

**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 June 30, 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)

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer

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

The number of shares of the registrant's common stock outstanding at August 9, 2019 was 41,435,918 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.

[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 those in pursuit of a follow-on indication for XHANCE for the treatment of 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 the full-year 2019 XHANCE net revenue will be between \$29 - \$34 million;
- our expectation that our GAAP operating expenses in 2019 will be between \$128.0 - \$133.0 million and that our non-cash stock-based compensation expense will be between \$10.0 - \$11.0 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 June 30, 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

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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)

	June 30, 2019	December 31, 2018
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 143,963	\$ 200,990
Accounts receivable, net	9,311	2,310
Grants and other receivables	290	242
Inventory	4,260	7,132
Prepaid expenses and other current assets	3,030	2,183
Total current assets	160,854	212,857
Property and equipment, net	3,531	3,884
Other assets	2,187	248
Total assets	<u>\$ 166,572</u>	<u>\$ 216,989</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,811	\$ 7,116
Accrued expenses and other current liabilities	21,556	18,421
Deferred other income	—	160
Total current liabilities	24,367	25,697
Long-term debt, net	72,869	72,500
Other liabilities	864	181
Total liabilities	98,100	98,378
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized at June 30, 2019 and December 31, 2018; 41,430,918 and 41,227,530 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	41	41
Additional paid-in capital	442,676	436,554
Accumulated deficit	(374,178)	(317,927)
Accumulated other comprehensive loss	(67)	(57)
Total stockholders' equity	68,472	118,611
Total liabilities and stockholders' equity	<u>\$ 166,572</u>	<u>\$ 216,989</u>

See accompanying notes to unaudited interim consolidated financial statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Net product revenues	\$ 6,677	\$ 1,274	\$ 10,653	\$ 2,139
Licensing revenues	—	—	500	—
Total revenues	6,677	1,274	11,153	2,139
Costs and expenses:				
Cost of product sales	1,089	351	1,827	551
Research and development	5,295	2,046	9,857	3,747
Selling, general and administrative	26,000	21,860	52,340	49,871
Total operating expenses	32,384	24,257	64,024	54,169
Loss from operations	(25,707)	(22,983)	(52,871)	(52,030)
Other (income) expense:				
Grant and other income	—	(145)	—	(333)
Interest income	(716)	(582)	(1,400)	(1,058)
Interest expense	2,389	2,301	4,777	4,494
Foreign currency (gains) losses	(3)	24	3	21
Net loss	\$ (27,377)	\$ (24,581)	\$ (56,251)	\$ (55,154)
Net loss per share of common stock, basic and diluted	\$ (0.66)	\$ (0.64)	\$ (1.36)	\$ (1.44)
Weighted average common shares outstanding, basic and diluted	41,310,608	38,688,366	41,283,478	38,271,101

See accompanying notes to unaudited interim consolidated financial statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	\$ (27,377)	\$ (24,581)	\$ (56,251)	\$ (55,154)
Other comprehensive (loss) income:				
Foreign currency translation adjustment	(13)	15	(10)	21
Comprehensive loss	<u>\$ (27,390)</u>	<u>\$ (24,566)</u>	<u>\$ (56,261)</u>	<u>\$ (55,133)</u>

See accompanying notes to unaudited interim consolidated financial statements

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

Six Months Ended June 30, 2019

	Stockholders' Equity					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	41,227,530	\$ 41	\$ 436,554	\$ (317,927)	\$ (57)	\$ 118,611
Stock compensation expense	—	—	2,425	—	—	2,425
Exercise of common stock options	5,000	—	15	—	—	15
Issuance of common stock under employee stock purchase plan	31,892	—	173	—	—	173
Foreign currency translation adjustment	—	—	—	—	3	3
Net loss	—	—	—	(28,874)	—	(28,874)
Balance at March 31, 2019	41,264,422	\$ 41	\$ 439,167	\$ (346,801)	\$ (54)	\$ 92,353
Stock compensation expense	—	—	2,716	—	—	2,716
Exercise of common stock options	88,587	—	354	—	—	354
Issuance of common stock under employee stock purchase plan	77,909	—	439	—	—	439
Foreign currency translation adjustment	—	—	—	—	(13)	(13)
Net loss	—	—	—	(27,377)	—	(27,377)
Balance at June 30, 2019	41,430,918	\$ 41	\$ 442,676	\$ (374,178)	\$ (67)	\$ 68,472

Six Months Ended June 30, 2018

	Stockholders' Equity					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	37,802,556	\$ 38	\$ 365,838	\$ (211,269)	\$ (111)	\$ 154,496
Stock compensation expense	—	—	2,050	—	—	2,050
Exercise of common stock options	106,502	—	130	—	—	130
Foreign currency translation adjustment	—	—	—	—	7	7
Net loss	—	—	—	(30,572)	—	(30,572)
Balance at March 31, 2018	37,909,058	\$ 38	\$ 368,018	\$ (241,841)	\$ (104)	\$ 126,111
Stock compensation expense	—	—	2,135	—	—	2,135
Sale of common stock, net of issuance costs	2,875,000	3	59,923	—	—	59,926
Exercise of common stock options	330,401	—	727	—	—	727
Exercise of warrants	7,098	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	15	15
Net loss	—	—	—	(24,581)	—	(24,581)
Balance at June 30, 2018	41,121,557	\$ 41	\$ 430,803	\$ (266,422)	\$ (89)	\$ 164,333

