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

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2021

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

For the transition period from _____ to _____.

Commission file number: 001-38241

OPTINOSE, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer ☐
Non-accelerated filer	☒	Smaller reporting company ☒
		Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

The number of shares of the registrant's common stock outstanding at April 30, 2021 was 53,112,574 shares.

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

Trademark Notice

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

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the impact of, our plans regarding and the uncertainties caused by, the COVID-19 pandemic;
- the potential uses for and advantages of XHANCE®, our product candidates and Exhalation Delivery System (EDS) devices and technologies;
- planned product development activities, studies and clinical trials 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 (FDA) for the treatment of chronic sinusitis;
- the potential for XHANCE to be the standard of care for the treatment of chronic rhinosinusitis with and without nasal polyps;
- potential for continued XHANCE prescription and net revenue growth and potential drivers of such growth;
- potential for direct to consumer (DTC) advertising to be a future driver of XHANCE prescription growth;
- the potential benefits of our patient affordability programs and their potential effect on XHANCE demand and financial results;
- the potential for XHANCE prescriptions to be affected by the seasonality impact observed in the intranasal steroid (INS) market;
- the potential for XHANCE prescriptions and average net revenue per prescription to be adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January;
- our expectation that XHANCE net product revenues for the full year of 2021 will be at least $80.0 million;
- our expectation that average net product revenues per prescription for the full year of 2021 will increase compared to the full year 2020 result of $185;
- our expectation that our GAAP operating expenses in 2021 will be between $137.0 million and $142.0 million and that our non-cash stock-based compensation expense will be approximately $10.0 million;
- our expectation that we complete enrollment in the first of our ongoing Phase 3b chronic sinusitis trials in the third quarter of 2021 with top-line results available in first quarter 2022 and the availability of top line results from the other trial in the first half of 2022;
- our belief that existing cash and cash equivalents will be sufficient to maintain the minimum cash balance required under our debt facility and to fund our operations for at least the next twelve months from the filing date of this Form 10-Q;
- our ability to maintain sufficient inventory of XHANCE and for our manufacturers to timely supply XHANCE;
- our development, timing of data and funding plans for OPN-019 and the potential benefits of OPN-019; and
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and need for additional financing;

as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. Forward-looking statements appear primarily in the sections of this Form 10-Q entitled “Item 1. Financial Statements,” and “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In some cases, you can identify forward-looking statements by words such as “may,” “will,” “could,” “would,” “should,” “expect,” “confident,” “intend,” “plan,” “anticipate,” “believe,”

“estimate,” “predict,” “project,” “potential,” “continue,” “ongoing,” “scheduled” and similar expressions, although not all forward-looking statements contain these identifying words.

Forward-looking statements are based upon our current expectations and assumptions and are subject to a number of known and unknown risks, uncertainties and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission (SEC), and in particular, the risks and uncertainties discussed therein under the caption “Risk Factors”. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. As a result, you should not place undue reliance on forward-looking statements.

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

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

MARKET, INDUSTRY AND OTHER DATA

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

PART I

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 115,984	$ 144,156
Accounts receivable, net	17,958	23,394
Inventory	12,703	9,042
Prepaid expenses and other current assets	3,671	4,060
Total current assets	150,316	180,652
Property and equipment, net	1,885	2,028
Other assets	5,745	6,133
Total assets	$ 157,946	$ 188,813
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 7,973	$ 5,489
Accrued expenses and other current liabilities	36,808	46,683
Total current liabilities	44,781	52,172
Long-term debt, net	125,584	125,202
Other liabilities	4,248	4,651
Total liabilities	174,613	182,025
Stockholders' (deficit) equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 53,112,574 shares issued and outstanding at March 31, 2021 and 52,945,865 shares issued and outstanding at December 31, 2020	53	53
Additional paid-in capital	537,181	534,585
Accumulated deficit	(553,818)	(527,765)
Accumulated other comprehensive loss	(83)	(85)
Total stockholders' (deficit) equity	(16,667)	6,788
Total liabilities and stockholders' (deficit) equity	$ 157,946	$ 188,813

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Operations
For the Three Months Ended March 31, 2021 and 2020
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Net product revenues	$ 10,960	$ 7,062
Licensing revenues	1,000	—
Total revenues	11,960	7,062
Costs and expenses:		
Cost of product sales	1,740	1,356
Research and development	5,225	4,932
Selling, general and administrative	27,184	27,060
Total operating expenses	34,149	33,348
Loss from operations	(22,189)	(26,286)
Other (income) expense:		
Interest income	(20)	(332)
Interest expense	3,876	2,863
Foreign currency losses	8	39
Net loss	$ (26,053)	$ (28,856)
Net loss per share of common stock, basic and diluted	$ (0.49)	$ (0.63)
Weighted average common shares outstanding, basic and diluted	52,997,730	45,906,162

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Comprehensive Loss
For the Three Months Ended March 31, 2021 and 2020
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Net loss	$ (26,053)	$ (28,856)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	2	(25)
Comprehensive loss	$ (26,051)	$ (28,881)

See accompanying notes to unaudited interim consolidated financial statements

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

Three Months Ended March 31, 2021

	Stockholders' (Deficit) Equity					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance at December 31, 2020	52,945,865	$ 53	$ 534,585	$ (527,765)	$ (85)	$ 6,788
Stock compensation expense	—	—	2,596	—	—	2,596
Vesting of restricted stock units	166,709	—				—
Foreign currency translation adjustment	—	—	—	—	2	2
Net loss	—	—	—	(26,053)	—	(26,053)
Balance at March 31, 2021	53,112,574	$ 53	$ 537,181	$ (553,818)	$ (83)	$ (16,667)

Three Months Ended March 31, 2020

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

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2021 and 2020
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Operating activities:		
Net loss	$ (26,053)	$ (28,856)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	165	309
Stock-based compensation	2,610	2,460
Amortization of debt discount and issuance costs	382	268
Changes in operating assets and liabilities:		
Accounts receivable	5,435	1,910
Prepaid expenses and other assets	894	425
Inventory	(3,634)	(2,225)
Accounts payable	2,587	2,131
Accrued expenses and other liabilities	(10,410)	(4,390)
Cash used in operating activities	(28,024)	(27,968)
Investing activities:		
Purchases of property and equipment	(91)	(70)
Cash used in investing activities	(91)	(70)
Financing activities:		
Proceeds from long-term debt	—	30,000
Cash paid for financing costs	(71)	(622)
Cash (used in) provided by financing activities	(71)	29,378
Effects of exchange rate changes on cash and cash equivalents	—	(5)
Net (decrease) increase in cash, cash equivalents and restricted cash	(28,186)	1,335
Cash, cash equivalents and restricted cash at beginning of period	144,179	147,165
Cash, cash equivalents and restricted cash at end of period	$ 115,993	$ 148,500
Supplemental disclosure of noncash activities:		
Fixed asset purchases within accounts payable and accrued expenses	$ 19	$ 218
Recognition of right-of-use assets	$ 133	$ 405
Recognition of lease liabilities	$ 133	$ 405

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, and Oslo, Norway. The Company's predecessor entity, OptiNose AS, was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became a wholly-owned subsidiary of the Company as part of an internal reorganization.

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

2. Liquidity

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio, conducting preclinical studies and clinical trials, pursuing regulatory approvals and most recently, commercializing XHANCE in the US. As of March 31, 2021, the Company had cash and cash equivalents of $115,984.

The Company will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet its debt service obligations, including repayment, under the Company's outstanding senior secured notes, and to carry out the Company's planned development and commercial activities. The terms of the outstanding Pharmakon Senior Secured Notes, including applicable covenants, are described in Note 8. If additional capital is not secured when required, the Company may need to delay or curtail its operations until additional funding is received.

The Company is subject to a number of risks similar to other life sciences companies, including, but not limited to, successful discovery, development and commercialization of its products and product candidates, raising additional capital, the development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products.

3. Basis of Presentation and Summary of Significant Accounting Policies

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

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2021 and its results of operations for the three months ended March 31, 2021 and 2020 and cash flows for the three months ended March 31, 2021 and 2020. Operating results for the three months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2020 contained in the Company’s annual report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 3, 2021.

Use of estimates

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

Concentration of credit risk

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

Customer and supplier concentration

XHANCE is sold to wholesale pharmaceutical distributors and Preferred Pharmacy Network (PPN) partners, who, in turn, sell XHANCE to pharmacies, hospitals and other customers, including patients. Five customers represent approximately 44% of the Company's accounts receivable at March 31, 2021 and five customers represent approximately 36% of the Company's net product sales for the three months ended March 31, 2021.

