

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, 2019

- 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**

(State of other jurisdiction of incorporation or organization)

**42-1771610**

(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)

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   
Non-accelerated filer

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

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

The number of shares of the registrant's common stock outstanding at May 6, 2019 was 41,264,422 shares.

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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.

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[Trademark Notice](#)

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

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the potential advantages of XHANCE® and our Exhalation Delivery System (EDS) devices and technologies;
- the potential benefits of our patient affordability programs and their potential effect on XHANCE demand and financial results;
- our expectation that the recent sales force expansion will increase the size of our called-on target audience by approximately 25% to over 10,000 physicians;
- our expectation that we will eventually increase the size of our sales force to approximately 120 territory managers to expand our called-on target audience to approximately 14,000 ENT, allergists and “specialty-like” primary care physicians;
- future XHANCE prescription growth and potential drivers of such growth;
- our commercial initiatives and objectives related to XHANCE;
- the potential for XHANCE prescriptions and net revenues to be affected by the seasonality impact observed in the INS market;
- our planned product development activities, studies and clinical trials, including our plans to initiate a second phase 3b clinical trial of XHANCE in the second quarter of 2019 in pursuit of a follow-on indication for chronic sinusitis;
- the potential for XHANCE to be the first drug therapy approved by the U.S. Food and Drug Administration for the treatment of chronic sinusitis;
- our expectation that our GAAP operating expenses in 2019 will be between \$135.0 - \$142.0 million and that our non-cash stock-based compensation expense will be between \$10.0 - \$12.0 million;
- our expectation that the full-year 2019 average net revenue per prescription will be between \$185 - \$205; and
- our expectation that existing cash and cash equivalents at March 31, 2019 will be sufficient to meet our debt service obligations under our Notes, and to carry out our planned development and commercial activities into the first quarter of 2021;

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

Forward-looking statements are based upon our current expectations and assumptions and are subject to a number of known and unknown risks, uncertainties and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission (SEC), and in particular, the risks and uncertainties discussed therein under the caption “Risk Factors”. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. As a result, you should not place undue reliance on forward-looking statements.

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

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

**MARKET, INDUSTRY AND OTHER DATA**

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

**PART I****ITEM 1. FINANCIAL STATEMENTS**

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

	March 31, 2019	December 31, 2018
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 171,316	\$ 200,990
Accounts receivable, net	5,793	2,310
Grants and other receivables	124	242
Inventory	5,716	7,132
Prepaid expenses and other current assets	3,833	2,183
Total current assets	186,782	212,857
Property and equipment, net	3,715	3,884
Other assets	2,495	248
Total assets	\$ 192,992	\$ 216,989
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 7,676	\$ 7,116
Accrued expenses and other current liabilities	19,192	18,421
Deferred other income	—	160
Total current liabilities	26,868	25,697
Long-term debt, net	72,680	72,500
Other liabilities	1,091	181
Total liabilities	100,639	98,378
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized at March 31, 2019 and December 31, 2018; 41,264,422 and 41,227,530 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	41	41
Additional paid-in capital	439,167	436,554
Accumulated deficit	(346,801)	(317,927)
Accumulated other comprehensive loss	(54)	(57)
Total stockholders' equity	92,353	118,611
Total liabilities and stockholders' equity	\$ 192,992	\$ 216,989

See accompanying notes to unaudited interim consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Operations**  
**For the Three Months Ended March 31, 2019 and 2018**  
**(in thousands, except share and per share data)**  
**(Unaudited)**

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Net product revenues	\$ 3,976	\$ 865
Licensing revenues	500	—
Total revenues	4,476	865
Operating expenses:		
Cost of product sales	738	200
Research and development	4,562	1,701
Selling, general and administrative	26,340	28,011
Total operating expenses	31,640	29,912
Loss from operations	(27,164)	(29,047)
Other (income) expense:		
Grant and other income	—	(189)
Interest income	(684)	(476)
Interest expense	2,388	2,193
Foreign currency (gains) losses	6	(3)
Net loss	\$ (28,874)	\$ (30,572)
Net loss per share of common stock, basic and diluted	\$ (0.70)	\$ (0.81)
Weighted average common shares outstanding, basic and diluted	41,256,050	37,849,199

See accompanying notes to unaudited interim consolidated financial statements

**OptiNose, Inc.**  
**Consolidated Statements of Comprehensive Loss**  
**For the Three Months Ended March 31, 2019 and 2018**  
**(in thousands)**  
**(Unaudited)**

	Three Months Ended March 31,	
	2019	2018
Net loss	\$ (28,874)	\$ (30,572)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	3	7
Comprehensive loss	<u>\$ (28,871)</u>	<u>\$ (30,565)</u>

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, 2019

	Stockholders' Equity					Total Stockholders' Equity
	Common Stock		Additional Paid -in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	
	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	<u>41,264,422</u>	<u>\$ 41</u>	<u>\$ 439,167</u>	<u>\$ (346,801)</u>	<u>\$ (54)</u>	<u>\$ 92,353</u>

