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 March 31, 2020

☐ **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 ☐

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 ☐

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 ☐	Accelerated filer	☒
Non-accelerated filer ☐	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 ☐ No ☒

The number of shares of the registrant's common stock outstanding at May 1, 2020 was 45,906,162 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 impact of, our plans regarding and the uncertainties caused by, the COVID-19 pandemic;
- the potential uses for and advantages of XHANCE®, our product candidates and Exhalation Delivery System (EDS) devices and technologies;
- planned product development activities, studies and clinical trials, and related increase in expenses, in pursuit of a follow-on indication for XHANCE for the treatment of chronic sinusitis;
- future XHANCE prescription and net revenue growth and potential drivers of such growth;
- planned operating expense reductions;
- commercial initiatives and objectives related to XHANCE;
- potential for direct to consumer (DTC) advertising to be a future driver of XHANCE prescription growth;
- the potential benefits of our patient affordability programs and their potential effect on XHANCE demand and financial results;
- the potential for XHANCE prescriptions to be affected by the seasonality impact observed in the intranasal steroid (INS) market;
- the potential for XHANCE prescriptions and average net revenue per prescription to be adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January;
- 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;
- the potential for XHANCE to be the standard of care for the treatment of chronic rhinosinusitis with and without nasal polyps;
- our intent to evaluate providing guidance for XHANCE net revenues if the effects of the COVID-19 pandemic on XHANCE net revenues become more certain;
- our expectation that top line results from both of our ongoing chronic sinusitis trials will be available in the second half of 2021;
- our expectation that our GAAP operating expenses in 2020 will be between $131.0 million and $136.0 million and that our non-cash stock-based compensation expense will be approximately $11.0 million;
- our expectation that the average net revenue per prescription will improve substantially for the remainder of 2020;
- our ability to maintain sufficient inventory of XHANCE and for our manufacturers to timely supply XHANCE; and
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and need for additional financing;

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,” “confident,” “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, 2019, filed with the Securities and Exchange Commission (SEC), and in particular, the risks and uncertainties discussed therein and in this Form 10-Q 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 markets for XHANCE, XHANCE market access, the INS market and prescription data. 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. As a result, 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)

	March 31, 2020	December 31, 2019
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 148,475	$ 147,144
Accounts receivable, net	11,733	13,643
Inventory	5,709	3,484
Prepaid expenses and other current assets	3,760	3,789
Total current assets	169,677	168,060
Property and equipment, net	2,980	3,052
Other assets	1,513	1,538
Total assets	$ 174,170	$ 172,650
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,403	$ 3,625
Accrued expenses and other current liabilities	28,822	32,514
Total current liabilities	34,225	36,139
Long-term debt, net	104,656	74,531
Other liabilities	158	397
Total liabilities	139,039	111,067
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2020 and December 31, 2019; 45,906,162 shares issued and outstanding at March 31, 2020 and December 31, 2019	46	46
Additional paid-in capital	491,994	489,565
Accumulated deficit	(456,836)	(427,980)
Accumulated other comprehensive loss	(73)	(48)
Total stockholders' equity	35,131	61,583
Total liabilities and stockholders' equity	$ 174,170	$ 172,650

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Operations
For the Three Months Ended March 31, 2020 and 2019
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Revenues:		
Net product revenues	$ 7,062	$ 3,976
Licensing revenues	—	500
Total revenues	7,062	4,476
Costs and expenses:		
Cost of product sales	1,356	738
Research and development	4,932	4,562
Selling, general and administrative	27,060	26,340
Total operating expenses	33,348	31,640
Loss from operations	(26,286)	(27,164)
Other (income) expense:		
Interest income	(332)	(684)
Interest expense	2,863	2,388
Foreign currency losses	39	6
Net loss	$ (28,856)	$ (28,874)
Net loss per share of common stock, basic and diluted	$ (0.63)	$ (0.70)
Weighted average common shares outstanding, basic and diluted	45,906,162	41,256,050

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Comprehensive Loss
For the Three Months Ended March 31, 2020 and 2019
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Net loss	$ (28,856)	$ (28,874)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	(25)	3
Comprehensive loss	$ (28,881)	$ (28,871)

See accompanying notes to unaudited interim consolidated financial statements

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

Three Months Ended March 31, 2020

	Stockholders' Equity					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	45,906,162	$ 46	$ 489,565	$ (427,980)	$ (48)	$ 61,583
Stock compensation expense	—	—	2,429	—	—	2,429
Foreign currency translation adjustment	—	—	—	—	(25)	(25)
Net loss	—	—	—	(28,856)	—	(28,856)
Balance at March 31, 2020	45,906,162	$ 46	$ 491,994	$ (456,836)	$ (73)	$ 35,131

Three Months Ended March 31, 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

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2020 and 2019
(in thousands)
(Unaudited)

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Operating activities:		
Net loss	$ (28,856)	$ (28,874)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	309	269
Stock-based compensation	2,460	2,422
Amortization of debt discount and issuance costs	268	113
Changes in operating assets and liabilities:		
Accounts receivable	1,910	(3,483)
Grants and other receivables	—	118
Prepaid expenses and other assets	425	(1,342)
Inventory	(2,225)	1,419
Accounts payable	2,131	584
Accrued expenses and other liabilities	(4,390)	(920)
Cash used in operating activities	(27,968)	(29,694)
Investing activities:		
Purchases of property and equipment	(70)	(168)
Cash used in investing activities	(70)	(168)
Financing activities:		
Proceeds from long-term debt	30,000	—
Cash paid for financing costs	(622)	—
Proceeds from issuance of common stock under employee stock purchase plan	—	173
Proceeds from the exercise of stock options	—	15
Cash provided by financing activities	29,378	188
Effects of exchange rate changes on cash and cash equivalents	(5)	(6)
Net decrease in cash, cash equivalents and restricted cash	1,335	(29,680)
Cash, cash equivalents and restricted cash at beginning of period	147,165	201,011
Cash, cash equivalents and restricted cash at end of period	$ 148,500	$ 171,331
Supplemental disclosure of noncash activities:		
Fixed asset purchases within accounts payable and accrued expenses	$ 218	$ 146
Recognition of right-of-use assets	$ 405	$ 2,484
Recognition of lease liabilities	$ 405	$ 2,961

See accompanying notes to unaudited interim consolidated financial statements

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) 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 referred to 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, commercializing XHANCE in the US. As of March 31, 2020, the Company had cash and cash equivalents of $148,475.

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 its debt service obligations, including repayment, under the Company's outstanding senior secured notes, and to carry out the Company's planned development and commercial activities. The terms of the outstanding senior secured notes, including applicable covenants, are described in Note 8. If additional capital is not secured when required, the Company may need to delay or curtail its operations until additional 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 March 31, 2020 and its results of operations for the three months ended March 31, 2020 and 2019 and cash flows for the three months ended March 31, 2020 and 2019. Operating results for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020. 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, 2019 contained in the Company's annual report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 5, 2020.

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.

Customer and supplier concentration

XHANCE is sold to wholesale pharmaceutical distributors and Preferred Pharmacy Network (PPN) partners, who, in turn, sell XHANCE to pharmacies, hospitals and other customers. Five customers represent approximately 52% of the Company's accounts receivable at March 31, 2020 and five customers represent approximately 55% of the Company's net product sales for the three months ended March 31, 2020.