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

	Six Months Ended June 30,	
	2019	2018
Operating activities:		
Net loss	\$ (56,251)	\$ (55,154)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	592	173
Stock-based compensation	5,117	4,123
Amortization of debt discount and issuance costs	234	180
Changes in operating assets and liabilities:		
Accounts receivable	(7,001)	(3,671)
Grants and other receivables	(48)	(165)
Prepaid expenses and other assets	1,096	(859)
Inventory	2,803	(2,723)
Accounts payable	(4,253)	2,917
Accrued expenses and other liabilities	129	7,686
Cash used in operating activities	<u>(57,582)</u>	<u>(47,493)</u>
Investing activities:		
Purchases of property and equipment	(423)	(881)
Cash used in investing activities	<u>(423)</u>	<u>(881)</u>
Financing activities:		
Proceeds from the sale of common stock	—	63,969
Cash paid for financing costs	—	(6,349)
Proceeds from issuance of common stock under employee stock purchase plan	612	—
Proceeds from the exercise of stock options	369	857
Cash provided by financing activities	<u>981</u>	<u>58,477</u>
Effects of exchange rate changes on cash and cash equivalents	(9)	25
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(57,033)</u>	<u>10,128</u>
Cash, cash equivalents and restricted cash at beginning of period	201,011	234,875
Cash, cash equivalents and restricted cash at end of period	<u>\$ 143,978</u>	<u>\$ 245,003</u>
Supplemental disclosure of noncash activities:		
Fixed asset purchases within accounts payable and accrued expenses	\$ 35	\$ 233
Fixed asset additions acquired through tenant allowance	\$ —	\$ 267
Financing costs within accounts payable and accrued expenses	\$ —	\$ 188
Recognition of initial right-of-use assets	\$ 3,724	\$ —
Recognition of initial lease liabilities	\$ 4,201	\$ —

See accompanying notes to unaudited interim consolidated financial statements

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

1. Organization and Description of Business

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

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

2. Liquidity

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio, conducting preclinical studies and clinical trials, pursuing regulatory approvals and most recently, preparing for and launching XHANCE. As of June 30, 2019, the Company had cash and cash equivalents of \$143,963.

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 June 30, 2019 and its results of operations for the three and six months ended June 30, 2019 and 2018 and cash flows for the six months ended June 30, 2019 and 2018. Operating results for the three and six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial

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 XHANCE. XHANCE is sold to wholesale pharmaceutical distributors and preferred pharmacy network partners (collectively, Customers), who, in turn, sell XHANCE to pharmacies, hospitals and other customers. Five Customers represent approximately 68% of the Company's accounts receivable at June 30, 2019 and five Customers represent approximately 67% and 68% of the Company's net product sales for the three and six months ended June 30, 2019, respectively.

Fair value of financial instruments

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

Restricted cash

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

Net Product Revenues

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, which was adopted on January 1, 2018. The Company recognizes revenue from XHANCE 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

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

than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

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

Product Returns. Consistent with industry practice, the Company has a product returns policy that provides Customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The Company estimates the amount of its product that may be returned and presents this amount as a reduction of revenue in the period the related product revenue is recognized, in addition to establishing a liability. The Company considers several factors in the estimation process, including expiration dates of product shipped to 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 six months ended June 30, 2019, the Company's licensing revenues were generated pursuant to the terms of a single license agreement (the Inexia License Agreement) with Inexia Limited (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 six months ended June 30, 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 and six months

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

ended June 30, 2019 and 2018, the outstanding Common Stock options, Common Stock warrants and shares to be issued under the Company's 2017 Employee Stock Purchase Plan have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

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

	June 30,	
	2019	2018
Stock options	7,983,370	6,126,560
Common stock warrants	1,866,831	1,878,660
Employee stock purchase plan	—	53,137
Total	<u>9,850,201</u>	<u>8,058,357</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 and six months ended June 30, 2019 and 2018, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of June 30, 2019 and December 31, 2018, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

Recent accounting pronouncements

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

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

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

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

lease identification, lease classification and initial indirect costs related to those leases entered into prior to the adoption of ASC 842; and (ii) to not separate lease and non-lease components for our office lease portfolio. Refer to *Note 6 — Leases* for further details.

4. Inventory

Inventory consisted of the following:

	June 30, 2019	December 31, 2018
Raw materials	\$ 1,754	\$ 1,969
Work-in-process	1,424	2,344
Finished goods	1,082	2,819
Total inventory	<u>\$ 4,260</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:

	June 30, 2019	December 31, 2018
Computer equipment and software	\$ 1,063	\$ 833
Furniture and fixtures	389	389
Machinery and equipment	3,137	2,723
Leasehold improvements	609	609
Construction in process	57	481
	<u>5,255</u>	<u>5,035</u>
Less: accumulated depreciation	<u>(1,724)</u>	<u>(1,151)</u>
	<u>\$ 3,531</u>	<u>\$ 3,884</u>

Depreciation expense was \$322 and \$16 for the three months ended June 30, 2019 and 2018, respectively. Depreciation expense was \$591 and \$172 for the six months ended June 30, 2019 and 2018, respectively. In addition, depreciation expense of \$42 and \$76 was charged to inventory and prepaid expenses and other assets, respectively, as of June 30, 2019, which represents depreciation expense related to equipment involved in the manufacturing process.