Three Months Ended March 31, 2018

	Stockholders' Equity					Total Stockholders' Equity
	Common Stock		Additional Paid -in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	
	Shares	Amount				
Balance at December 31, 2017	37,802,556	38	365,838	(211,269)	(111)	154,496
Stock compensation expense	—	—	2,050	—	—	2,050
Exercise of common stock options	106,502	—	130	—	—	130
Foreign currency translation adjustment	—	—	—	—	7	7
Net loss	—	—	—	(30,572)	—	(30,572)
Balance at March 31, 2018	<u>37,909,058</u>	<u>38</u>	<u>368,018</u>	<u>(241,841)</u>	<u>(104)</u>	<u>126,111</u>

**OptiNose, Inc.**  
**Consolidated Statements of Cash Flows**  
**For the Three Months Ended March 31, 2019 and 2018**  
**(in thousands)**  
**(Unaudited)**

	Three Months Ended March 31,	
	2019	2018
<b>Operating activities:</b>		
Net loss	\$ (28,874)	\$ (30,572)
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>		
Depreciation and amortization	269	157
Stock-based compensation	2,422	2,023
Amortization of debt discount and issuance costs	113	73
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(3,483)	(2,049)
Grants and other receivables	118	(225)
Prepaid expenses and other assets	(1,342)	(118)
Inventory	1,419	(1,543)
Accounts payable	584	3,723
Accrued expenses and other liabilities	(920)	5,533
Cash used in operating activities	(29,694)	(22,998)
<b>Investing activities:</b>		
Purchases of property and equipment	(168)	(382)
Cash used in investing activities	(168)	(382)
<b>Financing activities:</b>		
Proceeds from the sale of common stock	—	—
Cash paid for financing costs	—	(1,823)
Proceeds from issuance of common stock under employee stock purchase plan	173	—
Proceeds from the exercise of stock options	15	130
Cash provided by (used in) financing activities	188	(1,693)
Effects of exchange rate changes on cash and cash equivalents	(6)	(1)
Net increase in cash, cash equivalents and restricted cash	(29,680)	(25,074)
Cash, cash equivalents and restricted cash at beginning of period	201,011	234,875
Cash, cash equivalents and restricted cash at end of period	\$ 171,331	\$ 209,801
<b>Supplemental disclosure of noncash activities:</b>		
Fixed asset purchases within accounts payable and accrued expenses	\$ 146	\$ 303
Financing costs within accounts payable and accrued expenses	\$ —	\$ 671
Recognition of initial right-of-use assets	\$ 2,484	\$ —
Recognition of initial lease liabilities	\$ 2,961	\$ —

See accompanying notes to unaudited interim consolidated financial statements

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**  
**(in thousands, except share and per share data)**

## **1. Organization and Description of Business**

OptiNose, Inc. (the Company) was incorporated in Delaware in May 2010 (inception) and has facilities in Yardley, Pennsylvania, Ewing, New Jersey, Oslo, Norway and Swindon, England. The Company's predecessor entity, OptiNose AS, was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became a wholly-owned subsidiary of the Company as part of an internal reorganization.

The Company is a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. The Company's first commercial product, XHANCE<sup>®</sup> (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing its proprietary Optinose Exhalation Delivery System (EDS) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also known as chronic sinusitis). XHANCE was approved by the United States (US) Food and Drug Administration (FDA) in September 2017 for the treatment of nasal polyps in patients 18 years of age or older. XHANCE was made widely available through retail channels in April 2018.

## **2. Liquidity**

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio, conducting preclinical studies and clinical trials, pursuing regulatory approvals and most recently, preparing for and launching XHANCE. As of March 31, 2019, the Company had cash and cash equivalents of \$171,316.

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

The Company will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet the debt service obligations under the Company's outstanding senior secured notes (Senior Secured Notes), including repayment, and to carry out the Company's planned development and commercial activities. If additional capital is not secured when required, the Company may need to delay or curtail its operations until such funding is received. The Company is subject to a number of risks similar to other life sciences companies, including, but not limited to, successful discovery, development and commercialization of its products and product candidates, raising additional capital, the development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products.

## **3. Basis of Presentation and Summary of Significant Accounting Policies**

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with US generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2019 and its results of operations for the three months ended March 31, 2019 and 2018 and cash flows for the three months ended March 31, 2019 and 2018. Operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements (Continued)**  
**(in thousands, except share and per share data)**

statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2018 contained in the Company's annual report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 6, 2019.

**Use of estimates**

The preparation of the unaudited interim consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited interim consolidated financial statements and reported amounts of expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited interim consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined to be necessary.

**Concentration of credit risk**

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and accounts receivable. The Company generally invests its cash in deposits with high credit quality financial institutions. Additionally, the Company performs periodic evaluations of the relative credit standing of these financial institutions.

The Company has exposure to credit risk in accounts receivable from sales of product. XHANCE is sold to wholesale pharmaceutical distributors and preferred pharmacy network partners, who, in turn, sell XHANCE to pharmacies, hospitals and other customers. Five customers represent approximately 73% of the Company's accounts receivable at March 31, 2019 and five customers represent approximately 71% of the Company's net product sales for the three months ended March 31, 2019.

**Fair value of financial instruments**

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

**Restricted cash**

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

**Net Product Revenues**

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, which was adopted on January 1, 2018. The Company recognizes revenue from product sales at the point the Customer obtains 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

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements (Continued)**  
**(in thousands, except share and per share data)**

the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

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

**Product Returns.** Consistent with industry practice, the Company has a product returns policy that provides Customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The Company estimates the amount of its products 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 preferred pharmacy network partners and wholesalers, 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. These reserves 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.