The Company purchases XHANCE and its components from several third-party suppliers and manufacturing partners, certain of which are available through a single source. Although the Company could obtain each of these components from alternative third-party suppliers, it would need to qualify and obtain FDA approval for another supplier as a source for each such component.

Fair value of financial instruments

At March 31, 2020 and December 31, 2019, the Company's financial instruments included cash and cash equivalents, accounts receivable, grants receivable, 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. In addition, at March 31, 2020, the Company believes the carrying value of long-term debt approximates fair value as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions. At March 31, 2020 and December 31, 2019, there were no financial assets or liabilities measured at fair value on a recurring basis.

Restricted cash

As of March 31, 2020 and December 31, 2019, the restricted cash balance included in prepaid expenses and other assets was $25 and $21, 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.

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 eligible patients with prescription drug co-payments required by payors and coupon programs for cash payors. The calculation of the current liability 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

The Company has license agreements with Inexia Limited (Inexia) and Currax Pharmaceuticals LLC (Currax). 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. No licensing revenues were recognized during the three months ended March 31, 2020 (Note 7).

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 months ended March 31, 2020 and 2019, 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.

(in thousands, except share and per share data)

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

	March 31,	
	2020	**2019**
Stock options	8,373,040	7,777,367
Restricted stock units	1,287,986	—
Common stock warrants	2,677,188	1,866,831
Employee stock purchase plan	43,900	46,161
Total	12,382,114	9,690,359

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 months ended March 31, 2020 and 2019, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of March 31, 2020 and December 31, 2019, 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 December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*. ASU 2019-12 eliminated certain exceptions and changed guidance on other matters. The exceptions relate to the allocation of income taxes in separate company financial statements, tax accounting for equity method investments and accounting for income taxes when the interim period year-to-date loss exceeds the anticipated full year loss. Changes relate to the accounting for franchise taxes that are income-based and non-income-based, determining if a step up in tax basis is part of a business combination or if it is a separate transaction, when enacted tax law changes should be included in the annual effective tax rate computation, and the allocation of taxes in separate company financial statements to a legal entity that is not subject to income tax. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, 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 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 adopted ASU 2016-02 on January 1, 2020 using the prospective transition method, which did not have a material impact on the Company's results of operations, financial position, 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 adopted ASU 2018-13 on January 1, 2020, which did not have a material impact on the Company's 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, 2022 for companies deemed to be smaller reporting companies as of November 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 thousands, except share and per share data)

4. Inventory

Inventory consisted of the following:

	March 31, 2020	December 31, 2019
Raw materials	$ 1,900	$ 1,227
Work-in-process	1,008	676
Finished goods	2,801	1,581
Total inventory	$ 5,709	$ 3,484

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:

	March 31, 2020	December 31, 2019
Computer equipment and software	$ 1,089	$ 1,112
Furniture and fixtures	366	366
Machinery and equipment	3,116	3,142
Leasehold improvements	609	609
Construction in process	278	70
	5,458	5,299
Less: accumulated depreciation	(2,478)	(2,247)
	$ 2,980	$ 3,052

Depreciation expense was $308 and $269 for the three months ended March 31, 2020 and 2019, respectively. In addition, depreciation expense of $134 and $2 was charged to inventory and prepaid expenses and other assets, respectively, as of March 31, 2020, which represents depreciation expense related to equipment involved in the manufacturing process.

(in thousands, except share and per share data)

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	March 31, 2020	December 31, 2019
Accrued expenses:		
Selling, general and administrative expenses	$ 5,615	$ 5,544
Research and development expenses	4,001	3,379
Payroll expenses	3,884	7,810
Product revenue allowances	12,016	12,858
Other	1,960	1,788
Total accrued expenses	27,476	31,379
Other current liabilities:		
Lease liability	1,346	1,135
Total other current liabilities	1,346	1,135
Total accrued expenses and other current liabilities	$ 28,822	$ 32,514

7. Licensing Revenue

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.

8. 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. On February 13, 2020, the Company received an additional $30,000 (the First Delayed Draw Notes) after achieving the $9,000 XHANCE net sales and royalties threshold for the quarter ended December 31, 2019.

The remaining $40,000 of the Pharmakon Senior Secured Notes may be issued, at the Company's option, as follows:

- $20,000 of Pharmakon Senior Secured Notes 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 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 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 Third Delayed Draw Notes are not conditioned upon the issuance of the Second Delayed Draw Notes. Furthermore, if the Company fails to meet the XHANCE net sales and royalties thresholds required to issue 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 Second Delayed Draw Notes upon the closing date of the Third Delayed Draw Notes (subject to the Company's satisfaction of the net sales and royalties thresholds applicable to the Third Delayed Draw Notes).

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 $4,991 in debt issuance costs, including $2,404 related to the fair value of the warrants and $150 associated with the First Delayed Draw Notes, 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 remaining 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 March 31, 2020, 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.

(in thousands, except share and per share data)

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.

The Company recorded interest expense of $2,863 and $2,388 during the three months ended March 31, 2020 and 2019, respectively, in conjunction with both Pharmakon Senior Secured Notes and the Athyrium senior secured notes. Interest expense included total coupon interest, exit fees, front end fees and the amortization of debt issuance costs.

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

	March 31, 2020	December 31, 2019
Face amount	$ 110,000	$ 80,000
Front end fees	(1,013)	(1,030)
Debt issuance costs	(4,331)	(4,439)
Long-term debt, net	$ 104,656	$ 74,531

9. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of March 31, 2020, approximately $84 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 $5 and $6 for the three months ended March 31, 2020 and 2019, respectively.

10. Stockholders' Equity

As of March 31, 2020, 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

11. 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 months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
Cost of product sales	$ 54	$ 21
Research and development	257	243
General and administrative	2,149	2,158
	$ 2,460	$ 2,422

In addition, stock-based compensation expense of $38 and $1 was charged to inventory and prepaid expenses and other assets, respectively, during the three months ended March 31, 2020, 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.

(in thousands, except share and per share data)

Stock Options

The Company issues stock-based awards pursuant to its 2010 Stock Incentive Plan. Effective as of October 12, 2017, the Company's 2010 Stock Incentive Plan was amended and restated (A&R Plan).The Company has issued service-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 or committee thereof. 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 March 31, 2020, all of the performance conditions related to performance-based stock options issued by the Company have been achieved.

The following table summarizes the activity related to stock option grants to employees and nonemployees for the three months ended March 31, 2020:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2019	7,399,217	$ 9.81	6.37
Granted	1,146,258	5.65	
Exercised	—	—	
Expired	—	—	
Forfeited	(172,435)	10.57	
Outstanding at March 31, 2020	8,373,040	$ 9.22	6.59
Exercisable at March 31, 2020	4,844,852	$ 9.41	4.90
Vested and expected to vest at March 31, 2020	8,373,040	$ 9.22	6.59

During the three months ended March 31, 2020, stock options to purchase 1,146,258 shares of Common Stock were granted to employees and generally vest over four years. The stock options had an estimated weighted average grant date fair value of $3.44. During the three months ended March 31, 2019, stock options to purchase 1,686,800 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 $4.67.

Included in the table above are 90,000 of options granted outside the A&R Plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

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:

	Three Months Ended March 31,	
	2020	2019
Risk free interest rate	0.75 %	2.57 %
Expected term (in years)	6.08	6.08
Expected volatility	68.34 %	67.14 %
Annual dividend yield	0.00 %	0.00 %
Fair value of common stock	$ 5.65	$ 7.49

At March 31, 2020, the unrecognized compensation cost related to unvested stock options expected to vest was $19,423. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.5 years.