6. Leases

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* to require the recognition of lease assets and liabilities on the balance sheet of lessees. The Company implemented ASU 2016-02 as of January 1, 2019 using the optional modified retrospective transition method, which does not require the restatement of prior period amounts, and elected the following transition practical expedients: (i) to not reassess lease identification, lease classification and initial indirect costs related to those leases entered into prior to the adoption of ASC 842; and (ii) to not separate lease and non-lease components for 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
(in thousands, except share and per share data)

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

	Balance Sheet Line Item	June 30, 2019
Non-current operating lease assets	Other assets	\$ 2,110
Operating lease liabilities:		
Current operating lease liabilities	Accrued expenses and other current liabilities	1,448
Non-current operating lease liabilities	Other liabilities	864
Total operating lease liabilities		<u>\$ 2,312</u>

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

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

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

	June 30, 2019
Weighted average remaining lease term (years)	1.63
Weighted average discount rate	5.96%

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 June 30, 2019:

	June 30, 2019
2019	\$ 826
2020	1,152
2021	402
Thereafter	—
Total undiscounted future minimum lease payments	<u>2,380</u>
Less: difference between undiscounted lease payments and discounted operating lease liabilities	68
Total operating lease liabilities	<u>\$ 2,312</u>

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

Operating lease costs were \$690 and \$1,069 for the three and six months ended June 30, 2019, respectively. Operating lease costs are included within selling, general and administrative expenses on the consolidated statements of operations.

Cash paid for amounts included in the measurement of operating lease liabilities were \$688 for the six months ended June 30, 2019, and this amount is included in operating activities in the consolidated statements of cash flows.

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

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	June 30, 2019	December 31, 2018
Accrued expenses:		
Contract sales organization expenses	\$ 808	\$ 4,482
Selling, general and administrative expenses	5,115	4,812
Research and development expenses	1,790	933
Payroll expenses	5,392	4,199
Product revenue allowances	6,633	2,856
Other	370	1,139
Total accrued expenses	20,108	18,421
Other current liabilities:		
Lease liability	1,448	—
Total other current liabilities	1,448	—
Total accrued expenses and other current liabilities	\$ 21,556	\$ 18,421

8. License AgreementsAVP-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 June 30, 2019, under the terms of the AVP-825 License Agreement, the Company received aggregate cash payments of \$70,000 in connection with the initial signing and the achievement of certain development milestones. The Company did not recognize any licensing revenue under the arrangement during the three and six months ended June 30, 2019 and 2018 and does not expect any future revenue under the AVP-825 License Agreement.

On December 10, 2018, the Company received written notice from Avanir of its election to terminate the AVP-825 License Agreement. As a result, the AVP-825 License Agreement terminated on March 10, 2019. 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 in capital was issued immediately. The remaining \$25,000 (the Delayed Draw Notes) was available to the Company between April 1, 2019 and August 14, 2019, subject to the

OptiNose, Inc.
Notes to Unaudited Interim Consolidated Financial Statements
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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 12 month net revenues not exceeding 6.50 to 1.00, and certain other conditions. While the Company has met the conditions necessary to issue the Delayed Draw Notes, the Company has elected not to draw the additional funding.

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 11.4375% at June 30, 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 may make voluntary prepayments of the Senior Secured Notes, in whole or in part, and subject to certain exceptions, is required to make mandatory prepayments upon the occurrence of certain events as defined in the agreement, including, the occurrence of a change of control. All mandatory and voluntary prepayments of the Senior Secured Notes are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs prior to the second anniversary of the applicable date of issuance, an amount equal to the amount by which (a) the present value of 102% of the principal prepaid plus all interest that would have accrued on such principal through such second anniversary exceeds (b) the amount of principal prepaid, (ii) if prepayment occurs on or after the second anniversary of the applicable date of issuance but prior to the third anniversary of such issuance, an amount equal to 2% of the principal prepaid, and (iii) if prepayment occurs on or after the third anniversary of the applicable date of issuance but prior to the fourth anniversary of such issuance, an amount equal to 1% of the principal prepaid. No prepayment premium is due on any principal prepaid after the fourth anniversary of the applicable date of issuance of any Senior Secured Notes.

The Company recorded interest expense of \$2,389 and \$2,301 during the three months ended June 30, 2019 and 2018, respectively, and \$4,777 and \$4,494 during six months ended June 30, 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:

	June 30, 2019	December 31, 2018
Face amount	\$ 75,000	\$ 75,000
Front end fees	(799)	(872)
Debt issuance costs	(1,742)	(1,902)
Back end fees	410	274
Long-term debt, net	<u>\$ 72,869</u>	<u>\$ 72,500</u>

10. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of June 30, 2019, approximately \$117 is recorded in accrued liabilities related to the Company match. The Company's contributions are made in cash.

For Norway and UK employees, the Company maintains defined contribution pension plans which meet the statutory requirements of those jurisdictions. The Company incurred costs related to the pension plans of \$5 and \$7 for the three months ended June 30, 2019 and 2018, respectively, and \$11 and \$69 for the six months ended June 30, 2019 and 2018, respectively.

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

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 June 30, 2019.

Common Stock warrants

As of June 30, 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 and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of product sales	\$ 26	\$ 2	\$ 45	\$ 3
Research and development	284	166	527	405
General and administrative	2,387	1,932	4,545	3,715
	<u>\$ 2,697</u>	<u>\$ 2,100</u>	<u>\$ 5,117</u>	<u>\$ 4,123</u>

In addition, stock-based compensation expense of \$22 and \$38 was charged to inventory and prepaid expenses and other assets, respectively, during the six months ended June 30, 2019, which represents the total stock-based compensation expense incurred related to employees involved in the manufacturing process of finished goods and samples during the period.