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

### ***Licensing revenues***

During the three months ended March 31, 2019, the Company's licensing revenues were generated pursuant to the terms of a single license agreement (the Inexia License Agreement) with Inexia (Inexia) (Note 8). The Inexia License Agreement includes licensed rights to patented technology, a non-refundable up-front payment, development and sales milestones as well as royalty payments.

The Company analyzed the performance obligations under the Inexia License Agreement, the consideration received to date and the consideration the Company could receive in the future as part of its analysis related to ASC 606. The Company recognized the upfront payment received of \$500 as licensing revenue during the three months ended March 31, 2019 upon the delivery of the license performance obligation.

### ***Net income (loss) per common share***

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to Common Stock holders by the weighted average common shares outstanding during the period. For the three months ended March 31, 2019 and 2018, the outstanding Common Stock options, Common Stock warrants and shares to be

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements (Continued)**  
(in thousands, except share and per share data)

issued under the Company's 2017 Employee Stock Purchase Plan have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

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

	March 31,	
	2019	2018
Stock options	7,777,367	6,309,453
Common stock warrants	1,866,831	1,890,489
Employee stock purchase plan	46,161	33,181
Total	<u>9,690,359</u>	<u>8,233,123</u>

### **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, 2019 and 2018, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of March 31, 2019 and December 31, 2018, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

### **Recent accounting pronouncements**

In August 2018, the FASB issued ASU No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. ASU 2018-15 requires that certain implementation costs incurred in a cloud computing arrangement be deferred and recognized over the term of the arrangement. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 resulted in certain modifications to fair value measurement disclosures, primarily related to level 3 fair value measurements. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its disclosures.

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

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The FASB issued the update to require the recognition of lease assets and liabilities on the balance sheet of lessees. The standard is effective for fiscal years beginning after December 15, 2018. The ASU requires a modified retrospective transition method with the option to elect a package of practical expedients. The Company adopted ASU 2016-02 on January 1, 2019 using the optional modified retrospective transition method and elected the following transition practical expedients: (i) to not reassess lease identification, lease classification and initial indirect costs related to those leases entered into prior to the

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements (Continued)**  
(in thousands, except share and per share data)

adoption of ASC 842; and (ii) to not separate lease and non-lease components for our office lease portfolio. Refer to *Note 6 — Leases* for further details.

#### 4. Inventory

Inventory consisted of the following:

	March 31, 2019	December 31, 2018
Raw materials	\$ 1,903	\$ 1,969
Work-in-process	1,682	2,344
Finished goods	2,131	2,819
Total inventory	<u>\$ 5,716</u>	<u>\$ 7,132</u>

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:

	March 31, 2019	December 31, 2018
Computer equipment and software	\$ 955	\$ 833
Furniture and fixtures	391	389
Machinery and equipment	3,168	2,723
Leasehold improvements	605	609
Construction in process	29	481
	<u>5,148</u>	<u>5,035</u>
Less: accumulated depreciation	<u>(1,433)</u>	<u>(1,151)</u>
	<u>\$ 3,715</u>	<u>\$ 3,884</u>

Depreciation expense was \$269 and \$156 for the three months ended March 31, 2019 and 2018, respectively. In addition, depreciation expense of \$66 and \$8 was charged to inventory and prepaid expenses and other assets, respectively, during the three months ended March 31, 2019, which represents depreciation expense related to equipment involved in the manufacturing process.

#### 6. Leases

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

The Company leases office space, storage space and equipment (primarily vehicles). Certain office space leases include options to renew that generally can extend the lease term up to 3 years. The Company evaluates renewal options at lease inception and on an ongoing basis and includes renewal options that it is reasonably certain to exercise in its expected lease terms when classifying leases and measuring lease liabilities. Lease agreements generally do not require material variable lease payments, residual value guarantees or restrictive covenants.

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**  
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The table below presents the operating lease assets and liabilities recognized on the Company's consolidated balance sheets as of March 31, 2019:

	Balance Sheet Line Item	March 31, 2019
Non-current operating lease assets	Other assets	2,380
Operating lease liabilities:		
Current operating lease liabilities	Accrued expenses and other current liabilities	\$ 1,510
Non-current operating lease liabilities	Other liabilities	1,091
Total operating lease liabilities		<u>\$ 2,601</u>

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

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

The Company's weighted average remaining lease term and weighted average discount rate for operating leases as of March 31, 2019 are:

	March 31, 2019
Weighted average remaining lease term (years)	1.86
Weighted average discount rate	6.37%

The table below reconciles the undiscounted future minimum lease payments (displayed in aggregate by year) under non-cancelable operating leases with terms of more than one year to the total operating lease liabilities recognized on the consolidated balance sheets as of March 31, 2019:

	March 31, 2019
2019	\$ 1,227
2020	1,136
2021	401
Thereafter	—
Total undiscounted future minimum lease payments	<u>\$ 2,764</u>
Less: difference between undiscounted lease payments and discounted operating lease liabilities	163
Total operating lease liabilities	<u>\$ 2,601</u>

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

Operating lease costs were \$379 for the three months ended March 31, 2019. Operating lease costs are included within selling, general and administrative expenses on the consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were \$402 for the three months ended March 31, 2019, and this amount is included in operating activities in the consolidated statements of cash flows.