(in thousands, except share and per share data)

Restricted Stock Units

The Company has issued service-based and performance-based restricted stock units (RSUs). Vesting generally occurs over a period not greater than four years. Vesting of the performance-based RSUs is subject to the achievement of certain milestones in connection with the Company's development programs.

The following table summarizes the activity related to RSUs granted to employees for the three months ended March 31, 2020:

	Shares
Balance at December 31, 2019	—
Granted	1,290,203
Vested and settled	—
Expired/ forfeited/ canceled	(2,217)
Balance at March 31, 2020	1,287,986
Expected to vest at March 31, 2020	1,287,986

In March 2020, the Company granted 1,290,203 RSUs at a grant date fair value of $5.41, of which 718,150 were service-based RSUs and 572,053 were performance-based RSUs. As of March 31, 2020, the milestones associated with the performance based-RSUs are not probable of achievement, and accordingly, no stock based compensation expense has been recognized to date for these awards. At March 31, 2020, the unrecognized compensation cost related to unvested service-based RSUs expected to vest was $3,806, to be recognized over an estimated weighted-average amortization period of 4.0 years. The unrecognized compensation cost related to unvested performance-based RSUs was $3,095, which will be recognized commencing in the period in which the performance condition is deemed probable of achievement over the remaining service period.

Included in the table above are 60,000 of RSUs granted outside the A&R Plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

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 $150 and $114 during the three months ended March 31, 2020 and 2019, respectively, related to the 2017 Plan.

The Company calculated the fair value of each option grant and the shares issued under the 2017 Plan on the respective dates of grant using the following weighted average assumptions:

	Three Months Ended March 31,	
	2020	2019
Risk free interest rate	1.57 %	2.51 %
Expected term (in years)	0.5	0.5
Expected volatility	79.59 %	82.20 %
Annual dividend yield	0.00 %	0.00 %

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, 2019, filed with the Securities and Exchange Commission (SEC) on March 5, 2020. In addition to historical information, some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results could differ materially from the results described in or implied by such forward-looking statements. Please refer to the "Note Regarding Forward-Looking Statements" section of this Form 10-Q for additional information.

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 micrograms (mcg), is a therapeutic utilizing our proprietary 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 referred to 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.

In September 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.

Business Updates in Response to the COVID-19 Pandemic

The COVID-19 pandemic has caused business and economic disruption, and the duration and impact of that disruption is uncertain at this time.

- In mid-March 2020, we transitioned to a full-time, virtual work environment in which all employees, including sales representatives (whom we refer to as territory managers), were encouraged to work from their place of residence. Our decision was based on actions taken by federal, state and local governments to contain the spread of severe acute respiratory coronavirus 2 (SARS-CoV-2) and the related Coronavirus Disease 2019 (COVID-19), as well as the impact of “social distancing” efforts and various mitigation actions implemented by healthcare practices across the United States.
- The new federal, state and local government requirements and guidance impact virtually all of the physicians' offices in which our territory managers detail XHANCE. These impacts include reduced patient visits, temporary halt of territory managers' visits, and closings of physicians' offices. Shortly after our transition to a full-time, virtual work environment, our territory managers began virtual details of XHANCE to target audience physicians.
- We are monitoring federal, state, and local government communications in anticipation that the various mitigation efforts will be updated to facilitate a return to a working environment with fewer restrictions that may enable our territory managers to return to in-person detailing of physicians, depending on the policies of those physician offices. Given the localized nature of the restrictions that are in place we are preparing for our territory managers to operate in an environment that will include a mix of virtual and in-person physician detailing with dependencies on geography and time.
- Late in the first quarter we began to observe an impact of the COVID-19 pandemic on XHANCE prescription growth. Based on third-party prescription data as well as data from PPN partners, XHANCE prescriptions increased by 8% for the six-week period ended April 24th compared to the prior six-week period ended March 13th. This six-week period coincides with our territory managers transition to a virtual detailing model and the nationwide COVID-19 related environmental shifts. Although XHANCE prescriptions have grown during this initial COVID-19 period, the rate of growth was below our pre-pandemic expectations. Due to the adverse effect of the COVID-19 pandemic on XHANCE prescription growth to

date as well as the unknown effect in the future, we are withdrawing our previous XHANCE revenue guidance for 2020. If the effects of the COVID-19 pandemic on XHANCE net revenues become more certain, we will evaluate providing guidance for XHANCE net revenues. Additionally, the duration and magnitude of the negative impact from the COVID-19 pandemic on XHANCE net revenue are uncertain and may affect the availability of additional capital under our Pharmakon Note Purchase Agreement and our ability to remain in compliance with our revenue covenants thereunder.

- Due to the impacts of the COVID-19 pandemic, at least one of our contract manufacturers has implemented a reduced work schedule and additional precautions which will result in delays relating to the manufacture of XHANCE. Despite these delays, we believe that we have sufficient finished goods inventory of XHANCE available to support expected demand, however, the duration and magnitude of the negative impact from COVID-19 could constrain our supply of XHANCE.

- Previous guidance related to the expected timing of results from our ongoing chronic sinusitis trials indicated that results from both trials would be available in the second half of 2021. Pauses in patient enrollment due to factors related to COVID-19 have had, and may continue to have, varying effects in different geographies and over time but have not yet led to a change in our projected timeline for initial data availability. For those subjects currently participating in these studies, procedures to facilitate ongoing treatment and capture of data during periods of in-person care restrictions have been put in place.

- In light of the uncertainties created by the COVID-19 pandemic, we have taken actions to reduce 2020 operating expenses by approximately $17 million while preserving our ability to drive XHANCE growth and complete our ongoing chronic sinusitis trials. These expense reductions include a reprioritization of project spending, a reduction in payroll costs, and lower near-term clinical trial expenses as the result of temporarily paused patient enrollment at research sites in response to the acute COVID-19 environment.

The full impact of the COVID-19 pandemic on our business is still unknown. It is likely to continue to have negative impacts on XHANCE prescription growth and net revenues as result of fewer patients visiting physician offices, rising unemployment adversely affecting demand and payor mix, and the availability and cost of capital for us to fund our business operations and service our debt. We will continue to assess the evolving impact of the COVID-19 pandemic and will make adjustments to our operations as necessary.

Additional Business Updates

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

- XHANCE Prescriptions and Market Share. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE prescriptions in the first quarter of 2020 was 56,100, which represents 149% growth for prescriptions when compared to estimated first quarter 2019 prescriptions of 22,500. The INS prescription market increased approximately 6% from first quarter 2019 to first quarter 2020 based on third-party prescription data. In addition, the total estimated number of XHANCE prescriptions was 33,900 in the second quarter of 2019, 43,000 in the third quarter of 2019, and 54,300 in the fourth quarter of 2019. The total estimated number of XHANCE prescriptions in the six weeks ended April 24, 2020 was 28,000, which represents 8% growth for prescriptions when compared to the six weeks ended March 13, 2020 of 25,900. The INS prescription market decreased approximately 2% from the six weeks ended March 13, 2020 to the six weeks ended April 24, 2020 based on third-party prescription data.

  A seasonal effect has historically been 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 1% from the first quarter of 2019 to the second quarter of 2019, decreased 11% from the second quarter of 2019 to the third quarter of 2019, increased 9% from the third quarter of 2019 to the fourth quarter of 2019, and increased 8% from the fourth quarter of 2019 to the first quarter of 2020.

