UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark one)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission file number: 001-38241

OPTINOSE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**42-1771610**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1020 Stony Hill Road, Suite 300
Yardley, Pennsylvania 19067
(Address of principal executive offices, including zip code)

(267) 364-3500
(Registrant's telephone number including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	OPTN	Nasdaq Global Select Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No 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 ☒
Non-accelerated filer o	Smaller reporting company ☒
	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 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).Yes o No ☒

The number of shares of the registrant's common stock outstanding at November 8, 2019 was 41,581,666 shares.

Unless the context otherwise requires, all references in this Form 10-Q to "Optinose," "Company," "we," "us," and "our" refer to OptiNose, Inc. and its subsidiaries.

Trademark Notice

OPTINOSE® and XHANCE® are trademarks of ours in the United States. All other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-Q contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, among others, statements relating to:

- the potential advantages of XHANCE® and our Exhalation Delivery System (EDS) devices and technologies;
- future XHANCE prescription and net revenue growth and potential drivers of such growth;
- our commercial initiatives and objectives related to XHANCE, including our intention to increase the size of our sale force;
- the potential benefits of our patient affordability programs and their potential effect on XHANCE demand and financial results;
- the potential for XHANCE prescriptions and net revenues to be affected by the seasonality impact observed in the intranasal steroid (INS) market and annual deductible resets;
- our planned product development activities, studies and clinical trials, including those in pursuit of a follow-on indication for XHANCE for the treatment of chronic sinusitis;
- our expectation that top line results from the first of two Phase 3b clinical trials evaluating XHANCE as a potential treatment for chronic sinusitis will be available in the second half of 2021;
- the potential for XHANCE to be the first drug therapy approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic sinusitis;
- our expectation that the full-year 2019 XHANCE net revenue will be between $30.0 million and $33.0 million;
- our expectation that our operating expenses determined in accordance with U.S. generally accepted accounting principles (GAAP) in 2019 will be between $126.0 million and $129.0 million and that our non-cash stock-based compensation expense will be approximately $10.0 million;
- our expectation that the full-year 2019 average net revenue per prescription will be between $195 and $205; and
- the potential to issue up to an additional $70.0 million of senior secured notes under the Note Purchase Agreement entered into with funds managed by Pharmakon Advisors, LP, subject to the achievement of minimum XHANCE net sales and royalties and certain other conditions;

as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. Forward-looking statements appear primarily in the sections of this Form 10-Q entitled “Item 1. Financial Statements,” and “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In some cases, you can identify forward-looking statements by words such as “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing,” “scheduled” and similar expressions, although not all forward-looking statements contain these identifying words.

Forward-looking statements are based upon our current expectations and assumptions and are subject to a number of known and unknown risks, uncertainties and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission (SEC), and in particular, the risks and uncertainties discussed therein under the caption “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. As a result, you should not place undue reliance on forward-looking statements.

Additionally, the forward-looking statements contained in this Form 10-Q represent our views only as of the date of this Form 10-Q (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, even if new information becomes available in the future. However, you are advised to consult any further disclosures we make on related subjects in the reports that we file with the SEC.

The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-Q. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

MARKET, INDUSTRY AND OTHER DATA

This Form 10-Q contains estimates, projections, market research and other data generated by independent third parties, by third parties on our behalf and by us concerning XHANCE, market access, the INS market and prescriptions. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual results, events or circumstances may differ materially from results, events and circumstances reflected in this information. You are cautioned not to give undue weight to such information.

PART I

ITEM 1. FINANCIAL STATEMENTS

OptiNose, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2019	December 31, 2018
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 125,490	$ 200,990
Accounts receivable, net	10,746	2,310
Grants and other receivables	232	242
Inventory	4,404	7,132
Prepaid expenses and other current assets	3,230	2,183
Total current assets	144,102	212,857
Property and equipment, net	3,261	3,884
Other assets	2,014	248
Total assets	$ 149,377	$ 216,989
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,112	$ 7,116
Accrued expenses and other current liabilities	24,850	18,421
Deferred other income	—	160
Total current liabilities	29,962	25,697
Long-term debt, net	74,266	72,500
Other liabilities	631	181
Total liabilities	104,859	98,378
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 41,488,370 and 41,227,530 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	41	41
Additional paid-in capital	447,541	436,554
Accumulated deficit	(402,985)	(317,927)
Accumulated other comprehensive loss	(79)	(57)
Total stockholders' equity	44,518	118,611
Total liabilities and stockholders' equity	$ 149,377	$ 216,989

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Operations
For the Three and Nine Months Ended September 30, 2019 and 2018
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Net product revenues	$ 8,667	$ 1,902	$ 19,320	$ 4,042
Licensing revenues	3,730	—	4,230	—
Total revenues	12,397	1,902	23,550	4,042
Costs and expenses:				
Cost of product sales	1,389	319	3,216	870
Research and development	5,547	2,989	15,404	6,736
Selling, general and administrative	25,270	22,086	77,610	71,957
Total operating expenses	32,206	25,394	96,230	79,563
Loss from operations	(19,809)	(23,492)	(72,680)	(75,521)
Other (income) expense:				
Grant and other income	—	(42)	—	(374)
Interest income	(559)	(680)	(1,959)	(1,738)
Interest expense	2,372	2,361	7,148	6,855
Foreign currency (gains) losses	31	(8)	34	13
Loss on extinguishment of debt	7,155	—	7,155	—
Net loss	$ (28,808)	$ (25,123)	$ (85,058)	$ (80,277)
Net loss per share of common stock, basic and diluted	$ (0.69)	$ (0.61)	$ (2.06)	$ (2.04)
Weighted average common shares outstanding, basic and diluted	41,454,181	41,207,167	41,341,570	39,260,903

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Comprehensive Loss
For the Three and Nine Months Ended September 30, 2019 and 2018
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (28,808)	$ (25,123)	$ (85,058)	$ (80,277)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(12)	13	(22)	34
Comprehensive loss	$ (28,820)	$ (25,110)	$ (85,080)	$ (80,243)

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except share data)

Nine Months Ended September 30, 2019

	Stockholders' Equity					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	41,227,530	$ 41	$ 436,554	$ (317,927)	$ (57)	$ 118,611
Stock compensation expense	—	—	2,425	—	—	2,425
Exercise of common stock options	5,000	—	15	—	—	15
Issuance of common stock under employee stock purchase plan	31,892	—	173	—	—	173
Foreign currency translation adjustment	—	—	—	—	3	3
Net loss	—	—	—	(28,874)	—	(28,874)
Balance at March 31, 2019	41,264,422	$ 41	$ 439,167	$ (346,801)	$ (54)	$ 92,353
Stock compensation expense	—	—	2,716	—	—	2,716
Exercise of common stock options	88,587	—	354	—	—	354
Issuance of common stock under employee stock purchase plan	77,909	—	439	—	—	439
Foreign currency translation adjustment	—	—	—	—	(13)	(13)
Net loss	—	—	—	(27,376)	—	(27,376)
Balance at June 30, 2019	41,430,918	$ 41	$ 442,676	$ (374,177)	$ (67)	$ 68,473
Stock compensation expense	—	—	2,469	—	—	2,469
Exercise of common stock options	57,452	—	172	—	—	172
Issuance of warrants	—	—	2,224	—	—	2,224
Foreign currency translation adjustment	—	—	—	—	(12)	(12)
Net loss	—	—	—	(28,808)	—	(28,808)
Balance at September 30, 2019	41,488,370	$ 41	$ 447,541	$ (402,985)	$ (79)	$ 44,518

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Changes in Stockholders' Equity (cont'd)
(in thousands, except share data)

Nine Months Ended September 30, 2018

	Stockholders' Equity					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	37,802,556	$ 38	$ 365,838	$ (211,269)	$ (111)	$ 154,496
Stock compensation expense	—	—	2,050	—	—	2,050
Exercise of common stock options	106,502	—	130	—	—	130
Foreign currency translation adjustment	—	—	—	—	7	7
Net loss	—	—	—	(30,572)	—	(30,572)
Balance at March 31, 2018	37,909,058	$ 38	$ 368,018	$ (241,841)	$ (104)	$ 126,111
Stock compensation expense	—	—	2,135	—	—	2,135
Sale of common stock, net of issuance costs	2,875,000	3	59,923	—	—	59,926
Exercise of common stock options	330,401	—	727	—	—	727
Exercise of warrants	7,098	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	15	15
Net loss	—	—	—	(24,581)	—	(24,581)
Balance at June 30, 2018	41,121,557	$ 41	$ 430,803	$ (266,422)	$ (89)	$ 164,333
Stock compensation expense	—	—	2,209	—	—	2,209
Exercise of common stock options	45,287	—	561	—	—	561
Exercise of warrants	7,549	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	53,137	—	739	—	—	739
Foreign currency translation adjustment	—	—	—	—	13	13
Net loss	—	—	—	(25,123)	—	(25,123)
Balance at September 30, 2018	41,227,530	$ 41	$ 434,312	$ (291,545)	$ (76)	$ 142,732

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2019 and 2018
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	2018
Operating activities:		
Net loss	$ (85,058)	$ (80,277)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	878	326
Stock-based compensation	7,552	6,325
Amortization of debt discount and issuance costs	382	291
Loss on extinguishment of debt	7,155	—
Changes in operating assets and liabilities:		
Accounts receivable	(8,435)	(2,923)
Grants and other receivables	10	(136)
Prepaid expenses and other assets	(221)	(380)
Inventory	2,753	(4,686)
Accounts payable	(1,928)	2,566
Accrued expenses and other liabilities	4,203	7,271
Cash used in operating activities	(72,709)	(71,623)
Investing activities:		
Purchases of property and equipment	(485)	(1,450)
Cash used in investing activities	(485)	(1,450)
Financing activities:		
Proceeds from the sale of common stock	—	63,969
Proceeds from long-term debt	77,596	—
Proceeds from the issuance of warrants	2,404	—
Cash paid for financing costs	(3,277)	(6,464)
Proceeds from issuance of common stock under employee stock purchase plan	612	739
Proceeds from the exercise of stock options	542	1,418
Repayment of Athyrium debt facility	(80,179)	—
Cash (used in) provided by financing activities	(2,302)	59,662
Effects of exchange rate changes on cash and cash equivalents	(11)	41
Net decrease in cash, cash equivalents and restricted cash	(75,507)	(13,370)
Cash, cash equivalents and restricted cash at beginning of period	201,011	234,875
Cash, cash equivalents and restricted cash at end of period	$ 125,504	$ 221,505
Supplemental disclosure of noncash activities:		
Fixed asset purchases within accounts payable and accrued expenses	$ 17	$ 172
Fixed asset additions acquired through tenant allowance	$ —	$ 361
Financing costs within accounts payable and accrued expenses	$ 280	$ 82
Recognition of initial right-of-use assets	$ 2,479	$ —
Recognition of initial lease liabilities	$ 2,956	$ —

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Notes to Unaudited Interim Consolidated Financial Statements
(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 has facilities 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 first commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing its proprietary Exhalation Delivery System (EDS) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also known as chronic sinusitis). XHANCE was approved by the United States (US) Food and Drug Administration (FDA) in September 2017 for the treatment of nasal polyps in patients 18 years of age or older. XHANCE was made widely available through commercial channels in April 2018.