**OptiNose, Inc.**  
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## 7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	March 31, 2019	December 31, 2018
Accrued expenses:		
Contract sales organization expenses	\$ 4,367	\$ 4,482
Selling, general and administrative expenses	4,537	4,812
Research and development expenses	788	933
Payroll expenses	2,583	4,199
Product revenue allowances	4,630	2,856
Other	777	1,139
Total accrued expenses	<u>\$ 17,682</u>	<u>\$ 18,421</u>
Other current liabilities:		
Lease liability	\$ 1,510	\$ —
Total other current liabilities	<u>\$ 1,510</u>	<u>\$ —</u>
Total accrued expenses and other current liabilities	<u>\$ 19,192</u>	<u>\$ 18,421</u>

## 8. License Agreements

### AVP-825 License Agreement

In July 2013, the Company's wholly owned subsidiary, OptiNose AS, entered into the AVP-825 License Agreement with Avanir for the exclusive right to sell AVP-825 (now marketed as Onzetra® Xsail®), a product combining a low-dose powder form of sumatriptan with the Company's EDS technology platform, for the acute treatment of migraines in adults and any follow-on products under development that consist of a formulation that contains triptans as the sole active ingredient.

Through March 31, 2019, under the terms of the AVP-825 License Agreement, the Company received aggregate cash payments of \$70,000 in connection with the initial signing and the achievement of certain development milestones. The Company did not recognize any licensing revenue under the arrangement during the three months ended March 31, 2019 and 2018 and does not expect any future revenue under the AVP-825 License Agreement.

On December 10, 2018, the Company received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement terminated on March 10, 2019. The Company is evaluating options with respect to the future of Onzetra Xsail.

### Inexia License Agreement

On January 31, 2019, OptiNose AS, a wholly owned subsidiary of the Company, entered into the Inexia License Agreement with Inexia.

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

## 9. Long-term Debt

On December 29, 2017, the Company entered into a Senior Secured Note Purchase Agreement (the Senior Secured Notes) with Athyrium Opportunities III Acquisition LP. The Senior Secured Notes provided the Company with up to \$100,000 in capital, of which \$75,000 was issued immediately. The remaining \$25,000 (the Delayed Draw

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**  
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Notes) may be issued between April 1, 2019 and August 14, 2019, subject to the Company achieving trailing four quarter net revenues (as calculated pursuant to the terms of the Senior Secured Note Purchase Agreement) of \$15,000 and a pro forma ratio of total debt to trailing four quarter net revenues not exceeding 6.50 to 1.00, and certain other conditions.

The Senior Secured Notes bear interest at 9.0% plus the three-month London Inter-bank Offered Rate (LIBOR) rate, subject to a 1.0% floor and are scheduled to mature on June 29, 2023. The interest rate was 11.625% at March 31, 2019. The Senior Secured Notes bore front-end fees of 1.0% of the aggregate principal amount, which were paid at issuance. The Company is also required to pay an exit fee of 2.0% of any principal payments (whether mandatory, voluntary, or at maturity) made throughout the term of the Senior Secured Note Purchase Agreement.

The Company recorded interest expense of \$2,388 and \$2,193 during the three months ended March 31, 2019 and 2018, respectively, in conjunction with the Senior Secured Notes. Interest expense included total coupon interest, exit fees, front end fees and the amortization of debt issuance costs. The front-end fees of \$1,000 were recorded as debt discount at issuance and are being amortized to interest expense over the 5.5 year term of the loan. Additionally, back end fees of \$2,000 are being amortized to interest expense and are recorded as an increase in the carrying amount throughout the term of the Senior Secured Notes. The Company also incurred \$2,181 in debt issuance costs during the year ended December 31, 2017, which are also being amortized to interest expense over the term of the Senior Secured Notes.

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

	March 31, 2019	December 31, 2018
Face amount	\$ 75,000	\$ 75,000
Front end fees	(837)	(872)
Debt issuance costs	(1,825)	(1,902)
Back end fees	342	274
Long-term debt, net	<u>\$ 72,680</u>	<u>\$ 72,500</u>

## 10. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of March 31, 2019, approximately \$40 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 statutory requirements of those jurisdictions. The Company incurred costs of \$6 and \$62 related to the pension plans for the three months ended March 31, 2019 and 2018, respectively.

## 11. Stockholders' Equity

### Common Stock

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

Each share of Common Stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Subject to preferences that may apply to any outstanding preferred stock, holders of Common Stock are entitled to receive ratably any dividends that the Company's board of directors may declare out of funds legally available for that purpose on a non-cumulative basis. No dividends had been declared through March 31, 2019.

**OptiNose, Inc.**  
**Notes to Unaudited Interim Consolidated Financial Statements**  
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**Common Stock warrants**

As of March 31, 2019, the Company had warrants outstanding to purchase 1,866,831 shares of Common Stock with an exercise price of \$8.16. The warrants expire on November 1, 2020.