  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 to be prescribed a relatively new medication like XHANCE. Demand has historically been, and we expect will continue to be, impacted by the INS market seasonality and the seasonal variation in patient visits with their doctor resulting in reduced XHANCE prescription demand in the third quarter. Additionally, as we experienced in 2020, we expect that the first quarter prescription demand and average net revenue per prescription for XHANCE will be adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January.

We track 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, seasonal variation in patient visits with their doctor, annual deductible resets and annual changes in individual patient's healthcare insurance coverage referenced above. Based on third-party prescription data as well as data from PPN partners, we estimate XHANCE had a market share of 1.5% in the first quarter of 2019, 2.2% in the second quarter of 2019, 3.0% in the third quarter of 2019, 3.5% in the fourth quarter of 2019, and 3.8% in the first quarter of 2020. 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 New Prescriptions and Refill Prescriptions. The underlying disease that we are treating is chronic and, as a result, many patients may fill multiple prescriptions per year. We monitor new prescriptions as they create the potential for future refill prescriptions. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE new prescriptions in the first quarter of 2020 was 22,300, which represents 75% growth for new prescriptions when compared to estimated first quarter 2019 new prescriptions of 12,700. In addition, the total estimated number of XHANCE new prescriptions was 15,600 in second quarter 2019, 17,800 in the third quarter of 2019, and 21,200 in the fourth quarter of 2019.

  We track refill prescriptions and provide patient assistance to support refill programs that are administered by our PPN partners. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE refill prescriptions in the first quarter of 2020 was 33,700, which represents 246% growth for refill prescriptions when compared to estimated first quarter 2019 refill prescriptions of 9,800. In addition, the total estimated number of XHANCE refill prescriptions was 18,400 in second quarter 2019, 25,200 in the third quarter of 2019, and 33,000 in the fourth quarter of 2019.

- Prescribing Breadth and Depth. We track the number of physicians who prescribe XHANCE in a time period to evaluate the breadth of prescribing. Based on third-party prescription data as well as data from PPN partners, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE in the first quarter of 2020 was 6,345, which represents 71% growth when compared to the estimated 3,706 physicians who had at least one patient fill a prescription for XHANCE in the first quarter of 2019. In addition, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE was 4,442 in the second quarter of 2019, 5,075 in the third quarter of 2019, and 5,859 in the fourth quarter of 2019.

  We also track the number of prescriptions filled by a prescribing physician's patients in a time period to evaluate depth of prescribing. Based on third-party prescription data as well as data from PPN partners, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients in the first quarter of 2020 was 895, which represents 211% growth when compared to the estimated 288 physicians who had more than 15 XHANCE prescriptions filled by their patients in the first quarter of 2019. In addition, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients was 523 in the second quarter of 2019, 665 in the third quarter of 2019, and 828 in the fourth quarter of 2019.

Sales, Marketing & Distribution

We have established a commercial infrastructure designed to drive adoption and sales of XHANCE with healthcare professionals who treat patients with nasal polyps. We believe that approximately 15,000 physicians treat an estimated 3.5 million chronic rhinosinusitis patients, an estimated 1.2 million of whom have chronic rhinosinusitis with nasal polyps.

Customer Model We have hired and deployed approximately 100 territory managers into unique, geographically-defined territories. These territory managers target over 10,000 ENTs, allergists and "specialty-like" primary care physicians, and we target additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers. Our sales team is equipped with educational materials demonstrating the benefit and safety profile of XHANCE. In the future we may increase the number of geographic territories as well as hire additional territory managers in order to increase the number of called-on target physicians and frequency of calls. We believe that in the long term, direct to consumer (DTC) advertising could be an effective way to increase XHANCE prescription growth. In the second half of 2019 we conducted a single-season, multi-channel, pilot DTC advertising program in three markets. We extended the pilot in the same markets during the early part of 2020 in order to continue to evaluate the potential benefits of such a program.

XHANCE Co-Pay Savings Program We believe our co-pay savings program provides an affordability solution for patients that physicians will support. This program provides patient co-pay assistance including a first prescription at no out-of-pocket cost ($0 co-pay) to eligible commercially insured patients and low subsequent co-pays for refills ranging from $0 to $50 per XHANCE unit.

Market Access Based on currently available third-party data and our internal analyses as of March 31, 2020, we believe that approximately 75% of commercially insured lives are currently in a plan in which we have contracted for XHANCE coverage. However, payors may change coverage levels for XHANCE, positively or negatively, at any time. Additionally, payors generally impose restrictions on access to or usage of XHANCE, such as by requiring prior authorizations or "step-edits". For example, insurers may require that a patient first use a generic INS prior to becoming eligible for coverage for XHANCE. Some healthcare providers may not complete the administrative process required to demonstrate or document that the patients for whom XHANCE has been prescribed meet the payors' utilization management criteria (i.e., prior authorizations or step-edits) and, as a result, patients may not gain access to XHANCE treatment. In our contract negotiations with payors we seek to balance patient access and affordability, breadth of coverage, payor utilization management and rebates levels. We have also contracted with the Centers for Medicare and Medicaid Services for coverage of certain government insured lives and continue to expand XHANCE market access for other government-insured populations.

Trade and Distribution We sell XHANCE primarily to Preferred Pharmacy Network (PPN) partners with whom we contract to perform certain patient services such as patient insurance benefit verification. We established this channel to offer patients the option of filling prescriptions through a network of preferred pharmacies that may be able to better serve the needs of patients through services including delivery of XHANCE by mail and performing certain patient services such as patient insurance benefit verification. We also sell XHANCE to wholesale pharmaceutical distributors, who, in turn, sell XHANCE to pharmacies, hospitals and other customers. We have contracted with a third-party logistics provider for key services related to logistics, warehousing and inventory management, and distribution. Further, our third-party logistics provider provides customer order fulfillment services and accounts receivable management.

XHANCE Development

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 trial 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 is 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 both of our ongoing chronic sinusitis trials in the second half of 2021.

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 $7.1 million and $4.0 million in net product revenues for the three months ended March 31, 2020 and 2019, respectively. In accordance with 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.

Based on available XHANCE prescription data purchased from third parties and data from our PPN partners, who collectively dispensed 70% to 75% of our total prescriptions (TRxs) in the period, our average net product revenues per prescription for the first quarter of 2020 was approximately $126, a decrease compared to average net product revenues per prescription of $204 in fourth quarter of 2019.

We calculate average net product revenues per prescription, one metric that we use to gauge the profitability of XHANCE, by dividing net product revenues for the quarter by the estimated number of XHANCE prescriptions dispensed during the quarter. As a result, average net product revenues 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 PPN 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 net product revenues per prescription.

The decrease in average net product revenues in the first quarter of 2020 from the fourth quarter 2019 is largely a consequence of the reset of many patient insurance deductibles in January. As a result of this annual reset, we expect greater copay support to be provided by us under our assistance programs. In addition, we believe another contributor to the expected first quarter 2020 decrease is related to changes in patients' healthcare insurance coverage that reduce demand for refill prescriptions early in the year. This reduction in refill prescriptions also has the effect of lowering average net product revenues per prescription as it reduces the proportion of prescriptions that are covered (reimbursed) by a commercial insurer, which results in us providing greater copay support under our assistance programs.