2. Liquidity

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio, conducting preclinical studies and clinical trials, pursuing regulatory approvals and most recently, preparing for and launching XHANCE in the US. As of September 30, 2019, the Company had cash and cash equivalents of $125,490.

The Company will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet the debt service obligations under the Company's outstanding senior secured notes, including repayment, and to carry out the Company's planned development and commercial activities. If additional capital 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, development and commercialization of its products and product 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 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 September 30, 2019 and its results of operations for the three and nine months ended September 30, 2019 and 2018 and cash flows for the nine months ended September 30, 2019 and 2018. Operating results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The 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, 2018 contained in the Company’s annual report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 6, 2019.

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.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and accounts receivable. 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 has exposure to credit risk in accounts receivable from sales of XHANCE. XHANCE is sold to wholesale pharmaceutical distributors and preferred pharmacy network partners (collectively, Customers), who, in turn, sell XHANCE to pharmacies, hospitals, patients and other customers. Five Customers represent approximately 67% of the Company's accounts receivable at September 30, 2019 and five Customers represent approximately 62% and 65% of the Company's net product sales for the three and nine months ended September 30, 2019, respectively.

Fair value of financial instruments

At September 30, 2019 and December 31, 2018, the Company's financial instruments included cash and cash equivalents, accounts receivable, grants receivable, inventory, accounts payable and accrued expenses. The carrying amounts reported in the Company's financial statements for these instruments approximate their respective fair values because of the short-term nature of these instruments. The Company also believes the carrying value of long-term debt approximates fair value at September 30, 2019 as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions. At September 30, 2019 and December 31, 2018, there were no financial assets or liabilities measured at fair value on a recurring basis.

Restricted cash

As of September 30, 2019 and December 31, 2018, the restricted cash balance included in prepaid expenses and other assets was $15 and $20, respectively.

Net product revenues

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606), which was adopted on January 1, 2018. The Company recognizes revenue from XHANCE sales at the point Customers obtain control of the product, which generally occurs upon delivery. The transaction price that is recognized as revenue for products includes an estimate of variable consideration. The Company's estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of its anticipated performance and all information (historical, current and forecasted) that is reasonably available. The components of the Company's variable consideration include the following:

Provider Chargebacks and Discounts. Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified

healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Trade Discounts and Allowances. The Company generally provides Customers with discounts that include incentive fees which are explicitly stated in the Company's contracts. These discounts are recorded as a reduction of revenue and accounts receivable in the period in which the related product revenue is recognized. In addition, the Company reimburses (through discounts and allowances) its Customers for sales order management, data and distribution services.

Product Returns. Consistent with industry practice, the Company has a product returns policy that provides Customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The Company estimates the amount of its product that may be returned and presents this amount as a reduction of revenue in the period the related product revenue is recognized, in addition to establishing a liability. The Company considers several factors in the estimation process, including expiration dates of product shipped to Customers, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

Government Rebates. The Company is subject to discount obligations under state Medicaid programs and Medicare. Reserves related to these discount obligations are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. The Company's liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made for product that has been recognized as revenue but remains in the distribution channel inventories at the end of the reporting period.

Payor Rebates. The Company contracts with certain third-party payors, primarily health insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. These rebates are based on contractual percentages applied to the amount of product prescribed to patients who are covered by the plan or the organization with which it contracts. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Patient Assistance. Other programs that the Company offers include voluntary co-pay patient assistance programs intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors and coupon programs for cash payors. The calculation of the accruals for this assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.

Licensing revenues

During the nine months ended September 30, 2019, the Company's licensing revenues were generated pursuant to license agreements with Inexia Limited (Inexia) and Currax Pharmaceuticals LLC (Currax) (Note 8). These license agreements provide for exclusive licensed rights to certain intellectual property, a non-refundable up-front payment, potential milestone payment(s) and potential royalty payment(s).

The Company analyzed the performance obligations under the license agreements, the consideration received to date and the consideration the Company could receive in the future as part of its analysis related to ASC 606. The Company recognized the upfront payments from the licensing agreements of $4,230 as licensing revenue during the nine months ended September 30, 2019 upon the delivery of the license performance obligations.

(in thousands, except share and per share data)

Net income (loss) per common share

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to Company common stock (Common Stock) holders by the weighted average common shares outstanding during the period. For the three and nine months ended September 30, 2019 and 2018, the outstanding Common Stock options, Common Stock warrants and shares to be issued under the Company's 2017 Employee Stock Purchase Plan have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

Diluted net loss per common share for the periods presented do not reflect the following potential common shares, as the effect would be antidilutive:

	September 30,	
	2019	2018
Stock options	7,748,519	6,138,373
Common stock warrants	2,677,188	1,866,831
Employee stock purchase plan	48,279	18,507
Total	10,473,986	8,023,711

Income taxes

In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and nine months ended September 30, 2019 and 2018, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of September 30, 2019 and December 31, 2018, 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.

Recent accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. ASU 2018-15 requires that certain implementation costs incurred in a cloud computing arrangement be deferred and recognized over the term of the arrangement. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and 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 August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 resulted in certain modifications to fair value measurement disclosures, primarily related to level 3 fair value measurements. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU 2016-03, in conjunction with ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments,* introduces an approach, based on expected losses, to estimate credit losses on certain types of financial instruments and modifies the impairment model for available-for-sale debt securities. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption 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 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 is effective for fiscal years

(in thousands, except share and per share data)

beginning after December 15, 2018. The ASU requires a modified retrospective transition method with the option to elect a package of practical expedients. The Company adopted ASU 2016-02 on January 1, 2019 using the optional modified retrospective transition method and elected the following transition practical expedients: (i) to not reassess lease identification, lease classification and initial indirect costs related to those leases entered into prior to the adoption of ASC 842; and (ii) to not separate lease and non-lease components for our office lease portfolio. Refer to Note 6 for further details.

4. Inventory

Inventory consisted of the following:

	September 30, 2019	December 31, 2018
Raw materials	$ 1,438	$ 1,969
Work-in-process	1,081	2,344
Finished goods	1,885	2,819
Total inventory	$ 4,404	$ 7,132

Inventories are stated at the lower of cost or net realizable value, as determined on a first-in, first-out, basis.

5. Property and Equipment

Property and equipment, net, consisted of the following:

	September 30, 2019	December 31, 2018
Computer equipment and software	$ 1,108	$ 833
Furniture and fixtures	363	389
Machinery and equipment	3,114	2,723
Leasehold improvements	609	609
Construction in process	66	481
	5,260	5,035
Less: accumulated depreciation	(1,999)	(1,151)
	$ 3,261	$ 3,884

Depreciation expense was $286 and $153 for the three months ended September 30, 2019 and 2018, respectively. Depreciation expense was $877 and $325 for the nine months ended September 30, 2019 and 2018, respectively. In addition, depreciation expense of $90 and $57 was charged to inventory and prepaid expenses and other assets, respectively, as of September 30, 2019, which represents depreciation expense related to equipment involved in the manufacturing process.

6. Leases

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* to require the recognition of lease assets and liabilities on the balance sheet of lessees. The Company implemented ASU 2016-02 as of January 1, 2019 using the optional modified retrospective transition method, which does not require the restatement of prior period amounts, and elected the following transition practical expedients: (i) to not reassess lease identification, lease classification and initial indirect costs related to those leases entered into prior to the adoption of ASC 842; and (ii) to not separate lease and non-lease components for its office lease portfolio. As of the implementation date, all of the Company's leases were operating leases and its total operating lease assets and liabilities were $2,411 and $2,887, respectively.

The Company leases office space, storage space and equipment (primarily vehicles). Certain office space leases include options to renew that generally can extend the lease term up to three years. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. Lease

(in thousands, except share and per share data)

agreements generally do not require material variable lease payments, residual value guarantees or restrictive covenants.

The table below presents the operating lease assets and liabilities recognized on the Company's consolidated balance sheets as of September 30, 2019:

	Balance Sheet Line Item	September 30, 2019
Non-current operating lease assets	Other assets	$ 1,852
Operating lease liabilities:		
Current operating lease liabilities	Accrued expenses and other current liabilities	1,390
Non-current operating lease liabilities	Other liabilities	631
Total operating lease liabilities		$ 2,021

The depreciable lives of operating lease asset leasehold improvements are limited by the lease term.

The Company's leases generally do not provide an implicit rate, and therefore, the Company uses its incremental borrowing rate as the discount rate when measuring operating leases liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company used the incremental borrowing rates as of January 1, 2019 for operating leases that commenced prior to that date.