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

Fair value of financial instruments

At March 31, 2021 and December 31, 2020, the Company's financial instruments included cash and cash equivalents, accounts receivable, grants receivable, accounts payable and accrued expenses. The carrying amounts reported in the Company's financial statements for these instruments approximate their respective fair values because of the short-term nature of these instruments. In addition, at March 31, 2021, the Company believes the carrying value of long-term debt approximates fair value as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions. At March 31, 2021 and December 31, 2020, there were no financial assets or liabilities measured at fair value on a recurring basis.

Restricted cash

As of March 31, 2021 and December 31, 2020, the restricted cash balance included in prepaid expenses and other assets was $9 and $23, respectively.

Net product revenues

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

Provider Chargebacks and Discounts. Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Trade Discounts and Allowances. The Company generally provides customers with discounts that include incentive fees which are explicitly stated in the Company's contracts. These discounts are recorded as a reduction of revenue and accounts receivable in the period in which the related product revenue is recognized.

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

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

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

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

Licensing revenues

The Company has license agreements with Inexia Limited (Inexia) and Currax Pharmaceuticals LLC (Currax). These license agreements provide for exclusive licensed rights to certain intellectual property, a non-refundable up-front payment, potential milestone payment(s) and potential royalty payment(s). The Company analyzed the performance obligations under the license agreements, the consideration received to date and the consideration the Company could receive in the future as part of its analysis related to ASC 606. The Company recognized $1,000 as licensing revenue from Currax during the three months ended March 31, 2021 and is not eligible to receive any further payments under the license agreement other than reimbursement for certain expenses.

(in thousands, except share and per share data)

Net income (loss) per common share

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to Company common stock (Common Stock) holders by the weighted average common shares outstanding during the period. For the three months ended March 31, 2021 and 2020, the outstanding Common Stock options, restricted stock units, 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:

	March 31,	
	2021	2020
Stock options	8,296,492	8,373,040
Restricted stock units	2,282,204	1,287,986
Common stock warrants	810,357	2,677,188
Employee stock purchase plan	114,463	43,900
Total	11,503,516	12,382,114

Income taxes

In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three months ended March 31, 2021 and 2020, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of March 31, 2021 and December 31, 2020, the Company has concluded that a full valuation allowance is necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

Recent accounting pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*. ASU 2019-12 eliminated certain exceptions and changed guidance on other matters. The exceptions relate to the allocation of income taxes in separate company financial statements, tax accounting for equity method investments and accounting for income taxes when the interim period year-to-date loss exceeds the anticipated full year loss. Changes relate to the accounting for franchise taxes that are income-based and non-income-based, determining if a step up in tax basis is part of a business combination or if it is a separate transaction, when enacted tax law changes should be included in the annual effective tax rate computation, and the allocation of taxes in separate company financial statements to a legal entity that is not subject to income tax. The Company has adopted ASU 2019-12 in the first quarter of 2021, and there was no significant impact.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU 2016-03, in conjunction with ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments,* introduces an approach, based on expected losses, to estimate credit losses on certain types of financial instruments and modifies the impairment model for available-for-sale debt securities. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2022 for companies deemed to be smaller reporting companies as of November 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact of the adoption of this standard on its results of operations, financial position and cash flows and related disclosures.

(in thousands, except share and per share data)

4. Inventory

Inventory consisted of the following:

	March 31, 2021	December 31, 2020
Raw materials	3,643	$ 2,669
Work-in-process	3,216	$ 2,676
Finished goods	5,844	3,697
Total inventory	$ 12,703	$ 9,042

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

5. Property and Equipment

Property and equipment, net, consisted of the following:

	March 31, 2021	December 31, 2020
Computer equipment and software	$ 1,143	$ 1,128
Furniture and fixtures	366	366
Machinery and equipment	3,443	3,440
Leasehold improvements	609	609
Construction in process	314	271
	5,875	5,814
Less: accumulated depreciation	(3,990)	(3,786)
	$ 1,885	$ 2,028

Depreciation expense was $204 and $308 for the three months ended March 31, 2021 and 2020, respectively. In addition, depreciation expense of $500 and $4 was charged to inventory and prepaid expenses and other assets, respectively, as of March 31, 2021, which represents depreciation expense related to equipment involved in the manufacturing process.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	March 31, 2021	December 31, 2020
Accrued expenses:		
Selling, general and administrative expenses	$ 7,659	$ 7,385
Research and development expenses	3,448	5,202
Payroll expenses	4,079	9,063
Product revenue allowances	16,167	20,917
Other	3,324	2,008
Total accrued expenses	34,677	44,575
Other current liabilities:		
Lease liability	2,131	2,108
Total other current liabilities	2,131	2,108
Total accrued expenses and other current liabilities	$ 36,808	$ 46,683

7. Licensing Revenue

Currax License Agreement

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

Under the terms of the Currax License Agreement, Currax paid the Company an upfront payment of $3,730, which was recognized as license revenue during the year ended December 31, 2019. On December 29, 2020, the Company received an additional $750 upon the expiration of the escrow that was established for a limited period to cover potential indemnification obligations. In addition, in January 2021 the Company received a $1,000 milestone payment in connection with the achievement of a specified regulatory milestone. The Company does not expect to receive any further payments from Currax under the terms of the License Agreement other than reimbursement for certain expenses.

8. Long-term Debt

On September 12, 2019 (the Closing Date), the Company entered into a Note Purchase Agreement (the Pharmakon Senior Secured Notes) with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit funds (BioPharma). The Pharmakon Senior Secured Notes provide the Company with up to $150,000 in debt financing, of which $80,000 was issued on the Closing Date, $30,000 was issued on February 13, 2020 (the First Delayed Draw Notes) after achieving the $9,000 XHANCE net sales and royalties threshold for the quarter ended December 31, 2019 and $20,000 was issued on December 1, 2020 after achieving the $14,500 XHANCE net sales and royalties threshold for the quarter ended September 30, 2020.

On August 13, 2020, the Company entered into a letter agreement (the Pharmakon Letter Agreement) to the Pharmakon Senior Secured Notes. The Pharmakon Letter Agreement provides the Company with the option to issue an additional $20,000 of Pharmakon Senior Secured Notes, subject to the Company achieving XHANCE net sales and royalties for the quarter ended June 30, 2021 of at least $26,000 and certain other conditions. As consideration for the Pharmakon Letter Agreement, the Company issued 44,643 shares of Common Stock to Pharmakon. The aggregate fair value of $250 was recorded as debt issuance costs and is being amortized to interest expense over the term of the Pharmakon Senior Secured Notes.

On March 2, 2021, the Company entered into an amendment to the Pharmakon Senior Secured Notes. The amendment revised certain minimum trailing twelve-month consolidated XHANCE net sales and royalties the Company is required to achieve. As consideration for the amendment, the Company will pay an amendment fee of $1,300 upon the earlier of the prepayment of the Pharmakon Senior Secured Notes or the Maturity Date. The amendment fee was recorded as debt issuance costs and is being amortized to interest expense over the term of the Pharmakon Senior Secured Notes.

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

In conjunction with the Pharmakon Senior Secured Notes, the Company paid an upfront fee of $1,125 on the Closing Date and issued warrants to purchase an aggregate of 810,357 shares of Common Stock at an exercise price equal to $6.72 per share, which expire on September 12, 2022. The upfront fees were recorded as a debt discount at issuance and are being amortized to interest expense over the five year term of the loan. The Company also incurred $6,490 in debt issuance costs, including $2,404 related to the fair value of the warrants, which are also being amortized to interest expense over the term of the Pharmakon Senior Secured Notes.

(in thousands, except share and per share data)

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

The Pharmakon Senior Secured Notes are secured by a pledge of substantially all of the Company's assets and contains affirmative and negative covenants customary for financings of this type, including limitations on the Company's and its subsidiaries' ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, grant certain licenses related to the Company's products, technology and other intellectual property, pay dividends and distributions, repay junior indebtedness and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the Pharmakon Senior Secured Notes contain financial covenants requiring the Company to maintain at all times at least $30,000 of cash and cash equivalents and achieve certain minimum trailing twelve-month consolidated XHANCE net sales and royalties, tested on a quarterly basis. As of March 31, 2021, the Company was in compliance with the covenants.