**12. Stock-based Compensation**

The Company recorded stock-based compensation expense related to stock options and shares issued under the Company's 2017 Employee Stock Purchase Plan (2017 Plan) in the following expense categories of its accompanying consolidated statements of operations for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
Cost of product sales	\$ 21	\$ 1
Research and development	243	239
General and administrative	2,158	1,783
	<u>\$ 2,422</u>	<u>\$ 2,023</u>

In addition, stock-based compensation expense of \$3 and \$23 was charged to inventory and prepaid expenses and other assets, respectively, during the three months ended March 31, 2019, which represents the total stock-based compensation expense incurred related to employees involved in the manufacturing process of finished goods and samples during the period.

**Stock Options**

The Company has issued serviced-based and performance-based stock options that generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the Company's board of directors. Vesting generally occurs over a period of not greater than four years. Performance-based options may vest upon the achievement of certain milestones in connection with the Company's development programs. Additionally, the Company has issued stock options in excess of the fair market value of Common Stock on the issuance date that were only exercisable upon a change in control or upon or after an initial public offering. As of March 31, 2019, 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, 2019:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2018	6,182,873	\$ 10.60	6.67
Granted	1,686,800	7.49	
Exercised	(5,000)	3.05	
Expired	—	—	
Forfeited	(87,306)	10.53	
Outstanding at March 31, 2019	<u>7,777,367</u>	\$ 9.93	6.95
Exercisable at March 31, 2019	<u>4,016,100</u>	\$ 8.44	4.92
Vested and expected to vest at March 31, 2019	<u>7,777,367</u>	\$ 9.93	6.95

During the three months ended March 31, 2019, stock options to purchase 1,686,800 shares of Common Stock were granted to employees and directors and generally vest over four years. The stock options had an estimated weighted average grant date fair value of \$4.67. During the three months ended March 31, 2018, stock options to purchase 191,879 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 \$12.18.

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**Notes to Unaudited Interim Consolidated Financial Statements**  
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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,	
	2019	2018
Risk free interest rate	2.57%	2.59%
Expected term (in years)	6.08	6.05
Expected volatility	67.14%	76.21%
Annual dividend yield	0.00%	0.00%
Fair value of common stock	\$ 4.67	\$ 17.96

At March 31, 2019, the unrecognized compensation cost related to unvested stock options expected to vest was \$25,500. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.93 years.

#### **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 \$114 and \$156 during the three months ended March 31, 2019 and 2018, respectively, related to the 2017 Plan.

In July 2018, the Company issued 53,137 shares of Common Stock related to the offering periods ended June 30, 2018. In January 2019, the Company issued 31,892 shares of Common Stock related to the offering period ended December 31, 2018.

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

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

### Company Overview

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. Our first commercial product, XHANCE<sup>®</sup> (fluticasone propionate) nasal spray, 93 mcg, is a therapeutic utilizing our proprietary Optinose Exhalation Delivery System (EDS) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (also known as chronic sinusitis). Chronic rhinosinusitis is a serious nasal inflammatory disease that is treated using therapies, such as intranasal steroids (INS), which have significant limitations. We believe XHANCE has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by conventional INS.

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

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

- **Customer Model.** We have defined a sales force footprint of approximately 120 geographic territories targeting approximately 14,000 ENTs, allergists and "specialty-like" primary care physicians. In April 2019, we changed our model from a contract sales team to an internal sales team, and at the same time we hired and deployed additional territory managers into "XHANCE naive" geographies, increasing the number of territories in our deployment plan from 80 to 100, to expand our reach among our target physician audience. The additional territory managers are expected to increase the size of the target audience for our sales team by approximately 25% to over 10,000 physicians. We intend to eventually increase the size of our sales force to approximately 120 territory managers to expand our called-on target audience to approximately 14,000 ENT, allergists and "specialty-like" primary care physicians. Additionally, we expect to target additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers.
- **XHANCE Patient Affordability Programs.** In late August 2018, we implemented our current co-pay savings program. We believe this program, with an indefinite duration, provides an affordability solution for patients that physicians will support. The program provides patient co-pay assistance to commercially insured patients that includes a first prescription at no out-of-pocket cost (\$0 co-pay) and low subsequent co-pays for refills. Our data suggests these programs are playing a role in building demand for XHANCE, particularly as they become more widely understood in the prescribing community.
- **Market Access.** Based on currently available third-party data and our internal analyses, we believe that greater than 75% of commercially insured lives are currently in a plan in which XHANCE is covered in a Tier 3 formulary position. However, payors may change coverage levels for XHANCE or controls such as step edits and prior authorization, positively or negatively, at any time.

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

- **XHANCE Prescriptions.** Based on third-party prescription data as well as data from preferred pharmacy network partners, the total estimated number of XHANCE prescriptions in the first quarter of 2019 was 22,490 which represents 59% growth for prescriptions when compared to fourth quarter 2018 prescriptions of 14,106. The INS market increased approximately 3% from fourth quarter 2018 to first quarter 2019 based on third-party prescription data. In addition, the number of XHANCE prescriptions for the 4-week periods ended March 29 and April 26, 2019 was 8,298 and 9,515, respectively, which represents period-over-period

growth of 15%. The INS market increased approximately 3% from the 4-week period ended March 29, 2019 to the 4-week period ended April 26, 2019 based on third-party prescription data. We believe the internalization and expansion of our sales force, completed in April, with a 25% expansion in our sales territories and the availability of a new 7-day sample will that we believe will encourage trial and adoption of XHANCE, have the potential to help drive future XHANCE prescription growth.

