.14 **Counterparts; PDF or Facsimile Signatures**. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed through electronic (including .pdf) or facsimile transmitted counterparts.

[Signatures on Following Page]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Effective Date.

AVANIR PHARMACEUTICALS, INC.		**OPTINOSE AS**	
By:	/s/ Keith A. Katkin	By:	/s/ Peter K. Miller
Name:	Keith A. Katkin	Name:	Peter K. Miller
Title:	President and Chief Executive Officer	Title:	CEO

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 1.28

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 1.29

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 4.1

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 4.3

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 4.5(a)

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 4.5(b)

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 7.3(c)

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 9.2

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 10.2(k)

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 10.3

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 12.3

Avanir Pharmaceuticals and OptiNose Announce Development and Commercialization Agreement for Breath Powered Nasal Sumatriptan Product for the Treatment of Migraine

New Drug Application (NDA) Filing Expected by End of 2013

ALISO VIEJO, Calif. and YARDLEY, Pa.—June XX, 2013—Avanir Pharmaceuticals, Inc. (NASDAQ: AVNR) and OptiNose AS today announced that the companies have entered into an exclusive North American license agreement for the development and commercialization of OptiNose's novel, Breath Powered™ nasal delivery device containing sumatriptan powder (Avanir "AVP-XXX") to treat acute migraine headache.

Under the terms of the agreement, OptiNose received an upfront cash payment of $20 million and is eligible to receive certain shared development costs and up to an additional $90 million linked to the achievement of future clinical, regulatory and commercial milestones. In addition, Avanir will make tiered royalty payments based on net sales in North America.

"OptiNose has developed a unique device that we believe can significantly improve upon the current treatment options for migraine," said Greg Flesher, senior vice president of corporate development and chief business officer of Avanir Pharmaceuticals. "This easy to use device provides a rapid onset of action using 85% less drug than the standard of care to relieve headache pain associated with moderate to severe migraines."

"Avanir has a proven track record of successfully developing and commercializing neuroscience products," said Peter Miller, chief executive officer of OptiNose. "Our research has proven that OptiNose's novel Breath Powered device delivers medicine into the targeted, deep nasal regions better than traditional nasal sprays. So we believe this new delivery method offers significant benefits in many medical conditions with high unmet clinical needs, including migraine headache. We look forward to working with the Avanir team to bring an important new treatment to people who continue to suffer with migraines."

Under the terms of the agreement, Avanir will assume responsibility for commercialization, manufacturing and supply chain activities for AVP-XXX for migraine treatment. OptiNose will retain responsibility for the completion of ongoing clinical trials and additional research and development to support a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA).

In the United States, approximately 13 million prescriptions are written annually for triptans. Sumatriptan has a market share of nearly 50% of this class of medications, making it one of the most commonly prescribed migraine drugs.* If approved, the OptiNose Breath

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Powered sumatriptan product would be the first and only fast-acting, dry-powder nasal delivery form of sumatriptan.

About OptiNose Breath Powered Delivery Technology

OptiNose's Breath Powered delivery (BPD) technology is unique in that it uses the natural function of a user's breath to propel medications beyond the nasal valve into the deep, targeted areas of the nasal cavity more effectively, efficiently and consistently than current treatment approaches. A user exhales into the device, creating a naturally balanced closure of the soft palate and sealing off the nasal cavity completely. The exhaled breath carries medication from the device into one side of the nose through a sealing nosepiece. Narrow nasal passages are gently expanded and medication is transported well beyond the nasal valve to targeted sites. After delivering medication to the targeted sites, air painlessly flows around to the opposite side of the nasal cavity and exits through the other side of the nose rather than into the throat or lungs. For more information about Breath Powered delivery technology and its capabilities, please click on the link below.

To view the multimedia content associated with this release, please click: http://www.multivu.com/players/English/57713-optinose-innovative-breath-powered-nasal-delivery-technology-delivers-drugs-to-treat-variety-of-medical-conditions/

About AVP-XXX

AVP-XXX is an investigational drug-device combination product consisting of low-dose sumatriptan powder delivered intranasally utilizing OptiNose's novel breath powered nasal delivery technology.

About Avanir Pharmaceuticals, Inc.

Avanir Pharmaceuticals, Inc. is a biopharmaceutical company focused on bringing innovative medicines to patients with central nervous system disorders of high unmet medical need. As part of our commitment, we have extensively invested in our pipeline and are dedicated to advancing medicines that can substantially improve the lives of patients and their loved ones. For more information about Avanir, please visit www.avanir.com.

About OptiNose

OptiNose is a drug delivery company developing a breakthrough Breath Powered nasal technology set to transform the static nasal drug delivery market. OptiNose devices are designed to reliably deliver nasal medication to target regions of the nasal cavity, including the sinus and olfactory regions, while preventing lung deposition. The simple devices are intended to unlock the potential for significant new benefits, including better local activity, better systemic bioavailability and pharmacodynamics and for "nose-to-brain" delivery for treating neurologic and psychiatric disorders.

OptiNose has created single and multi-use nasal devices for delivering both liquid and powder formulations. The strongly patent-protected technology has been successfully tested in a

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

---

number of clinical trials evaluating the advantages of the technology compared to traditional nasal sprays. OptiNose is actively developing internal products using the new technology, which is also available to license for delivery of proprietary medicines. Investors in OptiNose include Avista Capital Partners in New York, WFD Ventures LLC located in New York and Entrepreneurs Fund LP based in Jersey, Channel Islands. For more information please visit www.optinose.com.

---

*IMS NPA Month/Year

Forward Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Avanir's plans, potential opportunities, financial or other expectations, projections, goals objectives, milestones, strategies, market growth, timelines, legal matters, product pipeline, clinical studies, product development and the potential benefits of its commercialized products and products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the risks and uncertainties associated with Avanir's operating performance and financial position, the market demand for and acceptance of Avanir's products domestically and internationally, research, development and commercialization of new products domestically and internationally, obtaining additional indications, obtaining and maintaining regulatory approvals domestically and internationally, and other risks detailed from time to time in the Company's most recent Annual Report on Form 10-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. These forward-looking statements are based on current information that

may change and you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.

Avanir Investor & Media Contact
Ian Clements, PhD
ir@avanir.com
+1 (949) 389-6700

OptiNose Media Contact
David Barton
david.barton@hkstrategies.com
+1 (212) 885-0432

###

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "Agreement") is made this, July 1, 2017 (the "Effective Date"), by and between Hovione Inter Ltd, Bahnhofstrasse 21, CH-6000 Lucerne 7, Switzerland ("Hovione"), and OptiNose US Inc., 1020 Stony Hill Road, Ste 300 Yardley, PA 19067, USA ("OptiNose US") — including its Affiliates, OptiNose AS ("OptiNose Norway") and OptiNose UK Ltd. ("OptiNose UK", and collectively, "OptiNose"). Hovione and OptiNose are each sometimes referred to herein as a "Party" and together as the "Parties."

WHEREAS, OptiNose desires to acquire fluticasone propionate micronized (the "API") from Hovione in accordance with the requirements of this Agreement including the Specifications set forth in Exhibit A hereto, which OptiNose intends to incorporate into the finished drug/device combination exhaler product known as OPN-375 ("Finished Product") as described more particularly in various OptiNose documents including the pending New Drug Application applicable thereto, which Finished Product is to be produced at an external contract manufacturing organization ("CMO"); and

WHEREAS, Hovione is willing to supply such API for OptiNose's use under the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the promises and the mutual covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree and covenant as follows:

1. Definitions.

1.1 "Active Pharmaceutical Ingredient" or "API" shall have the meaning given such term in the preamble hereof.

1.2 "Adverse Event" shall mean any undesirable experience in a patient associated with, related to or could reasonably affect the OptiNose application or approval or the manufacture of the API or Finished Product hereunder.

1.3 "Affiliate" shall mean any entity controlling, controlled by or under common control with either Party hereto. For purpose of this definition, "control" shall mean ownership of over fifty percent (50%) of the equity capital, the outstanding voting securities or other ownership interest of an entity, or the right to receive over fifty percent (50%) of the profits or earnings of an entity. In the case of non-stock organizations, the term "control" shall mean the power to control the distribution of profits.

1.4 "Applicable Law" shall mean the FD&C Act, and all other laws, regulations (including cGMP), rules and guidelines of any relevant Regulatory Agency (whether Federal, State, municipal or other, in the U.S., European Union, Japan, and any other country where the API is manufactured by or on behalf of Hovione) pertaining to the development, manufacture, packaging, labeling, storage, import, export, distribution, marketing, sale and/or intended use of the API or the Finished Product.

1.5 "Batch Record" shall mean a batch manufacturing record, prepared according to applicable cGMP guidelines, for every production batch of API.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.6 "Confidential Information" shall mean all the technical information, whether tangible or intangible, including (without limitation) any and all specification data, techniques, discoveries, inventions, processes, know-how, patents, patent applications, inventor certificates, trademarks, trade names, other intellectual property information, trade secrets, methods of production and other proprietary information, that either Party or its Affiliates have ownership rights to (as either owner, licensee or sub-licensee), or may hereafter obtain rights.

1.7 "Current Good Manufacturing Practices" or "cGMP" shall mean current Good Manufacturing Practice as set forth in the FD&C Act, as well as current good manufacturing practices applicable to the API, or the making thereof at Hovione's manufacturing facility, set forth by any applicable Regulatory Agency.

1.8 "Defect" with respect to the API shall mean failure of the API to comply with the Product Specifications and/or Applicable Law.

1.9 "DMF" shall mean Drug Master File

1.10 "FDA" shall mean the United States Food and Drug Administration, and any successor thereto.

1.11 "FD&C Act" shall mean the United States Food, Drug and Cosmetic Act, as amended, and includes the rules and regulations promulgated thereunder.

1.12 "Finished Product" shall have the meaning given to such term in the recitals.

1.13 "Firm Forecast" shall have the meaning given to such term in Section 3.2 hereof.

1.14 "GDUFA" shall mean the Generic Drug User Fee Act, as implemented by the US FDA

1.15 "Initial Term" shall have the meaning assigned to such term in Section 10.1.

1.16 "Product Specifications" shall have the meaning given to such term in Section 2.1(b) hereof.

1.17 "Quality Agreement" shall mean that certain Quality Assurance Agreement, dated of even date herewith, by and between OptiNose and Hovione, which sets forth (a) the roles and responsibilities of the Parties with respect to the quality assurance for the API and (b) how the Parties' quality operations shall interact with each other in connection with the same, and which, subject to the terms and conditions of the Entire Agreement clause in Section 13.3 hereof is incorporated by reference herein as if fully set forth at length.

1.18 "Regulatory Agency" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the API or the Finished Product, including, without limitation, the FDA in the US and the Applicable Regulatory agencies in the EU (including, but not limited to, EMA), Japan (including, but not limited to, PDMA) and any other country where the Finished Product is manufactured or sold,

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

and/or where API is manufactured, delivered, distributed, or sold by, or on behalf of Hovione and/or or on behalf of OptiNose hereunder.

1.19 "Serious Adverse Event" shall mean a product complaint of a serious or life threatening nature, the need for, results of or information relating to a recall, withdrawal, warning, inspection, hold, or other regulatory action or which is related to or could reasonably affect the OptiNose application or approval or the manufacture of the API or Finished Product hereunder.

2. Manufacture and Sale.

2.1. Supply. During the term of this Agreement and subject to the terms and conditions set forth herein, OptiNose shall purchase [***] API [***] from Hovione, and Hovione shall manufacture and supply API to OptiNose (or a third party designated by OptiNose) in such quantities as from time to time may be ordered by OptiNose in accordance with the applicable forecast and purchase orders provided by OptiNose pursuant to Section 3.2. During the term of this Agreement, Hovione shall [***].

(a) If OptiNose provides written notice [***].

(b) Product Specifications. The specifications of the API as set out in Hovione's US DMF are set forth in Exhibit A to this Agreement (the "Product Specifications"); as such Exhibit may be amended in accordance with the terms of the Quality Agreement and Section 4.1 hereof.

2.2. Costs. Hovione shall be responsible for [***] related to the submission and maintenance of a US DMF, Japanese DMF, or European CEP for the API, which Hovione represents are already prepared and on file. Any other foreign DMFs or CEPs, etc. applicable to regulatory authorities outside of the foregoing territories may be chargeable by Hovione to OptiNose (pro rata with any other entities to which Hovione does or may in the future supply API pursuant to such DMF or CEP, etc.) to the extent that Hovione has not previously prepared and filed such a DMF or CEP, etc. and must undertake [***] to complete same for such territory in order to comply with the requirements of this Agreement. Any additional technical work, documents, data or materials requested by Optinose beyond what is already contemplated in an existing DMF or CEP, etc. may also be chargeable by Hovione. Both parties agree to the regular and timely payment of their respective GDUFA fees to the US FDA.

3. Price, Orders and Terms of Payment.

3.1. Pricing. The transfer price for the API shall be as set forth on Exhibit B hereto, as the same may be amended from time to time by mutual agreement of the Parties subject to the limits in Exhibit B. All sums shall be expressed in and payable in UNITED STATES DOLLARS.

3.2. Forecasting. For each calendar year during the term of this Agreement, OptiNose shall submit a [***] ([***]) month rolling forecast updated on a quarterly basis, broken down on a quarterly basis covering OptiNose's anticipated requirements of API, each such forecast to be provided to Hovione at least [***] ([***]) days prior to the start of the relevant [***] ([***]) month period, except in the case of the first forecast which shall be delivered at a time mutually agreed upon by the Parties. The first [***] ([***]) months of each rolling forecast shall be a binding order (the "Firm Forecast"), and the last [***] ([***]) months will be for information purposes only and non-binding. For the [***] ([***]) month period of the Firm Forecast, OptiNose shall provide the forecasted volume by month, however OptiNose may adjust the monthly volumes taken provided that at least the total volume forecast is purchased over this [***] ([***]) month period. OptiNose shall place all purchase orders with Hovione at least [***] ([***])[***] in advance of required delivery

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

to OptiNose, except in the situation where the requirement exceeds [***] in which case purchase orders shall be placed at least [***] ([***]) days in advance of the required delivery to Optinose. Within [***] ([***]) days of receipt of a purchase order, Hovione shall acknowledge receipt of the purchase order and indicate the agreed delivery date, which delivery date shall be no less than [***] ([***]) days and no more than [***] ([***]) days after the date of the purchase order unless agreed upon by the parties. If the purchase order exceeds the Firm Forecast amount between [***] % and [***] % ([***]), Hovione shall supply such excess under this agreement. If the purchase order exceeds the Firm Forecasted amount by more than [***]% ([***]), Hovione shall use [***] to fill such order [***].

3.3. Delivery Terms. Each purchase order shall specify: (i) an identification of the API ordered; (ii) quantity requested; (iii) the requested delivery date; and (iv) shipping instructions and address. Hovione agrees to deliver API conforming to the Specifications and the requirements of this Agreement DDP (Incoterms 2000) to such U.S. or Canadian location as may be designated by OptiNose on the purchase order.

3.4. Late Delivery. If, for a reason attributable to Hovione, the ordered quantity of API is not delivered to the location on the purchase order by at least [***] ([***]) working days following the agreed delivery date, as defined in Section 3.2, the transfer price for such late API shall be reduced by [***]

% each week until the API is delivered covering the period from the [***] ([***]) to [***] ([***]) week. For the avoidance of doubt, the maximum penalty for late delivery shall not be more than [***]% of the price of the relevant shipment; provided, that, failure to deliver by the [***] ([***]) week shall constitute a breach of this Agreement and, for purposes of clarity, any liability of Hovione under this Agreement resulting from such breach shall be, to the extent applicable, subject to the limitations set forth in Section 8.4, and any penalties paid under this Section 3.4 shall be deducted to Hovione's liability for late delivery.

3.5. Launch Provisions. The Parties recognize that the Commercial Launch of the Finished Product can only occur after the FDA has approved a New Drug Application ("NDA") for the Finished Product. The "Commercial Launch" of the Finished Product shall be the date on which OptiNose begins to distribute Finished Product to third party customers in the ordinary course of its business. Commercial Launch does not include transfers of free samples of Finished Product or transfers of Finished Product solely for development purposes, such as for use in experimental studies or clinical trials.

3.6. Payment Terms. Hovione shall invoice OptiNose upon delivery of the API. OptiNose shall pay all undisputed amounts to Hovione for conforming API within [***] ([***]) calendar days of the date of receipt of invoice of such API. Payments shall be made to Hovione by wire transfer to the following bank account:

[***]

In case of delays on payment of more than [***] ([***]) business days, OptiNose agrees to pay interest on the outstanding amount at a rate of [***]% per month.

3.7. Minimum Number of Batches. Hovione shall use [***] to minimize the number of different batches shipped to fulfill an OptiNose purchase order.

3.8. Scope of Agreement. In no event shall any terms or conditions included on any purchase order, invoice or acknowledgement thereof or any other document, whether paper, electronic or otherwise, relating thereto, apply to the relationship between the Parties under this Agreement; provided that the Parties may enter into a signed agreement that specifically references this Section 3.8 and the additional or different terms which shall apply to a particular

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

purchase order hereunder. The Parties further agree that no course of dealing between the Parties shall in any way modify, change or supersede the terms and conditions of this Agreement.

3.9. CMO. OptiNose may request CMO to interact directly with Hovione regarding API supply (including, but not limited to, forecasting as per 4.2, purchase order placing as per 4.2, payment as per 4.4). In such case, Hovione shall supply CMO under the same terms and conditions applicable to OptiNose and as specified in this Agreement. Independently of being OptiNose or CMO issuing the forecasting (4.2), placing purchase orders (4.2) and paying supplies (4.4), it is OptiNose's ultimate and sole responsibility to ensure CMO fulfills entirely OptiNose obligations according to this Agreement.

4. Manufacture and Delivery of API.

4.1. Manufacture. The API shall be manufactured by Hovione at its facilities in Loures, Portugal, or at such other location as Hovione may utilize, in accordance with all relevant cGMPs, the Product Specifications, and Applicable Laws, and pursuant to Hovione's Drug Master File ("DMF") or CEP, prepared by Hovione and filed with the FDA, PMDA, or EMA. Any changes will be made according to the terms of the Quality Agreement between the parties. Hovione shall provide sufficient notice of any such change to OptiNose to allow OptiNose to make any required notices to, and obtain any required approvals, from any Regulatory Agency with respect to such change, and any delay in approval of the change by OptiNose until any such notice is given or approval is obtained shall not be deemed unreasonable.

4.2. Right of Audit. OptiNose and its representatives shall have the right to audit Hovione for compliance with applicable regulatory requirements, including but not limited to cGMPs, at reasonable intervals and upon [***] days written notice. Such audits shall be scheduled at mutually agreeable times and be no more frequent than once every three years, except that audits may be conducted at any time, for cause, including if an event occurs that may affect the ability to supply the Product, such as regulatory warnings, product recalls, or significant product defects. When appropriate, OptiNose agrees to consider the use of Rx360 audit reports in the place of on-site audits.

4.3. Certificate of Analysis; Product Release. The quality control(s) and the release(s) of API (including documentation) shall be done by Hovione in accordance with the Quality Agreement. Hovione shall provide certificates of analysis ("COAs") to OptiNose for each batch of API delivered under this Agreement. Hovione shall make Batch Records and other documents pertaining to shipments made to OptiNose readily available to OptiNose on site. Any API that does not conform to the Product Specifications or requirements of the Agreement shall not be shipped to OptiNose. API shall have at least [***] of retest period remaining on the date of delivery. Hovione shall be solely responsible for releasing the API to the agreed API Product Specification in Exhibit A.