Stock Options

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

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Notes to Unaudited Interim Consolidated Financial Statements
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The following table summarizes the activity related to stock option grants to employees and nonemployees for the six months ended June 30, 2019:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2018	6,182,873	\$ 10.60	6.67
Granted	2,013,173	7.73	
Exercised	(93,587)	3.98	
Expired	—	—	
Forfeited	(119,089)	11.34	
Outstanding at June 30, 2019	<u>7,983,370</u>	\$ 9.94	6.89
Exercisable at June 30, 2019	<u>4,208,609</u>	\$ 9.07	5.01
Vested and expected to vest at June 30, 2019	<u>7,983,370</u>	\$ 9.94	6.89

During the six months ended June 30, 2019, stock options to purchase 2,013,173 shares of Common Stock were granted to employees and directors and generally vest over four years. The stock options had an estimated weighted average grant date fair value of \$4.80. During the six months ended June 30, 2018, stock options to purchase 358,192 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 \$13.26.

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:

	Six Months Ended June 30,	
	2019	2018
Risk free interest rate	2.51%	2.69%
Expected term (in years)	6.05	5.90
Expected volatility	67.02%	74.92%
Annual dividend yield	0.00%	0.00%
Fair value of common stock	\$ 7.73	\$ 19.98

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

	Shares
Balance at December 31, 2018	—
Granted	20,600
Vested and settled	—
Expired/ forfeited/ canceled	—
Balance at June 30, 2019	<u>20,600</u>
Expected to vest at June 30, 2019	<u>20,600</u>

In April 2019, the Company granted 20,600 RSUs at a price of \$10.20, which vest over four years.

At June 30, 2019, the unrecognized compensation cost related to unvested stock options and RSUs expected to vest was \$24,690. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.76 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 \$123 during the three

OptiNose, Inc.
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months ended June 30, 2019 and 2018, respectively, and \$228 and \$279 during the six months ended June 30, 2019 and 2018, respectively, related to the 2017 Plan.

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

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

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

Company Overview

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

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

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

- **Customer Model.** We have defined a sales force footprint of approximately 120 geographic territories targeting approximately 14,000 ENTs, allergists and "specialty-like" primary care physicians. In April 2019, we changed our 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 programs. We believe these programs, with an indefinite duration, provide an affordability solution for patients that physicians will support. These programs provide patient co-pay assistance to commercially insured patients that includes a first prescription at no out-of-pocket cost (\$0 co-pay) and low subsequent co-pays for refills. Our data suggests these programs are playing an important role in supporting demand for XHANCE, particularly as they become more widely understood in the prescribing community.
- **Market Access.** Based on currently available third-party data and our internal analyses, we believe that greater than 75% of commercially insured lives are currently in a plan in which XHANCE is covered. However, payors may change coverage levels for XHANCE or controls such as step edits and prior authorization, positively or negatively, at any time.

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

- **XHANCE Prescriptions and Market Share.** Based on third-party prescription data as well as data from preferred pharmacy network partners, the total estimated number of XHANCE prescriptions in the second quarter of 2019 was 33,949, which represents 51% growth of prescriptions when compared to first quarter 2019 prescriptions of 22,490. The INS prescription market increased approximately 1% from first quarter 2019 to second quarter 2019 based on third-party prescription data. In addition, we estimate the number of XHANCE prescriptions for the month of July 2019 was 13,770, which represents growth of 17% compared

to the prior month. During this same period, the INS market is estimated to have changed 0% based on third-party prescription data. We believe the April 2019 internalization and expansion of our sales force, which expanded our sales territories by 25%, and the availability of a new 7-day sample starting in May 2019, will continue to encourage trial and adoption of XHANCE, and help drive future XHANCE prescription growth.

XHANCE prescribing may be subject to a seasonal effect historically observed in the INS prescription market in which market volume generally peaks near the middle of the second quarter and declines into the early part of the third quarter of each calendar year. Based on third party prescription data, the INS market increased 2% from the first quarter of 2018 to the second quarter of 2018, decreased 15% from the second quarter of 2018 to the third quarter of 2018, increased 11% from the third quarter of 2018 to the fourth quarter of 2018 and increased 3% from the fourth quarter of 2018 to the first quarter of 2019. Although the underlying disease that we are treating is chronic and causes symptoms year-round, we believe the variation in patient flow through the offices of relevant specialists, and seasonality in disease flare-ups, 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, which commonly occurs in January, 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.

We monitor the market share of XHANCE within our current target audience. For this purpose, we calculate market share as the proportion of XHANCE prescriptions to the number of prescriptions written for other INS within our current target audience of over 10,000 physicians. We believe market share, in addition to XHANCE prescription volume, provides important information regarding XHANCE utilization because market share normalizes XHANCE prescriptions for market effects including the INS market seasonality and annual deductible resets referenced above. Based on third-party prescription data as well as data from preferred pharmacy network partners, we estimate XHANCE market share of 0.9%, 1.2%, 1.6%, 1.7%, 2.0%, 2.3%, 2.6% and 2.9% for each of the months from December 2018 through July 26, 2019, respectively. Note that most of the INS prescriptions written within our target physician audience are for chronic sinusitis, allergic rhinitis and other conditions outside of our nasal polyp indication.