XHANCE prescribing may be subject to a seasonal effect historically observed in the INS market in which market volume generally peaks near the middle of the second quarter and declines into the early part of the third quarter of each calendar year. Based on third party prescription data, the INS market increased 2% from the first quarter of 2018 to the second quarter of 2018, decreased 15% from the second quarter of 2018 to the third quarter of 2018 and increased 11% from the third quarter of 2018 to the fourth quarter of 2018. 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, may have an impact on the number of patients that present themselves and who are therefore available for prescribing a new medication like XHANCE. Additionally, the annual resetting of patient healthcare insurance plan deductibles may have a negative impact on demand for XHANCE. Based on our limited commercial history, we are unable to estimate the extent to which INS market seasonality and annual deductible resets may affect XHANCE prescriptions and net revenues.

### ***XHANCE Development Update***

In addition to XHANCE's existing indication for the treatment of nasal polyps, in order to broaden our U.S. market opportunity, we initiated a clinical research program in pursuit of a follow-on indication for the treatment of chronic sinusitis in the U.S. We believe XHANCE has the potential to be the first drug therapy approved by the FDA for the treatment of chronic sinusitis. We expect the program will be comprised of two phase 3b clinical trials, the first of which was initiated in the fourth quarter of 2018 and is estimated to enroll approximately 378 subjects. We expect to initiate the second trial in the second quarter of 2019.

### ***Inexia License Agreement***

On January 31, 2019, we entered into a License Agreement (Inexia License Agreement), with Inexia Limited (Inexia). Under the terms of the Inexia License Agreement, we granted Inexia an exclusive, royalty-bearing, worldwide, non-transferable, sublicensable license to our EDS and other intellectual property for the development, sale, import and manufacture of products containing orexin receptor agonist and/or orexin receptor positive modulator molecule(s) as the sole active pharmaceutical ingredient(s) for the treatment, diagnosis or prevention of human diseases or conditions associated primarily with orexin receptor agonism and orexin receptor positive modulation. The license excludes the treatment of any disease or condition affecting the ear, nose or throat, or the treatment of any disease or condition associated primarily with another receptor, other than the Orexin 1 and Orexin 2 receptors. Inexia is solely responsible for all costs and activities related to its identification, development and commercialization of products under the Inexia License Agreement.

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

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

### ***AVP-825 License Agreement***

On December 10, 2018, the Company received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement terminated on March 10, 2019. The Company is evaluating options with respect to the future of Onzetra Xsail.

### **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 \$4.0 million in net product revenues for the three months ended March 31, 2019. 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 pharmacy network, our average net revenues per prescription for the first quarter of 2019 was approximately \$177, which represents a decrease compared to our average net product revenues per prescription of approximately \$214 in the fourth of 2018. The 18% decrease in the average net revenue per prescription in the first quarter of 2019 compared to the fourth quarter of 2018 is primarily attributable to higher rates of utilization of our patient affordability program as well as the annual reset of many patient insurance deductibles in January. The reset of patient insurance deductibles drove an expected increase in the copay support provided in the first quarter of 2019.

We calculate average net product revenues per prescription 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 preferred pharmacy network partners, patient utilization rates of affordability programs and the proportion of patients acquiring XHANCE through an insurance benefit. There is also the potential for variability that results from changes in estimation methodology by the third parties that we rely upon to provide prescription data which may lead to revisions of historical estimates of prescription volumes and our calculated average revenue per prescription.

We expect that the full-year 2019 average net revenue per prescription will be between \$185 - \$205. Factors that we believe will support this expected growth compared to the first quarter 2019 average net revenue per prescription of \$177 include patients meeting their annual out-of-pocket expense thresholds under their insurance plans, improvements in insurance coverage and an increase in the proportion of prescription refills.

### **Licensing revenues**

On January 31, 2019, OptiNose AS, a wholly owned subsidiary of the Company, entered into the Inexia License Agreement with Inexia.

Under the terms of the Inexia License Agreement, Inexia paid the Company a \$0.5 million upfront payment. For each product developed under the Inexia License Agreement, the Company is eligible to receive up to \$8.0 million of development milestone payments and up to \$37.0 million 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.

### **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 related to the continued development of our product sample portfolio;

- expenses incurred under agreements with contract manufacturing organizations (CMOs), including manufacturing scale-up expenses prior to regulatory approval of products for commercial sale and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- consultant fees and expenses associated with outsourced professional scientific development services;
- expenses for regulatory activities, including filing fees paid to regulatory agencies and costs incurred to compile and respond to filings with the FDA prior to regulatory approval of products for commercial sale;
- costs incurred to maintain, expand and protect our patent portfolio as it relates to product candidates in development; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

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

We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of XHANCE for the treatment of chronic sinusitis and our other product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, including rate of subject enrollment, number of subjects required, and trial duration, and the early stage of our other product candidates, we are unable to estimate with reasonable certainty the costs we will incur and the timelines we will require in our continued development efforts.

### ***Selling, general and administrative expense***

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

Sales and marketing related expenses incurred in early 2018 included expenses related to building brand awareness through advertising and the deployment of our nurse educator team, training and deploying our contract sales force and securing market access for XHANCE as well as salaries and related benefits for employees focused on such efforts. Current and expected commercial investments include our sales team and supporting promotional materials, digital promotion, peer-to-peer education, congresses / conventions, samples, and marketing activities such as direct-to-patient / direct-to-consumer initiatives.