4.4. Cooperation. During the term of this Agreement, Hovione shall assist and cooperate in a timely manner with OptiNose in its preparation of any documents or other materials which may be required by the FDA and/or any other Regulatory Authority to validate, sell, and/or distribute the API to be supplied by Hovione under this Agreement for the Finished Product. Hovione shall file with the FDA (and with PDMA and EMA and other applicable regulatory authorities hereunder as may be agreed), and shall maintain at all times as current, a DMF (and/or CEP, etc. , as applicable) for the API with FDA (and such other applicable regulatory authorities) in accordance with all Applicable Laws, Product Specifications and or requirements of this Agreement. Hovione shall also provide OptiNose with a referral letter permitting OptiNose to use Hovione's DMF or CEP, etc., as applicable. Hovione shall provide OptiNose with advance notice of any updates and amendments to the DMF or CEP, etc. in accordance with Section 4.1.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.5. Required Changes. OptiNose shall deliver to Hovione written notice of any changes to the Product Specifications requested by OptiNose or required by the FDA, PMDA, or EMA, and Hovione shall use its [***] to timely make such conforming changes to the Product Specifications in accordance with Applicable Laws and the requirements of this Agreement. If any change to Product Specifications requested by OptiNose [***], then Hovione shall promptly so inform OptiNose in writing and the Parties shall negotiate, in good faith, an adjustment to the pricing paid by OptiNose for API under this Agreement.

(a) In the case of required changes by the FDA, PMDA or EMA, Hovione shall deliver to OptiNose a good faith and detailed estimate of the increase in Hovione's cost to manufacture the API as a result of the required change. If the parties cannot agree to the applicable price adjustment resulting from such required changed, OptiNose may require Hovione to make the required change to the Specifications and/or process while the Parties continue negotiations in good faith as to the costs associated with such change, which shall not delay Hovione's obligations to, as soon as reasonably practicable, implement such changes, in which case, OptiNose shall pay the price requested by Hovione for such API; provided further, that Hovione shall promptly refund any overpayment by OptiNose should the price later be contradicted by the third-party audit specified in Section 4.5(b). Additionally, if the required change impacts any API already ordered by a Firm Forecast pursuant to Section 3.2, OptiNose shall cover any increased costs that impact such already ordered API, while the parties thereafter discuss in good faith pursuant to this Section 4.5 whether such increase was confirmed or contradicted by the auditor.

(b) OptiNose shall reserve the right to a third-party audit of the increased cost contributions with auditors reasonably agreeable to both parties, who shall communicate simultaneously to both parties hereto if the estimate amount is confirmed or contradicted. If contradicted, Hovione agrees to make all applicable changes to API required by the FDA and supply same to OptiNose at the price stated by the auditor for the duration of the Term of the Agreement. If the increase is confirmed, but OptiNose does not agree to pay such increase in transfer price, or if the parties cannot otherwise agree on an equitable adjustment to the transfer price, then either party may terminate this Agreement upon [***] ([***]) months advance written notice to the other party. In such case, the Agreement shall continue in force at the price stated by the auditor for said [***] ([***]) month period in order to provide OptiNose with an opportunity, in its discretion, to arrange for transition to an alternate supplier of its choosing, [***]. During such period Hovione shall continue to supply OptiNose with API and OptiNose shall continue purchasing API from Hovione as per the FDA required changed Product Specification and OptiNose must take delivery of all products for which firm orders have been placed.

(c) In the case of required changes by either Party not requested by regulatory action, if the parties cannot agree on an equitable adjustment to the pricing the Agreement may be terminated provided [***] ([***]) months written notice. During such period Hovione shall continue to supply OptiNose with API and OptiNose shall continue purchasing API from Hovione as per the previously agreed Product Specification and OptiNose must take delivery of all product for which firm orders have been placed

(d) In the case where a disagreement between the parties to a price change pursuant to this Section 4.5 causes a delay in delivery by Hovione, such delay shall be excused; provided [***] the parties separately continue discussions regarding such increased costs.

4.6. Inspection of API. Within [***] ([***]) calendar days of the arrival of each lot of API at the facility designated by OptiNose, OptiNose shall inspect and test each lot of API at its own cost and expense. If, upon inspecting and testing the API, OptiNose determines that a lot of API does not conform to the Product Specifications, then OptiNose shall, within such [***] ([***]) day period, give Hovione written notice of such non-conformity (setting forth the details of such non-conformity)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

in the form of a written complaint, and unless Hovione, within [***] working days from the notice by OptiNose, objects to the non-conformity or provides a status report indicating the investigation is still ongoing, OptiNose shall return the non-conforming API to Hovione at [***]. Any API rejected by OptiNose may not be reshipped to OptiNose except if the API is reprocessed according to the DMF. If approved by OptiNose in writing, Hovione shall replace any non-conforming API within [***] ([***]) days of receiving the notice of non-conformity [***]. Disputes between the Parties as to whether all or any part of a shipment rejected by OptiNose materially conforms to the Product Specifications shall be resolved by a mutually acceptable third party testing laboratory located in the continental United States. [***] shall pay all the fees of the third party laboratory, unless the third party testing laboratory determines that the delivered API materially conforms to the Product Specifications, in which case [***] shall pay all the fees of such third party laboratory and also any additional costs that [***] incurred in providing replacement material. If a Defect in API could not have been ascertained by OptiNose upon reasonable and customary inspection and analysis of the API, then the [***] ([***]) day time period referred to herein to notify Hovione of the Defect shall not apply nor shall any inspection that may have been undertaken by OptiNose operate to limit or bar OptiNose's rights and remedies or Hovione's warranties or obligations regarding same. For the avoidance of doubt, OptiNose expressly reserves all rights and remedies available to it hereunder, at law or in equity in the event of any defect in any API.

4.7. FDA Delays. To the extent that the FDA and/or any other applicable regulatory authority acts inordinately slowly in approving any Finished Product, clearing paperwork or otherwise releasing Finished Product to OptiNose, where such delay is not due to any action or failure to act by Hovione, OptiNose and Hovione shall confer and cooperate with each other on the effect that such delay may have on any obligations arising under this Agreement.

4.8. Regulatory Communications. During the Term, Hovione shall notify OptiNose after receipt of any communication from any Regulatory Agency in accordance with the following timelines: (a) in the event of any communication that is related to or could reasonably be construed as implicating or involving a Serious Adverse Event, Hovione shall provide to OptiNose a copy of any report or other written communications received from any Regulatory Agency on the same day received where possible and in any event, no less than [***] from receipt; b) in the event of any communication that is related to or could reasonably be construed as implicating or involving an Adverse Event, or a product complaint related to the API or Finished Product, that are not reasonably deemed to be Serious Adverse Event, Hovione shall provide to OptiNose a copy of any report or other written communications received from any Regulatory Agency within [***] of receipt; and c) with respect to any other communications from Regulatory Authorities, Hovione shall provide to OptiNose a copy of any report or other written communications received from any Regulatory Agency within [***] after receipt thereof.

4.9. Liability. It is understood that Hovione has no control over the ultimate use of the API once it leaves Hovione's manufacturing facility. Hovione shall have no liability arising out of or in connection with the sale or use of the API or any product or material made from or incorporating the API,

except to the extent that the API was not manufactured in accordance with the Product Specifications, the DMF, cGMPs and Applicable Law or the liability otherwise arises from a breach of this Agreement by Hovione.

4.10. Recall. OptiNose shall be responsible for conducting any recall of Finished Product, and Hovione shall co-operate with [***] OptiNose in conducting any such recall to the extent it relates directly to the API. [***]. [***]. In the event of such recall or similar action, each Party shall use [***] to mitigate the costs associated therewith. In the case of a disagreement as to the existence or level of nonconforming API, then the matter shall be referred to an independent third party laboratory. The decision of the laboratory shall be final and binding on the Parties. For the

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

avoidance of doubt, neither any dispute over responsibility nor the pending decision process by the laboratory shall operate to defer or delay the obligation of either party to cooperate or act in good faith to promptly address, strategize respecting, conduct or respond to any recall, withdrawal, warning, inspection, hold or other applicable regulatory action in accordance with the requirements of all Applicable Laws and standards of the industry. In the event responsibility for costs cannot be determined or agreed at the outset, the parties shall initially share such costs with OptiNose bearing [***] ([***] %) of such costs and Hovione bearing [***] ([***] %) percent of such costs, subject to any appropriate reimbursement following the decision of the independent third party laboratory.

4.11. Retention of Documentation. All documentation related to the manufacturing of the API shall be archived with Hovione after manufacturing in accordance with Hovione's document retention policies, which policies shall be consistent with the longest applicable retention period(s) required by Applicable Laws, including US FDA, PDMA, EMA or other applicable regulations.

4.12. Safety of API. Each Party shall immediately notify the other Party of any unusual health or environmental occurrence relating to API. Each Party shall advise the other Party immediately of any safety or toxicity problems of which it becomes aware regarding API.

5. Warranties.

5.1. Hovione's Warranties. Hovione represents and warrants to OptiNose that:

(a) It has full right and power to enter into this Agreement and perform its obligations hereunder in accordance with its terms;

(b) The API and all components and ingredients thereof shall be manufactured and delivered [***] with: (i) the Product Specifications; (ii) the terms of this Agreement; (iii) the methods processes and procedures, including the site manufacture, set forth in the DMF, together with all Applicable Law relating to the manufacture of the API; (iv) all Applicable Laws, including, but not limited to, the provisions of the FD&C Act, and cGMPs; and (v) quality control procedures and associated test methods for the manufacturing process as developed by Hovione and acceptance specifications and test methods for the API;

(c) the plant(s) for manufacture of the API is and shall be in compliance with all applicable cGMPs and that such plant(s) is and shall continue to be available for FDA inspection if and when the FDA so requests;

(d) Hovione shall not deviate from manufacturing API in accordance with Section 5.1(b) without the prior written consent of a duly authorized representative of OptiNose; and

(e) Good and valid title to the API will pass to OptiNose upon delivery by Hovione to OptiNose at the shipping address set forth in the applicable purchase order, free and clear of all third party liens, security interests, claims and/or encumbrances of any kind or nature.

5.2. OptiNose's Warranties. OptiNose represents and warrants to Hovione that:

(a) It has the full right and power to enter into this Agreement and perform its obligations hereunder in accordance with its terms; and

(b) That it will purchase the API in strict compliance with the terms of Section 2.1. and Section 3.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

5.3. Mutual Warranties. Each party represents and warrants to the other party that it holds all necessary and required permits and authorizations, including, but not limited to, those required by the FD&C Act, and shall undertake throughout the term of this Agreement to maintain the same in full force and effect, so as to enable the performance of the services hereunder. Each party further covenants that it shall use [***] to obtain all such other permits and authorizations as may [***] from time to time in either case to operate their respective facilities and/or businesses in order to manufacture, provide, distribute and/or sell API hereunder.

5.4. No Adulteration. For the purposes of Section 303(c) of the FD&C Act: (a) Hovione guarantees to OptiNose that all API shipped by or on behalf of Hovione hereunder will not, on the date or as of the time of delivery DDP to OptiNose's designated facility as required in Section 3.3, be adulterated or misbranded (i) within the meaning of the FD&C Act, or (ii) within the meaning of any applicable state law in which the definitions of "adulteration" and/or "misbranding" are substantially the same as those contained in the FD&C Act, the provisions of which are in effect at the time of such delivery, and will not be an article which may not, under the provisions of Section 404 or 505 of the FD&C Act, be introduced into interstate commerce; and (b) OptiNose guarantees to Hovione that all Finished Product shipped by or on behalf of OptiNose hereunder will not, on the date of shipment, be adulterated or misbranded (i) within the meaning of the FD&C Act, or (ii) within the meaning of any applicable state law in which the definitions of "adulteration" and/or "misbranding" are substantially the same as those contained in the FD&C Act, the provisions of which are in effect at the time of such shipment, and will not be an article which may not, under the provisions of Section 404 or 505 of the FD&C Act, be introduced into interstate commerce, except to the extent any such adulteration or misbranding is in violation of Section 5.4(a).

5.5. Debarment Certification. Each party will comply at all times with the provisions of Applicable Laws of the United States (and, as applicable, analogous such laws in any other territories where regulatory approval is sought) regarding debarment and will upon request certify in writing to the other parties that none of its employees nor any person providing services in connection with this Agreement and/or the API have been debarred under the provisions of such laws.

6. Confidentiality.

6.1. Confidentiality. Each party agrees to retain in confidence all Confidential Information disclosed to it pursuant to this Agreement, whether such disclosure occurred before or after the date hereof and to only use such Confidential Information in the performance of its obligations under this Agreement. Disclosed information shall not be deemed Confidential Information hereunder if: (a) it is now or later becomes publicly known, other than through the fault of the receiving party; (b) it is lawfully known without restriction to the receiving party at the time of disclosure as evidenced by written documentation; (c) it is rightfully obtained by the receiving party from a third party without restriction and without breach of this Agreement or any similar agreement; and/or (d) it is independently developed by the receiving party without access to the disclosing party's information, as evidenced by written documentation. If either Party is required under Applicable Law to disclose Confidential Information by any court or to any Regulatory Agency, the Party required to disclose the Confidential Information shall, prior to such disclosure, notify the other Party of such requirement and all particulars related to such requirement. The notified Party shall have the right, at its expense, to object to such disclosure and to seek confidential treatment of any Confidential Information to be so disclosed on such terms as it shall determine, and the other Party shall fully cooperate with the notified Party in this regard. The confidentiality of disclosed Confidential Information and the obligation of confidentiality hereunder shall survive any expiration or termination of this Agreement for the longer of a period of [***] or until it falls into a category referenced above in 6.1(a) through (d). The Parties specifically agree that all terms of this

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Agreement, all sales and API requirements and costs and all purchase orders shall be deemed to be confidential. Hovione acknowledges and agrees to indefinitely (a) maintain the Product Specifications in confidence and not disclose them directly or indirectly to any third party, and (b) not use them for itself or any third party in any manner other than in performing its obligations hereunder.

6.2. Separate Confidentiality Agreement. If the Parties entered into one or more separate confidentiality agreements or non-disclosure agreements (each, a "Confidentiality Agreement"), such Confidentiality Agreement(s) shall be and remain in full force and effect as provided therein. In the event of any conflict between the terms of this Agreement and the terms of any such Confidentiality Agreement, terms of this Agreement shall be deemed to control.

6.3 Public Announcements. During the term of this Agreement, no party hereto shall issue or release, directly or indirectly, any press release, marketing material or other communication to or for the media or the public that pertains to this Agreement, the API or the transactions contemplated hereby (collectively, a "Press Release") unless the content of such Press Release has been approved by the other party hereto, such approval not to be unreasonably withheld or delayed; provided, however, that nothing contained in this Agreement shall prevent or preclude any party from making such disclosures as may be required by applicable law, including, but not limited to, any disclosures required by applicable securities laws.

7. Reserved.

8. Indemnification.

8.1 OptiNose shall indemnify, defend and hold Hovione and its officers, directors, affiliates, agents and employees harmless from and against any and all claims, demands, costs, expenses, losses, liabilities and/or damages (including, but not limited to, reasonable attorneys' fees and court costs) of every kind and nature caused by, arising out of or resulting from [***].

8.2 Hovione shall indemnify, defend and hold OptiNose and its officers, directors, affiliates, agents and employees harmless from and against any and all claims, demands, costs, expenses, losses, liabilities and/or damages (including, but not limited to, reasonable attorneys' fees and court costs) of every kind and nature caused by, arising out of or resulting from [***]. [***].

8.3 Each party will promptly notify the other of any actual or threatened judicial or other proceedings which could involve either or both parties. Each party reserves the right to defend itself in any such proceedings; provided, however, that, if indemnity is sought, then the party from whom indemnity is sought shall have the right to control the defense of the claim, and the indemnified party may participate with counsel of its choice at its own expense. The Parties shall cooperate with each other to the extent reasonably necessary in the defense of all actual or potential liability claims and in any other litigation relating to the API supplied pursuant to this Agreement. Each party will cooperate with and supply information to the other relevant to any product liability claims and litigation affecting the API and/or the Finished Product, as the case may be.

8.4 ***NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. [***].[***].***

9. Insurance. Unless the Parties otherwise agree in writing, the following terms shall apply:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.1 During the term of this Agreement and for a period of [***] ([***]) years after any expiration or termination of this Agreement, each of OptiNose and Hovione shall maintain in full force and effect a comprehensive general liability insurance policy, including Product Liability coverage, with minimum

limits of not less than [***] Dollars ($[***]) per occurrence and as an annual aggregate, and any other insurances required by Applicable Law. Such policy shall be issued by an insurance company or insurance companies having an A.M. Best Rating of "[***]" or better.

9.2 On or before the date on which OptiNose begins to sell the Finished Product in the United States, each party shall deliver to the other party a Certificate of Insurance to verify the coverage required by this Agreement, which receipt and review by the other party shall not act as an acknowledgement of such other parties compliance with this Section 9.2. The Parties shall maintain the appropriate insurance coverage in effect for so long as OptiNose manufactures, processes, ships, stores and/or delivers any Finished Product under this Agreement and for a period of [***] ([***]) years thereafter. Each party agrees to promptly renew all insurance policies in a timely manner and if so requested by the other party to provide the other party with certificates evidencing the same or any replacement insurance. Each party further agrees to notify the other party at least [***] ([***]) days in advance of any proposed cancellation, termination or non-renewal of any such policies.

10. Term and Termination.

10.1 Term.

Unless terminated in accordance with the provisions of Section 10.2 below, the term of this Agreement shall commence on the Effective Date and shall continue in effect thereafter until the fifth (5th) anniversary of the Commercial Launch of the Finished Product (the "Initial Term"). [***] prior to expiry of the Initial Term, the Parties will discuss whether they wish to terminate the Agreement at the expiration of the Initial Term- in which case a [***] notice period will apply- or extend the Term of this Agreement. If neither party is in default, in any material respect, of any of its obligations under this Agreement, then the term of this Agreement may be extended, upon mutual agreement of the parties, for renewal terms of one (1) year (or such other period of time as the parties may mutually agree) at the expiration of the initial term or any renewal term unless and until this Agreement is terminated by any party in accordance with the terms hereof. For the avoidance of doubt, this Agreement does not automatically renew.

10.2 Grounds for Termination.

(a) Either party shall have the right to terminate this Agreement upon the occurrence of any of the following events: (i) the failure of the other party to comply with any of the terms of this Agreement or otherwise discharge its duties hereunder [***], or the breach by the other party of any of its representations or warranties herein [***], if such failure or breach is not cured within [***] ([***]) days of such breaching party's receipt of written notice specifying the nature of such failure or breach with particularity; or (ii) the making by the other party of an assignment for the benefit of its creditors, or the filing by or against such otherparty of any petition under any federal, state or local bankruptcy, insolvency or similar laws, if such filing has not been stayed or dismissed within [***] after the date thereof.