For the remainder of 2020, we believe average net product revenues per prescription will improve substantially. Factors supporting this expected growth include patients meeting their out-of-pocket expense thresholds, expected improvements in insurance coverage and continued strength in the proportion of prescription refills.

Licensing revenues

In January 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 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 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, compounded by the uncertainty introduced by the COVID-19 pandemic, the rate of subject enrollment, number of subjects required, and trial duration, 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 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. Additionally, sales and marketing-related expenses include fees paid to our PPN partners for services unrelated to traditional distribution functions, such as data fees and benefit claims adjudication.

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 (Pharmakon Senior Secured Notes) with Pharmakon Advisors, LP (Pharmakon) and our former note purchase agreement (Athyrium Senior Secured Notes) with Athyrium Opportunities III Acquisition LP (Athyrium).

Other (income) expense

Other (income) expense consists primarily of 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 March 31, 2020 and 2019

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

	Three Months Ended March 31,	
	2020	2019
Revenues:		
Net product revenues	$ 7,062	$ 3,976
Licensing revenues	—	500
Total revenues	7,062	4,476
Costs and expenses:		
Cost of product sales	1,356	738
Research and development	4,932	4,562
Selling, general and administrative	27,060	26,340
Total operating expenses	33,348	31,640
Loss from operations	(26,286)	(27,164)
Other (income) expense:		
Interest (income) expense	2,531	1,704
Other (income) expense	39	6
Total other (income) expense	2,570	1,710
Net loss	$ (28,856)	$ (28,874)

Net product revenues

Net product revenues related to sales of XHANCE were $7.1 million and $4.0 million for the three months ended March 31, 2020 and 2019, respectively. Revenue growth is attributable primarily to an increase in units sold to customers, as a result of a greater number of XHANCE prescriptions dispensed during the thee months ended March 31, 2020.

Licensing revenues

Licensing revenues were $0.5 million for the three months ended March 31, 2019 as a result of the upfront payment received under the terms of the Inexia License Agreement. No licensing revenue was recognized during the three months ended March 31, 2020.

Cost of product sales

Cost of product sales related to XHANCE were $1.4 million and $0.7 million for the three months ended March 31, 2020 and 2019, respectively, with the increase primarily attributed to an increase in units sold to customers during the period.

Research and development expense

Research and development expense was $4.9 million and $4.6 million for the three months ended March 31, 2020 and 2019, respectively. The $0.3 million increase was attributable primarily to a $0.3 million increase in clinical expenses related to the 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 $27.1 million and $26.3 million for the three months ended March 31, 2020 and 2019, respectively. The $0.8 million increase was due primarily to:

- a $1.3 million increase in service fees paid to our PPN partners, the result of a greater number of XHANCE prescriptions dispensed by our PPN partners during the period; and
- an $0.8 million increase in personnel, bonus and travel expenses due to increases in headcount and the expansion of our sales team.

This increase was offset by:

- a $1.5 million decrease in expenses related to the sale of XHANCE, including marketing expenses.

Interest (income) expense, net

Interest (income) expense, net, was $2.5 million and $1.7 million for the three months ended March 31, 2020 and 2019, respectively. Interest expense was $2.9 million and $2.4 million for the three months ended March 31, 2020 and 2019, respectively, the increase was primarily related to the increased principal balance of our long-term debt. Interest expense was offset by interest income of $0.3 million and $0.7 million for the three months ended March 31, 2020 and 2019, respectively. Interest income decreased by $0.4 million as compared to the three months ended March 31, 2019 as a result of lower cash balances.

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 $28.9 million for both of the three months ended March 31, 2020 and 2019. As of March 31, 2020, we had an accumulated deficit of $456.8 million. We have funded our operations primarily through the sale and issuance of stock and debt, as well as through licensing revenues. As of March 31, 2020, we had $148.5 million in cash and cash equivalents.

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

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	$ (27,968)	$ (29,694)
Net cash used in investing activities	(70)	(168)
Net cash provided by financing activities	29,378	188
Effects of exchange rates on cash and cash equivalents	(5)	(6)
Net decrease in cash and cash equivalents	$ 1,335	$ (29,680)

Operating activities

Cash used in operating activities decreased by $1.7 million, from $29.7 million for the three months ended March 31, 2019 to $28.0 million for the three months ended March 31, 2020. The decrease in cash used in operating activities was attributable primarily to an increase in revenue and the timing of payment of expenses.

Investing activities

Cash used in investing activities decreased $0.1 million from $0.2 million for the three months ended March 31, 2019 to $0.1 million for the three months ended March 31, 2020. The decrease in cash used in investing activities is related to purchases of manufacturing equipment during the three months ended March 31, 2019.

Financing activities

Cash provided by financing activities was $29.4 million for the three months ended March 31, 2020. Cash provided by financing activities was $0.2 million for the three months ended March 31, 2019. Cash provided by financing activities for the three months ended March 31, 2020 was primarily driven by the receipt of $30.0 million from the issuance of the First Delayed Draw Notes under the Pharmakon Senior Secured Notes offset by additional debt issuance costs of $0.2 million.

Senior Secured Note Purchase Agreement

On September 12, 2019 (the Closing Date), we entered into the Pharmakon Senior Secured Notes with funds managed by 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 and $30.0 million was issued on February 13, 2020 (the First Delayed Draw Notes). The remaining $40.0 million of the Pharmakon Senior Secured Notes may be issued, at our option, as follows:

- $20.0 million of Pharmakon Senior Secured Notes 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 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 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 Third Delayed Draw Notes are not conditioned upon the issuance of the Second Delayed Draw Notes. Furthermore, if we fail to meet the XHANCE net sales royalties thresholds required to issue the Second Delayed Draw Notes, we may request BioPharma to issue, in its sole discretion, the entire amount or any lesser amount of such Second Delayed Draw Notes upon the closing date of the Third Delayed Draw Notes (subject to our satisfaction of the net sales and royalties thresholds applicable to the Third 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 from the First Delayed Draw Notes are being 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 8 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, grant certain license rights to our products, technologies and other intellectual property rights; 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 2020 operating expenses

We expect that our total GAAP operating expenses (consisting of selling, general & administrative expenses and research & development expenses) for 2020 will be between $131.0 million and $136.0 million of which approximately $11.0 million is expected to be stock-based compensation expense. Total GAAP operating expenses excluding stock-based compensation expense are expected to be between $120.0 million and $125.0 million. This updated guidance reflects a $17.0 million reduction in operating expenses from our previous guidance. In light of the COVID-19 pandemic and resulting impact on the business, the Company has taken actions to reduce 2020 operating expenses while preserving its ability to drive XHANCE growth and complete its ongoing chronic sinusitis trials. These expense reductions included a reprioritization project spending, a reduction in workforce including the freezing of new hires, and lower clinical trial expenses as the result of new patient enrollment in its chronic sinusitis program being temporarily paused in response to the COVID-19 pandemic. Despite the 2020 reduction in expenses, an increase in expenses from 2019 to 2020 is anticipated due to the annualization of the 2019 sales force expansion, an increase in fees paid to our PPN partners associated with higher projected XHANCE TRx volumes, and an increase in research and development expenses related to our clinical trial program in pursuit of a follow-on indication for XHANCE for the treatment of chronic sinusitis in the U.S.