### ***Interest (income) expense***

Interest (income) expense consists of interest earned on our cash and cash equivalents held with institutional banks and interest expense related to our long-term debt.

### ***Other (income) expense***

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

**Consolidated Results of Operations****Comparison of three months ended March 31, 2019 and 2018**

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

	Three Months Ended March 31,	
	2019	2018
<b>Revenues:</b>		
Net product revenues	\$ 3,976	\$ 865
Licensing revenues	500	—
Total revenues	4,476	865
<b>Costs and expenses:</b>		
Cost of product sales	738	200
Research and development	4,562	1,701
Selling, general and administrative	26,340	28,011
Total operating expenses	31,640	29,912
Loss from operations	(27,164)	(29,047)
<b>Other (income) expense:</b>		
Interest (income) expense	1,704	1,717
Other (income) expense	6	(192)
Total other (income) expense	1,710	1,525
Net loss	\$ (28,874)	\$ (30,572)

*Net product revenues*

Net product revenues related to sales of XHANCE were \$4.0 million and \$0.9 million for the three months ended March 31, 2019 and 2018, respectively. The increase in net product revenues is due to an increase in sales of XHANCE as a result of a full quarter of XHANCE commercial availability in the first quarter of 2019 as compared to the first quarter of 2018. XHANCE became commercially available in late Q1 2018.

*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 received during the three months ended March 31, 2018.

*Cost of product sales*

Cost of product sales related to XHANCE were \$0.7 million and \$0.2 million for the three months ended March 31, 2019 and 2018, respectively.

*Research and development expense*

Research and development expense was \$4.6 million and \$1.7 million for the three months ended March 31, 2019 and 2018, respectively. The \$2.9 million increase was attributable primarily to:

- a \$2.5 million increase in clinical expenses related to the preparation for and initiation 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 \$26.3 million and \$28.0 million for the three months ended March 31, 2019 and 2018, respectively. The \$1.7 million decrease was due primarily to:

- a \$5.5 million decrease in sales expenses due to the completion of XHANCE initial launch activities in 2018.

This decrease was offset by:

- a \$2.2 million increase in sales and marketing expenses related to the commercialization of XHANCE; and
- a \$1.8 million increase in personnel and bonus expenses due to increases in headcount.

*Interest (income) expense, net*

Interest (income) expense, net, was \$1.7 million for the three month periods ended March 31, 2019 and 2018. Interest expense for the three month periods ended March 31, 2019 and 2018 was \$2.4 million and \$2.2 million, respectively. Interest expense was offset by interest income of \$0.7 million and \$0.5 million for the three month periods ended March 31, 2019 and 2018. Interest income increased by \$0.2 million as a result of higher interest rates on our cash balances.

*Other (income) expense, net*

Other (income) expense, net was \$0.2 million for the three months ended March 31, 2018. The income was attributable primarily to grant-eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary. No grant grant-eligible research and development expenses were incurred during the three months ended March 31, 2019.

**Liquidity and Capital Resources**

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. We incurred net losses of \$28.9 million and \$30.6 million for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had an accumulated deficit of \$346.8 million.

We have funded our operations primarily through the sale and issuance of stock and debt, as well as through licensing revenues received under the terms of the AVP-825 License Agreement. As of March 31, 2019, we had \$171.3 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,	
	2019	2018
Net cash used in operating activities	\$ (29,694)	\$ (22,998)
Net cash used in investing activities	(168)	(382)
Net cash provided by (used in) financing activities	188	(1,693)
Effects of exchange rates on cash and cash equivalents	(6)	(1)
Net decrease in cash and cash equivalents	<u>\$ (29,680)</u>	<u>\$ (25,074)</u>

*Operating activities*

Cash used in operating activities increased by \$6.7 million, from \$23.0 million for the three months ended March 31, 2018 to \$29.7 million for the three months ended March 31, 2019. The increase in cash used in operating activities was attributable primarily the timing of payment of operating expenses.

*Investing activities*

Cash used in investing activities decreased \$0.2 million from \$0.4 million for the three months ended March 31, 2018 to \$0.2 million for the three months ended March 31, 2019. The decrease was related primarily to purchases of equipment in 2018 in connection with infrastructure expansion activities to support the commercial launch of XHANCE and our transition to a public company.

*Financing activities*

Cash provided by financing activities was \$0.2 million for the three months ended March 31, 2019. Cash used in financing activities was \$1.7 million for the three months ended March 31, 2018, driven primarily by the payment of \$1.8 million in financings costs incurred in conjunction with our initial public offering and debt offering in the fourth quarter of 2017.

*Projected 2019 operating expenses*

We expect that our total GAAP operating expenses (consisting of selling, general & administrative expenses and research & development expenses) for 2019 will be between \$135.0 - \$142.0 million of which \$10.0 - \$12.0 million is expected to be stock-based compensation expense. Total GAAP operating expenses excluding stock-based compensation expense are expected to be in the range from \$125.0 - \$130.0 million.