The Company's weighted average remaining lease term and weighted average discount rate for operating leases as of September 30, 2019 are:

	September 30, 2019
Weighted average remaining lease term (years)	1.4
Weighted average discount rate	6.4%

The table below reconciles the undiscounted future minimum lease payments (displayed in aggregate by year) under non-cancelable operating leases with terms of more than one year to the total operating lease liabilities recognized on the consolidated balance sheets as of September 30, 2019:

	September 30, 2019
2019	$ 452
2020	1,191
2021	401
Thereafter	—
Total undiscounted future minimum lease payments	2,044
Less: difference between undiscounted lease payments and discounted operating lease liabilities	23
Total operating lease liabilities	$ 2,021

Operating lease payments include $44 related to options to extend lease terms that are reasonably certain of being exercised.

Operating lease costs were $494 and $1,563 for the three and nine months ended September 30, 2019, respectively. Operating lease costs are included within selling, general and administrative expenses on the consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were $1,135 for the nine months ended September 30, 2019, and this amount is included in operating activities in the consolidated statements of cash flows.

(in thousands, except share and per share data)

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	September 30, 2019	December 31, 2018
Accrued expenses:		
Contract sales organization expenses	$ —	$ 4,482
Selling, general and administrative expenses	5,881	4,812
Research and development expenses	2,600	933
Payroll expenses	6,601	4,199
Product revenue allowances	6,963	2,856
Other	1,415	1,139
Total accrued expenses	23,460	18,421
Other current liabilities:		
Lease liability	1,390	—
Total other current liabilities	1,390	—
Total accrued expenses and other current liabilities	$ 24,850	$ 18,421

8. License Agreements

AVP-825 License Agreement

In July 2013, the Company's wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement with Avanir Pharmaceuticals, Inc. (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 EDS 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 September 30, 2019, 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 the achievement of certain development milestones. The Company did not recognize any licensing revenue under the arrangement during the three and nine months ended September 30, 2019 and 2018 and does not expect any future revenue under the AVP-825 License Agreement.

On December 10, 2018, the Company received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement terminated on March 10, 2019.

Currax License Agreement

On September 25, 2019, OptiNose AS entered into a license agreement (the Currax License Agreement) with Currax Pharmaceuticals LLC (Currax) pursuant to which the Company granted Currax an exclusive license to certain intellectual property for the commercialization of Onzetra Xsail in the US, Canada and Mexico.

Under the terms of the Currax License Agreement, Currax paid the Company an upfront payment of $3,730, which was recognized as license revenue during the third quarter of 2019. In addition, the Company is eligible to receive an additional $750, which is being held in escrow for a limited period to cover certain indemnification obligations. The Company is also eligible to receive a one-time 10% royalty on Onzetra Xsail net sales in excess of $3,000 solely for calendar year 2020, and a $1,000 milestone payment subject to the achievement of a specified regulatory milestone.

Inexia License Agreement

On January 31, 2019, OptiNose AS entered into a license agreement (the Inexia License Agreement) with Inexia Limited (Inexia) pursuant to which the Company granted Inexia an exclusive worldwide license to certain intellectual property for the development and commercialization of products containing orexin receptor agonist and/or orexin receptor positive modulator molecules for the treatment, diagnosis or prevention of human diseases or conditions associated primarily with orexin receptor agonism and orexin receptor positive modulation.

Under the terms of the Inexia License Agreement, Inexia paid the Company a $500 upfront payment, which was recognized as license revenue in the first quarter of 2019. For each product developed under the Inexia License Agreement, the Company is eligible to receive up to $8,000 of development milestone payments and up to $37,000 of sales milestone payments. In addition, the Company is eligible to receive tiered, low-to-mid single digit royalties based on net sales of any products successfully developed and commercialized under the Inexia License Agreement. Other than the upfront payment, the Company does not anticipate the receipt of any milestone or royalty payments from Inexia in the near term.

9. Long-term Debt

On September 12, 2019 (the Closing Date), the Company entered into a Note Purchase Agreement (the Pharmakon Senior Secured Notes) with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit funds (BioPharma). The Pharmakon Senior Secured Notes provide the Company with up to $150,000 in debt financing, of which $80,000 was issued on the Closing Date. The remaining $70,000 of the Pharmakon Senior Secured Notes may be issued as follows:

- $30,000 of Pharmakon Senior Secured Notes shall be issued, between September 27, 2019 and February 15, 2020 (the First Delayed Draw Notes), subject to the Company achieving XHANCE net sales and royalties for the quarter ended December 31, 2019 of at least $9,000;

- $20,000 of Pharmakon Senior Secured Notes, at the Company's option, between 15 days after the closing of the First Delayed Draw Notes and August 15, 2020 (the Second Delayed Draw Notes), subject to the Company achieving, either (x) XHANCE net sales and royalties for the fiscal quarter ended March 31, 2020 of at least $11,000 or (y) XHANCE net sales and royalties for the six months ended June 30, 2020 of at least $25,000; and

- $20,000 of Pharmakon Senior Secured Notes, at the Company's option, between 15 days after the closing of the Second Delayed Draw Notes and February 15, 2021 (the Third Delayed Draw Notes, and together with the First Delayed Draw Notes and Second Delayed Draw Notes, collectively, the Delayed Draw Notes), subject to the Company achieving either (x) XHANCE net sales and royalties for the quarter ended September 30, 2020 of at least $14,500 or (y) XHANCE net sales and royalties for the six months ended December 31, 2020 of at least $31,000.

The issuance of the Second Delayed Draw Notes and Third Delayed Draw Notes are not conditioned upon the issuance of any prior Delayed Draw Notes. Furthermore, if the Company fails to meet the XHANCE net sales and royalties thresholds required to issue the First Delayed Draw Notes or the Second Delayed Draw Notes, the Company may request BioPharma to issue, in its sole discretion, the entire amount or any lesser amount of such First Delayed Draw Notes and/or Second Delayed Draw Notes upon the closing date of any subsequent Delayed Draw Notes (subject to the Company's satisfaction of the net sales and royalties thresholds applicable to such subsequent Delayed Draw Notes). The proceeds of the initial Pharmakon Senior Secured Notes issued on the Closing Date were used to repay all existing indebtedness under the note purchase agreement with Athyrium Opportunities III Acquisition LP (Athyrium). The proceeds of the Delayed Draw Notes, if issued, are expected to be used for general corporate purposes.

The Pharmakon Senior Secured Notes bear interest at a fixed per annum rate of 10.75% and are scheduled to mature on September 12, 2024 (the Maturity Date). The Company is required to make quarterly interest payments until the Maturity Date. The Company is also required to make principal payments, which are payable in eight equal quarterly installments beginning on December 15, 2022 and continuing until the Maturity Date; provided that the Company may, at its election, postpone any such principal payment until the Maturity Date if, as of the applicable payment date, certain trailing four-quarter consolidated XHANCE net sales and royalties thresholds have been achieved.

In conjunction with the Pharmakon Senior Secured Notes, the Company paid an upfront fee of $1,125 on the Closing Date and issued warrants to purchase an aggregate of 810,357 shares of Common Stock at an exercise price equal to $6.72 per share, which expire on September 12, 2022. The upfront fees were recorded as debt

discount at issuance and are being amortized to interest expense over the five year term of the loan. The Company also incurred $4,836 in debt issuance costs, including $2,404 related to the fair value of the warrants, which are also being amortized to interest expense over the term of the Pharmakon Senior Secured Notes. The Company will incur additional debt issuance costs of 0.5% of the principal amount of the Delayed Draw Notes, if issued.

The Company is required to repay the Pharmakon Senior Secured Notes in full upon the occurrence of a change of control (as defined in the Note Purchase Agreement). In addition, the Company may make voluntary prepayments in whole or in part. All mandatory and voluntary prepayments are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the third anniversary of the Closing Date, an amount equal to 2% of the principal prepaid, (ii) if prepayment occurs on or after the third anniversary of the Closing Date but prior to the fourth anniversary of the Closing Date, an amount equal to 1% of the principal prepaid, and (iii) if prepayment occurs on or after the fourth anniversary of the Closing Date, no prepayment premium is required. Additionally, the Company is also required to pay a "make-whole" amount in respect of any principal payments (whether mandatory or voluntary) made prior to the 30-month anniversary of the issuance of the applicable note, in an amount equal to the interest that would have accrued through the 30-month anniversary in respect of such note but for such principal payment.

The Pharmakon Senior Secured Notes are secured by a pledge of substantially all of the Company's assets and contains affirmative and negative covenants customary for financings of this type, including limitations on the Company’s and its subsidiaries’ ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay junior indebtedness and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the Pharmakon Senior Secured Notes contain financial covenants requiring the Company to maintain at all times certain minimum trailing twelve-month consolidated XHANCE net sales and royalties, tested on a quarterly basis, and at least $30,000 of cash and cash equivalents. As of September 30, 2019, the Company was in compliance with the covenants.

The Note Purchase Agreement also includes events of default customary for financings of this type, in certain cases subject to customary periods to cure, following which BioPharma may accelerate all amounts outstanding under the notes.

On September 12, 2019, in conjunction with the entry into the Pharmakon Senior Secured Notes, the Company terminated the Athyrium senior secured notes and all outstanding amounts under such notes were repaid in full, and all security interests and other liens granted to or held by Athyrium were terminated and released. At the time of termination, the Company paid Athyrium (i) accrued and unpaid interest since June 18, 2019 of $2,049, (ii) an exit fee of 2% of the aggregate principal amount of the notes outstanding under the under the Athyrium note purchase agreement, and (iii) a prepayment fee due under the Athyrium note purchase agreement of $3,669. As a result, the Company recorded a loss on extinguishment of $$7,155.

The Company recorded interest expense of $2,372 and $2,361 during the three months ended September 30, 2019 and 2018, respectively, and $7,148 and $6,855 during the nine months ended September 30, 2019 and 2018, respectively, in conjunction with both the Athyrium senior secured notes and the Pharmakon Senior Secured Notes. Interest expense included total coupon interest, exit fees, front end fees and the amortization of debt issuance costs.