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 and February 2020;
- 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:

- duration and impact of COVID-19 restrictions on our business;
- 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 maintain 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, we 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 our outstanding Pharmakon Senior Secured Notes, including repayment, and to carry out our planned development and commercial activities. As of March 31, 2020, we had access to up to an additional $40.0 million from the Pharmakon Senior Secured Notes subject to the achievement of certain milestones for 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 March 31, 2020:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(in thousands)		
Operating leases[1]	$ 1,557	$ 1,399	$ 158	$ —	$ —
Long-term debt[2]	153,465	11,956	51,109	90,400	—
Total	$ 155,022	$ 13,355	$ 51,267	$ 90,400	$ —

[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, 2019, as filed with the SEC on March 5, 2020, 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 March 31, 2020.

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 March 31, 2020 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, 2019, filed with the SEC on March 5, 2020. Except as set forth below, there have been no material changes to the risk factors disclosed in our Form 10-K.

The coronavirus (COVID-19) pandemic has and may continue to adversely affect our business, results of operations and financial condition.

On March 13, 2020, the President of the United States announced a national emergency relating to the coronavirus (COVID-19) pandemic. Government authorities in the U.S. have recommended or imposed various social distancing, quarantine, and isolation measures on large portions of the population, and similar measures have also been taken in many other countries around the world.

In March 2020, we modified our business practices and transitioned to a full-time, virtual work environment in which all employees were encouraged to work from their place of residence if their job functions allowed, and all work-related travel was temporarily discontinued. A significant portion of the physicians' offices in which our territory managers detail XHANCE either were closed, had reduced patient flow or temporarily stopped sales representatives' visits, which has hindered our ability to detail XHANCE to physicians' offices. If our territory managers continue to have a limited ability to meet with physicians and if patients' visits to doctors continue to be limited, XHANCE prescription growth and net revenues will be adversely impacted. In addition, changes in insurance coverage or reimbursement levels by governmental authorities, private health insurers and other third-party payors, or in the type of such coverage held by patients, due to the impacts of the COVID-19 pandemic, including the related increase in unemployment in the U.S., may negatively impact XHANCE prescription growth and net revenues.

The duration and magnitude of the negative impact from the COVID-19 pandemic on XHANCE net revenues could also affect our ability to meet net revenue thresholds to draw additional capital under our Pharmakon Note Purchase Agreement and to remain in compliance with our revenue covenants. Furthermore, capital markets in the U.S. and around the world have also been negatively impacted by COVID-19, which may harm our business, including our ability to obtain future financing.

Our ability to enroll patients and retain principal investigators and site staff for our ongoing clinical trials have been, and could continue to be, impaired due to the COVID-19 outbreak in their geographic areas, the prioritization of medical resources toward the COVID-19 pandemic, or as a result of quarantines and other restrictions that interrupt healthcare services. Furthermore, patients, investigators, or site staff may be unwilling or unable to comply with clinical trial protocols due to COVID-19 illness, concerns about the pandemic, or quarantines or other restrictions that impede their movement. Any interruption in the supply of the study drug might also delay our ability to complete our ongoing clinical trials. Significant delays in the completion of our ongoing clinical trials are costly and could adversely affect our business and financial condition.

COVID-19 may also have an adverse impact on our contract manufacturers, suppliers, PPN partners, wholesalers, distributors and third party logistic provider as a result of employees or other key personnel becoming infected, preventive and precautionary measures that governments or such third parties are taking, such as social distancing, quarantines, and other restrictions, and shortages of supplies necessary for the manufacture of XHANCE. Any of these circumstances could adversely impact the ability of third parties on which we rely to manufacture and distribute adequate volumes of XHANCE. For example, our contract manufacturer for the formulation and assembly of finished XHANCE drug product notified us in April that, in response to the current pandemic, it was implementing a reduced work schedule which will result in delays relating to the assembly of XHANCE finished goods. While we believe that we have sufficient inventory of XHANCE available to support expected demand, any further or other unexpected delays could constrain our supply of XHANCE.

The extent to which the coronavirus impacts our business and the third parties on whom we rely, such as our contract manufacturers, suppliers, PPN partners, wholesalers, distributors, third party logistics, contract research organizations, investigators for our clinical trials and other vendors, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that may emerge concerning the severity of the coronavirus, the actions to contain the coronavirus or treat its impact, and the speed with which and the extent to which normal economic and operating conditions resume, among others.

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).
10.1		Employment Agreement, dated February 17, 2020, between OptiNose US, Inc. and Victor M. Clavelli (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K (File No. 001-38241) as filed with the SEC on February 19, 2020).
10.2		Relocation Agreement, dated February 17, 2020, between OptiNose US, Inc. and Victor M. Clavelli (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K (File No. 001-38241) as filed with the SEC on February 19, 2020).
10.3		Form of Non-Qualified Stock Option Agreement (Inducement Grant) (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K (File No. 001-38241) as filed with the SEC on February 19, 2020).
10.4	*	Form of Restricted Stock Unit Agreement (Inducement Grant).
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.SCH	*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* 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: May 7, 2020	By: /s/ KEITH A. GOLDAN
	Name: Keith A. Goldan
	Title: *Chief Financial Officer*
	(Principal Financial and Accounting Officer)

OPTINOSE, INC.
RESTRICTED STOCK UNIT AGREEMENT
Inducement Grant

Pursuant to the attached Restricted Stock Unit Award Notice (the "**Award Notice**") and this Restricted Stock Unit Agreement (together with the Award Notice, this "**Agreement**"), OptiNose, Inc. (the "**Company**") has awarded you a Restricted Stock Unit Award (the "**Award**") for the number of restricted stock units indicated in the Award Notice ("**RSUs**"). The Award is granted to you as an inducement that is material to you entering into employment with the Company pursuant to the inducement grant exception under NASDAQ Listing Rule 5635(c), and not pursuant to the Company's 2010 Stock Incentive Plan, as amended and restated as of September 19, 2017 (the "Plan"), or any other equity plan incentive plan of the Company. Although the Award is not granted pursuant to the Plan, the Award shall be subject to and governed by, and shall be construed and administered in accordance with, the terms and conditions of this Agreement and the Plan (as from time to time in effect), which terms and conditions are incorporated herein by reference. In the event any provision of this Agreement should appear to be inconsistent with the Plan, the Plan shall control. Certain capitalized terms not explicitly defined in this Agreement shall have the same meanings given to them in the Plan.

Restricted Stock Units	This Agreement evidences the grant of an Award of Restricted Stock Units in the number set forth on the Award Notice. Each RSU represents the right to receive one share of Stock, subject to the vesting conditions and other terms and conditions set forth herein.
Vesting	Subject to the limitations contained herein and in the Plan, your Award will vest, if at all, in accordance with the vesting schedule provided in the Award Notice. Vesting will cease upon the termination of your continuous Service and any RSUs that are not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such Award or the shares of Stock to be issued in respect of such portion of the Award.
Termination of Service	Unless the termination of your Service triggers accelerated vesting or other treatment of the RSUs pursuant to the terms of the Plan or any written employment agreement or other written agreement entered into between the Company or an Affiliate and you, you shall immediately and automatically forfeit your unvested RSUs to the Company in the event your Service terminates for any reason.
Change of Control	In the event of a Change of Control, the RSUs shall be treated in the manner provided in Sections 18.3 and 18.4 of the Plan, as applicable.
Leaves of Absence	For purposes of this Agreement, your Service does not terminate when you go on a *bona fide* employee leave of absence that was approved by the Company in writing, if the terms of the leave provide for continued Service crediting, or when continued Service crediting is required by applicable law. However, your Service will be treated as terminating 90 days after you went on employee leave, unless your right to return to active work is guaranteed by law or by a contract. Your Service terminates in any event when the approved leave ends unless you immediately return to active employee work. The Company determines, in its sole discretion, which leaves count for this purpose, and when your Service terminates for all purposes under the Plan. The Company's decision is final and binding.