XHANCE Development Update

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

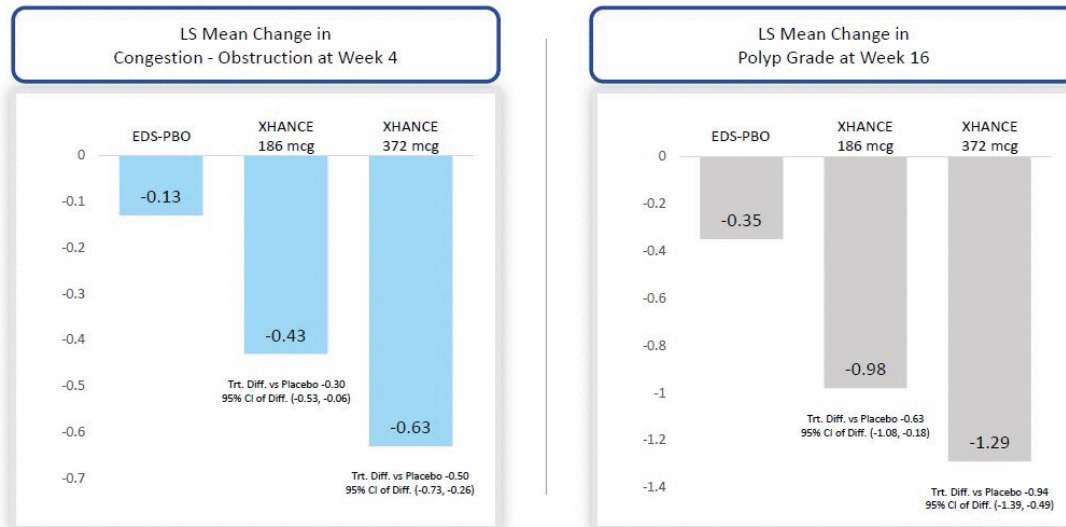
Analysis of Efficacy in Patients Who Report Symptoms Despite Use of Conventional Nasal Steroids

Efficacy for different patient types is important information for understanding how to best adopt XHANCE. Data suggest that many nasal polyp patients do not achieve satisfactory symptom response with conventional nasal steroids. In order to help inform whether XHANCE may offer benefits for the type of patient who has symptoms despite use of other nasal steroids, we performed a series of new post-hoc analyses of the large subgroup of patients who entered our pivotal clinical trials reporting current use of one of the then-available nasal steroids as captured on case record forms. Using pooled data (n=482), we found that 30% of those patients entered NAVIGATE I and NAVIGATE II using a nasal steroid within a month of trial entry. On average these patients reported use of these nasal steroids for approximately 3 years and all of them reported moderate-to-severe symptoms at trial entry.

On multiple measures of efficacy, this group of patients who switched from a prior nasal steroid to XHANCE improved, generally with comparable or more improvement, versus placebo, then other patients (those who did not report use of a nasal steroid in the month prior to trial entry). Note that these post-hoc analyses were not pre-specified and not controlled for multiplicity; therefore these results require cautious interpretation as they may represent chance findings. We anticipate communicating these new analyses to physicians and payers in support of XHANCE in the second half of this year.

Patients with moderate-to-severe symptoms despite using conventional nasal steroids[†] improved significantly when switched to XHANCE

Post-Hoc Analysis of NAVIGATE I/II Pooled Data (n=482): At study entry, a large subgroup (30%) of the patients in the pooled NAVIGATE I/II trials reported using a conventional nasal steroid for a minimum of 30 days prior to study entry.



This analysis was not pre-specified and was not controlled for multiplicity

6 EDS-PBO: Exhalation Delivery System delivering placebo vehicle; † Based on case record form reports of drug use at study entry, patients reported being on INS or steroid rinse at study entry for a minimum of 30 days and still had moderate-to-severe symptoms and bilateral nasal polyps



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 \$6.7 million and \$10.7 million in net revenues for the three and six months ended June 30, 2019, respectively. In accordance with GAAP, we determine net product revenues for XHANCE, with specific assumptions for variable consideration components including but not limited to trade discounts and allowances, co-pay assistance programs and payor rebates. For the full-year 2019, we expect XHANCE net revenue to be in the range of \$29 - \$34 million.

Based on available XHANCE prescription data purchased from third parties and data from our pharmacy network, our average net revenues per prescription for the second quarter of 2019 was approximately \$197, which represents an increase compared to our average net product revenues per prescription of approximately \$177 in the first quarter of 2019, and average net revenue per prescription for the first half of 2019 was \$189. We believe the 11% increase in the average net revenue per prescription in the second quarter of 2019 compared to the first quarter of 2019 is largely attributable to patients meeting annual out-of-pocket expense thresholds which reduces the amount of copay assistance that we provide through our affordability program.

We calculate average net product 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.

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

Costs of product sales

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

Research and development expense

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

- personnel expenses, including salaries, benefits and stock-based compensation expense;

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- 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 sales and marketing expenses include our sales team and supporting promotional materials, digital promotion, peer-to-peer education, congresses / conventions, samples, and marketing activities such as direct-to-patient / direct-to-consumer initiatives.

Interest (income) expense

Interest (income) expense consists of interest earned on our cash and cash equivalents held with institutional banks and interest expense 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 June 30, 2019 and 2018**

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

	Three Months Ended June 30,	
	2019	2018
Revenues:		
Net product revenues	\$ 6,677	\$ 1,274
Licensing revenues	—	—
Total revenues	6,677	1,274
Costs and expenses:		
Cost of product sales	1,089	351
Research and development	5,295	2,046
Selling, general and administrative	26,000	21,860
Total operating expenses	32,384	24,257
Loss from operations	(25,707)	(22,983)
Other (income) expense:		
Interest (income) expense	1,673	1,719
Other (income) expense	(3)	(121)
Total other (income) expense	1,670	1,598
Net loss	\$ (27,377)	\$ (24,581)

Net product revenues

Net product revenues related to sales of XHANCE were \$6.7 million and \$1.3 million for the three months ended June 30, 2019 and 2018, respectively. Revenue growth is primarily attributable to increased prescriptions of XHANCE which became commercially available in late Q1 2018.