(in thousands, except share and per share data)

The long-term debt balance is comprised of the following:

	September 30, 2019	December 31, 2018
Face amount	$ 80,000	$ 75,000
Front end fees	(1,082)	(872)
Debt issuance costs	(4,652)	(1,902)
Back end fees	—	274
Long-term debt, net	$ 74,266	$ 72,500

10. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of September 30, 2019, approximately $151 is recorded in accrued liabilities related to the Company match. The Company's contributions are made in cash.

For Norway and UK employees, the Company maintains defined contribution pension plans which meet the statutory requirements of those jurisdictions. The Company incurred costs related to the pension plans of $4 and $6 for the three months ended September 30, 2019 and 2018, respectively, and $15 and $75 for the nine months ended September 30, 2019 and 2018, respectively.

11. Stockholders' Equity

Common Stock

On June 11, 2018, the Company and certain stockholders closed an underwritten public offering (the Offering) of 5,750,000 shares of Common Stock at a price of $22.25 per share. The Offering consisted of 2,875,000 shares of Common Stock sold by the Company and 2,875,000 shares of Common Stock sold by certain stockholders. As a result of the Offering, the Company received $59,917 in net proceeds, after deducting discounts and commissions of $3,678 and offering expenses of $373 paid by the Company.

Each share of Common Stock entitles the holder to one vote on all matters submitted to a vote of the Company’s stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of Common Stock are entitled to receive ratably any dividends that the Company’s board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through September 30, 2019.

Common Stock warrants

On September 12, 2019, in conjunction with the issuance of the Pharmakon Senior Secured Notes, the Company issued warrants to purchase an aggregate of 810,357 shares of Common Stock at an exercise price of $6.72. Refer to Note 9 for further details.

(in thousands, except share and per share data)

The grant date fair value of the warrants issued in connection with the Pharmakon Senior Secured Notes was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

	Nine Months Ended September 30, 2019
Risk free interest rate	1.67%
Expected term (in years)	3.00
Expected volatility	65.10%
Annual dividend yield	0.00%
Fair value of common stock	$ 6.72

As of September 30, 2019, the Company had the following warrants outstanding to purchase shares of Common Stock:

Number of Shares	Exercise Price Per Share	Expiration Date
1,866,831	$ 8.16	November 1, 2020
810,357	$ 6.72	September 12, 2022

12. Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and shares issued under the Company's 2017 Employee Stock Purchase Plan (2017 Plan) in the following expense categories of its accompanying consolidated statements of operations for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of product sales	$ 33	$ 3	$ 78	$ 6
Research and development	90	329	617	734
General and administrative	2,312	1,870	6,857	5,585
	$ 2,435	$ 2,202	$ 7,552	$ 6,325

In addition, stock-based compensation expense of $62 and $29 was charged to inventory and prepaid expenses and other assets, respectively, during the nine months ended September 30, 2019, which represents the total stock-based compensation expense incurred related to employees involved in the manufacturing process of finished goods and samples during the period.

Stock Options

The Company has issued serviced-based and performance-based stock options that generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the Company's board of directors. Vesting generally occurs over a period of not greater than four years. Performance-based options may vest upon the achievement of certain milestones in connection with the Company's development programs. Additionally, the Company has issued stock options in excess of the fair market value of Common Stock on the issuance date that were only exercisable upon a change in control or upon or after an initial public offering. As of September 30, 2019, all of the performance conditions related to performance-based stock options issued by the Company have been achieved.

(in thousands, except share and per share data)

The following table summarizes the activity related to stock option grants to employees and nonemployees for the nine months ended September 30, 2019:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2018	6,182,873	$ 10.60	6.67
Granted	2,070,173	7.70	
Exercised	(151,039)	3.60	
Expired	—	—	
Forfeited	(353,488)	11.27	
Outstanding at September 30, 2019	7,748,519	$ 9.93	6.64
Exercisable at September 30, 2019	4,425,938	$ 9.49	4.96
Vested and expected to vest at September 30, 2019	7,748,519	$ 9.93	6.64

During the nine months ended September 30, 2019, stock options to purchase 2,070,173 shares of Common Stock were granted to employees and directors and generally vest over four years. The stock options had an estimated weighted average grant date fair value of $4.78. During the nine months ended September 30, 2018, stock options to purchase 423,892 shares of Common Stock were granted to employees that generally vest over four years. The stock options had an estimated weighted average grant date fair value of $20.35.

The grant date fair value of each stock option grant was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

	Nine Months Ended September 30,	
	2019	2018
Risk free interest rate	2.48%	2.71%
Expected term (in years)	6.05	5.93
Expected volatility	67.03%	74.61%
Annual dividend yield	0.00%	0.00%
Fair value of common stock	$ 7.70	$ 13.50

At September 30, 2019, the unrecognized compensation cost related to unvested stock options expected to vest was $21,214. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.56 years.

The following table summarizes the activity related to restricted stock units (RSUs) granted to employees for the nine months ended September 30, 2019:

	Shares
Balance at December 31, 2018	—
Granted	20,600
Vested and settled	—
Expired/ forfeited/ canceled	(20,600)
Balance at September 30, 2019	—
Expected to vest at September 30, 2019	—

In April 2019, the Company granted 20,600 RSUs at a price of $10.20, which forfeited during the three months ended September 30, 2019.

2017 Employee Stock Purchase Plan

Under the 2017 Plan, shares of Common Stock may be purchased by eligible employees who elect to participate in the 2017 Plan at 85% of the lower of the fair market value of Common Stock on the first or last day of designated offering periods. The Company recognized stock-based compensation expense of $91 and $84 during the three

months ended September 30, 2019 and 2018, respectively, and $319 and $363 during the nine months ended September 30, 2019 and 2018, respectively, related to the 2017 Plan.

The Company issued 53,137 and 31,892 shares of Common Stock related to the offering periods ended June 30, 2018 and December 31, 2018, respectively. The Company issued 77,909 shares of Common Stock related to the offering period ended June 30, 2019.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I. Item 1 of this Form 10-Q and our audited consolidated financial statements and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission (SEC) on March 6, 2019.

Company Overview

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. Our first commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing our proprietary Optinose Exhalation Delivery System (EDS) device that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also known as chronic sinusitis). Chronic rhinosinusitis is a serious nasal inflammatory disease that is treated using therapies, such as intranasal steroids (INS), which have significant limitations. We believe XHANCE 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 conventional INS.

On September 18, 2017, the U.S. Food and Drug Administration (FDA) approved XHANCE for the treatment of nasal polyps in patients 18 years of age or older. XHANCE was made widely available through commercial channels in April 2018.

We track and report metrics that we believe are an important part of assessing our progress in key strategic areas including:

- Customer Model. We have defined a sales force footprint of approximately 120 geographic territories targeting approximately 14,000 ENTs, allergists and “specialty-like” primary care physicians. In April 2019, we changed our commercial model from a contract sales team to an internal sales team, and at the same time we hired and deployed additional territory managers into “XHANCE naive” geographies, increasing the number of territories in our deployment plan from 80 to approximately 100, to expand our reach among our target physician audience. The additional territory managers have increased the size of the target audience for our sales team by approximately 25% to over 10,000 physicians. We intend to eventually increase the size of our sales force to approximately 120 territory managers to expand our called-on target audience to approximately 14,000 ENT, allergists and "specialty-like" primary care physicians. Additionally, we are targeting additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers.

- XHANCE Patient Affordability Programs. In late August 2018, we implemented our current co-pay savings programs. We believe these programs, with an indefinite duration, provide an affordability solution for patients that physicians will support. These programs provide patient co-pay assistance to commercially insured patients that includes a first prescription at no out-of-pocket cost ($0 co-pay) and low subsequent co-pays for refills. Our data suggests these programs are playing an important role in supporting demand for XHANCE, particularly as they become more widely understood in the prescribing community.

- Market Access. Based on currently available third-party data and our internal analyses, we believe that approximately 75% of commercially insured lives are currently in a plan in which XHANCE is covered. However, payors may change coverage levels for XHANCE or controls such as step edits and prior authorization, positively or negatively, at any time.

  We have also contracted with the Centers for Medicare and Medicaid Services for coverage of certain government insured lives and continue to seek to expand XHANCE market access for other government-insured populations.

- XHANCE Prescriptions and Market Share. Based on third-party prescription data as well as data from preferred pharmacy network partners, the total estimated number of XHANCE prescriptions in the third quarter of 2019 was 42,962, which represents 27% growth for prescriptions when compared to second quarter 2019 prescriptions of 33,949. Based upon third-party prescription data, the INS prescription market decreased approximately 11% from second quarter 2019 to third quarter 2019 based on third-party prescription data. In addition, we estimate the number of XHANCE prescriptions for the month of October

2019 was 17,600, which represents growth of 18% compared to the prior month. During this same period, the INS market is estimated to have decreased approximately 10% based on third-party prescription data. We believe the April 2019 internalization and expansion of our sales force, which expanded our sales territories by 25%, and a new 7-day sample which became available in May 2019, will continue to encourage trial and adoption of XHANCE, and help drive future XHANCE prescription growth.

XHANCE prescribing may be subject to a seasonal effect historically observed in the INS prescription market in which market volume generally peaks near the middle of the second quarter and declines into the early part of the third quarter of each calendar year. Based on third party prescription data, the INS market increased 2% from the first quarter of 2018 to the second quarter of 2018, decreased 15% from the second quarter of 2018 to the third quarter of 2018, increased 11% from the third quarter of 2018 to the fourth quarter of 2018, increased 3% from the fourth quarter of 2018 to the first quarter of 2019 and increased 1% from the first quarter of 2019 to the second quarter of 2019.

Although the underlying disease that we are treating is chronic and causes symptoms year-round, we believe the variation in patient flow through the offices of relevant specialists, and seasonality in disease flare-ups, has an impact on the number of patients that present themselves and who are therefore available for prescribing a new medication like XHANCE. Additionally, the annual resetting of patient healthcare insurance plan deductibles, which occurs for many health plans in January, may have a negative impact on demand for XHANCE. Based on our limited commercial history, we believe it is reasonable to expect INS market seasonality to reduce XHANCE prescription and net revenue growth rates in the third quarter. In addition, the annual deductible resets that often occur in January may negatively impact XHANCE prescriptions, net revenues and average net revenue per prescription.