Dividend Equivalent Rights

If the Company declares one or more cash dividends on the Stock during the period commencing on the Grant Date and ending on and including the day immediately preceding the day on which the shares of Stock subject to vested RSUs are issued to you, then, on the date each such dividend is paid to the holders of Stock, you will be credited with dividend equivalents in an amount equal to the product of (i) the amount of the dividend declared and paid per share of Stock and (ii) the number of RSUs granted to you under this Agreement that are outstanding as of the record date of such dividend. The dividend equivalents that are credited to you in respect of each cash dividend will be deemed to have been reinvested into additional RSUs (rounded to the nearest whole unit) as of the dividend payment date based on the closing price of the Stock on the dividend payment date. Any such additional RSUs shall be subject to the same terms and conditions which apply to the underlying RSUs to which they relate and shall vest or be forfeited, as applicable, at the same time as the underlying RSUs to which they relate. Such additional RSUs shall also be credited with additional RSUs as any further cash dividends are declared. The foregoing does not obligate the Company to pay dividends on the Stock and nothing in the Plan or in this Agreement shall be interpreted as creating such an obligation.

Notwithstanding anything to the contrary in this Agreement, if the RSUs are scheduled to vest and be settled between a dividend record date and a dividend payment date, then dividend equivalents with respect to such dividend will be credited to you, will be deemed to have been reinvested into additional RSUs (rounded to the nearest whole unit), and will be paid to you on the earlier of (i) the dividend payment date for such dividend and (ii) March 15th following the date on which the underlying RSUs vest.

Withholding Obligation

(a) By accepting this Award, you hereby (i) acknowledge and agree that you have elected a Sell to Cover (as defined in the Award Notice) to permit you to satisfy any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate which arise in connection with your Award (the "***Withholding Obligation***") and that the Withholding Obligation shall be satisfied pursuant to this section (a) and (ii) further acknowledge and agree to the following provisions:

(i) You hereby irrevocably appoint Morgan Stanley Smith Barney LLC or such other registered broker-dealer that is a member of the Financial Industry Regulatory Authority as the Company may select, as your agent (the "***Agent***"), and you authorize and direct the Agent to:

(1) Sell on the open market at the then prevailing market price(s), on your behalf, as soon as practicable on or after the date on which the shares of Stock are delivered to you pursuant to the section title "Issuance" in this Agreement in connection with the vesting of the RSUs, the number of shares of Stock expected to generate sufficient proceeds to cover (A) the satisfaction of the Withholding Obligation arising from the vesting of those RSUs and the related issuance of shares of Stock to you and (B) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto

(2) Remit directly to the Company and/or any Affiliate the proceeds from the sale of the shares of Stock referred to in clause (1) above to apply to the Withholding Obligation;

(3) Retain the amount required to cover all applicable fees and commissions due to, or required to be collected by, the Agent, relating directly to the sale of the shares of Stock referred to in clause (1) above; and

(4) Remit any remaining funds to you or apply them as additional tax withholdings.

(ii) You acknowledge that your election to Sell to Cover and the corresponding authorization and instruction to the Agent set forth in this section (a) to sell Stock to satisfy the Withholding Obligation is intended to comply with the requirements of Rule 10b5-1(c)(1) under the Exchange Act and to be interpreted to comply with the requirements of Rule 10b5-1(c) under the Exchange Act (your election to Sell to Cover and the provisions of this section (a), collectively, the "***10b5-1 Plan***"). You acknowledge that by accepting this Award, you are adopting the 10b5-1 Plan to permit you to satisfy the Withholding Obligation. You hereby authorize the Company and the Agent to cooperate and communicate with one another to determine the number of shares of Stock that must be sold pursuant to section (a)(i) above to satisfy your obligations hereunder.

(iii) You acknowledge that the Agent is under no obligation to arrange for the sale of Stock at any particular price under this 10b5-1 Plan and that the Agent may effect sales as provided in this 10b5-1 Plan in one or more sales and that the average price for executions resulting from bunched orders may be assigned to your account. You further acknowledge that you will be responsible for all brokerage fees and other costs of sale associated with this 10b5-1 Plan, and you agree to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale. In addition, you acknowledge that it may not be possible to sell shares of Stock as provided for in this 10b5-1 Plan due to (i) a legal or contractual restriction applicable to you or the Agent, (ii) a market disruption, (iii) a sale effected pursuant to this 10b5-1 Plan that would not comply (or in the reasonable opinion of the Agent's counsel is likely not to comply) with the Securities Act of 1933, as amended, (iv) the Company's determination that sales may not be effected under this 10b5-1 Plan or (v) rules governing order execution priority on the national exchange where the Stock may be traded. In the event of the Agent's inability to sell shares of Stock, you will continue to be responsible for the timely payment to the Company of all federal, state, local and foreign taxes that are required by applicable laws and regulations to be withheld, including but not limited to those amounts specified in section (a)(i)(1) above.

(iv) You acknowledge that regardless of any other term or condition of this 10b5-1 Plan, the Agent will not be liable to you for (A) special, indirect, punitive, exemplary, or consequential damages, or incidental losses or damages of any kind, or (B) any failure to perform or for any delay in performance that results from a cause or circumstance that is beyond its reasonable control.

(v) You hereby agree to execute and deliver to the Agent any other agreements or documents as the Agent reasonably deems necessary or appropriate to carry out the purposes and intent of this 10b5-1 Plan.

(vi) Your election to Sell to Cover and to enter into this 10b5-1 Plan is irrevocable. Upon acceptance of the Award, you have elected to Sell to Cover and to enter into this 10b5-1 Plan, and you acknowledge that you may not change this election at any time in the future. This 10b5-1 Plan shall terminate on the date on which the Withholding Obligation arising from the vesting of all of the RSUs and the related issuance of shares of Stock has been satisfied.

(b) In addition to or in combination with the Sell to Cover provided for under section (a) above, you authorize the Company, at its discretion, to satisfy the Withholding Obligation by the following means (or by a combination of the following means):

(i) Requiring you to pay to the Company any portion of the Withholding Obligation in cash;

(ii) Withholding from any compensation otherwise payable to you by the Company; and/or

(iii) Withholding shares of Stock from the shares of Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Stock are issued pursuant to the section title "Issuance" in this Agreement) equal to the amount of the Withholding Obligation; provided, however, that the number of such shares of Stock so withheld shall not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the maximum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income.

(c) Unless the Withholding Obligation of the Company and/or any affiliate are satisfied, the Company shall have no obligation to deliver to you any Stock.

(d) In the event the Withholding Obligation of the Company arises prior to the delivery to you of Stock or it is determined after the delivery of Stock to you that the amount of the Withholding Obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by accepting this Award, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

Issuance

(a) The issuance of shares of Stock in respect of the RSUs is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Obligation set forth above, in the event one or more RSUs vests, the Company shall issue to you one (1) share of Stock for each RSU that vests on the applicable vesting date(s) (subject to any adjustment set forth above). Each issuance date determined by this paragraph is referred to as an "***Issuance Date***".