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

The Company recorded interest expense of $3,876 and $2,863 during the three months ended March 31, 2021 and 2020, respectively. Interest expense included total coupon interest, and the amortization of back end fees, front end fees and the amortization of debt issuance costs.

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

	March 31, 2021	December 31, 2020
Face amount	$ 130,000	$ 130,000
Front end fees	(844)	(855)
Debt issuance costs	(4,872)	(3,943)
Back end fees	$ 1,300	$ —
Long-term debt, net	$ 125,584	$ 125,202

9. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of March 31, 2021, approximately $81 is recorded in accrued liabilities related to the Company match. The Company's contributions are made in cash.

For Norway employees, the Company maintains defined contribution pension plans which meet the statutory requirements of that jurisdiction. The Company maintained a defined contribution pension plan for former UK employees through August 5, 2020. The Company incurred costs related to the pension plans of $2 and $5 for the three months ended March 31, 2021 and 2020, respectively.

(in thousands, except share and per share data)

10. Stockholders' Equity

As of March 31, 2021, the Company had the following warrants outstanding to purchase shares of Common Stock:

Number of Shares	Exercise Price Per Share	Expiration Date
810,357	$ 6.72	September 12, 2022

11. Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and shares issued under the Company's 2017 Employee Stock Purchase Plan (2017 Plan) in the following expense categories of its accompanying consolidated statements of operations for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
Cost of product sales	$ 12	$ 54
Research and development	281	257
General and administrative	2,317	2,149
	$ 2,610	$ 2,460

In addition, stock-based compensation expense of $95 and $1 was charged to inventory and prepaid expenses and other assets, respectively, during the three months ended March 31, 2021, 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 issues stock-based awards pursuant to its 2010 Stock Incentive Plan. Effective as of October 12, 2017, the Company's 2010 Stock Incentive Plan was amended and restated (A&R Plan).The Company has issued service-based and performance-based stock options that generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the Company's board of directors or committee thereof. Vesting generally occurs over a period of not greater than four years. Performance-based options may vest upon the achievement of certain milestones in connection with the Company's development programs. Additionally, the Company has issued stock options in excess of the fair market value of Common Stock on the issuance date that were only exercisable upon a change in control or upon or after an initial public offering. As of March 31, 2021, all of the performance conditions related to performance-based stock options issued by the Company have been achieved.

(in thousands, except share and per share data)

The following table summarizes the activity related to stock option grants to employees and nonemployees for the three months ended March 31, 2021:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2020	6,852,733	$ 10.34	6.84
Granted	1,458,501	3.52	
Exercised	—	—	
Expired	—	—	
Forfeited	(14,742)	11.07	
Outstanding at March 31, 2021	8,296,492	$ 9.14	7.18
Exercisable at March 31, 2021	4,819,267	$ 11.33	5.88
Vested and expected to vest at March 31, 2021	8,296,492	$ 9.14	7.18

During the three months ended March 31, 2021, stock options to purchase 1,458,501 shares of Common Stock were granted to employees and generally vest over four years. The stock options had an estimated weighted average grant date fair value of 2.29. During the three months ended March 31, 2020, stock options to purchase 1,146,258 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 3.44.

Included in the table above are 140,000 of options granted outside the A&R Plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

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

	Three Months Ended March 31,	
	2021	2020
Risk free interest rate	1.00 %	0.75 %
Expected term (in years)	6.08	6.08
Expected volatility	74.37 %	68.34 %
Annual dividend yield	0.00 %	0.00 %
Fair value of common stock	$ 3.52	$ 5.65

At March 31, 2021, the unrecognized compensation cost related to unvested stock options expected to vest was $13,026. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.39 years.

Restricted Stock Units

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

The following table summarizes the activity related to RSUs granted to employees for the three months ended March 31, 2021:

(in thousands, except share and per share data)

	Shares
Balance at December 31, 2020	1,491,589
Granted	957,990
Vested and settled	(166,709)
Expired/ forfeited/ canceled	(666)
Balance at March 31, 2021	2,282,204
Expected to vest at March 31, 2021	2,282,204

In March 2020, the Company granted 957,990 RSUs at a grant date fair value of $3.51, all of which were service-based RSUs . No performance based-RSUs were granted in 2021. As of March 31, 2021, the milestones associated with the performance based-RSUs are not probable of achievement, and accordingly, no stock based compensation expense has been recognized to date for these awards. At March 31, 2021, the unrecognized compensation cost related to unvested service-based RSUs expected to vest was $6,796, to be recognized over an estimated weighted-average amortization period of 2.39 years. The unrecognized compensation cost related to unvested performance-based RSUs was $3,095, which will be recognized commencing in the period in which the performance condition is deemed probable of achievement over the remaining service period.

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

2017 Employee Stock Purchase Plan

Under the 2017 Plan, shares of Common Stock may be purchased by eligible employees who elect to participate in the 2017 Plan at 85% of the lower of the fair market value of Common Stock on the first or last day of designated offering periods. The Company recognized stock-based compensation expense of $108 and $150 during the three months ended March 31, 2021 and 2020, respectively, related to the 2017 Plan.

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

	Three Months Ended March 31,	
	2021	2020
Risk free interest rate	0.09 %	1.57 %
Expected term (in years)	0.5	0.5
Expected volatility	86.88 %	79.59 %
Annual dividend yield	0.00 %	0.00 %

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

You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I. Item 1 of this Form 10-Q and our audited consolidated financial statements and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission (SEC) on March 3, 2021. In addition to historical information, some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results could differ materially from the results described in or implied by such forward-looking statements. Please refer to the "Note Regarding Forward-Looking Statements" section of this Form 10-Q for additional information.

Company Overview

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. Our first commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 micrograms (mcg), is a therapeutic utilizing our proprietary Exhalation Delivery System (EDS) 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.

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

Business Updates in Response to the COVID-19 Pandemic

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

- In mid-March 2020, we transitioned to a full-time, virtual work environment in which all employees, including sales representatives (whom we refer to as territory managers), were encouraged to work from their place of residence. Our decision was based on actions taken by federal, state and local governments to contain the spread of severe acute respiratory coronavirus 2 (SARS-CoV-2) and the related Coronavirus Disease 2019 (COVID-19), as well as the impact of “social distancing” efforts and various mitigation actions implemented by healthcare practices across the United States. Shortly after our transition to a full-time, virtual work environment, our territory managers began virtual details of XHANCE to target audience physicians.
- We have been monitoring, and will continue to monitor, federal, state, and local government requirements and guidances. In certain instances, the various mitigation efforts have been updated to facilitate a return to a working environment with fewer restrictions. Where permitted by governmental requirements and the policies of physician offices, our territory managers began to return to in-person detailing of physicians in May and June 2020. Given the localized nature of the restrictions that are in place and the potential for restrictions to return, we have equipped our territory managers to operate in an environment that will include a mix of virtual and in-person physician detailing with dependencies on geography and time.
- Federal, state and local government requirements and guidances have impacted virtually all of the physicians' offices in which our territory managers detail XHANCE. These impacts include reduced patient visits, temporary halt of territory managers' visits, restrictions imposed on territory managers' visits and temporary closings of physicians' offices.
- Late in the first quarter of 2020 we began to observe an adverse impact of the COVID-19 pandemic on XHANCE prescription growth. Although XHANCE prescription growth (and in particular, new prescription growth) continues to be adversely impacted by the COVID-19 pandemic, the magnitude of the impact has slowly improved as federal, state and local government requirements and guidances have been updated to facilitate economic reopening. Based on third-party prescription data as well as data from Preferred Pharmacy Network (PPN) partners, XHANCE prescriptions increased 11% from first quarter 2020 to second

quarter 2020, increased 11% from second quarter 2020 to third quarter 2020, increased 7% from third quarter 2020 to fourth quarter 2020, and decreased 2% from fourth quarter 2020 to first quarter 2021. Although XHANCE prescriptions have grown during this COVID-19 period, the rate of growth was below our pre-pandemic expectations. Additionally, the duration and magnitude of the negative impact from the COVID-19 pandemic on XHANCE net revenue are uncertain and may affect the availability of additional capital under our Pharmakon Note Purchase Agreement and our ability to remain in compliance with our revenue covenants thereunder.