We monitor the market share of XHANCE within our current target audience. For this purpose, we calculate market share as the proportion of XHANCE prescriptions to the number of prescriptions written for other INS within our current target audience of over 10,000 physicians. We believe market share, in addition to XHANCE prescription volume, provides important information regarding XHANCE utilization because market share normalizes XHANCE prescriptions for market effects including the INS market seasonality and annual deductible resets referenced above. Based on third-party prescription data as well as data from preferred pharmacy network partners, we estimate XHANCE market share of 0.9% in the fourth quarter of 2018, 1.5% in the first quarter of 2019, 2.2% in the second quarter of 2019, 3.0% in the third quarter of 2019 and 3.4% in October 2019. Note that most of the INS prescriptions written within our target physician audience are for chronic sinusitis, allergic rhinitis and other conditions outside of our nasal polyp indication.

XHANCE Development Update

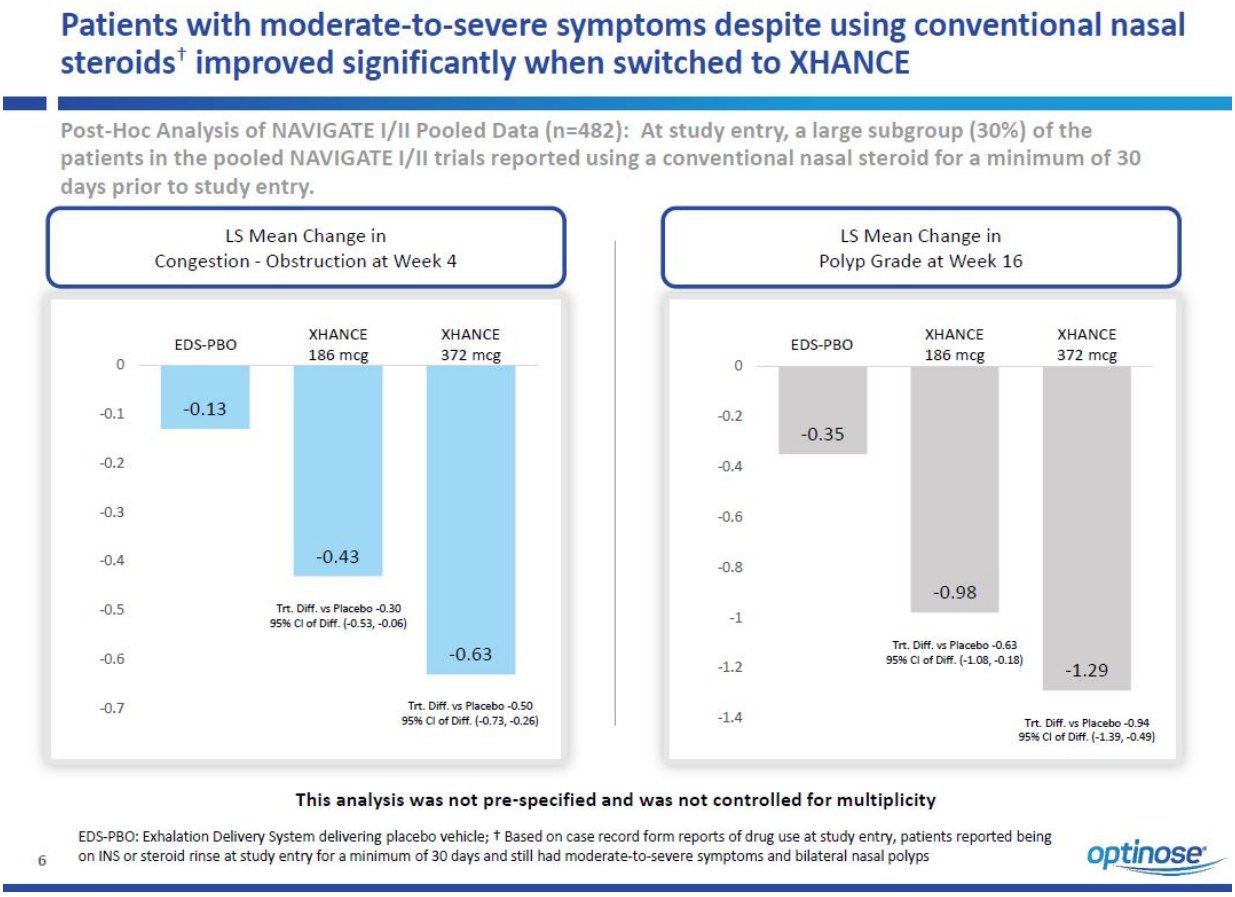
In addition to XHANCE's existing indication for the treatment of nasal polyps, in order to broaden our U.S. market opportunity, we initiated a clinical research program in pursuit of a follow-on indication for the treatment of chronic sinusitis in the U.S. We believe XHANCE has the potential to be the first drug therapy approved by the FDA for the treatment of chronic sinusitis. We expect the program will be comprised of two phase 3b clinical trials, the first of which was initiated in the fourth quarter of 2018 and is estimated to enroll approximately 378 subjects and the second of which was initiated in the second quarter of 2019 and is estimated to enroll approximately 399 subjects. Estimated enrollment for both trials are subject to change for factors that may include an interim analysis intended to inform the statistical powering of both trials. We expect top line results from the first of the two chronic sinusitis trials in the second half of 2021.

Analysis of Efficacy in Patients Who Report Symptoms Despite Use of Conventional Nasal Steroids

Efficacy for different patient types is important information for understanding how to best adopt XHANCE. Data suggest that many nasal polyp patients do not achieve satisfactory symptom response with conventional nasal steroids. In order to help inform whether XHANCE may offer benefits for the type of patient who has symptoms despite use of other nasal steroids, we performed a series of new post-hoc analyses of the large subgroup of patients who entered our pivotal clinical trials reporting current use of one of the then-available intranasal steroids as captured on case record forms. Using pooled data (n=482), we found that 30% of those patients entered NAVIGATE I and NAVIGATE II reporting being on a nasal steroid for at least one-month prior to trial entry. On average these patients reported use of these nasal steroids for approximately three years and all of them reported moderate-to-severe symptoms at trial entry.

On multiple measures of efficacy, this subgroup of patients improved, generally with comparable or more improvement, versus placebo, than other patients who did not report use of an intranasal steroid in the month prior

to trial entry. Note that these post-hoc analyses were not pre-specified and not controlled for multiplicity (i.e., risk of a false-positive finding); therefore these results require cautious interpretation as they may represent chance findings. We are communicating these new analyses to physicians and payers in support of XHANCE.



Licensing of Our Exhalation Delivery System (Outside of ENT/Allergy Indications)

Currax License Agreement

On September 25, 2019, we entered into a license agreement (the Currax License Agreement) with Currax Pharmaceuticals LLC (Currax). Under the terms of the Currax License Agreement, we granted Currax an exclusive license to certain OptiNose patents and a non-exclusive license to certain OptiNose know-how to use, sell, offer for sale, have sold and import Onzetra® Xsail® (sumatriptan nasal powder) in the US, Canada and Mexico.

Under the terms of the Currax License Agreement, we received a $3.7 million upfront payment. In addition, we are eligible to receive an additional $0.8 million, which is being held in escrow for a limited period to cover certain indemnification obligations. We are also eligible to receive a one-time 10% royalty on Onzetra net sales in excess of $3.0 million solely for calendar year 2020, and an additional $1.0 million milestone payment subject to the achievement of a specified regulatory milestone.

Inexia License Agreement

On January 31, 2019, we entered into a license agreement (Inexia License Agreement), with Inexia Limited (Inexia). Under the terms of the Inexia License Agreement, we granted Inexia an exclusive, royalty-bearing, worldwide, non-transferable, sublicensable license to our EDS and other intellectual property for the development, sale, import and manufacture of products containing orexin receptor agonist and/or orexin receptor positive modulator molecule(s) as the sole active pharmaceutical ingredient(s) for the treatment, diagnosis or prevention of human diseases or conditions associated primarily with orexin receptor agonism and orexin receptor positive modulation. The license excludes the treatment of any disease or condition affecting the ear, nose or throat, or the treatment of any disease

or condition associated primarily with another receptor, other than the Orexin 1 and Orexin 2 receptors. Inexia is solely responsible for all costs and activities related to its identification, development and commercialization of products under the Inexia License Agreement.

Under the terms of the Inexia License Agreement, we received a $0.5 million upfront payment. For each product developed under the Inexia License Agreement, we are eligible to receive up to $8.0 million of development milestone payments and up to $37.0 million of sales milestone payments. In addition, we are eligible to receive tiered, low-to-mid single digit royalties based on net sales of any products successfully developed and commercialized under the Inexia License Agreement. Other than the upfront payment, we do not anticipate the receipt of any milestone or royalty payments from Inexia in the near term.

As a result of the Inexia License Agreement, we have discontinued our preclinical OPN-021 program, which combined our EDS with orexin agonist molecules for the treatment of narcolepsy and symptoms of other diseases potentially amenable to the same pharmacologic activity, such as Parkinson's disease.

AVP-825 License Agreement

The AVP-825 License Agreement with Avanir Pharmaceuticals Inc. relating to Onzetra Xsail terminated on March 10, 2019. In September 2019, as described above, the Company entered into the Currax License Agreement.

Financial Operations Overview

The following discussion sets forth certain components of our consolidated statements of operations as well as factors that impact those items.

Net product revenues

Sales of XHANCE generated $8.7 million and $19.3 million in net revenues for the three and nine months ended September 30, 2019, respectively. In accordance with U.S generally accepted accounting principles (GAAP), we determine net product revenues for XHANCE, with specific assumptions for variable consideration components including but not limited to trade discounts and allowances, co-pay assistance programs and payor rebates. For the full-year 2019, we expect XHANCE net revenue to be in the range of $30.0 - $33.0 million.