(b) OptiNose shall also have the right to suspend further performance under this Agreement and/or terminate this Agreement in its entirety, without liability except for unpaid previously delivered API that conforms with the terms hereof, if: (i) Hovione loses any approval(s) from the FDA required to perform its obligations under this Agreement or if Hovione is involved in felonious or fraudulent activities; or (ii) Hovione does not submit a Corrective And Preventive Action plan to the FDA within [***] ([***]) days of being notified of deficiencies as a result of an inspection

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

of Hovione's facility; or (iii) [***]. OptiNose shall also have the right to suspend further performance under this Agreement and/or terminate this Agreement in its entirety without liability, except for unpaid previously delivered API and, subject to timely delivery, API subject to Firm Forecasts, in each case, that conforms to the terms of this Agreement if the Finished Product does not reach the market or if the parties do not reach an agreement regarding a price increase pursuant to Exhibit B or Section 4.5 hereof.

(c) Hovione shall also have the right to suspend further performance under this Agreement and/or terminate this Agreement in its entirety, without liability, if OptiNose does not receive FDA approval for its Finished Product by [***].

10.3 Continuing Obligations; Survival. In no event shall any termination or expiration of this Agreement excuse either party from: (a) any obligation which survives expiration or termination of this Agreement, (b) any breach or violation of this Agreement that occurred prior to such termination or expiration, or (c) making any payment due under this Agreement with respect to any period prior to the date of expiration or termination. In each such case, full legal and equitable remedies shall remain available to address such issues. Sections 4 to 11 and 13 hereof and the applicable requirements of the Quality Agreement incorporated by reference herein shall survive any termination or expiration of this Agreement for any reason. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the observation and performance of the aforementioned surviving portions of this Agreement. For purposes of clarity, Hovione's obligation to supply API shall not survive termination or expiration of this Agreement.

11. Agreement to Consummate; Further Assurances. Subject to the terms and conditions of this Agreement, each of the Parties hereto agrees to use [***] to do all things necessary, proper or advisable under this Agreement, applicable laws and regulations to consummate and make effective the transactions contemplated hereby. If, at any time after the date hereof, any further action is necessary, proper or advisable to carry out the purposes of this Agreement, then, as soon as is reasonably practicable, each party to this Agreement shall take, or cause its proper officers to take, such action.

12. Force Majeure. Any delay in the performance of any of the duties or obligations of either party hereto (except for the payment of money) caused by an event outside the affected party's reasonable control shall not be considered a breach of this Agreement and the time required for performance shall be extended for a period equal to the period of such delay. Such events shall include, but will not be limited to, acts of God, acts of a public enemy, acts of terrorism, insurrections, riots, injunctions, embargoes, fires, explosions, floods, or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the Party so affected. The Party so affected shall give prompt written notice to the other party of such event. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use its [***] to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for [***] ([***]) days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the non-affected Party may terminate this Agreement immediately by written notice to the affected Party.

13.0 General Provisions.

13.1 Assignment. Neither this Agreement nor any interest herein may be assigned, in whole or in part, by either party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except that either party may assign its rights and obligations under this Agreement: (a) to an affiliate, division or subsidiary of such party; and/or (b) to any third

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

party that acquires all or substantially all of the stock or assets of such party, whether by asset sale, stock sale, merger or otherwise, and, in any such event such assignee shall assume the transferring party's obligations hereunder. In addition, OptiNose may assign this Agreement, or its interest herein, to a licensee of OptiNose's Intellectual Property rights with respect to the Finished Product. However, notwithstanding any such assignment, in the case of an assignment to an affiliate, division or subsidiary, the transferring party shall remain liable under this Agreement (in addition to the transferee) unless such liability is specifically waived in writing by the other party hereto. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto, and their respective successors and permitted assigns.

13.2 Notice. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and sent by: (a) personal delivery against a signed receipt therefor, (b) certified mail, return receipt requested, first class postage prepaid, (c) nationally recognized overnight delivery service (signature required), or (d) electronic mail (with any notices to send by electronic mail to also be sent by one of the other methods set forth in this Section), addressed as follows:

If to Hovione, then to:	Hovione FarmaCiencia, SA Estrada do Paço do Lumiar — Campus do Lumiar Edifício R 1649-038 Lisboa Portugal Attention: Chief Executive Officer
With a copy, sent as provided herein, to:	Hovione FarmaCiencia, SA Estrada do Paço do Lumiar — Campus do Lumiar Edifício R 1649-038 Lisboa Portugal Attn: General Counsel
If to OptiNose, then to:	To OptiNose US: OptiNose US, Inc. 1020 Stony Hill Road Suite 300 Yardley, PA 19067 Attn: Chief Executive Officer To OptiNose UK: OptiNose UK, Ltd. Hunts Rise South Marston Park, Wiltshire SN3 4TG, England Attention: Chief Executive Officer To OptiNose Norway: OptiNose AS Gaustadalléen 21 0349 Oslo, NORWAY

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

	Attention: Chief Executive Officer
With a copy, sent as provided herein, to:	OptiNose US, Inc. 1020 Stony Hill Road Suite 300 Yardley, PA 19067 Attn: Chief Legal Officer

Any party may alter the address to which communications are to be sent by giving notice of such change of address in conformity with the provisions of this Section providing for the giving of notice. Notice shall be deemed to be effective, if personally delivered, when delivered; if mailed, at midnight on the third business day after being sent by certified mail; if sent by nationally recognized overnight delivery service, on the next business day following delivery to such delivery service; and if sent by confirmed electronic mail, on the next business day following transmission (so long as any notices sent by electronic mail are also sent by one of the other methods set forth in this Section).

13.3 Entire Agreement. This Agreement and (such applicable Quality agreement that may be executed by the parties hereunder and incorporated herein by reference as if fully set forth at length as contemplated in Section 1.17 above) sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and merges all prior discussions and negotiations between them, and neither party shall be bound by any conditions, definitions, warranties, understandings or representations with respect to such subject matter other than as expressly provided herein or as duly set forth on or subsequent to the date hereof in writing and signed by a proper and duly authorized officer or representative of the Parties to be bound thereby, except that this Agreement, other than expressly set forth in Section 6.2 above, shall not supersede any separate confidentiality or non-disclosure agreement that may have been, or that may be, entered into by the Parties, except as to term. To the extent that any conflict arises among the documents that comprise this Agreement (including any schedules or exhibits), the terms and conditions of this Agreement shall govern. The terms and conditions of this Agreement shall control over and supersede any contrary term in any purchase order.

13.4 Amendment and Modification. This Agreement may be amended, modified and supplemented only by written agreement duly executed and delivered by each of the Parties hereto.

13.5 Waiver. The failure of any party to exercise any right or to demand the performance by the other party of duties required hereunder shall not constitute a waiver of any rights or obligations of the Parties under this Agreement. A waiver by any party of a breach of any of the terms of this Agreement by any other party shall not be deemed a waiver of any subsequent breach of the terms of this Agreement.

13.6 Governing Law. This Agreement is to be governed by and construed in accordance with the laws of the State of New York, notwithstanding any conflict of law provisions to the contrary. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. Any action which in any way involves the rights, duties and obligations of either party hereto under this Agreement shall be brought exclusively in the federal courts sitting in the State of New York and the Parties to this Agreement hereby submit to the subject matter and personal jurisdiction of and venue in any such court. The Parties waive any and all rights to have any dispute, claim or controversy arising out of or relating to this Agreement tried before a jury.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

13.7 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any action in any other jurisdiction, to the extent reasonably severable without altering the parties' original intent but this Agreement shall be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had not been contained herein. In such case, the parties shall meet and diligently agree on a valid replacement term that tracks as closely as possible, the Parties' original intent.

13.8 Construction. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event of any ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any of the provisions of this Agreement. As used in this Agreement, the singular shall include the plural and vice versa, and the terms "include" and "including" shall be deemed to be immediately followed by the phrase "but not limited to." The terms "herein" and "hereunder" and similar terms shall be interpreted to refer to this entire Agreement, including any schedules attached hereto.

13.9 Parties/Relationship. Neither party shall hold itself out to third parties as possessing any power or authority to enter into any contract or commitment on behalf of any other party. This Agreement is not intended to, and shall not; create any agency, partnership or joint venture relationship between or among the Parties. Each Party is an independent contractor with respect to the other. No Party is granted any right or authority to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of any other Party hereto, or to bind any other party hereto in any manner or with respect to anything, whatsoever, or receives any license hereunder, otherwise other than as limited to the purposes of this Agreement and to the extent necessary to provide the services hereunder.

13.10 Captions. The captions and headings in this Agreement are inserted for convenience and reference only and in no way define or limit the scope or content of this Agreement and shall not affect the interpretation of its provisions.

13.11 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

13.12 Subcontractors and Affiliates. Hovione Inter Ltd. shall either perform the obligations of Hovione hereunder or shall cause its Affiliates to perform such obligations in accordance with the terms hereof. Any work that is to be done by any Party under this Agreement may be subcontracted to a third party in accordance with the approved NDA, cGMPs and any applicable FDA guidelines which relate to the work to be performed under the direction and supervision of such party, as the case may be; provided, however, that: (a) advanced notice of the proposed use of the subcontractor is first provided to the other party with an opportunity to object, (b) the subcontracting party exercises reasonable diligence in selecting such subcontractor (c) requires the subcontractor to accept and be bound in writing by the terms and conditions of this Agreement (including with respect to any Confidentially, Non-Use, Inventions hereunder) , and (d) as between the parties hereto, the subcontracting party shall be and remain responsible for all acts and omissions of any such subcontractor.

13.13 Schedules and Exhibits. All Schedules and Exhibits referenced in this Agreement, if any, are hereby incorporated by reference into, and made a part of, this Agreement.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

13.14 Currency. All sums set forth in this Agreement and ay appendices, exhibits or schedules hereto are, and are intended to be, expressed in U.S. Dollars.

13.15 OptiNose Parties. Notwithstanding anything in this Agreement to the contrary, (i) each of OptiNose US, OptiNose UK and OptiNose Norway shall be and is hereby individually vested with each and every right of OptiNose under this Agreement, (ii) the OptiNose parties shall inform Hovione which OptiNose party will be acting under this Agreement (the "Acting OptiNose Party") and thereafter Hovione shall be entitled to rely exclusively on instructions from such Acting OptiNose Party until notified by the OptiNose parties that a new Acting OptiNose Party has been so designated, and (iii) each of OptiNose US, OptiNose UK and OptiNose Norway shall be severally, and not jointly, liable or responsible to Hovione for any obligations of OptiNose to Hovione contained in this Agreement resulting from any actions or inaction by it as the Acting OptiNose Party or as a result of any event or occurrence while it was the Acting OptiNose Party and shall be the sole OptiNose party liable and responsible to Hovione for such obligation.

[Signature Page Follows]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the parties have executed the Agreement as of the date first above written.

Hovione Inter Ltd:

By: /s/ Guy Villax

Name: G. Villax

Its: Chief Executive

Date: 7 August 2017

OptiNose US, Inc:

By: /s/ Peter Miller

Name: Peter Miller

Its: CEO

Date: 8/9/17

OptiNose UK, Ltd:

By: /s/ Peter Miller

Name: Peter Miller

Its: CEO

Date: 8/9/17

OptiNose AS:

By: /s/ Peter Miller

Name: Peter Miller

Its: CEO

Date: 8/9/17

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT A

Product Specifications

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

Pricing

A. Development Phase (Clinical Supply)

The price of the API is USD $[***] per gram.

B. Commercialisation Phase

API price schedule for the Commercialization Phase (API manufactured for commercial use) will depend of the total annual quantity forecast provided to Hovione by OptiNose prior to the beginning of each calendar year.

Annual quantity in kg	Price in $ per g
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For annual quantities, defined as the volume purchased over 12 months from 1st January each contractual year, different from [***],[***],[***] and [***] kg price per kg for a given calendar year shall be the [***] between the defined [***]. For the initial year all API purchased for the initial commercial launch quantities will be included in the first contractual year.

Example given:

[***].

The interpolated price per gram between [***] and [***] kg quantity is [***] kg ([***] kg — [***] kg) times the interpolated value, which is [***].

Therefore the price for [***] kg would be as follow:

[***]

If the annual consumption at the end of the year is lower than [***] kg OptiNose will pay to Hovione the additional amount and if the annual quantity is higher than [***] kg Hovione will reimburse OptiNose for amount difference no later than the end of January following the end of that year.

Pricing Adjustments

Each January 1 during the term of this Agreement, but not before the first anniversary of the Commercial Launch, Hovione may adjust the transfer price based on (but not in excess of) an increase in Hovione's cost of supply. Hovione will provide to OptiNose written notice of any such increase decrease to the transfer price for the API by October 1 of the year preceding the price increase. Such notice shall include reasonable detail, including supporting documentation of the increase in cost of supply, justifying the basis for such price increase. In the event that a price increase hereunder materially negatively impacts the profitability of the Finished Product for OptiNose, then OptiNose shall notify Hovione and, if the parties cannot agree on a transfer price

---

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

following good faith negotiations, OptiNose may terminate this Agreement in accordance with the provisions of Section 4.5. Notwithstanding the foregoing, any increase due to (a) the change in cost of raw materials shall be equal to (and not more than) Hovione actual increase in costs for such raw materials; provided, however, that any such change will not include the amount of any price change already implemented under Section 4.5 of this Agreement, and (b) Hovione's actual change in its labor and overhead costs shall be as consistently applied to all products manufactured by Hovione incurred over the prior [***] ([***]) month period ("Conversion Cost"); provided, however, that if such change in Conversion Cost is an increase, the percent change may not exceed the percentage increase over the prior [***] ([***]) month period in the Pharmaceutical Producer Price Index Pharmaceutical Preparation Manufacturing Ref. No. pcu325412325412 ("PPI") as reported by the United States Department of Labor Bureau of Labor Statistics.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

MANUFACTURE AND SUPPLY AGREEMENT

This **MANUFACTURE AND SUPPLY AGREEMENT** (the "Agreement") is made as of August 18, 2017 (the "Effective Date") by and among, on the one hand, OptiNose US, Inc., duly organized and existing under the laws of Delaware and having offices located at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067 (referred to herein as "OptiNose US"), OptiNose UK Ltd. duly organized and existing under the laws of England and having offices located at Hunts Rise, South Marston Park, Wiltshire, SN3 4TG, England (referred to herein as "OptiNose UK"), and OptiNose AS, duly organized and existing under the laws of Norway and having offices located at Gaustadalleen 21 0349 Oslo, Norway (referred to herein as "OptiNose Norway", and collectively with OptiNose US and OptiNose UK, "OptiNose"), and, on the other hand, Contract Pharmaceuticals Limited Canada, duly organized under the laws of the Province of Ontario and having offices located at 7600 Danbro Crescent, Mississauga, Ontario Canada L5N 6L6 (referred to herein as "CPL"). OptiNose and CPL are each a "Party" and together constitute the "Parties" under this Agreement.

WHEREAS, CPL is a contract manufacturer that manufactures and supplies pharmaceutical products to third party companies; and

WHEREAS, OptiNose desires that CPL manufacture and supply finished dose forms of the Product (as defined below) appropriate for marketing, commercial sale and distribution in accordance with the requirements of this Agreement;

NOW, THEREFORE in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The following capitalized terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement and all Exhibits and Schedules hereto:

1.1 "**Affiliate(s)**" means any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with a Party. For purposes of this definition, "control" shall mean the ownership of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity or ownership interest, or the power to direct the management and policies of such person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise.

1.2 "**ANDA/NDA"** means any abbreviated new drug application or new drug application required to manufacture, market and sell finished dosage forms of the Products in the US Territories (as defined herein) filed by OptiNose with the FDA, and any supplements and amendments thereto which may be filed by OptiNose from time to time.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.3 "**Annual Minimum"** means the lesser of (i) [***]% of the Annual Threshold or (ii) the Annual Threshold minus [***] units of Product (the equivalent of [***] full [***] kg batch at the theoretical yield); provided, however, that from and after the timely cure of a Supply Failure described in subsections (i) and (ii) of Section 2.11 and OptiNose's resumption of ordering from CPL as described in Section 2.11, the applicable percentage in subsection (i) above shall be reduced by [***]% (for example, [***]% shall be reduced to [***]% upon the first instance, and then to [***]% upon the next instance), provided such percentage shall not go below [***]%.

1.4 "**Annual Threshold"** means the actual annual aggregate requirements of OptiNose for the Product in the Territory, as reflected by OptiNose's records of the number of Product units ordered from CPL and any other vendors by OptiNose, or manufactured by OptiNose itself, during the calendar year.

1.5 "**API"** means the active pharmaceutical ingredient, fluticasone propionate required for the Product.

1.6 "**Applicable Laws**" shall mean all laws, ordinances, codes, rules and regulations applicable: (a) to the obligations of CPL in the jurisdiction of manufacture to the manufacturing of the Product or any aspect thereof including without limitation the FD&C Act and cGMP; and (b) to the obligations of OptiNose.

1.7 "**Bailment Agreement**" means that certain Master Bailment Agreement by and between OptiNose US and CPL, dated as of June 24, 2016.

1.8 "**Batch Records**" shall have the meaning set forth in Section 6.1.

1.9 "**Binding Period**" shall have the meaning set forth in Section 2.3.

1.10 "**Calendar Quarter**" means a period of three (3) consecutive months commencing on January 1, April 1, July 1 or October 1 of any calendar year.

1.11 **"Capacity"** means the facility space, equipment, utilities, maintenance capabilities, infrastructure, human capital, and other capabilities sufficient to manufacture the Product.

1.12 "**Confidential Information**" shall have the meaning set forth in Section 8.2.

1.13 "**Conversion Cost"** shall have the meaning set forth in Section 4.1.5.

1.14 "**CPL Indemnitee**" shall the meaning set forth in Section 9.2.

1.15 "**Data**" shall refer to all data, materials, plans, reports, test results and other information developed solely by or for OptiNose in connection with the Manufacture of the Product.

1.16 "**Defective Product**" means any Product that contains a Patent Defect or Latent Defect.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.17 "**Delivery"** means delivery of Product after Release to Distribution, packed pursuant to Section 2.12 of this Agreement, F.C.A. CPL's loading dock at 7600 Danbro Crescent, Mississauga, ON Canada L5N 6L6.

1.18 "**Effective Date**" means the date set forth in the preamble of this Agreement.

1.19 "**Environmental Laws**" means all applicable laws, directives, rules, regulations, guidelines and court orders currently in existence or hereafter adopted relating to occupational safety and health, or safety, preservation or protection of the environment and/or relating to the release, threatened release, handling, treatment, transportation or storage of wastes or materials in the jurisdiction of manufacture.

1.20 "**Facility**" means; a) for manufacturing and Delivery purposes, CPL's manufacturing facility located at 7600 Danbro Crescent, Mississauga, Ontario, Canada L5N 6L6 or any other CPL controlled facility approved in writing by OptiNose (such approval not to be unreasonably delayed or withheld); and b) for laboratory testing purposes: 2145 Meadowpine Blvd. Mississauga, Ontario, Canada L5N 6R8.

1.21 "**FDA**" means the United States Food and Drug Administration and any successor bodies.

1.22 "**FD&C Act"** means the Federal Food, Drug, and Cosmetic Act, as amended, and includes the rules, and regulations and guidances promulgated thereunder.

1.23 "**Final Approval Date"** means the date OptiNose has received all regulatory approvals for the commercial sale of the Product in the Territory.

1.24 "**Force Majeure**" shall have the meaning set forth in Section 11.5.