- Due to the impacts of the COVID-19 pandemic, one of our contract manufacturers implemented a reduced work schedule and additional precautions which resulted in delays relating to the manufacture of XHANCE in second quarter 2020 but did not result in an interruption to commercial or clinical supply. We believe we are maintaining appropriate levels of finished product inventories in the event of future supply disruption; however, the duration and magnitude of a future negative impact from the COVID-19 pandemic could constrain our supply of XHANCE.
- Previous guidance related to the expected timing of results from our two ongoing chronic sinusitis clinical trials indicated that top-line results from both trials would be available in the second half of 2021. Pauses in patient enrollment due to factors related to the COVID-19 pandemic have had, and may continue to have, varying effects in different geographies and over time have led to a change in our projected timeline for initial data availability and may lead to additional changes in the future. We now expect to complete enrollment in the first of our ongoing chronic sinusitis trials in third quarter 2021 with top-line results available in first quarter 2022 and top-line results from the other trial in the first half of 2022. For those subjects currently participating in these studies, procedures to facilitate ongoing treatment and capture of data during periods of in-person care restrictions have been put in place.

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

Additional Business Updates

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

- XHANCE Prescriptions and Market Share. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE prescriptions in the first quarter of 2021 was 72,600, which represents 30% growth for prescriptions when compared to estimated first quarter 2020 prescriptions of 56,100. The INS prescription market decreased approximately 23% from first quarter 2020 to first quarter 2021 based on third-party prescription data. In addition, the total estimated number of XHANCE prescriptions was 62,500 in the second quarter of 2020, 69,000 in the third quarter of 2020, and 73,900 in the fourth quarter of 2020.

  A seasonal effect has historically been observed in the INS prescription market in which market volume generally peaks near the middle of the second quarter and declines into the early part of the third quarter of each calendar year. As a result of the COVID-19 pandemic, INS prescription market volumes did not experience the expected peak in the second quarter of 2020. Based on third-party prescription data, INS market prescriptions increased 7% from the fourth quarter of 2019 to the first quarter of 2020, decreased 16% from the first quarter of 2020 to the second quarter of 2020, decreased 6% from the second quarter of 2020 to the third quarter of 2020, increased 3% from the third quarter of 2020 to the fourth quarter of 2020 and decreased 4% from fourth quarter 2020 to the first quarter of 2021.

  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 physician specialists, and seasonality in disease flare-ups, has an impact on the number of patients that present themselves and who are therefore available to receive a new prescription for XHANCE. Demand has historically been, and we expect will continue to be, impacted by the INS market seasonality and the seasonal variation in patient visits with their doctor resulting in reduced XHANCE prescription demand in the third quarter.

Additionally, we believe that first quarter prescription demand and average net revenue per prescription for XHANCE is adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January

We track the market share of XHANCE within our current target audience. For this purpose, we calculate market share as the proportion of XHANCE prescriptions to the number of prescriptions written for other INS within our current target audience of approximately 18,000 physicians. Our target physician audience includes all ENT and Allergy specialist physicians who, based on third-party data, write intranasal steroid spray prescriptions. In addition, our current target audience includes specialty-like primary care physicians called on by our territory managers or kaléo sales representatives. Prior to the fourth quarter 2020 initiation of XHANCE co-promotion by kaléo, our target audience included approximately 10,000 physicians called on by Optinose sales territory managers.

We believe market share, in addition to XHANCE prescription volume, provides important information regarding XHANCE utilization because market share normalizes XHANCE prescriptions for market effects including the INS market seasonality, seasonal variation in patient visits with their doctor, annual deductible resets and annual changes in individual patient's healthcare insurance coverage referenced above. Based on third-party prescription data as well as data from PPN partners, we estimate XHANCE had a market share in our current target audience of 18,000 physicians of 3.4% in the first quarter of 2020, 4.4% in the second quarter of 2020, 4.9% in the third quarter of 2020, 5.1% in the fourth quarter of 2020 and 5.4% in the first quarter of 2021. 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. Our target physician audience is subject to revision each quarter to account for changes such as revised sales target prioritization, and physician retirements. Changes to the target physician audience can contribute to some of the quarter over quarter change in market share.

- XHANCE New Prescriptions and Refill Prescriptions. The underlying disease that we are treating is chronic and, as a result, many patients may fill multiple prescriptions per year. We monitor new prescriptions as they create the potential for future refill prescriptions. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE new prescriptions in the first quarter of 2021 was 25,900, which represents 16% growth for new prescriptions when compared to estimated first quarter 2020 new prescriptions of 22,300. The INS market for new prescriptions decreased approximately 30% from first quarter 2020 to first quarter 2021 based on third-party prescription data. In addition, the total estimated number of XHANCE new prescriptions was 18,700 in second quarter 2020, 23,000 in the third quarter of 2020, and 24,600 in the fourth quarter of 2020.

  We track refill prescriptions and provide patient assistance to support refill programs that are administered by our PPN partners. Based on third-party prescription data as well as data from PPN partners, the total estimated number of XHANCE refill prescriptions in the first quarter of 2021 was 46,700, which represents 38% growth for refill prescriptions when compared to estimated first quarter 2020 refill prescriptions of 33,700. In addition, the total estimated number of XHANCE refill prescriptions was 43,800 in second quarter 2020, 46,100 in the third quarter of 2020, and 49,300 in the fourth quarter of 2020.

- Prescribing Breadth and Depth. We track the number of physicians who prescribe XHANCE in a time period to evaluate the breadth of prescribing. Based on third-party prescription data as well as data from PPN partners, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE in the first quarter of 2021 was 6,920, which represents 9% growth when compared to the estimated 6,345 physicians who had at least one patient fill a prescription for XHANCE in the first quarter of 2020. In addition, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE was 6,209 in the second quarter of 2020, 6,443 in the third quarter of 2020, and 6,708 in the fourth quarter of 2020.

  We also track the number of prescriptions filled by a prescribing physician's patients in a time period to evaluate depth of prescribing. Based on third-party prescription data as well as data from PPN partners, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients in the first quarter of 2021 was 1,285, which represents 44% growth when compared to the estimated 895 physicians who had more than 15 XHANCE prescriptions filled by their patients in the first quarter of 2020. In addition, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients was 1,028 in the second quarter of 2020, 1,153 in the third quarter of 2020, and 1,275 in the fourth quarter of 2020.

- XHANCE Net Product Revenues per Prescription. We calculate average net product revenues per prescription, one metric that we use to gauge the profitability of XHANCE, by dividing net product revenues for the quarter by the estimated number of XHANCE prescriptions dispensed during the quarter. Average XHANCE net product revenues per prescription were $151 in the first quarter of 2021 which represents an approximately 20% increase when compared to the $126 of average XHANCE net product revenues per prescription in the first quarter of 2020. In addition, average XHANCE net product revenues per prescription were $164 in the second quarter of 2020, $224 in the third quarter of 2020, and $211 in the fourth quarter of 2020.

Sales, Marketing & Distribution

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

Customer Model. We have a sales force of approximately 100 territory managers who target over 10,000 ENTs, allergists and “specialty-like” primary care physicians, and we target additional physicians through digital and non-personal promotion in areas where we do and do not have territory managers. In addition, we initiated a co-promotion agreement with kaléo in October 2020 to promote XHANCE to an audience of up to 6,000 prescribers, about half of whom are outside of our current called-on universe. In the future we may increase the number of geographic territories as well as hire additional territory managers in order to increase the number of called-on target physicians and frequency of calls. Our sales team, and the sales team of our co-promotion partner, are equipped with educational materials demonstrating the benefit and safety profile XHANCE. We believe that in the long term, direct to consumer (DTC) advertising could be an effective way to increase XHANCE prescription growth.

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

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

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

XHANCE Development 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 trial program in pursuit of a follow-on indication for the treatment of chronic sinusitis. We believe XHANCE has the potential to be the first drug therapy approved by the FDA for the treatment

of chronic sinusitis. We expect the program will be comprised of two Phase 3b clinical trials, the first of which was initiated in the fourth quarter of 2018 and is estimated to enroll approximately 378 subjects and the second of which was initiated in the second quarter of 2019 and is estimated to enroll approximately 399 subjects. Estimated enrollment for both trials is subject to change for factors that may include interim analyses intended to inform the statistical powering of both trials.

In April 2021, we completed an interim analysis to assess the variance in one of the two co-primary endpoints in our first trial. The analysis was performed on blinded interim data on approximately half the number of patients we project to enroll in the trial for the change in Composite Score of Nasal Symptoms, our symptom endpoint, from baseline to week 4. The result of this interim analysis was that the observed variance was lower than the variance assumed when we estimated sample size/power during the design of the study. As a result, we have determined not to make any alteration in the sample size on the basis of this interim analysis. For clarity, this interim analysis was blinded to treatment group and therefore could not evaluate the magnitude of difference, if any, between treatment groups. Accordingly, this interim analysis was not designed to, and does not, provide evidence regarding possible superiority of active treatment over placebo with respect to this endpoint in the trial

We expect to complete enrollment in the first of our two ongoing Phase 3b chronic sinusitis trials in the third quarter of 2021 with top line results available in the first quarter of 2022 and the availability of top line results from the other trial in the first half of 2022.