(b) If the Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Stock on an established stock exchange or stock market, *and*

(ii) either (1) a Withholding Obligation does not apply, or (2) the Company decides, prior to the Issuance Date, (A) not to satisfy the Withholding Obligation by withholding shares of Stock from the shares otherwise due, on the Issuance Date, to you under this Award, and (B) not to permit you to then effect a Sell to Cover under the 10b5-1 Plan (as defined above) to satisfy the Withholding Obligation, if applicable, (C) not to satisfy the Withholding Obligation from compensation otherwise payable to you by the Company, and (D) not to permit you to pay your Withholding Obligation in cash, then the shares that would otherwise be issued to you on the Issuance Date will not be delivered on such Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Stock in the open public market, but in no event later than December 31 of the calendar year in which the Issuance Date occurs (that is, the last day of your taxable year in which the Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) The form of delivery of Stock underlying vested RSUs shall be determined by the Company, in its discretion, including without limitation, book-entry, registration or issuance of one or more stock certificates.

Transfer of RSUs	You may not sell, transfer, assign, pledge, or otherwise encumber or dispose of the RSUs. If you attempt to do any of these things, you will immediately and automatically forfeit the RSUs.
Retention Rights	Neither your RSUs nor this Agreement constitutes an agreement of employment or gives you the right to be retained by the Company or an Affiliate in any capacity. Except as otherwise provided in any applicable employment agreement between you and the Company, the Company and its Affiliates reserve the right to terminate your Service at any time and for any reason.
Stockholder Rights	You, or your estate or heirs, have no rights as a stockholder of the Company until a certificate for the shares underlying your RSUs has been issued (or an appropriate book entry has been made). No adjustments are made for dividends or other rights if the applicable record date occurs before your stock certificate is issued (or an appropriate book entry has been made), except as described in the Plan.
Clawback	The RSUs are subject to mandatory repayment by you to the Company to the extent you are, or in the future become, subject to (x) any Company or Affiliate "clawback" or recoupment policy that is adopted to comply with the requirements of any Applicable Laws, or (y) any Applicable Laws which impose mandatory recoupment, under circumstances set forth in such Applicable Laws.
Adjustments	In the event of a stock split, a stock dividend or a similar change in the Stock, the number of shares covered by the RSUs shall be adjusted (and rounded down to the nearest whole number) if required pursuant to the Plan.
Applicable Law	This Agreement will be interpreted and enforced under the laws of the State of Delaware, other than any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

Forfeiture of Rights

If you should take actions in competition with the Company, the Company shall have the right to cause a forfeiture of your rights hereunder, including, but not limited to, the right to cause: (i) a forfeiture of the RSUs, and (ii) with respect to the period commencing twelve (12) months prior to your termination of Service with the Company and ending twelve (12) months following such termination of Service, a forfeiture of any Stock acquired by you in respect of the RSUs. Unless otherwise specified in an employment or other agreement between the Company or an Affiliate and you, you take actions in competition with the Company if you, directly or indirectly, as an individual proprietor, partner, stockholder, executive, manager, officer, employee, director, joint venturer, investor, lender, consultant or in any other capacity whatsoever in any business or venture that competes with any line of business, product or product candidate that the Company is engaged in as of the date of your termination of Service or is actively planning to engage in as of the date of your termination of ; provided, however, (i) being a holder of less than 1% of the outstanding equity of a public company or mutual fund shall not be deemed to be in competition with the Company and (ii) employment by or consultation for a publicly traded company that derives less than five percent (5%) of its net revenues from activities that compete with any line of business, product or product candidate that the Company engages in, or is actively planning to engage in, shall not constitute competition so long as you do not personally provide employment or consulting services to the business segment of such publicly traded company that engages in such competitive activities

If you are not a party to a confidentiality, non-disclosure, non-solicitation, non-competition and invention assignment agreement with the Company on the date of this Agreement, you, as consideration for this Award, will concurrently herewith enter into such agreement in a form reasonably acceptable to the Company.

Data Privacy

In order to administer the Award, the Company may keep and process personal data about you. Such data includes but is not limited to the information provided in this Agreement and any changes thereto, other appropriate personal and financial data about you such as home address and business addresses and other contact information, payroll information and any other information that might be deemed appropriate by the Company to facilitate the administration of the Award.

By electronically accepting this Award, you give explicit consent to the Company to keep and process any such personal data. You also give explicit consent to the Company to transfer any such personal data outside the country in which you work or are employed, including, with respect to non-U.S. resident grantees, to the United States, to transferees who shall include the Company and other persons who are designated by the Company to administer the Award.

Consent to Electronic Delivery

The Company may choose to deliver certain statutory materials relating to the Award in electronic form. By electronically accepting this Award you agree that the Company may deliver the Award prospectus and the Company's annual report to you in an electronic format. If at any time you would prefer to receive paper copies of these documents, as you are entitled to, you may request paper copies of these documents.

Severability

The provisions of this Agreement are severable and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

Waiver

No waiver of any breach or condition of this Agreement shall be deemed to be a waiver of any other or subsequent breach or condition whether of like or different nature.

Award Subject to Plan Provisions

The Award is an inducement grant pursuant to NASDAQ Listing Rule 5635(c), and is not granted pursuant to the Company's 2010 Stock Incentive Plan, as amended and restated as of September 19, 2017 (the "Plan"), or any other equity plan incentive plan of the Company. Although the Award is not granted pursuant to the Plan, the Award shall be subject to and governed by, and shall be construed and administered in accordance with, the terms and conditions of the Award (as from time to time in effect), which terms and conditions are incorporated herein by reference. Each of the Board and the Committee shall have the authority to interpret and construe the Award pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder. The text of the Plan is incorporated in this Agreement by reference.

Entire Agreement

This Agreement and the Plan (and the other agreements or documents referred to herein or therein) constitute the entire contract between the parties hereto with regard to the subject matter hereof. They supersede any other agreements, representations or understandings (whether oral or written and whether express or implied) which relate to the subject matter hereof.

Code Section 409A

It is intended that the RSUs comply with Section 409A of the Code ("**Section 409**") or an exemption to Section 409A. To the extent that the Company determines that you would be subject to the additional taxes or penalties imposed on certain non-qualified deferred compensation plans pursuant to Section 409A as a result of any provision of this Agreement, such provision shall be deemed amended to the minimum extent necessary to avoid application of such additional tax. The nature of any such amendment shall be determined by the Company. Notwithstanding anything to the contrary in this Agreement, neither the Company, any Affiliate, the Board, nor the Committee will have any liability to you for any excise tax or penalty imposed on you under Section 409A.

For purposes of this Agreement, a termination of Service only occurs upon an event that would be a Separation from Service. Notwithstanding anything in this Agreement to the contrary, if at the time of your Separation from Service, (i) you are a specified employee (within the meaning of Section 409A and using the identification methodology selected by the Company from time to time), and (ii) the Company makes a good faith determination that an amount payable to you on account of such separation from service constitutes deferred compensation (within the meaning of Section 409A) the payment of which is required to be delayed pursuant to the six (6)-month delay rule set forth in Section 409A in order to avoid taxes or penalties under Section 409A (the "**Delay Period**"), then the Company will not pay such amount on the otherwise scheduled payment date but will instead pay it in a lump sum on the first payroll date after such Delay Period (or upon your death, if earlier), without interest thereupon.

* * *

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: May 7, 2020

/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: May 7, 2020

/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 March 31, 2020 (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: May 7, 2020

/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 March 31, 2020 (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: May 7, 2020

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