Based on available XHANCE prescription data purchased from third parties and data from our preferred pharmacy network partners, who collectively dispensed 75% to 80% of our prescriptions in the period, our average net revenue per prescription of XHANCE for the third quarter of 2019 was approximately $202, which represents an increase compared to our average net product revenue per prescription of approximately $197 in the second quarter of 2019. Average net revenue per prescription for the first nine months of 2019 was $194. We believe the 3% increase in the average net revenue per prescription in the third quarter of 2019 compared to the second quarter of 2019 is largely attributable to patients meeting annual out-of-pocket expense thresholds which reduces the amount of copay assistance that we provide through our affordability program.

We calculate average net product revenue per prescription by dividing net product revenue for the quarter by the estimated number of XHANCE prescriptions dispensed during the quarter. As a result, average net product revenue per prescription is subject to variability. That variability is impacted by factors that do not necessarily reflect a change in the price that is paid for an individual unit of XHANCE, including but not limited to ordering patterns and inventory levels for our wholesale customers and preferred pharmacy network partners, patient utilization rates of affordability programs and the proportion of patients acquiring XHANCE through an insurance benefit. There is also the potential for variability that results from changes in estimation methodology by the third parties that we rely upon to provide prescription data which may lead to revisions of historical estimates of prescription volumes and our calculated average revenue per prescription.

We expect that the full-year 2019 average net revenue per prescription of XHANCE will be between $195 - $205.

Licensing revenues

On September 25, 2019, OptiNose AS, a wholly owned subsidiary of the Company, entered into the Currax License Agreement with Currax. Under the terms of the Currax License Agreement, Currax paid us a $3.7 million upfront payment. We are also eligible to receive an additional $0.8 million which is being held in escrow for a limited period to cover certain indemnification obligations. In addition, we are eligible to receive a one-time 10% royalty on Onzetra net sales in excess of $3.0 million solely for calendar year 2020, and an additional $1.0 million milestone payment subject to the achievement of a specified regulatory milestone.

On January 31, 2019, OptiNose AS entered into the Inexia License Agreement with Inexia. Under the terms of the Inexia License Agreement, Inexia paid us a $0.5 million upfront payment. For each product developed under the Inexia License Agreement, we are eligible to receive up to $8.0 million of development milestone payments and up to $37.0 million of sales milestone payments. In addition, we are eligible to receive tiered, low-to-mid single digit royalties based on net sales of any products successfully developed and commercialized under the Inexia License Agreement. Other than the upfront payment, we do not anticipate the receipt of any milestone or royalty payments from Inexia in the near term.

Costs of product sales

Costs of product sales includes the cost of inventory sold, which includes direct and indirect manufacturing and certain supply chain costs.

Research and development expense

Research and development expense consists primarily of expenses incurred to prepare for, initiate and conduct our planned clinical trials, ongoing research efforts of new products and device improvements. We expense research and development costs as incurred. These expenses include:

- personnel expenses, including salaries, benefits and stock-based compensation expense;
- costs of funding clinical development performed by third parties, including pursuant to agreements with contract research organizations (CROs), as well as investigative sites and consultants that conduct or support our nonclinical studies and clinical trials;
- expenses associated with the continued development of our EDS devices;
- expenses related to the continued development of our product sample portfolio;
- expenses incurred under agreements with contract manufacturing organizations (CMOs), including manufacturing scale-up expenses prior to regulatory approval of products for commercial sale 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 and respond to filings with the FDA prior to regulatory approval of products for commercial sale;
- costs incurred to maintain, expand and protect our patent portfolio as it relates to product candidates in development; 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 continue the development of XHANCE 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, including rate of subject enrollment, number of subjects required, and trial duration, and the early stage of our other product candidates, we are unable to estimate with reasonable certainty the costs we will incur and the timelines we will require in our continued development efforts.

Selling, general and administrative expense

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, information technology, 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 regulatory fees and professional fees for legal, patent, accounting and other consulting services.

Sales and marketing related expenses incurred in early 2018 included expenses related to building brand awareness through advertising and the deployment of our nurse educator team, training and deploying our contract

sales force and securing market access for XHANCE as well as salaries and related benefits for employees focused on such efforts. Current sales and marketing expenses include our sales team and supporting promotional materials, digital promotion, peer-to-peer education, congresses / conventions, samples, and marketing activities such as direct-to-patient / direct-to-consumer initiatives.

Interest (income) expense

Interest (income) expense consists of interest earned on our cash and cash equivalents held with institutional banks and interest expense is primarily related to our note purchase agreement (Athyrium Senior Secured Notes) with Athyrium Opportunities III Acquisition LP (Athyrium).

Other (income) expense

Other (income) expense consists primarily of the loss on the extinguishment of the Athyrium Senior Secured Notes, 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 three months ended September 30, 2019 and 2018

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

	Three Months Ended September 30,	
	2019	2018
Revenues:		
Net product revenues	$ 8,667	$ 1,902
Licensing revenues	3,730	—
Total revenues	12,397	1,902
Costs and expenses:		
Cost of product sales	1,389	319
Research and development	5,547	2,989
Selling, general and administrative	25,270	22,086
Total operating expenses	32,206	25,394
Loss from operations	(19,809)	(23,492)
Other (income) expense:		
Interest (income) expense	1,813	1,681
Other (income) expense	7,186	(50)
Total other (income) expense	8,999	1,631
Net loss	$ (28,808)	$ (25,123)

Net product revenues

Net product revenues related to sales of XHANCE were $8.7 million and $1.9 million for the three months ended September 30, 2019 and 2018, respectively. Revenue growth is primarily attributable to increased prescriptions of XHANCE which became commercially available in late Q1 2018.

Licensing revenues

Licensing revenues were $3.7 million for the three months ended September 30, 2019 as a result of the upfront payment received under the terms of the Currax License Agreement. No licensing revenue was recognized during the three months ended September 30, 2018.

Cost of product sales

Cost of product sales related to XHANCE were $1.4 million and $0.3 million for the three months ended September 30, 2019 and 2018, respectively, with the increase primarily attributed to increased prescriptions of XHANCE during the period.

Research and development expense

Research and development expense was $5.5 million and $3.0 million for the three months ended September 30, 2019 and 2018, respectively. The $2.5 million increase was attributable primarily to a $2.3 million increase in clinical expenses related to the preparation for and initiation and conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis and FDA-mandated pediatric studies.

Selling, general and administrative expense

Selling, general and administrative expense was $25.3 million and $22.1 million for the three months ended September 30, 2019 and 2018, respectively. The $3.2 million increase was due primarily to:

- a $1.3 million increase in expenses related to the sale of XHANCE including marketing expenses; and
- a $1.9 million increase in personnel, bonus and travel expenses due to increases in headcount and the expansion of our sales team.

Interest (income) expense, net

Interest (income) expense, net, was $1.8 million and $1.7 million for the three months ended September 30, 2019 and 2018, respectively. Interest expense was $2.4 million for the three months ended September 30, 2019 and 2018 and was primarily related to the Athyrium Senior Secured Notes. Interest expense was offset by interest income of $0.6 million and $0.7 million for the three months ended September 30, 2019 and 2018, respectively.

Other (income) expense, net

Other (income) expense, net was $7.2 million and $(0.1) million for the three months ended September 30, 2019 and 2018, respectively. Other expense for the three months ended September 30, 2019 was primarily due to the loss on the extinguishment of the Athyrium Senior Secured Notes. Other income for the three months ended September 30, 2018 was attributable primarily to grant-eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary. No grant-eligible research and development expenses were incurred during the three months ended September 30, 2019.

Comparison of nine months ended September 30, 2019 and 2018

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

	Nine Months Ended September 30, 2019	
	2019	**2018**
Revenues:		
Net product revenues	$ 19,320	$ 4,042
Licensing revenues	4,230	—
Total revenues	23,550	4,042
Costs and expenses:		
Cost of product sales	3,216	870
Research and development	15,404	6,736
Selling, general and administrative	77,610	71,957
Total operating expenses	96,230	79,563
Loss from operations	(72,680)	(75,521)
Other (income) expense:		
Interest (income) expense	5,189	5,117
Other (income) expense	7,189	(361)
Total other (income) expense	12,378	4,756
Net loss	$ (85,058)	$ (80,277)

Net product revenues

Net product revenues related to sales of XHANCE were $19.3 million and $4.0 million for the nine months ended September 30, 2019 and 2018, respectively. Revenue growth is primarily attributable to increased prescriptions of XHANCE which became commercially available in late Q1 2018.

Licensing revenues

Licensing revenues were $4.2 million for the nine months ended September 30, 2019 as a result of upfront payments received under the terms of the Inexia License Agreement and the Currax License Agreement. No licensing revenue was recognized during the nine months ended September 30, 2018.

Cost of product sales

Cost of product sales related to XHANCE were $3.2 million and $0.9 million for the nine months ended September 30, 2019 and 2018, respectively, with the increase primarily attributed to increased prescriptions of XHANCE during the period.

Research and development expense

Research and development expense was $15.4 million and $6.7 million for the nine months ended September 30, 2019 and 2018, respectively. The $8.7 million increase was attributable primarily to:

- an $8.0 million increase in clinical expenses related to the preparation for and initiation and conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis and FDA-mandated pediatric studies; and
- a $0.6 million increase in personnel, bonus and travel expenses due to increases in headcount.

Selling, general and administrative expense

Selling, general and administrative expense was $77.6 million and $72.0 million for the nine months ended September 30, 2019 and 2018, respectively. The $5.6 million increase was due primarily to:

- a $6.1 million increase in expenses related to the sale of XHANCE including marketing expenses;
- a $5.6 million increase in personnel, bonus and travel expenses due to increases in headcount and the expansion of our sales team; and
- a $1.4 million increase stock compensation expense.

This increase was offset by:

- a $6.7 million decrease in sales expenses due to the completion of XHANCE initial launch activities in 2018.