OPN-019 Development Update

In June 2020, we announced the initiation of development of a new product candidate, OPN-019, which combines our proprietary intranasal Exhalation Delivery System (EDS) device with an antiseptic.

Because components of the drug-device combination product candidate, including both the active drug and delivery device, are currently commercially available in the U.S., we anticipate that the development of OPN-019 may be streamlined and accelerated. Subsequent to a pre-Investigational New Drug (IND) submission we have engaged with the FDA regarding an IND and clinical development pathway.

We have performed in vitro testing against SARS-CoV-2 with a candidate formulation in which a 4-log reduction (a 99.99% reduction) in virus count was produced. In addition, we performed tests against other pathogens. For most pathogens tested, 3-log to 6-log reductions (99.9% to 99.9999% reductions) in virus count were observed.

In March 2021, we announced our plan to conduct a randomized, proof of concept study in subjects who have tested positive for SARS-CoV-2 infection, are recently infected, and who have mild or no symptoms. This pilot study, which will be conducted in Mexico, will evaluate both the magnitude and duration of viral load reduction after a single dose of OPN-019. Regulatory approval to initiate the pilot study is pending. We expect top-line results from this study in second quarter 2021.

We are focused on supporting the initial stages of development within our current operating expense guidance and intend to seek grants, partnerships, and/or other sources of capital to fund future development.

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 $11.0 million and $7.1 million in net product revenues for the three months ended March 31, 2021 and 2020, respectively. In accordance with GAAP, we determine net product revenues for XHANCE, with specific assumptions for variable consideration components including but not limited to trade discounts and allowances, co-pay assistance programs and payor rebates.

Based on available XHANCE prescription data purchased from third parties and data from our PPN partners, who collectively dispensed more than 85% of our total prescriptions (TRxs) in the period, our average net product revenue per prescription for the first quarter of 2021 was approximately $151,which represented an increase compared to average net product revenues per prescription of $126 in first quarter of 2020 and a decrease compared to average net product revenues per prescription in of $211 in fourth of 2020.

The decrease in average net product revenue per prescription in the first quarter of 2021 from the fourth quarter 2020 is largely a consequence of the reset of many patient insurance deductibles in January. As a result of this annual reset, greater copay support was provided by us under our patient assistance programs in the first quarter of 2021 as compared to the fourth quarter of 2020. In addition, we believe another contributor to the first quarter 2021 decrease is related to changes in patients' healthcare insurance coverage that reduces demand for refill prescriptions early in the year. This reduction in refill prescriptions also has the effect of lowering average net product revenues per prescription as it reduces the proportion of prescriptions that are covered (reimbursed) by a commercial insurer, which results in us providing greater copay support under our assistance programs. XHANCE prescriptions and average net product revenues per prescription were similarly impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage in the first quarter of 2020 compared to the fourth quarter of 2019, and we expect to experience a similar impact in the first quarter of 2022.

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

We expect full year 2021 net product revenues to be at least $80.0 million. In addition, we expect average net product revenue per prescription for the full year of 2021 will increase compared to the full year 2020 result of $185. Factors supporting this expected growth include patients meeting their out-of-pocket expense thresholds, expected improvements in insurance coverage and continued strength in the proportion of prescription refills.

Licensing revenues

In September 2019, OptiNose AS, a wholly owned subsidiary of the Company, entered into the Currax License Agreement. Under the terms of the Currax License Agreement, Currax paid us a $3.7 million upfront payment in 2019, an additional $0.8 million in December 2020 upon expiration of the escrow that was established for a limited period to cover potential indemnification obligations, and an additional $1.0 million milestone payment in January 2021 upon the achievement of a specified regulatory milestone. We are not eligible to receive any further payments from Currax under the terms of the License Agreement other than reimbursement for certain expenses.

Costs of product sales

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

Research and development expense

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

- personnel expenses, including salaries, benefits and stock-based compensation expense;
- costs of funding clinical development performed by third parties, including pursuant to agreements with contract research organizations (CROs), as well as investigative sites and consultants that conduct or support our nonclinical studies and clinical trials;
- expenses associated with the continued development of our EDS devices;
- expenses incurred under agreements with contract manufacturing organizations (CMOs), including manufacturing scale-up expenses prior to regulatory approval of products for commercial sale and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- consultant fees and expenses associated with outsourced professional scientific development services;

- expenses for regulatory activities, including filing fees paid to regulatory agencies and costs incurred to compile and respond to filings with the FDA prior to regulatory approval of products for commercial sale;
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

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

We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of XHANCE for the treatment of chronic sinusitis and our other product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development, compounded by the uncertainty introduced by the COVID-19 pandemic, the rate of subject enrollment, number of subjects required, and trial duration and outcome, we are unable to estimate with reasonable certainty the costs we will incur and the timelines we will require in our continued development efforts.

Selling, general and administrative expense

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

Sales and marketing expenses include our sales team and supporting promotional materials, digital promotion, peer-to-peer education, congresses / conventions, samples, and marketing activities such as direct-to-patient / direct-to-consumer initiatives and fees related to our co-promotion agreement with kaléo. Additionally, sales and marketing-related expenses include fees paid to our PPN partners for services unrelated to traditional distribution functions, such as data fees, benefit claims adjudication and other enhanced services performed as part of our PPN.

Interest (income) expense

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

Other (income) expense

Other (income) expense consists primarily of foreign currency (income) losses due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

Consolidated Results of Operations

Comparison of three months ended March 31, 2021 and 2020

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

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Net product revenues	$ 10,960	$ 7,062
Licensing revenues	1,000	—
Total revenues	11,960	7,062
Costs and expenses:		
Cost of product sales	1,740	1,356
Research and development	5,225	4,932
Selling, general and administrative	27,184	27,060
Total operating expenses	34,149	33,348
Loss from operations	(22,189)	(26,286)
Other (income) expense:		
Interest (income) expense	3,856	2,531
Other (income) expense	8	39
Total other (income) expense	3,864	2,570
Net loss	$ (26,053)	$ (28,856)

Net product revenues

Net product revenues related to sales of XHANCE were $11.0 million and $7.1 million for the three months ended March 31, 2021 and 2020, respectively. Revenue growth is attributable primarily to an increase in units sold to customers, as a result of a greater number of XHANCE prescriptions dispensed during the three months ended March 31, 2021 as well as increased net product revenue on a per unit basis.

Cost of product sales

Cost of product sales related to XHANCE were $1.7 million and $1.4 million for the three months ended March 31, 2021 and 2020, respectively, with the increase primarily attributed to an increase in the number of units sold to customers during the period.

Research and development expense

Research and development expense was $5.2 million and $4.9 million for the three months ended March 31, 2021 and 2020, respectively. The $0.3 million increase was attributable primarily to an increase in clinical expenses related to the conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis.

Selling, general and administrative expense

Selling, general and administrative expense was $27.2 million and $27.1 million for the three months ended March 31, 2021 and 2020, respectively. The $0.1 million increase was due primarily to:

- a $0.6 million increase in service fees paid to our PPN partners, the result of a greater number of XHANCE prescriptions dispensed by our PPN partners during the period; and
- a $0.6 million increase in fees related to our co-promotion agreement with kaléo.

This increase was offset by:

- a $0.7 million decrease related to delayed expenses and/or expenses not incurred as a result of the impact of COVID-19 on business operations, including marketing and selling efforts, including travel; and
- a $0.5 million decrease in direct-to-consumer marketing, market access and medical education expenses.

Interest (income) expense, net

Interest (income) expense, net, was $3.9 million and $2.5 million for the three months ended March 31, 2021 and 2020, respectively, which was primarily comprised of interest expense on the Pharmakon Senior Secured Notes. The increase was related to the increased principal balance of our long-term debt.

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 $26.1 million and $28.9 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $553.8 million. We have funded our operations primarily through the sale and issuance of stock and debt, as well as through licensing revenues. As of March 31, 2021, we had $116.0 million in cash and cash equivalents.