1.25 "**Initial Term**" shall have the meaning set forth in Section 11.1.

1.26 "**Intellectual Property**" means any and all of the following, and rights in, arising out of, or associated therewith: U.S. and non-U.S. (a) patents, utility models, supplementary protection certificates and applications thereof (including provisional applications, invention disclosures, certificates of invention and applications for certificates of invention) and divisionals, continuations, continuations-in-part, reissues, renewals, extensions, re-examinations, and equivalents thereof, (b) trade secrets, know-how, proprietary information, inventions, discoveries, improvements, technology, technical data, and research and development, whether or not patentable, (c) trademarks, service marks, trade dress, trade names, and equivalents thereof, (d) copyrights, mask works, registrations and applications thereof, and any equivalents thereof.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.27 "**Latent Defect**" means any instance where a Product fails to conform to the Specifications, Applicable Laws or the Quality Agreement, in each case if proximately caused by the acts or omissions of CPL prior to Delivery hereunder (which shall include CPL's failure to confirm that the OptiNose Components conform to the Specifications, and any failure to conform arising from the Raw Materials other than the OptiNose Components), which is not a Quantitative Defect or Patent Defect.

1.28 "**Losses**" shall have the meaning set forth in Section 9.1.

1.29 "**Manufacture(d)**" or "**Manufacturing**" means the compounding, filling, manufacture, assembly, packaging and, testing of the API and Raw Materials into the Product in accordance with the Specifications and the terms and conditions set forth in this Agreement.

1.30 "**Notice(s)**" shall have the meaning set forth in Article 13.

1.31 "**OptiNose Components**" shall have the meaning set forth in Section 2.1(e).

1.32 **"OptiNose Equipment"** shall mean OptiNose Equipment as defined in the Bailment Agreement, as modified by Section 3.1 to include the items described on Schedule 1 attached hereto.

1.33 "**OptiNose Indemnitee**" shall have the meaning set forth in Section 9.1.

1.34 "**OptiNose Vendors**" shall have the meaning set forth in Section 2.1(e).

1.35 "**Patent Defect**" shall mean any instance where a Product fails to conform to the Specifications, Applicable Laws or the Quality Agreement, in each case if proximately caused by the acts or omissions of CPL prior to Delivery hereunder (which shall include CPL's failure to confirm that the OptiNose

Components conform to the Specifications, and any failure to conform arising from the Raw Materials other than the OptiNose Components), where such failure is or was discovered upon actual inspection, if any, upon receipt by OptiNose or its designee.

1.36 "**Product**" means the full saleable or sample product unit for OPN-375 including without limitation active ingredient, delivery system, container closure system, and market package.

1.37 "**Purchase Order**" shall have the meaning set forth in Section 2.5.

1.38 "**Purchase Price**" shall have the meaning set forth in Section 4.1.1.

1.39 "**Quality Agreement"** shall mean that Quality Agreement to be entered between the parties related to production of the Product.

1.40 **"Quantitative Defect"** means any instance in which CPL has Delivered a quantity of Product that is at least [***]% less than the quantity stated in any invoice or bill of lading.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.41 "**Raw Material**" means all raw materials, including API, supplies, components and packaging components and material necessary to manufacture and ship the Product in accordance with the Specifications.

1.42 "**Regulatory Authority**" means any governmental authority within the Territory or applicable to any Facility (including, but not limited to, the FDA and the applicable Canadian Health Authority) involved in regulating any aspect of the development, manufacture, testing, packaging, storage, handling, market approval, sale, distribution, Delivery or use of the Products in accordance with Applicable Laws.

1.43 **"Release to Distribution"** shall mean the written approval provided by OptiNose to CPL approving the Batch Records and authorizing CPL to Deliver the Products.

1.44 "**Renewal Term**" shall have the meaning set forth in Section 11.1.

1.45 "**Required Change**" shall have the meaning set forth in Section 2.2.2.

1.46 "**Rolling Forecast**" shall have the meaning set forth in Section 2.3.

1.47 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and requirements for the Product set forth in Exhibit A as such Exhibit may be amended in accordance with the terms of this Agreement.

1.48 "**Supply Failure**" has the meaning provided in Section 2.11.

1.49 "**Term**" shall have the meaning set forth in Section 11.1.

1.50 "**Territory**" means the United States of America, its territories, possessions, commonwealths, and any other country which the Parties agree in writing to add to this definition of Territory in an amendment to this Agreement.

ARTICLE 2
MANUFACTURE AND SUPPLY

2.1 Purchase and Supply of Product.

(a) Overview. From and after the Final Approval Date and during the Term hereof, OptiNose shall (except as otherwise provided in this Agreement) purchase at least the Annual Minimum of Product from CPL in accordance with the terms and conditions hereof, and CPL shall Manufacture the Product at the Facility in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement. It is expressly understood and agreed that at OptiNose's sole cost and expense, OptiNose shall have the right to qualify a secondary supplier of Product (a "**Back-Up Supplier**") and may purchase Product from such Back-Up

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Supplier so long as it purchases the Annual Minimum from CPL. CPL agrees to promptly (and in any event within [***] days) transfer to such Back-Up Supplier all documentation related to the processes, protocols, procedures, methods and tests relating to the Manufacturing of Product in accordance with the Specifications and Applicable Law. In connection with a transfer to a Back-Up Supplier, CPL shall provide OptiNose a list of all suppliers of Raw Materials and any other components used in connection with the manufacture of the Product. [***]. The obligations of CPL under this Section 2.1(a) shall survive for [***] ([***]) days after the expiration or termination of this Agreement.

(b) Labeling. OptiNose shall provide CPL with all artwork, copy or other materials necessary for the Product labels, printed packaging materials and Product inserts. CPL shall accurately implement copy changes as reasonably required by OptiNose, and CPL shall not make any changes to the artwork, copy or other materials without the prior written approval of OptiNose. CPL shall ensure that all Product is packaged and assembled with labeling affixed in accordance with the Specifications, before Delivery of any such Product.

(c) Annual Minimum. Within [***] ([***]) days following the end of each calendar year during the Term of this Agreement and within [***] (***) days following the expiry or earlier termination of the Term of this Agreement, OptiNose shall determine the Annual Threshold and the Annual Minimum and shall provide such numbers to CPL together with sufficient information, certified by an officer of OptiNose to enable CPL to confirm OptiNose's determination and the quantity of any deficiency. If OptiNose fails to order from CPL the Annual Minimum, then as OptiNose's sole and exclusive liability and CPL's sole and exclusive remedy, OptiNose shall, within [*******] ([*******]) days following determination of such fact, pay to CPL an amount equal to [*******] as noted on Exhibit B hereto. For purposes of calculating any amount to be paid by OptiNose to CPL for an Annual Minimum shortfall, the supply prices in effect at the end of the applicable annual period in which the shortfall occurred shall apply.

(d) Raw Material Procurement. OptiNose, [***], is responsible for the purchase of all API, cap and liquid delivery subassembly, and CPL is responsible for the purchase of all other Raw Materials. CPL is responsible for the receipt, storage, sampling, testing and release for use of all Raw Materials, including without limitation the OptiNose Components, according to Specifications, the Quality Agreement and Applicable Laws. For some Raw Materials, OptiNose may instruct CPL to use specific suppliers to leverage existing contracts. CPL shall be entitled to include in the Purchase Price [***].

(e) Selected Vendors. Unless otherwise instructed by OptiNose at a subsequent date, CPL shall order the Raw Material identified in Schedule 3 attached hereto from those suppliers identified thereon (the "OptiNose Vendors"). The Raw Material to be supplied by those suppliers set forth in Schedule 3, as such Schedule may be amended from time to time pursuant to the terms of this Agreement, are collectively referred to as the "OptiNose Components". With each of these vendors, OptiNose shall enter supply agreements, which agreements shall provide for CPL to be the agent of OptiNose for the limited purposes of (i) instructing each vendor on the time and destination for shipments of the relevant Raw Material from each such vendor, and (ii) inspecting and ensuring that Raw Material provided by each such vendor meets the applicable specifications. Further, CPL shall enter quality agreements with such vendors, in consultation

with OptiNose (including OptiNose's review and comment on such quality agreements), requiring such vendors to comply with Applicable Law and to supply their respective Raw Material in a manner that enables CPL to Manufacture and supply the Product in compliance with Applicable Law and in accordance with the Specifications. CPL shall conduct audits [***] of, and otherwise manage, suppliers of the OptiNose Components as appropriate to ensure compliance with the above-referenced quality agreements. By mutual written agreement, OptiNose and CPL may decide to adjust responsibility and any fee for Raw Material procurement. If such audits by CPL result in CPL determining that such vendors are not in compliance with such quality agreements, CPL shall inform OptiNose of CPL's audit findings and OptiNose shall negotiate to resolve disputes regarding any right, obligation, duty or liability which may arise between CPL and the vendor under the quality agreement, provided it is understood and agreed that CPL shall, upon request by OptiNose, use [***] to assist OptiNose in any such investigations and dispute resolution [***]. Any failure by CPL to meet Product Delivery timelines as a result of such dispute resolution with an OptiNose Vendor or as a result of non-compliance by an OptiNose Vendor with the above referenced supply and/or quality agreements shall not be a Supply Failure and/or a breach of this Agreement, save for an OptiNose Vendor failure to provide Raw Material that conforms to the Specifications and such non-conformance was not detected by CPL in accordance with CPL's obligations under this Agreement or the Quality Agreement. Notwithstanding anything to the contrary in this Agreement and/or in the Quality Agreements between CPL and the OptiNose Vendors and/or between CPL and OptiNose, resolution of any quality issues and/or performance of Raw Materials received by CPL from the OptiNose Vendors (other than confirmation by CPL that such Raw Materials conform to the Specifications) shall be the responsibility of OptiNose. Upon CPL's receipt of OptiNose Components, CPL shall inspect such OptiNose Components and ensure that such OptiNose Components provided by such OptiNose Vendor meets the applicable specifications for such OptiNose Components and that no patent defects or quantitative defects exist. CPL shall do such inspection within [***] ([***]) business days of its receipt of such OptiNose Components, provided it shall have [***] ([***]) days for its inspection of the API. Should the OptiNose Components fail any such inspection or should CPL identify any issues with the OptiNose Components CPL shall provide written notice to OptiNose and the applicable OptiNose Vendor within [***] of such failure and/or issue.

2.2 Product Information.

2.2.1 Source/License. Subject to the terms of this Agreement, including but not limited to the warranties and representations of CPL set forth in Article 7 and the obligations of CPL set forth in Article 8, OptiNose shall provide to CPL, and hereby grants CPL a limited (as set forth in the next sentence hereof) license to use, all Specifications, formulas, processes, analytical methods, Data, regulatory approvals, technology, Confidential Information and Intellectual Property of OptiNose necessary for the Manufacture of the Product in accordance with this Agreement (including, but not limited to, CPL's full compliance with the confidentiality and Intellectual Property obligations hereof). The license granted to CPL pursuant to this Section shall be a non-exclusive, royalty-free license (without the right to grant sublicenses) limited to CPL's use solely for purposes of fulfilling its obligations under, or otherwise effectuating, this Agreement.

2.2.2 Specifications. All Specifications shall be provided by OptiNose to CPL, or created by CPL or a third party and approved by OptiNose and CPL. Any changes in the Specifications agreed to by the Parties from time to time shall be in writing, dated and signed by the Parties. Except as provided in this subsection, no change in the Specifications, Manufacturing process, or Facility (other than changes to the Facility that are not prohibited under the Quality Agreement and do not substantially adversely impact the Manufacture of the Product), shall be implemented by CPL until the Parties have agreed in writing to such change, the implementation date of such change, any regulatory implications, and any increase or decrease in costs, expenses or fees associated with such change. CPL shall respond promptly to any request made by OptiNose for a change in the Specifications, and both Parties shall use [***] to agree to the terms of such change in a timely manner. If changes in Specifications result in implementation and/or increased Product costs to CPL, [***]. Changes resulting in reduction in cost of goods, following reimbursement or recapture of costs incurred by CPL to effect such reduction in costs, [***]. CPL shall provide documentation of the changes in any such costs. Notwithstanding the foregoing, the Parties shall promptly notify each other of any change in Specifications or Manufacturing process requested or required by a Regulatory Authority or an Applicable Law (a "Required Change"), and the Parties

shall thereafter work in good faith to agree in writing upon the change in Specification or process, its effective date and the costs, expenses and fees associated with such Required Change (which, CPL shall in any event use [***] to limit to the reasonable and necessary costs of effecting such Required Change) and to effect a corresponding written amendment to this Agreement reflecting same. However, it is understood and agreed that, if the Parties fail to agree upon the change in Specification or process to be made in response to a Required Change, OptiNose shall have the right to terminate this Agreement upon not less than [***] ([***]) days prior written notice to CPL, and if OptiNose does not so terminate this Agreement, CPL shall make each Required Change that OptiNose requests in writing; provided that CPL's implementation of such Required Change does not have a material effect on the CPL facility or CPL's ability to carry on its business in the ordinary course consistent with how it was being conducted prior to OptiNose's Required Change request, while the Parties continue negotiations in good faith as to costs, expenses and fees; provided, further, that [***]. In the event that the implementation of such Required Change would have a material effect on the CPL facility or CPL's ability to carry on its business in the ordinary course consistent with how it was being conducted prior to OptiNose's change request, and CPL provides OptiNose written notice thereof as soon as is reasonably practicable (provided such notice is not provided more than [***] ([***]) business days after CPL determines a Required Change would have such a material effect), OptiNose shall have the right to terminate this Agreement upon written notice to CPL.

2.3 Forecasts. Commencing on the Effective Date, OptiNose shall provide CPL each month with non-binding, rolling [***] ([***]) month forecast of its Product requirements ("Rolling Forecast"). OptiNose shall be obligated to purchase the unit quantity of Products for the first [***] months of any Rolling Forecast that was requested in the Rolling Forecast for that [***] ([***]) month period (a "Binding Period"). During the [***] of each calendar month OptiNose will issue a new Rolling Forecast which shall be updated monthly by OptiNose no later than the [***] ([***]) business day of each calendar month with the Binding Period updated with each Rolling Forecast to include the new [***] month of the going forward [***] month Rolling Forecast. CPL shall participate in periodic sales and operations planning meetings with

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

OptiNose and other suppliers as both Parties reasonably deem appropriate. Notwithstanding any other provision of this Agreement, for Rolling Forecasts issued prior to Final Approval Date, OptiNose shall not be required to place any Purchase Order for quantities that otherwise would be applicable for any Binding Period, and OptiNose may, in its sole discretion, cancel or modify any Purchase Order placed prior to the Final Approval Date; [***]. The Parties will work collaboratively together regarding planning of production of initial Product required to build initial launch quantities of Product in anticipation of the Final Approval Date. During the term of this Agreement, CPL shall ensure that, subject to utilization of OptiNose Equipment, it has the Capacity to meet all of OptiNose's requirements for Product in a timely manner based on the applicable Rolling Forecast under this Agreement and subject to the Product's standard lead time pursuant to Section 2.5; provided that if new or additional OptiNose Equipment is required CPL will inform OptiNose with sufficient lead time for such OptiNose Equipment to be acquired and qualified for use under this Agreement.

2.4 Reliance on Forecasts. CPL may order those Raw Materials necessary or appropriate to fulfill the forecasted Product requirements at the forecasted times, taking into account necessary lead times, agreed upon order policies, any minimum quantities required by suppliers, the Binding Period and any Purchase Orders for Product outside the Binding Period. In no case shall CPL maintain more than a [***] ([***]) month supply of Raw Materials without OptiNose's prior written consent. If the Purchase Orders for the corresponding period from OptiNose are for a quantity less than would reasonably support the amount of Raw Materials that CPL purchased in good faith in accordance with the preceding sentence, and CPL warrants and represents that it is ultimately, in the exercise of [***], unable to return such Raw Materials or use them, including to make Product hereunder within [***] ([***]) months of receipt of such Raw Materials by CPL and provided [***] has not already been provided by OptiNose for such Raw Materials otherwise under this Agreement, [***]; provided, however, that if CPL later uses such Raw Materials, [***].

2.5 Purchase Orders. OptiNose shall submit written Purchase Orders on its standard form for Product specifying: (a) the number of units of Product to be purchased, (b) the Purchase Price (determined in accordance with Exhibit B hereto) and (c) the expected date of Delivery ("Purchase Orders"). For Delivery of each Product, unless agreed with CPL under the circumstances, a Purchase Order shall not request a date of Delivery sooner than [***] ([***]) calendar days from the date of the Purchase Order. CPL shall confirm Purchase Orders and projected dates of Delivery within [***] of receiving a Purchase Order, and CPL may only reject such a Purchase Order if permitted under Section 2.7 of this Agreement or in the event of Force Majeure. Failure of CPL to confirm any Purchase Order within the [***] period shall be deemed to be acceptance of such Purchase Order.

2.6 Terms of Sale. ANY ADDITIONAL OR INCONSISTENT TERMS OR CONDITIONS OF ANY STANDARDIZED FORM OF EITHER PARTY, INCLUDING WITHOUT LIMITATION, ANY PURCHASE ORDER, INVOICE, CONFIRMATION, OR ACKNOWLEDGMENT GIVEN OR RECEIVED PURSUANT TO THIS AGREEMENT WILL HAVE NO EFFECT AND SUCH TERMS AND CONDITIONS ARE HEREBY EXCLUDED UNLESS THE PARTIES SPECIFICALLY AGREE IN WRITING SIGNED BY BOTH

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

PARTIES FOR SUCH TERMS OR CONDITIONS TO SUPPLEMENT OR SUPERCEDE THE TERMS AND CONDITIONS OF THIS AGREEMENT.

2.7 Purchase Orders for the Binding Period. OptiNose shall issue Purchase Orders for unit quantities of Product that are equal to or greater than the amount set forth in the Rolling Forecast for the applicable Binding Period, and CPL shall accept all such Purchase Orders except to the extent such Purchase Orders are for unit quantities of Product greater than [***]% of the amount set forth in the Rolling Forecast for such Binding Period (rounding such calculation up to the nearest batch size). In the event OptiNose issues Purchase Orders for unit quantities in excess of such [***]% of the Rolling Forecast for an applicable Binding Period (rounding such calculation up to the nearest batch size) or requests a change to a Purchase Order to increase unit quantities, CPL shall use [***] to accept (wholly or in part) such Purchase Orders for additional quantities or requested increases. Within [***] ([***]) business days of receipt of a Purchase Order for unit quantities in excess of [***]% of the Rolling Forecast for an applicable Binding Period ([***]) or request for a change to a Purchase Order to increase unit quantities, CPL shall (subject to its obligations pursuant to the foregoing sentence) notify OptiNose whether it can accept, wholly or in part, such Purchase Order or requested increase, and for all amounts that CPL accepts CPL shall be obligated to supply such excess quantities as if it was a part of the original Purchase Order governed by the terms of this Agreement. In the case of a partial acceptance, CPL shall specify quantities

and/or the date of projected Delivery. OptiNose shall not decrease the quantity of Product ordered in a Purchase Order. Except to the extent set forth above, failure of CPL to accept the increased quantity of Product as a result of a change to a Purchase Order in excess of the original amount ordered shall not be a breach of this Agreement.

2.8 Order Cancellation. Subject to the other provisions of this Agreement, in the event that OptiNose cancels or defers any Purchase Order issued by OptiNose and confirmed by CPL, OptiNose shall be bound to purchase [***] percent ([***]%) of Product ordered against such Purchase Order.