Cost of product sales

Cost of product sales related to XHANCE were \$1.1 million and \$0.4 million for the three months ended June 30, 2019 and 2018, respectively.

Research and development expense

Research and development expense was \$5.3 million and \$2.0 million for the three months ended June 30, 2019 and 2018, respectively. The \$3.3 million increase was attributable primarily to:

- a \$3.3 million increase in clinical expenses related to the preparation for and initiation and conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis and FDA-mandated pediatric studies;

Selling, general and administrative expense

Selling, general and administrative expense was \$26.0 million and \$21.9 million for the three months ended June 30, 2019 and 2018, respectively. The \$4.1 million increase was due primarily to:

- a \$2.9 million increase in expenses related to the sale of XHANCE including marketing expenses, specialty pharmacy fees and samples; and
- a \$1.4 million increase in personnel, bonus and travel expenses due to increases in headcount and the expansion of our sales team.

This increase was offset by:

- a \$0.5 million decrease in sales expenses due to the completion of XHANCE initial launch activities in 2018.

[Table of Contents](#)*Interest (income) expense, net*

Interest (income) expense, net, was \$1.7 million for the three month periods ended June 30, 2019 and 2018. Interest expense for the three month periods ended June 30, 2019 and 2018 was \$2.4 million and \$2.3 million, respectively. Interest expense was offset by interest income of \$0.7 million and \$0.6 million for the three month periods ended June 30, 2019 and 2018, respectively. Interest income increased by \$0.1 million as a result of higher interest rates on our cash balances.

Other (income) expense, net

Other (income) expense, net was \$0.1 million for the three months ended June 30, 2018. The income was attributable primarily to grant-eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary. No grant-eligible research and development expenses were incurred during the three months ended June 30, 2019.

Comparison of six months ended June 30, 2019 and 2018

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

	Six Months Ended June 30,	
	2019	2018
Revenues:		
Net product revenues	\$ 10,653	\$ 2,139
Licensing revenues	500	—
Total revenues	11,153	2,139
Costs and expenses:		
Cost of product sales	1,827	551
Research and development	9,857	3,747
Selling, general and administrative	52,340	49,871
Total operating expenses	64,024	54,169
Loss from operations	(52,871)	(52,030)
Other (income) expense:		
Interest (income) expense	3,377	3,436
Other (income) expense	3	(312)
Total other (income) expense	3,380	3,124
Net loss	\$ (56,251)	\$ (55,154)

Net product revenues

Net product revenues related to sales of XHANCE were \$10.7 million and \$2.1 million for the six months ended June 30, 2019 and 2018, respectively. Revenue growth is primarily attributable to increased prescriptions of XHANCE which became commercially available in late Q1 2018.

Licensing revenues

Licensing revenues were \$0.5 million for the six months ended June 30, 2019 as a result of the upfront payment received under the terms of the Inexia License Agreement. No licensing revenue was received during the six months ended June 30, 2018.

Cost of product sales

Cost of product sales related to XHANCE were \$1.8 million and \$0.6 million for the six months ended June 30, 2019 and 2018, respectively.

Research and development expense

Research and development expense was \$9.9 million and \$3.7 million for the six months ended June 30, 2019 and 2018, respectively. The \$6.2 million increase was attributable primarily to:

- a \$5.7 million increase in clinical expenses related to the preparation for and initiation and conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis and FDA-mandated pediatric studies;

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Selling, general and administrative expense

Selling, general and administrative expense was \$52.3 million and \$49.9 million for the six months ended June 30, 2019 and 2018, respectively. The \$2.4 million increase was due primarily to:

- a \$4.9 million increase in expenses related to the sale of XHANCE including marketing expenses, specialty pharmacy fees and samples;
- a \$3.4 million increase in personnel, bonus and travel expenses due to increases in headcount and the expansion of our sales team; and
- a \$1.0 million increase stock compensation expense.

This increase was offset by:

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

Interest (income) expense, net

Interest (income) expense, net, was \$3.4 million for the six month periods ended June 30, 2019 and 2018. Interest expense for the six month periods ended June 30, 2019 and 2018 was \$4.8 million and \$4.5 million, respectively. Interest expense was offset by interest income of \$1.4 million and \$1.1 million for the six month periods ended June 30, 2019 and 2018, respectively. Interest income increased by \$0.3 million as a result of higher interest rates on our cash balances.

Other (income) expense, net

Other (income) expense, net was \$0.3 million for the six months ended June 30, 2018. The income was attributable primarily to grant-eligible research and development expenses incurred by OptiNose AS, our Norwegian subsidiary. No grant-eligible research and development expenses were incurred during the six months ended June 30, 2019.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. We incurred net losses of \$56.3 million and \$55.2 million for the six months ended June 30, 2019 and 2018, respectively. As of June 30, 2019, we had an accumulated deficit of \$374.2 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 June 30, 2019, we had \$144.0 million in cash and cash equivalents.

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

	Six Months Ended June 30,	
	2019	2018
Net cash used in operating activities	\$ (57,582)	\$ (47,493)
Net cash used in investing activities	(423)	(881)
Net cash provided by financing activities	981	58,477
Effects of exchange rates on cash and cash equivalents	(9)	25
Net (decrease) increase in cash and cash equivalents	\$ (57,033)	\$ 10,128

Operating activities

Cash used in operating activities increased by \$10.1 million, from \$47.5 million for the six months ended June 30, 2018 to \$57.6 million for the six months ended June 30, 2019. The increase in cash used in operating activities was attributable primarily to increased operating expenses and the timing of payment of those expenses.