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

	Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	$ (28,024)	$ (27,968)
Net cash used in investing activities	(91)	(70)
Net cash (used in) provided by financing activities	(71)	29,378
Effects of exchange rates on cash and cash equivalents	—	(5)
Net (decrease) increase in cash and cash equivalents	$ (28,186)	$ 1,335

Operating activities

Cash used in operating activities was $28.0 million for both of the three month periods ended March 31, 2021 and March 31, 2020.

Investing activities

Cash used in investing activities was $0.1 million for both of the three month periods ended March 31, 2021 and March 31, 2020. Cash used in investing activities is related to purchases of manufacturing equipment in each period.

Financing activities

Cash used in financing activities was $0.1 million for the three months ended March 31, 2021. Cash provided by financing activities was $29.4 million for the three months ended March 31, 2020. Cash provided by financing activities for the three months ended March 31, 2020 was primarily driven by the receipt of $30.0 million from the issuance of the First Delayed Draw Notes under the Pharmakon Senior Secured Notes offset by additional debt issuance costs of $0.2 million.

Senior Secured Note Purchase Agreement

On September 12, 2019 (the Closing Date), we entered into the Note Purchase Agreement (the Pharmakon Senior Secured Notes) with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit funds (BioPharma). The Pharmakon Senior Secured Notes provide us with up to $150.0 million in debt financing, of which $80.0 million was issued on the Closing Date, $30.0 million was issued on February 13, 2020 and $20.0 million was issued on December 1, 2020.

On August 13, 2020, we entered into a letter agreement (the Pharmakon Letter Agreement) to the Pharmakon Senior Secured Notes. The Pharmakon Letter Agreement provides us with the option to issue $20.0 million of Pharmakon Senior Secured Notes, subject to the Company achieving XHANCE net sales and royalties for the quarter ended June 30, 2021 of at least $26.0 million and certain other conditions. As consideration for the Pharmakon Letter Agreement, the Company issued 44,643 shares of Common Stock to Pharmakon. The aggregate fair value of $250,000 was recorded as debt issuance costs and is being amortized to interest expense over the term of the Pharmakon Senior Secured Notes.

On March 2, 2021, we entered into an amendment to the Pharmakon Senior Secured Notes. The amendment revised certain minimum trailing twelve-month consolidated XHANCE net sales and royalties we are required to maintain. As consideration for the amendment, we will pay an amendment fee of $1,300 upon the earlier of the prepayment of the Pharmakon Senior Secured Notes or September 12, 2024.

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

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

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

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

Projected 2021 operating expenses

We expect that our total GAAP operating expenses (consisting of selling, general & administrative expenses and research & development expenses) for 2021 will be between $137.0 million and $142.0 million of which approximately $10.0 million is expected to be stock-based compensation expense. As a result, total GAAP operating expenses excluding stock-based compensation expense are expected to be between $127.0 million and $132.0 million. An increase in expenses from 2020 to 2021 is anticipated due to an increase in fees paid to our PPN partners associated with higher projected XHANCE prescription volumes and an increase in research and development expenses related to our clinical trial program in pursuit of a follow-on indication for XHANCE for the treatment of chronic sinusitis.

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, including the kaléo co-promotion, to support the commercialization of XHANCE;
- continue to provide co-pay and other patient affordability programs;
- continue clinical development activities for XHANCE, including an FDA-mandated post-marketing pediatric study and clinical trials for a follow-on indication for the treatment of chronic sinusitis;
- continue research and development activities for additional product candidates, including OPN-019;
- continue to contract to manufacture XHANCE and our other product candidates;
- maintain, expand and protect our patent portfolio;

- service our debt obligations under the Pharmakon Senior Secured Notes issued in September 2019, February 2020 and December 2020;
- maintain infrastructure necessary to operate as a publicly-traded, FDA-regulated commercial-stage company; and
- hire additional staff and add operational, financial and information systems to execute our business plan.

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

- duration and impact of COVID-19 pandemic on our business;
- the success of our commercialization of XHANCE for the treatment of nasal polyps including, among other things, patient and physician acceptance of XHANCE and our ability to maintain adequate insurance coverage and reimbursement for XHANCE;
- the cost of commercialization activities for XHANCE, including product manufacturing, distribution, marketing and sales;
- net product revenues received from sales of XHANCE;
- the costs and timing of expanding our sales force;
- the level of co-pay assistance and other patient affordability programs offered for XHANCE;
- our clinical development plans for XHANCE, including the outcome, timing and cost of an FDA-mandated post-marketing pediatric study and clinical trials for the supplemental indication for the treatment of chronic sinusitis;
- the outcome, timing and cost of the regulatory approval process of XHANCE for chronic sinusitis by the FDA, including the potential for the FDA to require that we perform more studies and clinical trials than those that we currently expect;
- the costs involved in preparing, filing and prosecuting patent applications and annuity fees relating to issued patents;
- the cost of maintaining and enforcing our intellectual property rights, as well as the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the initiation, progress, timing, costs and results of clinical trials and other research and development related to additional product candidates, including OPN-019; and
- the extent to which we in-license, acquire or otherwise partner in development or commercialization of other products, product candidates or technologies.

Although it is difficult to predict our future liquidity requirements, we will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet the debt service obligations under our outstanding Pharmakon Senior Secured Notes, including repayment, and to carry out our planned development and commercial activities. We believe that our existing cash and cash equivalents will be sufficient to maintain the minimum cash balance required under our debt facility and to fund our operations for at least twelve months from the filing date of this Quarterly Report on Form 10-Q. 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 fail to satisfy our debt covenants, may never become profitable, or if we do, may not be able to sustain profitability on a recurring basis.

Off-balance sheet arrangements

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

Contractual obligations and commitments

The following table summarizes our contractual obligations at March 31, 2021:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(in thousands)		
Operating leases[1]	$ 3,775	$ 1,617	$ 1,990	$ 168	$ —
Long-term debt[2]	168,537	14,169	119,234	35,134	—
Total	$ 172,312	$ 15,786	$ 121,224	$ 35,302	$ —

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

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

We are also party to a manufacturing services agreement with one of our suppliers pursuant to which we are obligated to purchase a minimum number of products per month or potentially be subject to a payment of $5,000 per week for any month in which we do not purchase such minimum number of products.

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, 2020, as filed with the SEC on March 3, 2021, have not materially changed.

Recent accounting pronouncements

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

JOBS Act

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

ITEM 3. QUALITATIVE AND QUANTITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

Our Chief Executive Officer and our Chief Financial Officer evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a 15(e) and 15d 15(e) under the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2021 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	*†	Renewal and Amendment No. 1, dated February 22, 2021 to Manufacture and Supply Agreement, dated as of August 18, 2017, by and among OptiNose US, Inc., OptiNose UK Ltd. and OptiNose AS and Contract Pharmaceuticals Limited Canada.
10.2		First Amendment, dated March 2, 2021, to the Note Purchase Agreement, dated September 12, 2019, among OptiNose US, Inc., OptiNose, Inc., OptiNose UK Limited and OptiNose AS, BioPharma Credit PLC, as collateral agent and the purchasers from time to time party thereto (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K (File No. 001-38241), as filed with the SEC on March 3, 2021).
31.1	*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
31.2	*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
32.1	*	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.
32.2	*	Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.
101.SCH	*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

† Portions of this exhibit (indicated by asterisks) have been omitted in compliance with Item 601 of Regulation S-K.

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: May 5, 2021

OPTINOSE, INC.

By: /s/ KEITH A. GOLDAN

Name: Keith A. Goldan

Title: *Chief Financial Officer*

(Principal Financial and Accounting Officer)

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

RENEWAL AND AMENDMENT NO. 1
TO MANUFACTURE AND SUPPLY AGREEMENT

This **RENEWAL AND AMENDMENT NO. 1 TO MANUFACTURE AND SUPPLY AGREEMENT** (this "**Amendment**") is entered into as of this 22nd day of February 2021 (the "**Execution Date**"), and is entered into by and among, on the one hand, OptiNose US, Inc., duly organized and existing under the laws of Delaware and having offices located at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067 (referred to herein as "**OptiNose US**"), OptiNose UK Ltd. duly organized and existing under the laws of England and having offices located at Hunts Rise, South Marston Park, Wiltshire, SN3 4TG, England (referred to herein as "**OptiNose UK**"), and OptiNose AS, duly organized and existing under the laws of Norway and having offices located at Gaustadalleen 21 0349 Oslo, Norway (referred to herein as "**OptiNose Norway**", and collectively with OptiNose US and OptiNose UK, "**OptiNose**"), and, on the other hand, Contract Pharmaceuticals Limited Canada, duly organized under the laws of the Province of Ontario and having offices located at 7600 Danbro Crescent, Mississauga, Ontario Canada L5N 6L6 (referred to herein as "**CPL**"). OptiNose and CPL are each a "**Party**" and together constitute the "**Parties**" under this Agreement.