Interest (income) expense, net

Interest (income) expense, net, was $5.2 million and $5.1 million for the nine months ended September 30, 2019 and 2018, respectively. Interest expense for the nine months ended September 30, 2019 and 2018 was $7.1 million and $6.9 million, respectively, and was primarily related to the Athyrium Senior Secured Notes. Interest expense was offset by interest income of $2.0 million and $1.7 million for the nine months ended September 30, 2019 and 2018, respectively. Interest income increased by $0.3 million as a result of higher interest rates on our cash balances.

Other (income) expense, net

Other (income) expense, net was $7.2 million and $(0.4) million for the nine months ended September 30, 2019 and 2018, respectively. Other expense for the nine months ended September 30, 2019 was primarily due to the loss on the extinguishment of the Athyrium Senior Secured Notes. Other income for the nine months ended September 30, 2018 was attributable primarily to grant-eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary. No grant grant-eligible research and development expenses were incurred during the nine months ended September 30, 2019.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. We incurred net losses of $85.1 million and $80.3 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $403.0 million.

We have funded our operations primarily through the sale and issuance of stock and debt, as well as through licensing revenues. As of September 30, 2019, we had $125.5 million in cash and cash equivalents.

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

	Nine Months Ended September 30,	
	2019	2018
Net cash used in operating activities	$ (72,709)	$ (71,623)
Net cash used in investing activities	(485)	(1,450)
Net cash (used in) provided by financing activities	(2,302)	59,662
Effects of exchange rates on cash and cash equivalents	(11)	41
Net decrease in cash and cash equivalents	$ (75,507)	$ (13,370)

Operating activities

Cash used in operating activities increased by $1.1 million, from $71.6 million for the nine months ended September 30, 2018 to $72.7 million for the nine months ended September 30, 2019. The increase in cash used in operating activities was attributable primarily to increased operating expenses and the timing of payment of those expenses.

Investing activities

Cash used in investing activities decreased $1.0 million from $1.5 million for the nine months ended September 30, 2018 to $0.5 million for the nine months ended September 30, 2019. The decrease was related primarily to purchases of equipment in 2018 in connection with infrastructure expansion activities to support the commercial launch of XHANCE and our transition to a public company.

Financing activities

Cash used in financing activities was $2.3 million for the nine months ended September 30, 2019. Cash provided by financing activities was $59.7 million for the nine months ended September 30, 2018. Cash used in financing activities for the nine months ended September 30, 2019 was driven by the repayment of the Athyrium Senior Secured Notes of $80.2 million offset by net proceeds of $76.7 million from the issuance of the Pharmakon Senior Secured Notes.

Cash provided by financing activities for the nine months ended September 30, 2018 was driven by net proceeds of $59.9 million as a result of a June 2018 underwritten public offering of 5,750,000 shares of our common stock (Common Stock) at a price of $22.25 per share, which consisted of 2,875,000 shares of Common Stock sold by us and 2,875,000 shares of Common Stock sold by certain stockholders. This receipt was partially offset by $2.5 million of cash paid for financing costs during the nine months ended September 30, 2018 related to our IPO and debt offering in the fourth quarter of 2017.

Senior Secured Note Purchase Agreement

On September 12, 2019 (the Closing Date), we entered into a Note Purchase Agreement (the Pharmakon Senior Secured Notes) with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit funds (BioPharma). The Pharmakon Senior Secured Notes provide us with up to $150.0 million in debt financing, of which $80.0 million was issued on the Closing Date. The remaining $70.0 million of the Pharmakon Senior Secured Notes may be issued as follows:

- $30.0 million of Pharmakon Senior Secured Notes shall be issued, between September 27, 2019 and February 15, 2020 (the First Delayed Draw Notes), subject to our achievement of XHANCE net sales and royalties for the quarter ended December 31, 2019 of at least $9.0 million;
- $20.0 million of Pharmakon Senior Secured Notes, at our option, between 15 days after the closing of the First Delayed Draw Notes and August 15, 2020 (the Second Delayed Draw Notes), subject to our achievement of, either (x) XHANCE net sales and royalties for the fiscal quarter ended March 31, 2020 of at least $11.0 million or (y) XHANCE net sales and royalties for the six months ended June 30, 2020 of at least $25.0 million; and
- $20.0 million of Pharmakon Senior Secured Notes, at our option, between 15 days after the closing of the Second Delayed Draw Notes and February 15, 2021 (the Third Delayed Draw Notes, and together with the First Delayed Draw Notes and Second Delayed Draw Notes, collectively, the Delayed Draw Notes), subject to our achievement of either (x) XHANCE net sales and royalties for the quarter ended September 30, 2020

of at least $14.5 million or (y) XHANCE net sales and royalties for the six months ended December 31, 2020 of at least $31.0 million.

The issuance of the Second Delayed Draw Notes and Third Delayed Draw Notes are not conditioned upon the issuance of any prior Delayed Draw Notes. Furthermore, if we fail to meet the XHANCE net sales and royalties thresholds required to issue the First Delayed Draw Notes or the Second Delayed Draw Notes, we may request BioPharma to issue, in its sole discretion, the entire amount or any lesser amount of such First Delayed Draw Notes and/or Second Delayed Draw Notes upon the closing date of any subsequent Delayed Draw Notes (subject to our satisfaction of the net sales and royalties thresholds applicable to such subsequent Delayed Draw Notes). The proceeds of the initial Pharmakon Senior Secured Notes issued on the Closing Date were used to repay all existing indebtedness under the note purchase agreement with Athyrium. The proceeds of the Delayed Draw Notes, if issued, are expected to be used for general corporate purposes.

The Pharmakon Senior Secured Notes bear interest at a fixed per annum rate of 10.75% and are scheduled to mature on September 12, 2024 (the Maturity Date). We are required to make quarterly interest payments until the Maturity Date. We are also required to make principal payments, which are payable in eight equal quarterly installments beginning on December 15, 2022 and continuing until the Maturity Date; provided that we may, at our election, postpone any such principal payment until the Maturity Date if, as of the applicable payment date, certain trailing four-quarter consolidated XHANCE net sales and royalties thresholds have been achieved.

We are required to repay the Pharmakon Senior Secured Notes in full upon the occurrence of a change of control (as defined in the Note Purchase Agreement). In addition, we may make voluntary prepayments in whole or in part. All mandatory and voluntary prepayments are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the third anniversary of the Closing Date, an amount equal to 2% of the principal prepaid, (ii) if prepayment occurs on or after the third anniversary of the Closing Date but prior to the fourth anniversary of the Closing Date, an amount equal to 1% of the principal prepaid, and (iii) if prepayment occurs on or after the fourth anniversary of the Closing Date, no prepayment premium is required. Additionally, we are also required to pay a "make-whole" amount in respect of any principal payments (whether mandatory or voluntary) made prior to the 30-month anniversary of the issuance of the applicable note, in an amount equal to the interest that would have accrued through the 30-month anniversary in respect of such note but for such principal payment.

The Pharmakon Senior Secured Notes are secured by a pledge of substantially all of our assets and contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries' ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay junior indebtedness and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the Pharmakon Senior Secured Notes contain financial covenants requiring us to maintain at all times certain minimum trailing twelve-month consolidated XHANCE net sales and royalties, tested on a quarterly basis, and at least $30.0 million of cash and cash equivalents.

The Note Purchase Agreement also includes events of default customary for financings of this type, in certain cases subject to customary periods to cure, following which BioPharma may accelerate all amounts outstanding under the notes.

Projected 2019 operating expenses

We expect that our total GAAP operating expenses (consisting of selling, general & administrative expenses and research & development expenses) for 2019 will be between $126.0 million and $129.0 million of which approximately $10.0 million is expected to be stock-based compensation expense. Total GAAP operating expenses excluding stock-based compensation expense are expected to be in the range from $116.0 million to $119.0 million.

Future funding requirements

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

- maintain and expand our sales force and the commercial infrastructure to support the sales and marketing for XHANCE;
- continue advertising and other promotional activities to support the commercialization of XHANCE;
- continue to provide co-pay and other patient affordability programs;

- continue clinical development activities for XHANCE, including FDA-mandated pediatric studies and clinical trials for a follow-on indication for the treatment of chronic sinusitis;
- continue research and development activities for additional product candidates;
- continue to contract to manufacture XHANCE and our other product candidates;
- maintain, expand and protect our patent portfolio;
- service our debt obligations under the Pharmakon Senior Secured Notes issued in September 2019;
- maintain infrastructure necessary to operate as a publicly-traded, commercial-stage company; and
- hire additional staff and add operational, financial and information systems to execute our business plan.

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 XHANCE for the treatment of nasal polyps including, among other things, patient and physician acceptance of XHANCE and our ability to obtain adequate insurance coverage and reimbursement for XHANCE;
- the cost of commercialization activities for XHANCE, including product manufacturing, distribution, marketing and sales;
- net product revenues received from sales of XHANCE;
- the costs and timing of expanding our sales force;
- the level of co-pay assistance and other patient affordability programs offered for XHANCE;
- our clinical development plans for XHANCE, including the outcome, timing and cost of FDA-mandated pediatric studies and clinical trials for the supplemental indication for the treatment of chronic sinusitis;
- the outcome, timing and cost of the regulatory approval process of XHANCE for 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 costs involved in preparing, filing and prosecuting patent applications and annuity fees relating to issued patents;
- the cost of maintaining and enforcing our intellectual property rights, as well as the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the initiation, progress, timing, costs and results of clinical trials and other research and development related to additional product candidates; and
- the extent to which we in-license, acquire or otherwise partner in development or commercialization of other products, product candidates or technologies.

Although it is difficult to predict our future liquidity requirements, the Company will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet the debt service obligations under the Company's outstanding Senior Secured Notes, including repayment, and to carry out the Company's planned development and commercial activities. As described above, we have access to up to an additional $70.0 million under the Pharmakon Note Purchase Agreement subject to the achievement of minimum XHANCE net sales and royalties and certain other conditions. Additional capital, secured in the future through equity or debt financings, partnerships, collaborations, or other sources, may not be available on a timely basis, on favorable terms, or at all, and such capital, if raised, may not be sufficient to meet our debt service obligations, including repayment, or enable us to continue to implement our long-term business strategy. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received. 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. Additionally, we may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

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.