2.9 Non- or late Deliveries. In the event that CPL is unable to provide Delivery of the Product on or before a date of Delivery specified in the applicable Purchase Order, CPL shall notify OptiNose of such delay and provide the revised date for Delivery. If CPL fails to Deliver the Product in the quantities ordered in any accepted Purchase Order within [***] ([***]) business days of the date specified in such Purchase Order, for reasons other than Force Majeure, then in addition to, and without waiver or limitation of any of its other rights hereunder, at law or in equity, OptiNose shall be entitled to a discount of [***] percent ([***]%) off the price of the late-delivered Product for each week that Delivery is delayed (retroactive to the first day of such delay) up to a maximum discount of [***] percent ([***]%). The adjusted price for the Product shall be reflected by CPL in its invoice. However, if CPL fails, for any reason other than Force Majeure lasting more than [***] ([***]) calendar days, to Deliver Product pursuant to an accepted Purchase Order in accordance with its terms, in addition to, and without waiver or limitation of any of its other rights hereunder, at law or in equity, such failure shall constitute a Supply Failure pursuant to Section 2.11, and OptiNose may elect to cancel such Purchase Order and order the Product from the unfulfilled Purchase Order from a Back-up Supplier, as provided in Section 2.11 below.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.10 Back-up Supplier due to Supply Failure. In the event of a Supply Failure as set forth in subsection 2.11 below, at the option of OptiNose, CPL shall [***] (but in no event later than [***] ([***]) days after notice from OptiNose) transfer to OptiNose or a Back-Up Supplier all of the processes, protocols, procedures, methods and tests relating to the Manufacture of Product in accordance with the Specifications and Applicable Law pursuant to the terms set forth in Section 2.1(a), plus provide any technical assistance to OptiNose or the Back-Up Supplier that is reasonably necessary for OptiNose or the Back-Up Supplier to Manufacture Product during the Supply Failure.

2.11 Supply Failure. In the event that:

(i) the Facility fails an inspection or suffers a hold or disciplinary action by the FDA or any other government authority that prevents CPL from Delivering Product and CPL fails to cure such inspection shortcoming, or remove or resolve such hold or disciplinary action in such a manner that the Facility passes re-inspection by the FDA or applicable government authority and/or is free of the hold or disciplinary action, in good standing with FDA or such other applicable government authority, and is lawfully able to and does resume timely and conforming manufacture and delivery of OptiNose's Product requirements in accordance with this Agreement within [***] ([***]) days of such original inspection, or imposition of the hold or disciplinary action;

(ii) CPL materially breaches obligations or requirements under this Agreement related to the Manufacture and Delivery of the Product as set forth herein and fails to cure such breach within [***] ([***]) days of notice thereof by OptiNose, provided, however, that such [***] ([***]) day cure period shall be extended by up to an additional [***] ([***]) days if such breach is reasonably curable within such period and if CPL is diligently working to cure such breach as soon as practicable;

(iii) a Force Majeure preventing CPL from effecting timely Manufacture and/or Delivery of OptiNose's requirements of Product endures, or CPL cannot provide prompt written assurance upon OptiNose's reasonable written request that CPL can effect timely Manufacture and/or Delivery for more than [***] ([***]) days after such request, or

(iv) this Agreement is terminated by OptiNose pursuant to Section 11.3,

(each of (i) — (iv), a "Supply Failure"), OptiNose shall be relieved of its obligation to obtain any Product from CPL under this Agreement and shall be entitled to instead obtain Product from the Back-up Supplier, provided, that upon subsequent timely cure by CPL of a Supply Failure described in subsections (i), (ii) or (iii) above, OptiNose shall within [***] ([***]) days of such cure resume ordering the Annual Minimum requirements of Product from CPL, with the Annual Minimum modified from and after such resumption for the remainder of the Term, as provided in the definition of Annual Minimum.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.12 Delivery. All Products provided for Delivery by CPL under this Agreement shall be (i) suitably packed by CPL for Delivery in accordance with good commercial practice and instructions provided to CPL by OptiNose with respect to protection of such Product during transportation, (ii) marked for shipment to OptiNose or its distributor, (iii) accompanied by a certificate of analysis, certificate of compliance, import/export documents, and other documents as necessary and appropriate and in accordance with the terms of the Quality Agreement.

2.13 Competitive Products. Provided that in so doing, no Confidential Information or Intellectual Property of OptiNose is in any manner infringed by, or used (including the OptiNose Equipment) or disclosed to anyone, CPL shall have the right to manufacture, package and/or supply products to third parties which may compete with the Product and which may or may not contain the same active ingredient or ingredients as the Product; provided, however, that neither CPL nor any of its Affiliates shall directly or indirectly (whether for itself or a third party), Manufacture, import, export, develop, obtain Regulatory Approval for, or commercialize, market, sell, offer for sale, package or distribute the Product other than as required pursuant to this Agreement (including with respect to any Back-up Supplier or secondary supplier), nor shall CPL or any of its Affiliates directly or indirectly (whether for itself or a third party), develop a generic equivalent to the Product that involves the exhalation delivery of drug product(s) to the nasal cavity. For purposes of clarity, this Section shall not prohibit CPL from manufacturing, packaging or supplying a product that involves the exhalation delivery of any and all drug product(s) to the nasal cavity that has been submitted for regulatory approval or approved for marketing, commercialization or sale by the FDA before CPL's involvement.

ARTICLE 3
OPTINOSE EQUIPMENT

3.1 OptiNose Equipment; Bailment Agreements. OptiNose and CPL have entered that certain Bailment Agreement with respect to the OptiNose Equipment which is attached hereto in Exhibit C. The Parties hereby agree that the term OptiNose Equipment as used in the Bailment Agreement will include both the items described on Schedule A to the Bailment Agreement and the items described on Schedule 1 hereto. The Parties further agree that the term of the Bailment Agreement shall be co-terminus with the termination of this Agreement. Any additional OptiNose equipment not covered by the Bailment Agreement shall be added to Schedule A to the Bailment Agreement.

ARTICLE 4
PRICES AND PAYMENT

4.1 Price and Continuous Efficiencies Pass Through.

4.1.1 Price. OptiNose shall pay CPL the unit price set forth in Exhibit B for all Product Manufactured by CPL ("Purchase Price"). The Parties expressly acknowledge and agree that the unit pricing specified in Exhibit B is predicated upon the batch size designated therein. If a smaller or larger batch size is requested by OptiNose, prior to the Manufacture of such smaller or larger batch size, CPL shall advise OptiNose of the proposed adjustment to the Purchase Price, as applicable, to reflect the [***] impact of the batch size change, including the reasons for the

adjustment, including but not limited to process and/or packaging validation, claimed to be applicable. The Parties shall agree on such adjusted Purchase Price prior to the Manufacture of such smaller or larger batch size. The Parties also acknowledge and agree that the entire batch will be filled into a single Stock Keeping Unit ("SKU") and should OptiNose request that a batch be split into two or more SKUs, CPL shall issue a revised unit price based on a line change over fee, such fee to be agreed upon by the Parties prior to implementation. The maximum number of splits in any particular batch is [***] ([***]).

4.1.2 Waste Factor Price Adjustment. After the Final Approval Date and provided that CPL has Manufactured the first [***] ([***]) batches of commercial quantities of the Product, the Parties will agree upon maximum waste factors for Raw Materials, and the Parties will agree upon an equitable adjustment of the Purchase Price to reflect the results of and learnings from Manufacture of such batches.

4.1.3 Cost Reduction Plan**.** The Parties shall meet from time to time, but no less than [***] annually, to seek initiatives to improve quality of the Product and/or to reduce material, labor and other costs, and the Parties shall work reasonably after such meeting to implement such initiatives. For each such initiative, the following shall be subject to mutual agreement: the capital and expense to implement the initiative, the Party to provide funds for such capital and expense, the expected cost savings to result, and an equitable sharing of the cost and other benefits from the initiative after recoupment of the funds provided for the initiative (which sharing shall take into account a reasonable return on investment for the party providing the funds to implement such initiative).

4.1.4 Raw Material Price Increase. Upon advance written notice to OptiNose in each instance, CPL shall be entitled to an immediate adjustment to the unit price for a Product by the amount of the increase in Raw Materials cost where any increase in Raw Material costs increase the total unit price for the Product by [***] percent ([***]%) or more. CPL shall provide sufficient documentation to support any unit price adjustment in accordance with this Section.

4.1.5 Annual Price Adjustment. During the Term of this Agreement after [***], the unit price of each Product shall be increased or decreased, which adjustment shall become effective on January 1 of the subsequent calendar year by (a) the change in the cost of Raw Materials; provided, however, that any such change will not include the amount of any price change already implemented under Section 4.1.4 of this Agreement and (b) the actual change in CPL's labor and overhead costs as consistently applied to all products manufactured by CPL incurred over the prior [***] ([***]) month period ("Conversion Cost"); provided, however, that if such change in the labor and overhead is an increase, the percent change may not exceed the percentage increase over the prior [***] ([***]) month period in the Pharmaceutical Producer Price Index Pharmaceutical Preparation Manufacturing Ref. No. pcu325412325412 ("PPI") as reported by the United States Department of Labor Bureau of Labor Statistics.

4.1.6 [***]. Beginning on the later of (i) the [***] ([***]) anniversary of this Agreement and (ii) OptiNose having ordered [***] units of Product where a unit is a unit intended for commercial sale in the Territory or sample use in the Territory (provided that at the time such sample unit is ordered, the price payable to CPL for such sample unit is no more than

[***] percent ([***]%) less than the then current price payable to CPL for a unit intended for commercial sale, such sample unit herein called a "Qualified Sample Unit") under this Agreement and so long as OptiNose pays CPL for such units in full (such later date called the "Price Reduction Date"), CPL shall reduce the then current price of a unit of Product by [***] percent ([***]%) and such price shall remain in effect and apply to all purchases of Product in years from and after the Price Reduction Date. For clarity, any price reduction available to OptiNose under this paragraph will not apply to orders for Product placed before the [***] ([***]) Anniversary of this Agreement or prior to an aggregate of [***] commercial units and Qualified Sample Units of Product being ordered and paid for in full under this Agreement.

4.2 Payment Terms. All undisputed amounts payable under this Agreement shall be expressed in United States Dollars and shall be due and payable by OptiNose to CPL within [***] ([***]) days from the date of issuance of CPL's invoice to OptiNose for Product, subject to the terms of this Agreement.

CPL may not issue to OptiNose an invoice for Product until after Delivery of such Product. However, CPL shall not be required to store Product for more than [***] ([***]) business days after Release to Distribution. All invoices shall reference the applicable Purchase Order, be sent to the address specified in the applicable Purchase Order, and state the Purchase Price and unit price for Product in a given shipment, plus any taxes that are applicable pursuant to Section 4.3. All payments shall be made in United States dollars by check to CPL or by wire transfer in accordance with written instructions given by CPL from time to time.

4.3 Taxes; Duty. CPL shall be the importer of record for the the Raw Material identified in Schedule 3, to the extent requested in writing by OptiNose. [***]. If applicable, OptiNose shall provide to CPL any document, certificate, statement or other information reasonably required to be provided to CPL under applicable law in order for CPL not to charge and collect Transfer Taxes in respect of goods and services provided to OptiNose under this agreement, and CPL shall provide such document, certificate, statement or other information as reasonably requested by OptiNose in connection with any Transfer Taxes. Further, the parties will work together [***] to minimize Transfer Taxes, duties and other taxes as allowable under applicable law.

ARTICLE 5
PRODUCT CONFORMITY TO SPECIFICATIONS

5.1 Notification of Defective Product. OptiNose or its designee shall notify CPL within:

- [***] ([***]) calendar days after receiving a shipment of Product at OptiNose's warehouse if it determines that such shipment contains a Quantitative Defect,
- [***] ([***]) calendar days after receiving a shipment of Product at OptiNose's warehouse if it determines that such shipment contains a Patent Defect, and
- [***] ([***]) calendar days after OptiNose becomes aware of a Latent Defect.

OptiNose shall provide CPL a sample of what it alleges contains a Latent Defect or Patent Defect. Subject to compliance with the foregoing notice requirements and the provisions of

Section 5.2, below, OptiNose shall have the right to reject any batch of Product having a Patent or Latent Defect, provided that, in the case of any Latent Defect, notice of the defect by OptiNose must also be made prior to the expiry of such batch of Product, to the extent such defect was then reasonably known or knowable. Any Product that is not rejected within the applicable period shall be deemed accepted by OptiNose, and any shipment with respect to which OptiNose does not notify CPL of a Quantitative Defect within the applicable period shall be deemed accepted by OptiNose.

5.2 Resolution of Defective Product.

(a) Patent Defect or Latent Defect. Subject to, and without waiver or limitation of OptiNose's and/or CPL's rights and remedies hereunder, at law and/or in equity, if OptiNose believes that a Product or shipment has a Patent Defect or Latent Defect, OptiNose shall, at its option, [***]. If CPL does not agree with OptiNose's determination that such Product or shipment has a Latent Defect or Patent Defect, then after [***] to resolve the disagreement, and subject to, and without waiver or limitation of OptiNose's and/or CPL's rights and remedies hereunder, at law and/or in equity, either Party may submit a sample of such Product to a mutually agreed upon independent third party testing laboratory which is an expert in the industry and which will expertly apply the agreed upon testing protocol in order to determine whether the Product constitutes Defective Product. The independent party's results shall be final and binding for purposes of determining whether payment is owed (but not for purposes of any pending or potential product liability litigation which shall be governed by Article 9 hereof). If such results indicate that the Product was Defective Product, then in addition to, and without waiver or limitation of OptiNose's or CPL's rights and remedies hereunder, at law and/or in equity, OptiNose shall be entitled, at its option, to [***]. If the independent party's results indicate the Product was not a Defective Product, OptiNose shall [***]. If the independent party is unable to determine that a Product is Defective Product, [***]. Unless otherwise agreed to by the Parties in writing, the costs associated with testing and review of a Product pursuant to this Section shall be borne by [***]. Notwithstanding anything herein to the contrary, a Product shall be deemed not to be a Defective Product if the alleged defect or subject matter of the alleged defect is related to an error in or failure to properly conduct the Antimicrobial Effectiveness Test, provided that such defect or alleged defect is not due to the negligence or willful misconduct of CPL and CPL otherwise is in compliance with its obligations under this Agreement with respect to such test.

(b) Quantitative Defect. Subject to, and without waiver or limitation of OptiNose's and/or CPL's rights and remedies hereunder, at law and/or in equity, if OptiNose believes that a shipment has a Quantitative Defect, OptiNose shall notify CPL within the applicable period. If CPL agrees with such Quantitative Defect, CPL will promptly and as soon as practicable, and in no event more than [***] ([***]) business days, ship sufficient Product at OptiNose's direction to remedy such Quantitative Defect. If CPL does not agree with OptiNose's determination that such shipment has a Quantitative Defect, then after [***] to resolve the disagreement, and subject to, and without waiver or limitation of OptiNose's and/or CPL's rights and remedies hereunder, at law and/or in equity, CPL may require a mutually agreed upon independent third party to determine whether the shipment had a Quantitative Defect. The independent party's results shall be final and binding for purposes of determining whether CPL is obligated to ship

additional Product, [***]. If such results indicate that the shipment had a Quantitative Defect Product, then in addition to, and without waiver or limitation of OptiNose's or CPL's rights and remedies hereunder, at law and/or in equity, OptiNose shall be entitled to [***], made by OptiNose for such Product comprising the Quantitative Defect.

ARTICLE 6
RECORDS AND REGULATORY MATTERS

6.1 Batch Records and Data. Within [***] ([***]) business days prior to Delivery of the first and each subsequent batch of each Product, CPL shall provide OptiNose with properly completed and accurate copies of manufacturing work orders, packaging work orders, certificates of analysis, and certificates of compliance, each in the forms attached as Schedule 2, and any other documents properly associated with the Product batch release (for example, without limitation, documents relating to any investigations concerning the batch release) ("Batch Records"). OptiNose shall have [***] ([***]) business days after receipt of all Batch Records to either provide CPL with comments or corrections to be addressed or incorporated in such documents or with a Release to Distribution letter authorizing CPL to provide Delivery of the Product.

6.2 Recordkeeping. CPL shall maintain true and accurate books, records, test and laboratory data, reports and all other information relating to Manufacturing under this Agreement, including all information required to be maintained by all Applicable Laws. Such information shall be maintained for a period of at least [***] from the relevant finished Product expiration date or longer if required under Applicable Laws. CPL shall provide monthly inventory reports of OptiNose Components and all other Raw Material inventoried by CPL solely for the manufacture of Product.

6.3 Regulatory Compliance. Except as provided in the following sentence, OptiNose shall be solely responsible for obtaining and maintaining all permits and licenses required by any Regulatory Authority with respect to the Product, the NDA and any other marketing authorizations in other jurisdictions, as applicable, including any Product licenses, applications and amendments in connection therewith. CPL will be responsible for obtaining and maintaining all permits and licenses required by any Applicable Law with respect to the Facility, its equipment, and the Manufacture and Delivery of the Product. CPL will also maintain the Specifications, subject to Section 2.2.2, in accordance with the written instructions from OptiNose. CPL will Manufacture and provide Delivery of the Product in accordance with the requirements of this Agreement, Specifications and all Applicable Laws. In addition, during the Term of this Agreement, at OptiNose's request and at OptiNose's expense, CPL will reasonably assist OptiNose with all regulatory matters related to Manufacturing under this Agreement. Each Party intends and commits to cooperate to satisfy all Applicable Laws within the scope of its respective responsibilities under this Agreement.

6.4 Regulatory Correspondence. CPL shall notify OptiNose [***]) of any correspondence, any inspections, and the result of any inspection(s) with the FDA or any Regulatory Authority related to the Product. CPL shall send a draft to OptiNose of all correspondence related to the Product that CPL intends to send to any Regulatory Authority. All correspondence with a

Regulatory Authority related to the Product shall be subject to OptiNose's review and comment. OptiNose shall have [***] ([***]) business days to review the draft correspondence and provide its comments. CPL shall, acting reasonably, determine whether to incorporate such comments into the final correspondence. If OptiNose fails to review and/or provide comments to such correspondence within [***] ([***]) business days, OptiNose shall be deemed to have no comments to the correspondence. In no event shall OptiNose cause CPL to be late in responding to any Regulatory Authority. With respect to all correspondence and reports provided to OptiNose pursuant to this Section 6.4, CPL shall be entitled to redact any information that is specific to its customers other than OptiNose and is not directly related to the Product, and OptiNose agrees that such correspondence and reports shall constitute Confidential Information of CPL.

6.5 Governmental Inspections and Requests. CPL and OptiNose shall as soon as reasonably practicable (on the same day as receipt of notice of same, where feasible, but in no event more than within [***] of receipt of notice) inform each other in writing of any inspection, application for inspection, and other regulatory action, by any regulatory agency substantially relating to the Product or the manufacture of Product and/or, in the case of the Facility, substantially related to CPL's manufacturing, packaging, testing and storage of the Product, so that the other party has as much advance notice as reasonably possible to enable it to, as applicable and relevant, participate in preparation and/or strategy regarding and/or attend the inspection. Each Party will permit the other's representatives to be present during any such inspection related directly to the Product, and in the case of OptiNose, CPL will also permit it to be present at any inspection of the Facility to the extent such inspection is directly related to CPL's manufacturing, packaging, testing or storage of the Product, provided that in such case, it is understood and agreed by OptiNose that all communication with the Regulatory Authority shall be directly between CPL and the Regulatory Authority unless the FDA requests to communicate with OptiNose. Each Party will provide the other with the results of all regulatory inspection or audits directly related to the Product within [***] ([***]) business days after such Party's receipt of such results.