Investing activities

Cash used in investing activities decreased \$0.5 million from \$0.9 million for the six months ended June 30, 2018 to \$0.4 million for the six months ended June 30, 2019. The decrease was related primarily to purchases of equipment

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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 \$1.0 million and \$58.5 million for the six months ended June 30, 2019 and 2018, respectively. Cash provided by financing activities for the six months ended June 30, 2018 was driven by net proceeds of \$59.9 million as a result of a June 2018 underwritten public offering of 5,750,000 shares of our common stock (Common Stock) at a price of \$22.25 per share, which consisted of 2,875,000 shares of Common Stock sold by us and 2,875,000 shares of Common Stock sold by certain stockholders. This receipt was partially offset by \$2.5 million of cash paid for financing costs during the six months ended June 30, 2018 related to our IPO 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 \$128.0 - \$133.0 million of which \$10.0 - \$11.0 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 \$118.0 - \$122.0 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;

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- 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 June 30, 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 June 30, 2019:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	(in thousands)				
Operating leases ⁽¹⁾	\$ 2,402	\$ 1,498	\$ 904	\$ —	\$ —
Long-term debt ⁽²⁾	111,599	8,673	17,395	85,531	—
Total	<u>\$ 114,001</u>	<u>\$ 10,171</u>	<u>\$ 18,299</u>	<u>\$ 85,531</u>	<u>\$ —</u>

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

⁽²⁾ Reflects principal, interest obligations and exit fees pursuant to the 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 June 30, 2019 of 11.4375%.

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 June 30, 2019.

Changes in Internal Control over Financial Reporting

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

PART II

ITEM 6. EXHIBITS

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

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
3.1	Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).
3.2	Amended and Restated Bylaws of OptiNose, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).
10.1 *	Form of Restricted Stock Unit Agreement Under the 2010 Stock Incentive Plan.
31.1 *	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
31.2 *	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
32.1 *	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.
32.2 *	Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.
101.INS *	XBRL Instance Document.
101.SCH *	XBRL Taxonomy Extension Schema Document.
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB *	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

SIGNATURES

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

Date: August 12, 2019

OPTINOSE, INC.
By: /s/ KEITH A. GOLDAN
Name: Keith A. Goldan
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Grant No.:

**OPTINOSE, INC.
2010 STOCK INCENTIVE PLAN
(AS AMENDED AND RESTATED AS OF SEPTEMBER 19, 2017)**

RESTRICTED STOCK UNIT AGREEMENT

OptiNose, Inc., a Delaware corporation (the “**Company**”), hereby grants an Award of Restricted Stock Units in respect of its common stock, \$0.001 par value per share (the “**Stock**”), to the Grantee named below (the “**RSUs**”). The terms and conditions of the RSUs are set forth in this cover sheet, in the attachment (together with the cover sheet, the “**Agreement**”) and in the Company’s 2010 Stock Incentive Plan, as amended and restated as of September 19, 2017 (the “**Plan**”).

Grant Date: (the “**Grant Date**”)

Name of Grantee:

Number of RSUs Covered by Award:

Vesting Start Date:

Vesting Schedule: [_____ RSUs will be eligible to vest based on the passage of time as set forth herein]; and _____ RSUs will be eligible to vest based on the achievement of certain performance goals as set forth herein].

Issuance of Shares: [issuance of the Stock underlying vested RSUs shall be made within sixty (60) days after the applicable vesting date]; [other share issuance schedule as set forth herein]

By signing this cover sheet, you agree to all of the terms and conditions described in this Agreement and in the Plan, a copy of which is also attached. You acknowledge that you have carefully reviewed the Plan, and agree that the Plan will control in the event any provision of this Agreement should appear to be inconsistent. Certain capitalized terms used in this Agreement are defined in the Plan, and have the respective meanings set forth in the Plan.

Grantee: _____
(Signature)

Company: _____
(Signature)

Title:

Attachment

This is not a stock certificate or a negotiable instrument



OPTINOSE, INC.
2010 STOCK INCENTIVE PLAN
(AS AMENDED AND RESTATED AS OF SEPTEMBER 19, 2017)

RESTRICTED STOCK UNIT AGREEMENT

Restricted Stock Units

This Agreement evidences the grant of an Award of Restricted Stock Units in the number set forth on the cover sheet of this Agreement. Each RSU represents the right to receive one share of Stock, subject to the vesting conditions and other terms and conditions set forth herein.

[Applicable time and/or performance-based vesting conditions.]

Vesting

Unless the termination of your Service triggers accelerated vesting or other treatment of the RSUs pursuant to the terms of the Plan, you shall immediately and automatically forfeit your unvested RSUs to the Company in the event your Service terminates for any reason.

Termination of Service

In the event of a Change of Control, the RSUs shall be treated in the manner provided in Sections 18.3 and 18.4 of the Plan, as applicable.

Change of Control

For purposes of this Agreement, your Service does not terminate when you go on a *bona fide* employee leave of absence that was approved by the Company in writing, if the terms of the leave provide for continued Service crediting, or when continued Service crediting is required by applicable law. However, your Service will be treated as terminating 90 days after you went on employee leave, unless your right to return to active work is guaranteed by law or by a contract. Your Service terminates in any event when the approved leave ends unless you immediately return to active employee work.