*Future funding requirements*

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

- maintain and expand our sales force and the commercial infrastructure to support the sales and marketing for XHANCE;
- continue advertising and other promotional activities to support the commercialization of XHANCE;
- continue to provide co-pay and other patient affordability programs;
- continue clinical development activities for XHANCE, including FDA-mandated pediatric studies and clinical trials for a follow-on indication for the treatment of chronic sinusitis;
- continue research and development activities for additional product candidates;
- continue to contract to manufacture XHANCE and our other product candidates;
- maintain, expand and protect our patent portfolio;
- service our debt obligations under the Notes issued in December 2017;
- maintain infrastructure necessary to operate as a publicly-traded, commercial-stage company; and
- hire additional staff and add operational, financial and information systems to execute our business plan.

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

- the success of our commercialization of XHANCE for the treatment of nasal polyps including, among other things, patient and physician acceptance of XHANCE and our ability to obtain adequate insurance coverage and reimbursement for XHANCE;
- the cost of commercialization activities for XHANCE, including product manufacturing, distribution, marketing and sales;
- net product revenues received from sales of XHANCE;
- the costs and timing of expanding our sales force;
- the level of co-pay assistance and other patient affordability programs offered for XHANCE;
- our clinical development plans for XHANCE, including the outcome, timing and cost of FDA-mandated pediatric studies and clinical trials for the supplemental indication for the treatment of chronic sinusitis;
- the outcome, timing and cost of the regulatory approval process of XHANCE for chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect;
- the costs involved in preparing, filing and prosecuting patent applications and annuity fees relating to issued patents;
- the cost of maintaining and enforcing our intellectual property rights, as well as the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- fluctuations in the three-month LIBOR-based floating interest rate of our Notes;
- 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 of other products, product candidates or technologies.

Although it is difficult to predict our future liquidity requirements, we believe that existing cash and cash equivalents at March 31, 2019 will be sufficient to meet our debt service obligations under our Notes, and to carry out our planned development and commercial activities into the first quarter of 2021. 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, 2019:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	(in thousands)				
Operating leases <sup>(1)</sup>	\$ 2,767	\$ 1,634	\$ 1,133	\$ —	\$ —
Long-term debt <sup>(2)</sup>	114,451	8,888	17,656	87,907	—
Total	\$ 117,218	\$ 10,522	\$ 18,789	\$ 87,907	\$ —

<sup>(1)</sup> Reflects obligations pursuant to our office leases in Yardley, Pennsylvania, Ewing, New Jersey, Oslo, Norway and Swindon, England and leases of certain other equipment.

<sup>(2)</sup> Reflects principal, interest obligations and exit fees pursuant to the Note Purchase Agreement entered into on December 29, 2017. The Notes bear interest at 9.0% plus the three-month LIBOR rate, subject to a 1.0% floor. We are required to make quarterly, interest only payments until the maturity date. Interest amounts included above are calculated at the quarterly rate as of March 31, 2019 of 11.625%.

### Critical accounting policies

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

### Recent accounting pronouncements

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

### JOBS Act

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

### ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes to our market risk since December 31, 2018.

### 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, 2019.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II**

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

Recent Issuances of Unregistered Securities

None.

Use of Proceeds

Our initial public offering (IPO) was effected through a Registration Statement on Form S-1 (File No. 333-220515) that was declared effective by the SEC on October 12, 2017. On October 17, 2017, 8,625,000 shares of our common stock were sold at a price to the public of \$16.00 per share, for aggregate gross proceeds of \$138.0 million. All of the securities registered pursuant to the offering were sold prior to termination of the offering. Jefferies and Piper Jaffray acted as lead joint book-running managers in the IPO, and BMO Capital Markets and RBC Capital Markets acted as joint book-running managers in the IPO.

On October 17, 2017 we received proceeds from the IPO of \$128.3 million, which was net of underwriting discounts and commissions of approximately \$9.7 million. Of this amount, we paid offering expenses of approximately \$2.8 million.

There has been no material change in the use of proceeds from the IPO as described in the final prospectus for the IPO filed with the SEC on October 12, 2017 (the Final Prospectus). During the period from the closing of our IPO to March 31, 2019, we used the \$125.5 million of proceeds as follows:

- approximately \$75.1 million to support the launch of XHANCE, including investments in marketing and sales, inventory and our commercial infrastructure;
- approximately \$11.1 million to fund further development efforts for XHANCE; and
- approximately \$39.3 million to fund other working capital and general corporate purposes, including costs of operating as a public company.

The foregoing expenses are a reasonable estimate of the expenses incurred by us in the offering and do not represent the exact amount of expenses incurred. All of the foregoing expenses were direct or indirect payments to persons other than (i) our directors, officers or any of their associates; (ii) persons owning 10% or more of our common stock; or (iii) our affiliates.

**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**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
31.1 *	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>
31.2 *	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>
32.1 *	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.</a>
32.2 *	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.</a>
101.INS *	XBRL Instance Document.
101.SCH *	XBRL Taxonomy Extension Schema Document.
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB *	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document.

\* Filed herewith.



**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 9, 2019

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

**CERTIFICATION UNDER SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Keith A. Goldan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2019

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

**CERTIFICATION UNDER SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

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

1. the Quarterly Report on Form 10-Q of the Company for the period ending March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
  
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: May 9, 2019

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

**CERTIFICATION UNDER SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

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

1. the Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
  
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: May 9, 2019

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