6.6 Recall. In the event CPL believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, CPL shall as soon [***] (but in no event more than [***] after forming such belief) notify OptiNose in writing. CPL will not act to initiate a recall, field alert, Product withdrawal or field correction. In the event OptiNose believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, OptiNose shall immediately notify CPL in writing and CPL shall provide all [***] necessary cooperation and assistance to OptiNose. [***] any recall, field alert, Product withdrawal or field correction, and any assistance in connection therewith, shall be borne by [***], provided that [***] shall be obligated to [***] for [***] of a recall, field alert, Product withdrawal or field correction costs incurred by [***] to the extent such recall, field alert, Product withdrawal or field correction is caused by [***]'s breach of its representations, warranties, or obligations under this Agreement [***], Applicable Laws or [***]'s gross negligence or willful misconduct. For purposes of this Agreement, [***] shall be limited to, as applicable, [***]. For avoidance of doubt, OptiNose shall have the ultimate and final authority to initiate a recall.

6.7 Inspections and Audits by OptiNose. Representatives of OptiNose shall have access to each Facility with reasonable notice, as more particularly described below, for the purpose of: (a) conducting inspections of such Facility and CPL's maintenance and usage of the equipment utilized in the Manufacture of the Products, (b) performing quality control audits or (c) witnessing the Manufacture, storage of the Products or the Raw Materials related to

or used in the Manufacture of the Products. OptiNose shall have access to the results of any tests performed by CPL relating to Products and the Raw Materials that CPL purchases directly from a third party in the Manufacture of the Product. CPL shall endeavor (without the payment of any additional fees) to ensure that OptiNose has similar access to the facilities, data and records of CPL's agents and suppliers. Further, CPL will make available to OptiNose any audit reports from audits that CPL conducts, or has conducted, regarding such third parties. Such inspections do not relieve CPL of any of its obligations under this Agreement or create new obligations on the part of OptiNose. This right of inspection, audit and witnessing can be exercised [***] (and as often as necessary for cause), subject to a written notice to CPL given at least [***] prior to the inspection, or at any time or more frequently for cause. CPL shall permit such inspection during normal business hours at reasonable and mutually acceptable times. At all times, OptiNose's representatives shall be accompanied by CPL personnel and follow all site environmental health and safety policies of CPL. Each inspection, audit and witnessing shall be subject, at all times, to CPL's confidentiality and non-disclosure obligations to its other third party customers.

ARTICLE 7
REPRESENTATIONS AND WARRANTIES

7.1 CPL. CPL hereby represents, warrants and covenants to OptiNose that:

7.1.1 At the time of each Delivery of the Product as provided in Article 2, such Product and its corresponding Raw Materials will conform to the Specifications, and such Product shall have been manufactured, assembled, packaged, labeled, tested and Delivered in accordance with all Applicable Laws, including without limitation, cGMP and shall be free of any Latent, Patent or Quantitative Defect;

7.1.2 The Product shall not, at the time of Delivery to OptiNose, contain any material or be manufactured, handled or stored in any way that would cause the Product to be adulterated in any way within the meaning of Section 501, or misbranded within the meaning of Section 502, of the FD&C Act, as amended from time to time;

7.1.3 As of the Effective Date and at all times during the Term, CPL and the Facility and all equipment utilized in the Manufacture of the Product is and will be in compliance with all Applicable Laws;

7.1.4 At all times during the Term, CPL shall obtain OptiNose's written approval for the use of any third party contract laboratory for the testing and release of Product, shall be responsible to ensure that any such contractor is bound to and fully complies with all applicable terms and conditions of this Agreement, including but not limited to those respecting

Confidentiality and Intellectual Property, the Specifications and the requirements of all Applicable Laws;

7.1.5 CPL and its Affiliates covenant not to challenge, or assist any third party in any challenge of, the validity or enforceability of any of OptiNose's Intellectual Property Rights, including any claim of OptiNose's patents related to the Product, in any context, in any court or forum in the Territory, including but not limited to, any judicial, agency or USPTO proceeding (including reexamination proceedings) and/or any efforts to initiate a declaratory judgment action with respect to any of the patents;

7.1.6 To the best of its knowledge, information and belief, CPL warrants, represents and agrees that neither CPL nor any of its employees has ever been: (a) debarred under Section 306 (a) or (b) of the Generic Drug Enforcement Act of 1992, (Article 306(a) or (b)); or (b) (i) convicted of a crime for which a person can be debarred, (ii) threatened to be debarred or (iii) indicted for a crime or otherwise engaged in conduct for which a person can be debarred, in each case under Section 306 (a) or (b), provided, it is understood and agreed that the foregoing representations, warranties and agreements contained in this Section, the use of the phrase "to the best of its knowledge" means that CPL has made appropriate inquiries of its employees and has conducted searches of the FDA Debarment List (available at: http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm2005408.htm), the U.S. Department of Health & Human Services Office of Inspector General Exclusions Database (available at: https://exclusions.oig.hhs.gov), the U.S. Federal Government System for Award Management Records (available at: https://www.sam.gov) and http://www.ustreas.gov/offices/enforcement/ofac/ maintained by the U.S. Treasury Department's Office of Foreign Assets Control and as a result thereof no information has come to CPL's attention which contradicts or is inconsistent with such facts or circumstances. OptiNose acknowledges and agrees that CPL shall be entitled to assume the accuracy, currency and completeness of the records, indices and filing systems maintained at the public offices where such searches are conducted and the information and advice provided to CPL by appropriate government, regulatory or other like officials with respect to such matters, and CPL's reliance on such assumption shall be full compliance with CPL's obligations under this Section. CPL agrees to immediately notify OptiNose should any Regulatory Authority threaten any action that could possibly result in a breach of this Section;

7.1.7 CPL's Manufacture of the Product shall be in accordance with the Specifications and Product will be made, stored, packaged, labeled, tested, controlled, Delivered by CPL in accordance with all Applicable Laws;

7.1.8 CPL shall review and approve all in-process and finished Product test results to ensure conformity of such results with the Specifications;

7.1.9 The certificate of analysis and certificate of compliance, which will accompany each shipment of Product, shall be accurate, truthful and made in good faith; and

7.1.10 CPL will comply with all Applicable Laws in the performance of its obligations under this Agreement.

7.2 OptiNose. OptiNose hereby represents, warrants and covenants to CPL that:

7.2.1 The Specifications conform to all Applicable Laws, and during the Term, OptiNose will inform CPL of any changes in Applicable Laws that are a Required Change pursuant to Section 2.2.2;

7.2.2 OptiNose will comply with all Applicable Laws in the performance of its obligations under this Agreement and its use of any materials or Product provided by CPL under this Agreement;

7.2.3 OptiNose has all necessary authority and has requisite rights to OptiNose's Intellectual Property to be used with respect to each Product and any Purchase Order under this Agreement; and

7.2.4 To the best of OptiNose's current knowledge, information and belief, CPL's use, in accordance with the terms of this Agreement, of OptiNose's Intellectual Property, Confidential Information or other proprietary information of OptiNose, or materials supplied by OptiNose to CPL, in the manufacture, packaging, assembly, testing, Delivery, importing, exporting of Product or any other service provided by CPL hereunder, does not infringe or misappropriate the Intellectual Property rights of any third party.

7.3 Mutual. Each Party hereby represents, warrants and covenants to the other Party that:

7.3.1. Existence and Power. Such Party: (a) is duly organized, validly existing and in good standing under the laws of the state or province in which it is organized, (b) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (c) is in compliance with all requirements of Applicable Laws.

7.3.2 Authorization and Enforcement of Obligations. Such Party: (a) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

7.3.3 Execution and Delivery. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

7.3.4 No Consents. All necessary consents, approvals and authorizations of all Regulatory Authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained; and

7.3.5 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (a) do not conflict with or violate any requirement of

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Applicable Laws; and (b) do not materially conflict with, or constitute a material default or require any consent under, any current contractual obligation of such Party.

7.4 Disclaimer. EXCEPT AS PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS, WARRANTIES OR CONDITIONS (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF AND EACH PARTY EXPRESSLY DISCLAIMS ANY SUCH ADDITIONAL REPRESENTATIONS, WARRANTIES OR CONDITIONS.

ARTICLE 8
CONFIDENTIAL INFORMATION AND INTELLECTUAL PROPERTY

8.1 Mutual Obligation. CPL and OptiNose agree that they will not use or disclose the other Party's Confidential Information (defined below) to any third party without the prior written consent of the other Party except as required by law, regulation or court or administrative order; provided, however, that prior to making any such legally required disclosure, the Party making such disclosure shall give the other Party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances and cooperate with the [***] of such party to obtain an appropriate protective order. Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information as necessary to fulfill its obligations under this Agreement to the extent the recipients of the Confidential Information: (a) need to know such Confidential Information for the purpose of performing under this Agreement, (b) are advised of the contents of this Article, and (c) agree in a signed writing to be bound by the terms of this Article.

8.2 Definition. As used in this Agreement, the term "Confidential Information" includes all information related to the Product furnished by CPL or OptiNose, or any of their respective representatives or Affiliates, to the other or its representatives or Affiliates, whether furnished before, on or after the date of this Agreement and furnished in any form, including but not limited to written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all products, raw materials, components, specifications, formulae, reports, methods, drawings, tools, models, proprietary technologies whether commercial or developmental, Intellectual Property (including, but not limited to inventions, patents, patent applications, patent disclosures, trademarks, copyrights and know-how), regulatory, manufacturing, quality control or assurance, clinical, R&D, human resources, and/or compliance information, data or materials, analyses, compilations, business (including, but not limited to corporate structure, financial, accounting, strategy, plans, documents, contracts, practices, policies and procedures, software, tax, customer, supplier, marketing, sales, forecasting, distribution and/or shipping information, materials or data) or technical information, data and other materials prepared by either Party, or any of their respective representatives, containing or based in whole or in part on any such information furnished by the other Party or its representatives. Confidential Information also includes the existence of this Agreement and its terms, as well as the Confidentiality Agreement signed as of June 26, 2013, which is hereby made a part of this Agreement and attached hereto at Exhibit D.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

8.3 Exclusions. Notwithstanding Section 8.2, Confidential Information does not include information that: (a) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, or (b) is already known by the receiving Party at the time of disclosure as evidenced by the receiving Party's written records, or (c) becomes available to the receiving Party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis, or (d) was or is independently developed or discovered by or for the receiving Party without reference to the Confidential Information, as evidenced by the receiving Party's written records.

8.4 Return of Confidential Information. Upon termination of this Agreement, the receiving Party shall, upon request, promptly return within [***] ([***]) days all such Confidential Information, including any copies thereof, and cease its use or, at the request of the disclosing Party, shall promptly destroy the same and certify such destruction to the disclosing Party; except for a single copy thereof, which may be retained for the sole purpose of complying with the scope of the obligations incurred under this Agreement.

8.5 Intellectual Property Rights and Disclosure and Ownership of Results**.**

8.5.1 All right, title and interest in and to, and ownership of and/or Intellectual Property rights in and to the Product, the Specifications, the Regulatory Approval, the Manufacture, marketing, sale, offer for sale, import, export, components, testing, assembly, packaging and distribution of the Product is and at all times remains in OptiNose hereunder and nothing in this Agreement shall operate or be construed so as to grant any license or convey to or confer upon CPL, whether expressly or by implication, any such rights to other than such limited, nonexclusive license (without right to sublicense) as is necessary to permit CPL to Manufacture the Product and provide the Manufacturing to OptiNose on the terms and conditions of and for the periods and limited purposes contemplated in this Agreement.

8.5.2 Moreover, CPL shall promptly and fully disclose to OptiNose in writing all findings, data, results, and conclusions and all inventions, discoveries, trade secrets, techniques, processes, materials, know-how, trademarks, copyrights and other intellectual property rights related thereto, that are prepared, made or discovered by CPL, either alone or with others, directly related to the performance of, or in connection with, the Manufacturing or which result, to any extent, from the use of OptiNose Confidential Information, data, materials, Intellectual Property, Specifications, Regulatory Approval or other OptiNose property, during the Term (collectively, "Inventions"). In consideration of the promises made hereunder by OptiNose to CPL, OptiNose shall own all rights, title and interest in and to all Inventions, including, without limitation, all Intellectual Property regarding formulation with respect to the Product, except to the extent constituting improvements to CPL's then pre-existing Intellectual Property (the "CPL Manufacturing Improvements"). CPL will own all rights, title and interest in and to the CPL Manufacturing Improvements and hereby grants to OptiNose, in consideration of the promises made hereunder, a perpetual, non-terminable, worldwide, royalty-free, transferable and sublicensable (through multiple tiers) non-exclusive license to use the CPL Manufacturing Improvements for any purpose related to OptiNose or its transferees, successors and/or assignees products and services. CPL hereby assigns, transfers and conveys all of their right, title and interest in and to any and all Inventions, other than the CPL Manufacturing Improvements, to

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

OptiNose. Any materials (including the information contained therein) produced by CPL for OptiNose pursuant to the terms of this Agreement shall be the sole and exclusive property of OptiNose. OptiNose hereby grants to CPL a royalty-free, non-transferable, non-exclusive license to use any Inventions solely to the extent and for the duration necessary to enable CPL to perform its obligations hereunder. CPL shall not acquire any other right, title or interest in or to the Inventions as a result of its performance hereunder.

8.5.3 All materials subject to copyright protection prepared by or on behalf of CPL to the extent related to the performance of the Manufacturing, or to the extent that they relate to or involve the use of Confidential Information of OptiNose, shall be "works made for hire," the entire right, title and interest of which shall vest and reside in OptiNose. To the extent any such works prepared by or on behalf of CPL that are directly related to the performance of the Manufacturing hereunder, or that relate to or involve the use of Confidential Information of OptiNose, may not be interpreted as "works made for hire," such works shall be subject to CPL's granting to OptiNose an exclusive, non-royalty bearing, perpetual, non-terminable, worldwide, royalty-free license, with the right to assign and/or sub-license (including through multiple tiers) such works. OptiNose shall have the right to use all materials and other works subject to copyright protection prepared by or on behalf of CPL directly related to the performance of the Manufacturing, and CPL hereby grants to OptiNose, in consideration of the payments made hereunder, a perpetual, non-terminable, worldwide, royalty-free, transferable and sublicensable (through multiple tiers) non-exclusive license to use such materials for any purpose related to OptiNose or its transferees, successors and/or assignees products and services.

8.5.4 Upon the request and at the expense of OptiNose, CPL will execute and deliver any and all instruments and documents and take such other acts as may be necessary or desirable to document such transfer or to enable OptiNose or its affiliates to prepare, file, apply for, prosecute, enforce and maintain patents, trademark registrations or copyrights.

8.5.5 For clarification, except as specifically provided herein all Intellectual Property rights and know-how owned by each Party before the Effective Date of this Agreement remain the property of the said Party.

8.6 Survival. The obligations of this Article 8 shall at all times survive the expiration or sooner termination of the term of this Agreement.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by CPL. CPL shall defend, indemnify and hold harmless OptiNose, its Affiliates, and their respective directors, officers, employees and agents ("OptiNose Indemnitees") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees) in connection with any suit, demand or action by any third party ("Losses") arising out of or resulting from: [***].

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.2 Indemnification by OptiNose. OptiNose shall defend, indemnify and hold harmless CPL, its Affiliates, and their respective directors, officers, employees and agents ("CPL Indemnitees") from and against all Losses arising out of or resulting from: [***].

9.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification: (a) promptly notifying the indemnifying Party of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure; (b) cooperating with the indemnifying Party in the defense of any such claim or liability; and (c) not compromising or settling any claim or liability without prior written consent of the indemnifying Party provided, such consent shall not be unreasonably withheld where the compromise or settlement: (w) provide for the unconditional release of the Party seeking indemnification; (x) require the payment of compensatory monetary damages by the indemnifying Party only; (y) requires no requirement whatsoever for the indemnified party to either take any action or to avoid any action whether as a matter of injunctive relief, court order, or any other form; and (z) expressly state that neither the fact of settlement nor the settlement agreement shall constitute, or be construed or interpreted as, an admission by the Party seeking indemnification of any issue, fact, allegation or any other aspect of the claim being settled. In all other cases, the Party seeking indemnification and the indemnifying Party must agree to enter into any proposed settlement. The indemnifying Party shall be entitled to control the defense of any claim or liability for which indemnification is sought hereunder and under such circumstances, the indemnified Party shall not be entitled to be indemnified for attorney fees in connection with such claim or liability; provided that the indemnified Party shall be entitled at its own expense to participate in the defense of such claim or liability with its own counsel and at its own expense.

ARTICLE 10
INSURANCE

10.1 CPL Insurance. CPL shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the Term of this Agreement: (a) Commercial General Liability Insurance, (b) Product Liability Insurance and Completed Operations Liability Insurance, and (c) Professional Liability and/or Errors and Omissions Liability Insurance, in each case with per-occurrence and general aggregate limits of not less than $[***], and from and after the date of first commercial sale of a Product, of not less than $[***]. This requirement may be satisfied through the use of an umbrella policy. Additionally, CPL shall, at its own cost and expense, obtain and maintain in full force and effect, Worker's Compensation Insurance with employer's liability limits no less than $[***]. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term of this Agreement and for a period of not less than [***] following the termination or expiration of this Agreement. CPL's policies shall be specifically endorsed to include OptiNose as an Additional Insured. CPL shall supply OptiNose with the above proof of insurance and forms as required upon request.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

10.2 OptiNose Insurance. OptiNose shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the Term of this Agreement: (a) Commercial General Liability Insurance, and (b) Product Liability Insurance and Completed Operations Liability Insurance, in each case with per-occurrence and general aggregate limits of not less than $[***], and from and after the date of first commercial sale of a Product, of not less than $[***]. This requirement may be satisfied through the use of an umbrella policy. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than [***] following the termination or expiration of this Agreement. OptiNose's policies shall be specifically endorsed to include CPL as an Additional Insured. OptiNose shall supply CPL with the above proof of insurance and forms as required upon request.

ARTICLE 11
TERM AND TERMINATION

11.1 Term of Agreement. The Term of this Agreement shall commence as of the Effective Date and shall remain in effect for a period of five (5) years from when OptiNose provides a Purchase Order for validation batches, unless sooner terminated by mutual consent or pursuant to this Agreement ("Initial Term"). Thereafter, this Agreement shall automatically expire at the end of the Initial Term unless at least [***] before the end of the Initial Term the Parties agree in writing to renew for a renewal term of [***] on terms and conditions to be mutually agreed upon (the "Renewal Term"). Any renewal of a Renewal Term shall be subject to the Parties agreeing in writing at least [***] before the expiry of the then current Renewal Term to renew for a further renewal term of [***] on terms and conditions to be mutually agreed upon**.**

11.2 Default. If either Party at any time commits a material breach of the provisions of this Agreement, the Bailment Agreement or the Quality Agreement, the other Party shall have the right to terminate this Agreement upon [***] ([***]) days written notice, whereupon this Agreement shall terminate, unless the breach complained of is cured within the said notice period or if the breach cannot, using [***], be cured within such [***] ([***]) day period but is reasonably expected to be cured within an additional [***] ([***]) day period, and the Party in default has promptly commenced to cure such breach within such [***] ([***]) day period and exercises [***] to effect such cure as soon as is reasonably practicable in the circumstances, and in any event such breach is cured within such additional [***] ([***]) day period. Notwithstanding the foregoing, should CPL have [***] ([***]) or more material breaches during a consecutive [***] ([***]) month period (even if subsequently cured), OptiNose shall have the right thereafter to terminate this Agreement by providing CPL written notice within [***] from the date of such third material breach, which termination shall be no less than [***] ([***]) days from the date of the notice.