The Company determines, in its sole discretion, which leaves count for this purpose, and when your Service terminates for all purposes under the Plan. The Company's decision is final and binding.

Leaves of Absence

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

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

Dividend Equivalent Rights

The Company or an Affiliate, as the case may be, shall have the right to deduct from payments of any kind otherwise due to you any foreign, federal, state, or local taxes of any kind required by law to be withheld with respect to the vesting of the RSUs or the issuance of any shares of Stock in respect of the RSUs. At the time of such vesting or issuance, as applicable, you shall pay to the Company or the Affiliate, as the case may be, any amount that the Company or the Affiliate may reasonably determine to be necessary to satisfy such withholding obligation. Subject to the prior approval of the Company or the Affiliate, which may be withheld by the Company or the Affiliate, as the case may be, in its sole discretion, you may elect to satisfy such obligations, in whole or in part, (i) by causing the Company or the Affiliate to withhold shares of Stock otherwise issuable to you or (ii) by delivering to the Company or the Affiliate shares of Stock already owned by you that are not subject to any repurchase, forfeiture, unfulfilled vesting, or other similar requirements. The shares of Stock so delivered or withheld shall have an aggregate Fair Market Value equal to such withholding obligations. The Fair Market Value of the shares of Stock used to satisfy such withholding obligation shall be determined by the Board as of the date that the amount of tax to be withheld is to be determined. The maximum number of shares of Stock that may be withheld from the RSUs to satisfy any foreign, federal, state, or local tax withholding requirements upon the vesting of the RSUs or the issuance of shares of Stock in respect of the RSUs, as applicable, may not exceed such number of shares of Stock having a Fair Market Value equal to the minimum statutory amount (or, if permitted by the Company, such other rate as will not cause adverse accounting consequences and is permitted under applicable IRS withholding rules) required by the Company or the applicable Affiliate to be withheld and paid to any such foreign, federal, state, or local taxing authority with respect to such vesting or issuance.

Withholding Taxes

[Upon the vesting of the RSUs, the issuance of the Stock underlying the vested RSUs shall be made within sixty (60) days after the applicable vesting date.] [other issuance schedule as set forth herein] Any such issuance shall be evidenced in such a manner as the Company, in its discretion, will deem appropriate, including, without limitation, book-entry, registration or issuance of one or more Stock certificates.

Issuance

Transfer of RSUs

You may not sell, transfer, assign, pledge, or otherwise encumber or dispose of the RSUs. If you attempt to do any of these things, you will immediately and automatically forfeit the RSUs.

Retention Rights	Neither your RSUs nor this Agreement constitutes an agreement of employment or gives you the right to be retained by the Company or an Affiliate in any capacity. Except as otherwise provided in any applicable employment agreement between you and the Company, the Company and its Affiliates reserve the right to terminate your Service at any time and for any reason.
Stockholder Rights	You, or your estate or heirs, have no rights as a stockholder of the Company until a certificate for the shares underlying your RSUs has been issued (or an appropriate book entry has been made). No adjustments are made for dividends or other rights if the applicable record date occurs before your stock certificate is issued (or an appropriate book entry has been made), except as described in the Plan.
Clawback	The RSUs are subject to mandatory repayment by you to the Company to the extent you are or in the future become subject to (x) any Company or Affiliate "clawback" or recoupment policy that is adopted to comply with the requirements of any Applicable Laws, or (y) any Applicable Laws which impose mandatory recoupment, under circumstances set forth in such Applicable Laws.
Adjustments	In the event of a stock split, a stock dividend or a similar change in the Stock, the number of shares covered by the RSUs shall be adjusted (and rounded down to the nearest whole number) if required pursuant to the Plan.
Applicable Law	This Agreement will be interpreted and enforced under the laws of the State of Delaware, other than any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.
Forfeiture of Rights	<p>If you should take actions in competition with the Company, the Company shall have the right to cause a forfeiture of your rights hereunder, including, but not limited to, the right to cause: (i) a forfeiture of the RSUs, and (ii) with respect to the period commencing twelve (12) months prior to your termination of Service with the Company and ending twelve (12) months following such termination of Service, a forfeiture of any Stock acquired by you in respect of the RSUs. Unless otherwise specified in an employment or other agreement between the Company or an Affiliate and you, you take actions in competition with the Company if you directly or indirectly, own, manage, operate, join or control, or participate in the ownership, management, operation or control of, or are a proprietor, director, officer, stockholder, member, partner or an employee or agent of, or a consultant to any business, firm, corporation, partnership or other entity which engages, directly or indirectly, in research, developing, manufacturing, marketing, sale or licensing pharmaceutical, medical device or specialty pharmaceutical products or products in the healthcare sector; <u>provided, however</u>, being a holder of less than 1% of the outstanding equity of a public company or mutual fund shall not be deemed to be in competition with the Company.</p> <p>If you are not a party to a non-competition and confidentiality agreement with the Company on the date of this Agreement, you will concurrently herewith enter into such non-competition and confidentiality agreement in a form reasonably acceptable to the Company.</p>

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

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

Data Privacy

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

Consent to Electronic Delivery

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

Severability**Waiver**

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

The text of the Plan is incorporated in this Agreement by reference.

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

Entire Agreement

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

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

Code Section 409A

By signing the cover sheet of this Agreement, you agree to all of the terms and conditions described above and in the Plan.

**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: August 12, 2019

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

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

I, Keith A. Goldan, certify that:

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

Date: August 12, 2019

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

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

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

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

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

Date: August 12, 2019

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

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

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

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

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

Date: August 12, 2019

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