Contractual obligations and commitments

The following table summarizes our contractual obligations at September 30, 2019:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(in thousands)		
Operating leases[1]	$ 2,070	$ 1,414	$ 656	$ —	$ —
Long-term debt[2]	116,048	8,815	17,439	89,794	—
Total	$ 118,118	$ 10,229	$ 18,095	$ 89,794	$ —

[1] Reflects obligations pursuant to our office leases in Yardley, Pennsylvania, Ewing, New Jersey, Oslo, Norway and Swindon, England and leases of certain other equipment.

[2] Reflects principal, interest obligations and exit fees pursuant to the Pharmakon Senior Secured Notes entered into on September 12, 2019 (the Closing Date). The Pharmakon Senior Secured Notes bear interest at 10.75% and are scheduled to mature on September 12, 2024 (the Maturity Date). We are required to make quarterly interest payments until the Maturity Date. Principal payments are payable in eight equal quarterly installments beginning on December 15, 2022 and continuing until the Maturity Date; provided that we may, at our election and upon achieving certain trailing four-quarter consolidated XHANCE net sales and royalties, postpone any such amortization payment until the Maturity Date. The Pharmakon Senior Secured Notes include events of default customary for financings of this type (including, among others, failure to comply with affirmative, negative and financial covenants), in certain cases subject to customary periods to cure, following which BioPharma may accelerate all amounts outstanding under the notes.

Critical accounting policies

The Critical Accounting Policies and Significant Judgments and Estimates included in our annual report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 6, 2019, have not materially changed.

Recent accounting pronouncements

See Note 3 to our unaudited interim consolidated financial statements of this Form 10-Q for a description of recent accounting pronouncements applicable to our consolidated financial statements.

JOBS Act

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (Exchange Act) refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that

the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our Chief Executive Officer and our Chief Financial Officer evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a 15(e) and 15d 15(e) under the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2019.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 1A. RISK FACTORS

You should carefully consider the risk factors described under the caption "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 6, 2019. Except as set forth below, there have been no material changes to the risk factors disclosed in our Form 10-K.

Risks Related to Our Financial Position and Capital Resources

Our failure to comply with the covenants or other terms of the Note Purchase Agreement, including as a result of events beyond our control, could result in a default under the Note Purchase Agreement that could materially and adversely affect the ongoing viability of our business.

On September 12, 2019 (the Closing Date), we entered into a Note Purchase Agreement with funds managed by Pharmakon Advisors, LP, as collateral agent (the Collateral Agent) and the purchasers party thereto (the Purchasers) that provides for the issuance of up to $150.0 million of senior secured notes (the Pharmakon Senior Secured Notes), of which $80.0 million were issued on the Closing Date (the Initial Notes). The remaining $70.0 million of the Pharmakon Senior Secured Notes (the Delayed Draw Notes) may be issued in 2020 and 2021 subject to the achievement of minimum XHANCE net sales and royalties and certain other conditions. The Pharmakon Senior Secured Notes bear interest at a fixed per annum rate of 10.75% and are scheduled to mature on September 12, 2024 (the Maturity Date). The Company is required to make quarterly interest payments until the Maturity Date. The Company is also required to make principal payments, which are payable in eight equal quarterly installments beginning on December 15, 2022 and continuing until the Maturity Date; provided that the Company may, at its election, postpone any such principal payment until the Maturity Date if, as of the applicable payment date, certain trailing four-quarter consolidated XHANCE net sales and royalties thresholds have been achieved.

The Note Purchase Agreement contains various covenants that limit our ability to engage in specified types of transactions without our lenders' prior consent, as well as financial covenants that require us to maintain at least $30.0 million of cash and cash equivalents in certain deposit accounts and require us to achieve certain minimum trailing twelve-month consolidated XHANCE net sales and royalties, tested on a quarterly basis and increasing from $15 million for the twelve month period ending December 31, 2019 to $125 million for the twelve-month period ending December 31, 2023. For 2020, we are required to achieve consolidated XHANCE net sales and royalties of $20 million, $27 million, $33 million and $40 million for the trailing twelve-month periods ending March 31, June 30, September 30 and December 31, 2020, respectively, if the only Notes issued under the Note Purchase Agreement are the Initial Notes, or $25 million, $32 million, $40 million and $48 million for the trailing twelve-month periods ending March 31, June 30, September 30 and December 31, 2020, respectively, if any Delayed Draw Notes have been issued under the Note Purchase Agreement. See Section 8.16(a) of the Note Purchase Agreement for the minimum trailing twelve-month consolidated XHANCE net sales and royalties applicable during the term of the Notes.

Each holder of an Initial Note or Delayed Draw Note (collectively, the Notes) may elect to accelerate the repayment of all unpaid principal and accrued interest under such holder's Note upon consummation of a specified change of control transaction or occurrence of certain events of default (as specified in the Note Purchase Agreement), including, among other things:

- our default in a payment obligation under the Notes;
- our breach of the restrictive covenants or other terms of the Notes;
- our breach of reporting obligations;
- our failure to properly maintain the collateral;
- any circumstance that could reasonably be expected to have a material adverse effect (as defined in the Note Purchase Agreement) on the Issuer;
- certain regulatory and/or commercial actions that causes an ongoing delay in commercialization of XHANCE; and
- certain specified insolvency and bankruptcy-related events.

Subject to any applicable cure period set forth in the Notes, all amounts outstanding with respect to the Notes (principal and accrued interest), as well as any applicable prepayment premiums or interest “make-whole” payments, would become due and payable immediately upon an event of default at a default interest rate of 13.75%. Our assets or cash flow may not be sufficient to fully repay our obligations under the Notes if the obligations thereunder are accelerated upon any events of default. Further, if we are unable to repay, refinance or restructure our obligations under the Notes, the holders of such Notes could proceed to protect and enforce their rights under the Notes by exercising such remedies (including foreclosure on the collateral granted to them to secure the Notes) as are available to the holders thereunder and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Notes or in aid of the exercise of any power granted in the Notes. The foregoing would materially and adversely affect the ongoing viability of our business.

Our Note Purchase Agreement contains restrictions that limit our flexibility in operating our business.

The Note Purchase Agreement contains various covenants that limit our ability to engage in specified types of transactions without our lenders’ prior consent. These covenants limit our ability to, among other things:

- sell, transfer, lease or dispose of our assets;
- create, incur or assume additional indebtedness;
- encumber or permit liens on certain of our assets;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our common stock;
- make specified investments (including loans and advances);
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets;
- enter into certain transactions with our affiliates;
- grant certain license rights related to our products, technology and other intellectual property rights; and
- permit our cash and cash equivalents held in certain deposit accounts to be less than $30.0 million at any time.

The covenants in our Note Purchase Agreement and related security agreements may limit our ability to take certain actions that may be in our long-term best interests. In the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding under the Notes, plus penalties and interest, terminate their commitments to purchase additional Notes and foreclose on the collateral granted to them to secure the Notes. Such repayment could have a material adverse effect on our business, operating results and financial condition.

Provisions of the Notes for certain potential payments to the holders of such Notes that could impede a sale of the Company.

Subject to certain exceptions, we are required to make mandatory prepayments of the Notes, with the proceeds of assets sales, extraordinary receipts and prohibited debt issuances, and upon the occurrence of a change of control (as defined in the Note Purchase Agreement). In addition, we may make voluntary prepayments of the Notes, in whole or in part. All mandatory and voluntary prepayments of the Notes are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the third anniversary of the Closing Date, an amount equal to 2% of the principal prepaid, (ii) if prepayment occurs on or after the third anniversary of the Closing Date but prior to the fourth anniversary of the Closing Date, an amount equal to 1% of the principal prepaid, and (iii) if prepayment occurs on or after the fourth anniversary of the Closing Date no prepayment premium is due. Additionally, we are also required to pay a "make-whole" amount in respect of any principal payments (whether mandatory or voluntary) made prior to the 30-month anniversary of the issuance of the applicable Note, in an amount equal to the interest that would have accrued through the 30-month anniversary in respect of such Note but for such principal repayment. These provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q. Where so indicated, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

INDEX TO EXHIBITS

Exhibit Number		Exhibit Description
3.1		Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).
3.2		Amended and Restated Bylaws of OptiNose, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).
4.1		Common Stock Warrant issued by Optinose, Inc. dated September 12, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-38241) as filed with the SEC on September 12, 2019).
10.1		Note Purchase Agreement, dated September 12, 2019, among OptiNose US, Inc., OptiNose, Inc., OptiNose UK Limited and OptiNose AS, BioPharma Credit PLC, as Collateral Agent and the purchasers from time to time party thereto (including Form of Initial Senior Secured Note)(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-38241) as filed with the SEC on September 12, 2019).
31.1	*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
31.2	*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
32.1	*	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.
32.2	*	Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.
101.INS	*	XBRL Instance Document.
101.SCH	*	XBRL Taxonomy Extension Schema Document.
101.CAL	*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	*	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

OPTINOSE, INC.

Date: November 12, 2019

By: /s/ KEITH A. GOLDAN

Name: Keith A. Goldan

Title: *Chief Financial Officer*

(Principal Financial and Accounting Officer)

CERTIFICATION UNDER SECTION 302 OF THE

SARBANES-OXLEY ACT OF 2002

I, Peter K. Miller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Peter K. Miller
Peter K. Miller
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION UNDER SECTION 302 OF THE

SARBANES-OXLEY ACT OF 2002

I, Keith A. Goldan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Keith A. Goldan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

CERTIFICATION UNDER SECTION 906 OF THE

SARBANES-OXLEY ACT OF 2002

I, Peter K. Miller, Chief Executive Officer of OptiNose, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the period ending September 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: November 12, 2019

/s/ Peter K. Miller
Peter K. Miller
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION UNDER SECTION 906 OF THE

SARBANES-OXLEY ACT OF 2002

I, Keith A. Goldan, Chief Financial Officer of OptiNose, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge

1. the Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: November 12, 2019

/s/ Keith A. Goldan
Keith A. Goldan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)