11.3 Bankruptcy or Insolvency. If either Party shall (a) become bankrupt or insolvent, (b) file for petition therefore, (c) make an assignment for the benefit of creditors, or (d) have a receiver appointed for its assets, which appointment shall not be vacated within [***] ([***]) days after the filing, then the other Party shall be entitled to terminate this Agreement forthwith by written notice to such Party.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

11.4 Termination by OptiNose. OptiNose shall have the right to terminate this Agreement immediately upon written notice if (i) any Intellectual Property of any third party is reasonably alleged by a third party to be infringed, misappropriated or otherwise violated by the Manufacture, import, use, sale or distribution of the Product, (ii) any Regulatory Authority requires OptiNose to cease production or sale of Product(s) or (iii) the liability cap specified in Article 12 is exhausted prior to the end of the Term. OptiNose agrees that in the event it exercises any right to terminate the Agreement pursuant to this Section that [***]. CPL will cooperate with OptiNose to return inventory where applicable and feasible, [***]. It is understood and agreed, however, that where CPL is able to return inventory, [***]. In the event that CPL has not been reimbursed in full by any vendor or by any other third party for any Raw Material, [***]. Subject to and without waiver or limitation of OptiNose's rights and remedies in Section 11.2 above, 11.6 below and elsewhere in this Agreement, at law and/or in equity, [***].

11.5 Force Majeure. Except as to payments required under this Agreement, if any default or delay occurs which prevents or materially impairs a Party's performance and is due to a cause beyond the Party's reasonable control, and provided that the default or delay is not caused by or the fault of such Party, including but not limited to an act of God, flood, fire, explosion, earthquake, casualty, accident, war, revolution, civil commotion, blockade, terrorism or embargo or failure of available supply of raw materials and/or packaging components not reasonably preventable (in each case "Force Majeure"), the affected Party shall promptly notify the other Party in writing of such cause and shall exercise [***] to resume performance under this Agreement as soon as possible. Neither Party will be liable to the other Party for any loss or damage due to such cause, nor will the Term be extended thereby. Either Party may terminate this Agreement because of such default or delay upon not less than [***] ([***]) days' prior written notice to the other Party provided that the default or delay has already existed for [***] at the time of such notice and is continuing at the end of such termination notice period (e.g., the force majeure need not be suffered by the other party for more than [***] ([***]) days).

11.6 Effect of Termination. Expiration or termination of this Agreement on any basis shall be without prejudice to (i) any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination and (ii) any claims, remedies or other rights either Party may have at law, in equity or otherwise pursuant to or in connection with this Agreement. The rights and obligations of the Parties shall continue under Articles 1, 3, 5, 6, 7, 8, 9, and 10, Sections 11.4 and 11.6, Articles 12, 13, and 14 notwithstanding expiration or termination of this Agreement. In addition, any other provision required to interpret and to enforce the parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the observation and performance of the aforementioned surviving portions of this Agreement.

ARTICLE 12
LIMITATIONS OF LIABILITY

EXCEPT WHERE DUE TO [***], NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF REVENUES, PROFITS, DATA, OR BUSINESS OPPORUNITY, WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SUCH DAMAGES. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, [***].

NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT OR IN THE QUALITY AGREEMENT BETWEEN CPL AND OPTINOSE, IT IS UNDERSTOOD AND AGREED THAT [***].

ARTICLE 13
NOTICE

13.1 Notices. All notices and other communications hereunder ("Notices") shall be in writing and shall be deemed given: (a) when delivered personally; (b) when delivered by facsimile transmission (receipt verified); (c) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; (d) when delivered if sent by reliable express courier service with a confirmation, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof**);** or (e) when delivered by email followed up by registered or certified mail, return receipt requested.

To OptiNose US:
OptiNose US, Inc.
1020 Stony Hill Road
Suite 300
Yardley, PA 19067
Attention: Chief Executive Officer

To OptiNose UK:
OptiNose UK, Ltd.
Hunts Rise
South Marston Park, Wiltshire
SN3 4TG, England
Attention: Chief Executive Officer

To OptiNose Norway:
OptiNose AS
Gaustadalleen 21
0349 Oslo, Norway
Attention: Chief Executive Officer

In each instance, with cc to:

OptiNose US, Inc.
1020 Stony Hill Road
Suite 300
Yardley, PA 19067
Attn: Chief Legal Officer

To CPL:

Contract Pharmaceuticals Limited
7600 Danbro Crescent

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Mississauga, Ontario, Canada L5N 6L6
Attention: Ken Paige, Chief Executive Officer
Email: kpaige@cplltd.com

ARTICLE 14
MISCELLANEOUS

14.1 Entire Agreement; Amendments. This Agreement, the Quality Agreement, the Bailment Agreement, and any exhibits, schedules, attachments, and any amendments hereto or thereto, constitute the entire understanding between the Parties with respect to the specific subject matter hereof. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise provided in this Agreement.

14.2 Recitals. The recitals are hereby incorporated in and made part of this Agreement.

14.4 Further Assurances. The Parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

14.5 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

14.6 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect to the extent reasonably severable without altering the Parties' original intent. In such case, the Parties shall promptly undertake in good faith to negotiate a valid replacement provision for any such invalidated or severed provision that tracks as nearly as possible the Parties' original intent.

14.7 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent.

14.8 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent, assign this Agreement to an Affiliate or to an acquirer of or a successor to substantially all of the business or assets of the assigning Party. In the case of assignment to an Affiliate, where the assignee is not also the acquirer or successor to substantially all of the business or assets of the assigning Party (a "Permitted Transferee"), the following conditions apply:

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(a) the transferor is not in breach of its obligations under this Agreement;

(b) the Permitted Transferee is, and remains, an Affiliate of the transferor; and

(c) the Permitted Transferee has the reasonable wherewithal to and is reasonably capable of discharging the obligations of the transferor hereunder to the same extent as transferor, and the Permitted Transferee agrees to assume and be bound by and entitled to the benefits and obligations and rights under this Agreement to the extent and with the same effect as if such Permitted Transferee was the original party to this Agreement and the Permitted Transferee and the transferor shall be jointly and severally liable to the other Party for the performance of the Permitted Transferee of the obligations of the transferor contained in this Agreement.

14.9 Prevailing Party. In any dispute resolution proceeding between the Parties in connection with this Agreement, the prevailing Party will be entitled to [***].

14.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

14.11 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under applicable law or by any governmental agency or stock exchange rule or regulation, in which case the Party required to make the press release or public disclosure shall use [***] to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

14.12 Conflicting Terms. To the extent this Agreement and the Quality Agreement have directly conflicting terms, this Agreement shall govern.

14.13 Currency. Wherever a currency is indicated throughout this Agreement, that currency shall be United States Dollars.

14.14 Days. Wherever reference is made to days, working days or any measurement of time in days, business days shall be used, except where calendar days are specified.

14.15 Sophisticated Parties. Each Party to this Agreement is a sophisticated business party negotiating in good faith with the advice of legal counsel.

14.16 English Language. This Agreement has been negotiated and is written in the English language, and the English original shall prevail over any translation hereof.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

14.17 Interpretations. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections, Schedules or Exhibits mean the particular Articles, Sections, Schedules or Exhibits to this Agreement and references to this Agreement include all Schedules and Exhibits hereto. Unless context clearly requires otherwise, whenever used in this Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (ii) the word "or" shall have its inclusive meaning of "and/or;" (iii) the word "notice" shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Manufacturing Agreement; (iv) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement (including any Schedules and Exhibits); (v) provisions that require that a Party or the Parties "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing; (vi) words of any gender include the other gender; (vii) words using the singular or plural number also include the plural or singular number, respectively; and (viii) references to any specific law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof.

14.18 Dispute Resolution. The senior executives of the respective Parties shall use [***] to negotiate in good faith to resolve disputes regarding any right, obligation, duty or liability which may arise between the Parties under this Agreement. Subject to Section 5.2 hereof, in the event that the Parties are unable to resolve such dispute within a reasonable period of time, either party may pursue appropriate legal and equitable relief, as provided by Applicable Law, consistent with Section 14.19, below.

14.19 Governing Law and Venue. This Agreement shall be governed by and construed in accordance with the laws (except for the laws governing choice of law) of and in the state and/or federal courts located within the State of Delaware, U.S.A, wherein jurisdiction and venue over the parties and any dispute shall be exclusively had.

14.20 OptiNose Parties. Notwithstanding anything in this Agreement to the contrary, (i) each of OptiNose US, OptiNose UK and OptiNose Norway shall be and is hereby individually vested with each and every right of OptiNose under this Agreement, (ii) the OptiNose parties shall inform CPL which OptiNose party will be acting under this Agreement (the "Acting OptiNose Party") and thereafter CPL shall be entitled to rely exclusively on instructions from such Acting OptiNose Party until notified by the OptiNose parties that a new Acting OptiNose Party has been so designated, and (iii) each of OptiNose US, OptiNose UK and OptiNose Norway shall be severally, and not jointly, liable or responsible to CPL for any obligations of such party to CPL contained in this Agreement resulting from any actions or inaction by it as the Acting OptiNose Party or as a result of any event or occurrence while it was the Acting OptiNose Party and shall be the sole OptiNose party liable and responsible to CPL for such obligation.

[Signature Page Follows]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this Agreement.

CONTRACT PHARMACEUTICALS LIMITED CANADA	**OPTINOSE US, INC.**
By: /s/ Jan Sahai	By: /s/ Peter Miller
Name: Jan Sahai	Name: Peter Miller
Its: VP Business Development	Its: CEO

OPTINOSE UK LTD.

By: /s/ Peter Miller

Name: Peter Miller

Its: CEO

OPTINOSE AS

By: /s/ Peter Miller

Name: Peter Miller

Its: CEO

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT A

PRODUCT SPECIFICATIONS

The Specifications are to be finalized by the Parties using [***] as soon as practicable after the Effective Date for the initial commercial and related sample product for use in the Territory (provided such sample unit is substantially similar to the unit intended for commercial sale), with OptiNose providing its final written approval thereto. The Parties shall work together in good faith to finalize such Specifications for any additional Products set forth in that certain Quotation Version 35 from CPL to OptiNose, dated August 11, 2017.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

PRICE

The Purchase Price shall be as set forth in that certain Quotation Version 35 from CPL to OptiNose, dated August 11, 2017; provided, that the [***] specified therein for Raw Materials procured by OptiNose shall be adjusted once OptiNose's purchase price for such Raw Materials is finalized ([***] and OptiNose shall provide reasonable written, formal documentation of such purchase prices to CPL).

As part of the Purchase Price, pursuant to Section 2.1(d), the Purchase Price shall include the following:

- [***]% of the cost of Raw Materials procured by OptiNose
- [***]% of the cost of Raw Materials procured by CPL

Pursuant to Section 2.1(c), the following costs shall be payable in the event of an Annual Minimum shortfall:

- [***]
- [***]
- [***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT C

Bailment Agreements

See attached.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

MASTER BAILMENT AGREEMENT

THIS AGREEMENT is made as of the 24th day of June, 2016,

BETWEEN:

OptiNose US, Inc.,
a corporation incorporated under the laws of the State of Delaware;

(hereinafter referred to as "**OptiNose**")

- and -

Contract Pharmaceuticals Limited Canada
a corporation incorporated under the laws of **[the province of Ontario]**;

(hereinafter referred to as the "**Manufacturer**", OptiNose and Manufacturer, each, a "**Party**" and collectively, the "**Parties**")

RECITALS

1. The Manufacturer carries on the business of development and manufacturing of non-sterile liquid and semi-solid pharmaceutical products in the Province of Ontario.

2. The Manufacturer and OptiNose may become parties to certain contract manufacturing and supply agreements pursuant to which OptiNose would hire the Manufacturer, among other things, to process or otherwise convert various raw materials and packaging components into finished products that incorporate OptiNose's unique and patented Bi-Directional Breath Powered technology platform (the "**Products**"). Any contract manufacturing and supply agreement described above, if and when entered into between the Parties from time to time, as may be amended, modified, supplemented or restated from time to time, shall be referred to herein as, a "**Supply Contract**".

3. OptiNose wishes to deliver or have delivered certain property, machinery and equipment of OptiNose, as forth and described in Schedule "A" hereto (the "**OptiNose Equipment**"), to the Manufacturer from time to time for storage and use by the Manufacturer for the purpose of performing the services prescribed by the Supply Contract for and on behalf of OptiNose in accordance with the terms and conditions set out in the Supply Contract at the facility leased and operated by the Manufacturer and located at 7600 Danbro Crescent, Mississauga, Ontario, Canada L5N 6L6 (the "**Facility**").

4. OptiNose and the Manufacturer wish to confirm the ownership, storage, use and maintenance of the OptiNose Equipment and certain related obligations of the Manufacturer, on the terms and subject to the conditions set forth herein.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

NOW THEREFORE THIS AGREEMENT WITNESSES THAT in consideration of the mutual covenants and agreements herein contained and for other good and valuable consideration (the receipt and sufficiency of which is hereby acknowledged), the Parties agree as follows:

1. **OPTINOSE EQUIPMENT**

1.1 Ownership of OptiNose Equipment. All right, title and interest in and to any and all OptiNose Equipment shall belong exclusively to OptiNose at all times, notwithstanding any storage, changes, transformations to or work performed by the Manufacturer on any part or portion of the OptiNose Equipment.

1.2 No Interest of Manufacturer in the OptiNose Equipment. Nothing in this Agreement shall be construed as granting the Manufacturer any right, title or interest in or to the OptiNose Equipment. To the extent that the Manufacturer or any of its employees, agents or representatives acquires any right, title or interest in the OptiNose Equipment, the Manufacturer shall, and shall cause all such persons to, hold such rights in trust for OptiNose. The Manufacturer hereby assigns, and/or shall cause all such persons to assign, all such rights to OptiNose and shall do all such acts, execute all such documents and provide such further assurances and instruments, from time to time, as may reasonably be required for the foregoing.

1.3 No Encumbrances. The Manufacturer shall not, at any time, create, grant, or suffer to exist, any liens, security interests, charges or other encumbrances whatsoever upon the OptiNose Equipment, other than any liens in favor of OptiNose, OptiNose creditors, and/or the manufacturers of the OptiNose Equipment.

1.4 Restriction on Use. The Manufacturer shall receive and hold the OptiNose Equipment solely for the purpose of performing the services prescribed by and in accordance with the Supply Contract for and on behalf of OptiNose in accordance with the terms and conditions set out in the Supply Contract or other written instructions of OptiNose (the "**Permitted Purpose**"). Notwithstanding the foregoing, the Parties acknowledge and agree that in addition to the Permitted Purpose, the Manufacturer shall have the right to use the OptiNose Equipment, from time to time, to manufacture any other product or products for itself or any one or more third parties, provided: (i) such other product or products are not fluticasone for nasal inhalation obtained by prescription (for clarity, Manufacturer is permitted to use OptiNose Equipment for the manufacture of any and all non-prescription product(s) that contain fluticasclue), and (ii) the manufacture of the Product will have priority over any other use of the OptiNose Equipment including any manufacturing of any other product or products by the Manufacturer for itself or any one or more third parties ("**Other**

Manufacturing") provided that such Other Manufacturing has not been scheduled previously. For the avoidance of doubt, OptiNose shall have no liability to the manufacturer in connection with the OptiNose Equipment not being available, for any reason, for such Other Manufacturing The Parties intend to settle and execute the Supply Contract on or before July 31, 2016.

2. **DELIVERY AND STORAGE OF PROPERTY**

2.1 Delivery of OptiNose Equipment. Pursuant to delivery arrangements to be made between OptiNose and the Manufacturer, with assistance and direction from the Manufacturer pursuant

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

to Section 3.1 below, OptiNose shall deliver or shall arrange for delivery of the OptiNose Equipment to the Facility for purposes of use in manufacturing by the Manufacturer. Upon receipt of any part or portion of the OptiNose Equipment, the Manufacturer shall deliver to OptiNose by email or facsimile a confirmation of receipt in the form of Exhibit A hereto (or as may otherwise be reasonably acceptable to OptiNose).

2.2 Terms of Storage.

(1) During the term of the to be executed Supply Contract between the Parties, the Manufacturer shall store the OptiNose Equipment at the Facility [***] and no other location without the written authorization of OptiNose. Any storage of the OptiNose Equipment elsewhere by the Manufacturer without written authorization of OptiNose shall be deemed a violation of this Agreement and the Manufacturer shall be liable to OptiNose for any loss or damage to the OptiNose Equipment.

(2) From the time the OptiNose Equipment is delivered to the Facility by or on behalf of OptiNose until such time as the OptiNose Equipment is removed from the Facility by or on behalf of OptiNose pursuant to OptiNose's written authorization, the Manufacturer shall be responsible for any physical damage to, and any physical loss of, the OptiNose Equipment to the extent arising from or relating to the negligence or willful misconduct of the Manufacturer or those for whom the Manufacturer is in law responsible, except to the extent such loss or damage is caused by the negligence or willful misconduct of OptiNose or its agents (which, for the avoidance of doubt, shall not include the Manufacturer or its agents). [***]. Any such replacements shall constitute accessions to the OptiNose Equipment stored by the Manufacturer for OptiNose, and title thereto shall immediately vest and remain in OptiNose.

(3) At all times during the term of this Agreement OptiNose shall, [***], place and maintain special form property insurance on the OptiNose Equipment for its full replacement value, subject to reasonable deductibles. In the event of any physical damage or loss suffered by the OptiNose Equipment, OptiNose agrees to diligently pursue any reasonably available insurance claim with respect to such loss, and that any proceeds thereof may be applied towards repair or replacement of the OptiNose Equipment, and will, net of any deductibles and resulting premium increases, reduce the Manufacturer's liability to OptiNose (if any) related to such loss.

(4) At all times during the term of this Agreement, the OptiNose Equipment will be conspicuously tagged and marked *"Property of OptiNose US, Inc."*

(5) The Manufacturer shall keep and maintain accurate and up-to-date records of the status and other reasonable particulars of the OptiNose Equipment. The Manufacturer shall deliver such records to OptiNose forthwith upon reasonable request, from time to time.

2.3 Records of OptiNose Equipment; No Misleading Representations. The Manufacturer shall keep correct books of account and records in respect of the OptiNose Equipment. Such books of account and records shall be open to inspection by OptiNose or its agents [***] during regular business hours of the Manufacturer upon reasonable advance notice. The Manufacturer

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

shall not carry or otherwise account for the OptiNose Equipment as equipment or other property and goods of the Manufacturer, nor shall the Manufacturer perform any acts or make any representations which may cause any of the Manufacturer's creditors, potential creditors, customers or any other third party whatsoever to believe that the Manufacturer is the owner of the OptiNose Equipment.