RECITALS

WHEREAS, OptiNose and CPL entered into that certain Manufacture and Supply Agreement effective as of August 18, 2017 (the "**Agreement**"), which outlines the rights and obligations of OptiNose and CPL with respect to the conduct of certain services to be performed by CPL;

WHEREAS, the Parties wish to enter into this Amendment in order to set forth the renewal terms of the Agreement and to amend certain terms of the Agreement in accordance with the terms and conditions set forth herein; and

WHEREAS, certain terms of this Amendment shall become effective as of August 18, 2022 (the "**Amendment Effective Date**"), which is the commencement of the Renewal Term, while other terms shall become effective as of the Execution Date or such other date as set forth herein.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. **Defined Terms**. All capitalized terms used herein shall have the meaning ascribed to each of them as defined herein and, if not defined herein, shall have the meaning ascribed to each of them in the Agreement.

2. **Amendment to Agreement**. The Parties agree that:

a. Effective as of January 1, 2023, Section 1.3 of the Agreement shall be amended and restated in its entirety as follows:

> ""**Annual Minimum**" means the lesser of (A) [***] ([***]) of the Annual Threshold (rounded down to the applicable lot size) and (B) [***] ([***]) units of Product; provided, however, that from and after the timely cure of a Supply Failure described in subsections (i) and (ii) of Section 2.11 and OptiNose's

resumption of ordering from CPL as described in Section 2.11, [***] ([***]) shall be reduced by [***] ([***]) for each Supply Failure that has occurred under the Agreement (for example, [***] ([***]) shall be reduced to [***] ([***]) upon the first instance, and then to [***] ([***]) upon the next instance) and [***] ([***]) shall be reduced by [***] ([***]) for each Supply Failure that has occurred under the Agreement (for example, [***] ([***]) shall be reduced by [***] ([***]) to [***] ([***]) upon the first instance, and then to [***] ([***]) upon the next instance)."

b. Effective as of January 1, 2023, Section 1.4 of the Agreement shall be amended and restated in its entirety as follows:

""**Annual Threshold**" means the actual annual (on a calendar basis) aggregate requirements of OptiNose for the Product in the Territory less [***], as reflected by OptiNose's records of the number of Product units: (i) ordered from CPL, and (ii) ordered from any other vendors/suppliers by OptiNose, and (iii) manufactured by OptiNose itself, during the calendar year (provided, in all instances such number shall not be below zero); provided that any Purchase Order(s) cancelled or not accepted due to or during a Supply Failure, or that relate to any Binding Period in effect as of CPL's cure of such Supply Failure (which CPL shall provide prompt notice thereof to OptiNose), shall in each instance count against such Annual Threshold as if such Purchase Order was fulfilled hereunder and further provided that OptiNose shall not submit a Purchase Order following CPL's notice of Supply Failure that is more than the amount specified within the Rolling Forecast (as allowed by Section 2.7 of the Agreement) once such amount falls within the Binding Period (i.e. the 4th month of a Rolling Forecast becomes the 3rd month of the Rolling Forecast)."

c. Effective as of the Execution Date, Section 1.36 of the Agreement shall be amended and restated in its entirety as follows:

""**Product**" means the full saleable or sample product unit for OPN-375/XHANCE®, including without limitation active ingredient, delivery system, container closure system, and market package; provided, "Product" shall also include any such OPN-375/XHANCE® unit without the market packaging (which instead shall be packaged as Brite-Stock by CPL (the "**Brite-Stock**", as referenced in Exhibit B hereto)) to the extent OptiNose submits a Purchase Order for such Brite-Stock."

d. Effective as of the Amendment Effective Date, the words "a secondary" in the second sentence of Section 2.1(a) of the Agreement shall be amended and restated to instead be "an additional".

e. Effective as of January 1, 2023, the second sentence of Section 2.1(c) of the Agreement shall be amended and restated in its entirety as follows:

"If OptiNose fails to order from CPL the Annual Minimum, then as OptiNose's sole and exclusive liability and CPL's sole and exclusive remedy, OptiNose shall, within [***] ([***]) days following determination of such fact, pay to

CPL an amount equal to [***] ([***]) of the product of (x) the number of Product units below the Annual Minimum that OptiNose did not order from CPL during the applicable calendar year (and instead ordered from any one or more vendors/suppliers or manufactured by itself) and (y) [***] ([***]).”

f. Notwithstanding anything in this Amendment or the Agreement to the contrary, the Parties acknowledge and agree that during the period from and including the Amendment Effective Date and to and including December 31, 2022 (the “**Gap Period**”), (i) the references to “[***]” in the definition of “Annual Minimum”, as amended by this Amendment, shall be “[***]” rounded down to the nearest batch size, with Supply Failure reductions as set forth in such amended “Annual Minimum” definition still applicable at the same rate for all Supply Failure(s) that may have occurred prior to January 1, 2023; and (ii) (A) the corresponding measure of the “Annual Threshold” for purposes of such Gap Period shall only apply to such Gap Period (and not any annual period), and (B) the reference to “less [***] ([***])” in the definition of “Annual Threshold”, as amended by this Amendment, shall be removed solely for purposes of the corresponding measure of the “Annual Threshold” for purposes of such Gap Period. Notwithstanding anything here or in the Agreement to the contrary, the Parties hereby acknowledge and agree that (a) any Product orders OptiNose may place with a Back-Up Supplier prior to the Amendment Effective Date but that are delivered during the Gap Period shall count towards the Annual Minimum calculation for the Gap Period and not the period prior to the Amendment Effective Date and (b) any Product orders OptiNose may place with a Back-Up Supplier that are delivered following December 31, 2022, shall count towards the Annual Minimum calculation for the applicable period following December 31, 2022, and not the period prior to the Amendment Effective Date or the Gap Period.

g. Notwithstanding anything in this Amendment or the Agreement to the contrary, any Supply Failure(s) that may have occurred prior to the Amendment Effective Date or that may have occurred during the Gap Period shall in all instance count as Supply Failure(s) for purposes of the Renewal Term such that the respective Annual Minimum after the Amendment Effective Date, whether during the Gap Period or otherwise during the full Renewal Term, shall be reduced as if such Supply Failure(s) happened after the Amendment Effective Date (i.e. the Annual Minimum reductions due to a Supply Failure shall apply at all points during the term of the Agreement, as amended).

h. Effective as of the Amendment Effective Date, the second sentence of Section 2.1(c) of the Agreement as amended by Section 2(e) of this Amendment shall apply with respect to any failure of OptiNose to order the applicable Annual Minimum during the Gap Period.

i. Effective as of the Execution Date, the first sentence of Section 2.1(d) of the Agreement shall be amended and restated in its entirety as follows:

“OptiNose, [***], is responsible for the purchase of all API, cap, vial base, and liquid delivery subassembly, and CPL is responsible for the purchase of all other Raw Materials.”

j. Effective as of the Execution Date, the second sentence of Section 2.4 of the Agreement shall be amended and restated in its entirety as follows:

"In no case shall CPL maintain less than a [***] ([***]) month nor more than a [***] ([***]) month supply of Raw Materials based on the then existing Rolling Forecast ("**Safety Stock**") without OptiNose's prior written consent."

k. Effective as of the Amendment Effective Date, Section 2.8 of the Agreement shall be amended and restated in its entirety as follows:

"Subject to the other provisions of this Agreement, OptiNose shall not cancel any Purchase Order issued by OptiNose and confirmed by CPL. To the extent requested in writing by OptiNose, any deferment of the date of Delivery of Product in a Purchase Order may only occur upon the written consent of CPL and in the event that CPL agreed to such deferment, the Parties shall mutually agree upon an acceptable revised Delivery date."

l. Effective as of the Execution Date, a new Section 2.14 shall be added to the Agreement as follows:

"OptiNose-Designated Vendor; Suitability Issue.