3. **FURTHER OBLIGATIONS OF MANUFACTURER**

3.1 Equipment Procurement and Installation Services.

(a) The Manufacturer covenants and agrees to select and procure the OptiNose Equipment at a competitive commercial cost for and on behalf of OptiNose. For and on behalf of OptiNose, the Manufacturer shall be responsible for all necessary selection, performance evaluation, contract negotiation, arrangements for shipment and delivery, inspection, customization, modification and installation of the OptiNose Equipment at the Facility including all related communications with the suppliers of the OptiNose Equipment in order to ensure that the OptiNose Equipment meets the needs and objectives of OptiNose in respect of the Manufacturer's manufacturing, assembly, quality testing, inspection and packaging of the Products pursuant to the Supply Contract, including without limitation meeting OptiNose's prescribed timelines for commencement of such activities, provided that any delay in meeting such timelines is not due to the acts or omissions of OptiNose or those for whom the OptiNose is, in law, responsible (which, for the avoidance of doubt, shall not include the Manufacturer or its agents).

(b) All costs associated with the delivery and installation of the OptiNose Equipment, including without limitation, capital investments related to the preparation of the Facility to incorporate the OptiNose Equipment, specifically and without limitation, work related to the installation of the OptiNose Equipment, modification, commissioning and validation of the Facility, computer systems and utilities, up to the amounts set forth on the budget attached hereto as Schedule "B", [***]. Any amounts exceeding the aggregate budget attached hereto as Schedule "B" shall be approved by OptiNose.

3.2 Standard of Care. The Manufacturer shall use the same level of care, skill, prudence and diligence that a prudent person acting in a like capacity and familiar with such matters would use with respect to storage, use and maintenance and repair of the OptiNose Equipment. The Manufacturer shall take all [***] steps necessary or appropriate to protect the OptiNose Equipment from loss or damage.

3.3 Operation and Maintenance of OptiNose Equipment. During the term of this Agreement, the Manufacturer will:

(a) operate and maintain the OptiNose Equipment in a prudent, reasonable, and efficient manner and in accordance with the operating manuals, recommendations, procedures and guidelines and in compliance with the applicable warranty terms and conditions of the vendors or manufacturers of such equipment;

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(b) provide all labour, parts and equipment necessary to inspect, manage, and perform Routine and Preventative Maintenance (where "Routine and Preventative Maintenance" means any task that is performed at a regular predefined interval on the Equipment in accordance with the written instructions of the Equipment manufacturer in order to ensure that the Equipment continues to perform its intended function). Without limiting the generality of the foregoing, [***]. Any and all costs associated with modifications to the Equipment as a result of written instructions from OptiNose and/or a change in specifications of the Product shall be at [***]. OptiNose shall assist the Manufacturer during the term of this Agreement in enforcing any and all warranties, guarantees, service contracts, licenses and representations given to OptiNose by the vendor or a manufacturer or supplier of the OptiNose Equipment with respect to the OptiNose Equipment;

(c) maintain, at the Facility, the operating logs, records, and reports that document the operation and maintenance of the OptiNose Equipment, all in form and substance acceptable to OptiNose, acting reasonably; and

(d) notify and communicate with OptiNose regarding the occurrence or reasonable belief of the imminent occurrence of an unplanned outage of the OptiNose Equipment and take all [***] action to prevent or to mitigate such unplanned outage and minimize any costs associated with repairs that may be required to the OptiNose Equipment.

3.4 Audit and Inspection Rights. OptiNose shall be entitled to conduct audits and/or inspections of the Facility and/or the OptiNose Equipment to ensure that the Manufacturer complies with its duties and obligations under this Agreement [***] during business hours on reasonable, and, if OptiNose will require assistance from the Manufacturer in conducting such audit and/or inspection, not less than [***], and without unreasonably interfering with the Manufacturer's operations. OptiNose personnel and/or its agents shall be accompanied at all times by the Manufacturer's personnel (which shall be made available by the Manufacturer) and shall act in accordance with any reasonable applicable Standard Operating Procedures set out by the Manufacturer. All such audits and/or inspections shall be subject to Manufacturer's confidentiality and non-disclosure obligations to third party customers.

4. **INDEMNITY**

4.1 Indemnity. The Manufacturer shall indemnify and hold harmless OptiNose, its affiliates and their respective directors and officers, employees, agents and representatives (collectively, the "**Releasees**") from and against any and all liability, losses, costs, damages and expenses (including reasonable legal fees) causes of action, actions, claims, demands, lawsuits or other proceedings (collectively, the "**Claims**") by whomever made, sustained, brought or prosecuted, [***], other than [***] to the extent (i) not arising from the negligence and/or willful misconduct of the Manufacturer or those for whom the Manufacturer is in law responsible (which, for the avoidance of doubt, shall not include OptiNose or its agents), or (ii) arising from or relating to the negligence or willful misconduct of OptiNose or those for whom OptiNose is in law responsible (which, for the avoidance of doubt, shall not include the Manufacturer or its agents). The Manufacturer covenants and agrees with the Releasees not to make claim or cross claim or to take proceedings against any other person, firm, partnership,

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

business or company who or which might claim contribution from, or to be indemnified by any of the Releasees, under the provisions of any statute or otherwise.

4.2 Further Indemnity. Without limiting the generality of the foregoing, the Manufacturer shall indemnify the Releasees for the Manufacturer's [***].

4.3 Survival. Notwithstanding any termination of this Agreement, Sections 4 and 5 of this Agreement shall survive and continue without limitation in time.

5. **GENERAL**

5.1 Entire Agreement. This Agreement constitutes the entire agreement between the Parties pertaining to the subject matter hereof and supersedes all prior agreements, understandings, negotiations and discussions, whether oral or written, of the Parties and there are no warranties, representations or

other agreements between the Parties in connection with the subject matter hereof except as specifically set forth herein and therein, including work orders delivered pursuant to this Agreement, provided however that the obligations and duties of care of the Manufacturer hereunder are in addition to, and not in substitution for obligations and duties of care of the Manufacturer, as bailee, at law. This Agreement may not be amended or modified in any respect except by written instrument signed by all Parties.

5.2 No Waiver. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision (whether or not similar) nor shall such waiver constitute a continuing waiver unless otherwise expressly provided.

5.3 Further Assurances. The Parties agree to do or cause to be done all acts or things and to provide such further documents or instruments required to implement and carry into effect this Agreement to its full extent.

5.4 [***]. The Parties intend that title to the OptiNose Equipment held or stored for or on behalf of OptiNose pursuant to this Agreement shall remain in OptiNose at all times and that this Agreement shall be construed as a bailment agreement in all respects. [***].

5.5 Consent of the Manufacturer's Creditors; No Further Liens. The Parties recognize that certain of the Manufacturer's creditors may from time to time hold interests in certain property and assets of the Manufacturer. By execution of this Agreement, the Manufacturer represents and warrants to OptiNose that, except as set forth on Schedule "D", no such secured creditors of the Manufacturer hold currently effective liens or such other security interests on or in the Manufacturer's assets. For so long as any OptiNose Equipment is held or stored by the Manufacturer, if any secured creditor of the Manufacturer (other than OptiNose) hereinafter acquires a lien or security interest on or in any of the Manufacturer's assets after the date hereof, the Manufacturer will promptly (and in advance of the creation of any such lien) notify OptiNose thereof in writing. For so long as any OptiNose Equipment is held or stored by the Manufacturer, the Manufacturer shall obtain and provide to OptiNose the written acknowledgement, in all respects acceptable to OptiNose in its sole discretion, of the existence of this Agreement and the ownership by OptiNose of all of the OptiNose Equipment held or stored by the Manufacturer for or on behalf of OptiNose at the Facility from each such creditor.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

5.6 Repair and Storage Liens Act. The Parties agree that the transactions contemplated by this Agreement shall not create a lien or other encumbrance in the OptiNose Equipment or any part thereof pursuant to the *Repair and Storage Liens Act* (Ontario).

5.7 Severability. If any term, provision, covenant, condition, obligation or agreement of this Agreement, or the application thereof to any person or circumstance shall, to any extent, be invalid or unenforceable the remainder of this Agreement or the application of such terms, provisions, covenants, conditions, obligations or agreements to persons or circumstances other than those to which it is held invalid or unenforceable shall not be affected, impaired or invalidated thereby and each term, provision, covenant, condition, obligation and agreement of this Agreement shall be separately valid and enforceable to the fullest extent permitted by law.

5.8 Assignment. This Agreement shall enure to the benefit of and be binding upon the Parties hereto and their respective personal representatives, successors (including any successor by reason of amalgamation of any Party) and permitted assigns. This Agreement may be assigned by the Manufacturer only with the prior written consent of OptiNose, such consent not to be unreasonably withheld or delayed. Any purported assignment by the Manufacturer without such consent shall be null, void and of no effect.

5.9 Headings. The insertion of headings herein and the division of this Agreement into sections are for convenience of reference only and shall not affect the interpretation hereof.

5.10 Notices. All notices, documents or other or other communications required or permitted to be given under this Agreement shall be in writing and shall be effectively given if sent by prepaid courier service or registered mail, delivered personally or sent by facsimile transmission or e-mail to the other Party as out forth below.

If to OptiNose:

OptiNose US, Inc.
1010 Stony Hill Road, Suite 375
Yardley PA
USA
19067

Attention: CEO

Email: peter.miller@optinose.com

And to:

Kevin Clayton

Partner, Hogan Lovells US LLP

Columbia Square, 555 Thirteenth Street, NW

Washington, DC 20004

Tel: +1 202 637 5600; Direct: +1 202 637 5489

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Fax: +1 202 637 5910

If to the Manufacturer:

Contract Pharmaceuticals Limited Canada
7600 Danbro Crescent
Mississauga ON
Canada
L5N 6L6

Attention: CEO

Fax: 1 905 821 7601
Email: kpaige@cplltd.com

Any such notice, document or other communication so given or made shall be deemed to have been given or made and to have been received on the day of delivery if delivered personally, or on the day of facsimile transmission or sending by e-mail, provided that such day is not a Saturday or Sunday or a statutory holiday ("**Business Day**") and the communication is so delivered, transmitted by facsimile or sent prior to 4:30 p.m. EST on such day. Otherwise, such communication will be deemed to have been given and made and to have been received on the next Business Day if sent by courier, personal delivery, e-mail or fax, or on the third Business Day following the mailing thereof; provided that no such communication shall be mailed during any actual or apprehended disruption of postal services.

Each of the Parties hereto shall be entitled to specify a different address for purposes of this section only by giving notice in accordance with the terms hereof.

5.11 Time. Time is of the essence in this Agreement.

5.12 Termination. This Agreement may be terminated: (i) by either Party immediately upon written notice to the other Party if the other party has breached its obligations hereunder in any material respect and such breach has not been cured within a reasonable period of time; (ii) immediately, in the event that either Party is liquidated or dissolved; or is generally not paying its debts as such debts become due; or has filed against it in a court of competent jurisdiction a petition for an order for relief in bankruptcy or liquidation or reorganization; or makes a general assignment for the benefit of creditors; or there is entered against such Party an order for relief under the bankruptcy laws by a court of competent jurisdiction; or such Party commences a voluntary action under the bankruptcy laws or for the appointment or taking possession of a receiver, custodian, or trustee for such Party or with respect to all or substantially all of its assets; or a receiver, custodian, or trustee is appointed by a court of competent jurisdiction for such Party or with respect to all or substantially all of its assets; (iii) by either Party, for any reason, on [***] prior written notice provided a Supply Contract has been executed ; and (iv) upon the effective date of termination or expiration of the Supply Contract in accordance with its terms. At any time after a notice of termination has been given or an event has occurred which, with the passage of time, will cause this Agreement to terminate, OptiNose shall have the right to require the Manufacturer, as soon as reasonably

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

practicable and in no more than [***] from the effective date of termination, to make available for removal by OptiNose or its designee the OptiNose Equipment then held at the Facility, free and clear of all liens (other than liens created by OptiNose). In the event of termination by OptiNose pursuant to Sections 5.12(i) or 5.12(ii), such removal shall be at the Manufacturer's sole cost and expense.

5.13 Governing Law. This Agreement shall be governed by the laws of the Province of Ontario and the laws of Canada applicable therein.

5.14 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which taken together constitute one and the same instrument.

[*signature page to follow*]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF the Parties have each executed and delivered this Agreement effective the date first written above.

OPTINOSE US, INC.

By: /s/ Ramy Mahmoud
Name: Ramy Mahmoud
Title: President

(I have authority to bind the corporation)

CONTRACT PHARMACEUTICALS LIMITED CANADA

By: /s/ Jan Sahai
Name: Jan Sahai
Title: Vice President Business Development

(I have authority to bind the corporation)

[Signature page of Master Bailment Agreement dated June 24, 2016]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT A

DELIVERY RECEIPT

This is to confirm that, as of the date hereof, Contract Pharmaceuticals Limited (the "**Bailee**") has received at its facility located at 7600 Danbro Crescent Mississauga, ON L5N 6L6 [· - QUANTITY, TYPE AND DESCRIPTION OF PROPERTY] ("**OptiNose Equipment**") for the account of OptiNose US, Inc. ("**Customer**"), as owner thereof, pursuant to the terms of the Master Bailment Agreement, dated as of , 2016, between Customer and the Bailee (as amended, modified, supplemented or restated from time to time, the "**Bailment Agreement**"). The Bailee represents and warrants that it has segregated (as applicable), tagged and marked the OptiNose Equipment for purposes of identifying it as the Customer's property in accordance with the terms of the Bailment Agreement.

Date:

CONTRACT PHARMACEUTICALS LIMITED CANADA

By: _____
Name:
Title:

(I have authority to bind the corporation)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

HOLDING CERTIFICATE

In connection with the Master Bailment Agreement dated as of , 2016 (as amended, modified, supplemented or restated from time to time, the "**Bailment Agreement**") between OPTINOSE US, INC. ("**Customer**") and CONTRACT PHARMACEUTICALS LIMITED (the "**Bailee**") pertaining to the delivery into storage of the OptiNose Equipment (as defined in the Bailment Agreement), the Bailee hereby acknowledges that, as of , 20 , it holds the following OptiNose Equipment at the Facility identified in the Bailment Agreement for the Customer, as owner, free and clear of all liens and encumbrances [***]:

OptiNose Equipment	Quantity

This Certificate constitutes a document of title under the *Personal Property Security Act* (Ontario).

The Bailee represents and warrants that the OptiNose Equipment identified herein is segregated (as applicable), tagged and marked in accordance with the Bailment Agreement.

Date:

CONTRACT PHARMACEUTICALS LIMITED CANADA

By: _____
Name:
Title:

(I have authority to bind the corporation)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE "A"

Description of OptiNose Equipment

1. **[*****]; and
2. **[*****].

(Quotations attached)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Schedule B

Budget

[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE "D"

Manufacturer Secured Creditors

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT D

Confidentiality Agreement

See attached.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

MUTUAL CONFIDENTIALITY AGREEMENT

THIS AGREEMENT is made on the June 26th, 2013.

BETWEEN:

(1) **OPTINOSE US INC.** with a place of business at 1010 Stony Hill Road, Ste 375, 19067 Yardley, PA, USA- including its affiliates OptiNose AS whose registered office is situated at Austliveien 1, 0751 Oslo (mailing address: Pb 288 Roa, 0702 Oslo), Norway and OptiNose UK Ltd., Berkeley House, Hunts Rise, South Marston Park, Wiltshire SN3 4TG, UK) - ("OptiNose"); and

(2) **Contract Pharmaceuticals Limited Canada** whose registered office is situated 1.4 at 7600 Danbro Crescent, Mississauga, Ontario, Canada L5N 6L6 ("Company").

WHEREAS:

OptiNose and Company are entering into discussions to provide each other with information relating to formulation development and contract manufacturing ("the Project") and in the course of the Project information of a confidential nature will be disclosed by OptiNose and Company to each other.

NOW IT IS HEREBY AGREED as follows:

1. In consideration for each party disclosing information to the other, each party hereby agrees and undertakes:

   (i) to keep confidential all information of whatever nature provided to it by the other party or generated as a direct result of any work which may be undertaken by the other or which otherwise becomes known to it during the course of the Project including (for the avoidance of doubt and without limitation) any business plans for the exploitation of the Project, information relating to customers and suppliers of the disclosing party, the terms of business of the disclosing party, its business, financial, sales and marketing information, business systems, software data, plans, specifications and other technical information ("the Information");

   (ii) not to use copy or retain any copies of Information, except for the purposes for which it is so provided or generated, without the prior written consent of the other;

   (iii) to keep all Information in a safe and secure place; and

   (iv) to ensure that Information is disclosed in confidence only to such of its employees as is essential for the purposes of the Project and that there is no disclosure of Information by its employees other than as is provided for in this Agreement.

2. Each party hereby undertakes not to disclose any Information to any third party except with the prior written consent of the other party.

3. The obligations contained in clauses above do not apply to any Information which is:

   (i) already known to either party prior to the commencement of the Project (but, for the avoidance of doubt, this exception shall not apply to any Information which became known to that party during the course of any previous discussions, negotiations or relationship with the other party);

   (ii) published or otherwise comes into the public domain otherwise than in consequence of a breach of this Agreement by either party or a breach of confidence by a third party;

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

   (iii) required to be disclosed to the parties' professional advisers provided that such professional advisers agree to be bound by the terms of this agreement;

   (iv) received from a third party lawfully entitled to supply the same;

   (v) required to be disclosed pursuant to any law or regulation from time to time in force in the USA, Norway or the United Kingdom or on behalf of any competent regulatory authority or by a court of competent jurisdiction; or

   (vi) developed by either party at any time independently of the Information disclosed to it by the other party by persons who have had no access to or knowledge of the Information.

4. Any Information supplied to either party or copied by it for the purposes of the Project will be returned by the other party upon demand and in any case upon the cessation of the Project.

5. The provisions of this Agreement shall remain in full force and effect for five years after the date of this Agreement.

6. No licence is hereby granted by OptiNose or Company to the other of them either directly or indirectly in respect of (1) their respective existing intellectual property rights or the rights of any third party, (2) the subject-matter of the Project or (3) any intellectual property rights created in the course of the Project.

7. The construction, validity and performance of this Agreement shall be governed in all respects in accordance with the laws of the State of New York. Any dispute concerning the interpretation of this Agreement shall be determined by the courts in the State of New York and the parties submit to the jurisdiction of that Court for such purpose.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS whereof this agreement has been entered into on the date inserted at the head of this Agreement.

Signed: /s/ Peter Miller
For and on behalf of OptiNose US Inc.

By: Peter Miller
Position: President &CEO

Signed: /s/ Jan Sahai
For and on behalf of Contract Pharmaceuticals Limited Canada

By: Jan Sahai
Position: Vice President, Business Development

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 1

OptiNose Equipment

[***]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 2

Form of Batch Records

The Form of Batch Records are to be finalized by the Parties concurrent with or as soon as practicable after the finalization of each relevant Specification, with OptiNose providing its final written approval thereto.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 3

Hovione Inter Ltd. for API

Ximedica, LLC for liquid delivery subassemblies

Advanced Mold and Manufacturing Inc. (d/b/a Vision Technical Molding) for caps