(a) OptiNose may reasonably require CPL from time to time, in writing, to have a direct commercial relationship for the purposes of this Agreement with certain vendors (each such vendor, an "**OptiNose-Designated Vendor**") and obtain from such OptiNose-Designated Vendors components necessary for the Manufacture of the Product (the "**OptiNose-Designated Components**"). CPL shall use [***] to source the OptiNose-Designated Components and use [***] to ensure that the OptiNose-Designated Vendors provide reasonable warranties for such OptiNose-Designated Components. CPL shall inspect and use OptiNose-Designated Components in accordance with the Specifications; provided in all instances such inspection and use shall be consistent with what CPL does for any other Raw Materials it sources for this Agreement or otherwise in the ordinary course of its business.

(b) To the extent not otherwise addressed in the Agreement, in the event that CPL reasonably believes that any OptiNose Components or OptiNose-Designated Components may ultimately not be suitable for use in the Manufacture of the Product for reasons other than (i) the failure to meet Specifications, (ii) the OptiNose-Designated Vendor's failure to comply with its obligations to CPL, or (iii) CPL's negligence, misconduct or failure to comply with the terms of the Agreement ("**Suitability Issue**") that could result in delay in manufacturing the Product and/or CPL to incur additional costs in connection with the Manufacturing of the Product (including but not limited to wasted/rejected materials or CPL Engineering time), CPL shall as soon as reasonably practicable notify OptiNose in writing of the possible Suitability Issue, provide (to the extent reasonably available or reasonably possible to provide) reasonable details about the possible Suitability Issue, provide (to the extent reasonably available or reasonably possible to provide) a reasonable suggestion of a resolution to such Suitability Issue, and provide CPL's estimated costs to rectify and/or address such Suitability Issue. ("**Suitability Issue Notice**"). The Parties shall then discuss in good faith to determine if a Suitability Issue has

occurred and to determine a potential resolution to such Suitability Issue. With respect to such additional, reasonably estimated costs that CPL expects to incur regarding a Suitability Issue with either OptiNose Components or OptiNose-Designated Components, such estimated costs shall be as agreed to in writing between the Parties; provided, for clarity, that CPL shall be solely liable for all costs and expenses it may have incurred prior to providing OptiNose a Suitability Issue Notice, as well CPL shall be solely liable for all costs and expenses related to such Suitability Issue proximately caused by CPL's failure to meet Specifications or by CPL's negligence, misconduct or failure to comply with the terms of the Agreement, in each such instance, including CPL promptly reimbursing OptiNose for all reasonable costs and expenses OptiNose incurs as a result thereof. CPL shall then as soon as practicable implement such resolution as agreed between the Parties. Should the Parties fail to come to an agreement on such costs and/or resolution of an identified Suitability Issue, the dispute shall be resolved as set forth in Section 2.14(c) below. CPL shall issue an invoice to OptiNose for such additional costs as agreed to in writing between the Parties or otherwise determined by the preceding sentence, which OptiNose shall pay in full within [***] ([***]) days of receipt of an invoice for such costs. For clarity, the provisions set forth in this Section 2.14 shall not excuse CPL's inspection obligations as set forth in the Agreement, and any and all Purchase Orders which may be affected by a potential or actual Suitability Issue shall be held in abeyance until such Suitability Issue is resolved and such abeyance shall not be a Supply Failure nor a CPL non-performance or default under this Agreement. Should CPL fail to inspect the OptiNose Designated Components in accordance with the incoming testing Specifications or otherwise in compliance with the terms of the Agreement, it shall not be considered a Suitability Issue and instead CPL shall be solely liable for all such costs, fees and expenses related to such failure to inspect or as otherwise set forth in the Agreement."

(c) Should the Parties fail to come to an agreement regarding the costs or existence of a Suitability Issue within [***] ([***]) business days following the Suitability Issue Notice, the senior executives of the respective Parties shall use reasonable efforts to negotiate in good faith to resolve. Should the senior executives fail to come to such resolution within [***] ([***]) business days, the Parties hereby agree that such matter will be settled by arbitration conducted before one (1) arbitrator (who is a technical expert in this field) mutually agreed to by the Parties, sitting in Delaware or such other location agreed to by the Parties, in accordance with the rules of the American Arbitration Association then in effect; provided, however, that if the Parties are unable to agree on a single arbitrator within [***] ([***]) business days of the demand by another Party for arbitration, an arbitrator will be designated by the Delaware Office of the American Arbitration Association. The determination of the arbitrator will be final and binding on the Parties. Each Party will bear their own costs and expenses associated with such arbitration.

m. Effective as of the Execution Date, Exhibit B of the Agreement shall be amended and restated in its entirety as set forth in Appendix 1 attached hereto. For clarity, the Parties hereby agree that the pricing set forth in Exhibit B hereto shall be applicable during the Renewal Term, notwithstanding any changes in pricing prior to such Renewal Term, subject to any subsequent changes in pricing pursuant to Section 4.1.5 of the Agreement as amended by section (o) of this Amendment. Such pricing in Exhibit B is based on the

Specifications received by CPL from OptiNose at the time of the Effective Date. In the event that such Specifications change in accordance with the terms of the Agreement, the price in Exhibit B shall change up or down as the case may be in compliance with the terms set forth in Section 2.2.2 of the Agreement.

n. Effective as of the Execution Date, the fifth sentence of Section 4.1.1 of the Agreement shall be amended and restated in its entirety as follows:

"The Parties also acknowledge and agree that the entire batch shall be split into no more than two Stock Keeping Unit ("**SKU**") if OptiNose so requests."

o. Effective as of the Amendment Effective Date, Section 4.1.5 of the Agreement shall be amended and restated in its entirety as follows:

"Annual Price Adjustment. During the Term of this Agreement, provided that OptiNose has ordered from CPL at least [***] units of Product [***], the unit price of each Product shall be increased or decreased, which adjustment shall become effective on [***] by the change in the cost of Raw Materials; provided, however, that any such change will not include the amount of any price change already implemented under Section 4.1.4 of this Agreement. In the event that OptiNose has ordered from CPL less than [***] units of Product during the preceding [***], CPL may (upon prior written notice to OptiNose if such notice is provided before [***]) increase the conversion portion of the Price of the Product by a percentage increase that shall not exceed the percentage increase over the prior [***] ([***]) month period in the Pharmaceutical Price Index Ref # 325412325412 (PPI) as reported by the United States Department of Labor Bureau of Labor Statistics, in which case such increase shall become effective [***] (For clarity, if Optinose ordered from CPL less than [***] units of Product in [***], and if CPL give notice before [***], then the price increase shall be applied for [***], retroactive to [***])."

p. Effective as of the Amendment Effective Date, the Agreement shall be renewed for the period beginning as of the Amendment Effective Date and expiring at the end of the calendar day on December 31, 2024 (the "**Renewal Term**").

q. Effective as of the Execution Date, the Parties agree that OptiNose UK shall be immediately removed as a party to the Agreement and shall have no further rights or obligations under to the Agreement.

r. Effective as of the Execution Date, Schedule 3 of the Agreement is hereby amended and restated with Schedule 3 as attached hereto.

3. **Entire Agreement**. Each Party acknowledges that this Amendment, together with the Agreement, constitutes the entire agreement of the Parties with respect to the subject matter hereof.

4. **Full Force and Effect**. Except as expressly amended hereby, all of the other terms and conditions of the Agreement shall remain unchanged and in full force and effect in accordance with their original terms.

5. **Authority**. Each Party hereby represents and warrants that is has full power and authority to enter into this Amendment.

[Signature page follows]

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties have each caused a duly authorized representative to execute this Amendment as of the Amendment Effective Date.

Contract PharmacEUticals Limited CANADA

By: _____

Name:_____

Its: _____

OPTINOSE US, INC.

By: _____

Name:_____

Its: _____

OPTINOSE UK LTD.

By: _____

Name:_____

Its: _____

OPTINOSE AS

By: _____

Name:_____

Its: _____

Appendix 1

Exhibit B

PRICE

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***]

Appendix 2

SCHEDULE 1

OptiNose Equipment

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***]

SCHEDULE 3

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

[***]

CERTIFICATION UNDER SECTION 302 OF THE

SARBANES-OXLEY ACT OF 2002

I, Peter K. Miller, certify that:

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2021

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

CERTIFICATION UNDER SECTION 302 OF THE

SARBANES-OXLEY ACT OF 2002

I, Keith A. Goldan, certify that:

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2021

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

CERTIFICATION UNDER SECTION 906 OF THE

SARBANES-OXLEY ACT OF 2002

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

1. the Quarterly Report on Form 10-Q of the Company for the period ending March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: May 5, 2021

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

CERTIFICATION UNDER SECTION 906 OF THE

SARBANES-OXLEY ACT OF 2002

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

1. the Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: May 5, 2021

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