NovaBay Pharmaceuticals, Inc.
Form 10-Q
May 12, 2016

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, 2016

OR

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 001-33678

NOVABAY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**68-0454536**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

5980 Horton Street, Suite 550, Emeryville CA 94608

(Address of principal executive offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (510) 899-8800

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

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

As of May10, 2016, there were 9,154,121 shares of the registrant's common stock outstanding.

NOVABAY PHARMACEUTICALS, INC.

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Unless the context requires otherwise, all references in this report to “we,” “our,” “us,” the “Company” and “NovaBay” refer to NovaBay Pharmaceuticals, Inc. and its subsidiaries.

PART I

FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except shares and per share data)

	March 31, 2016 (unaudited)	**December 31, 2015** Footnote 2
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,430	$ 2,385
Accounts receivable, net of allowance for doubtful accounts ($71 and $40 at March 31, 2016 and December 31, 2015, respectively)	1,497	536
Inventory	1,201	1,345
Prepaid expenses and other current assets	433	261
Total current assets	4,561	4,527
Property and equipment, net	370	395
Other assets	-	155
TOTAL ASSETS	$ 4,931	$ 5,077
LIABILITIES AND STOCKHOLDERS' (DEFICIT)		
Liabilities:		
Current liabilities:		
Accounts payable	$ 1,820	$ 2,483
Accrued liabilities	2,019	1,980
Deferred revenue	189	170
Total current liabilities	4,028	4,633
Deferred revenues - non-current	3,115	2,248
Deferred rent	189	189
Notes payable, related party	3,063	1,655
Warrant liability	1,835	1,450
Total liabilities	12,230	10,175

Stockholders' (deficit):		
Common stock, $0.01 par value; 240,000 shares authorized; 5,075 and 3,486 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	51	35
Additional paid-in capital	88,248	85,387
Accumulated deficit	(95,598)	(90,520)
Total stockholders' (deficit)	(7,299)	(5,098)
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT)	$ 4,931	$ 5,077

The accompanying notes are an integral part of these consolidated financial statements.

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except shares and per share data)

	Three Months Ended March 31,	
	2016	2015
Sales:		
Product revenue	$1,655	$492
Other revenue	64	46
Total net sales	1,719	538
Product cost of goods sold	611	148
Gross profit	1,108	390
Research and development	933	1,583
Sales and marketing	3,144	1,914
General and administrative	1,655	1,554
Total operating expenses	5,732	5,051
Operating Loss	(4,624)	(4,661)
Non cash (loss) gain on changes in fair value of warrant liability	(385)	34
Other expense, net	(68)	(11)
Loss before provision for income taxes	(5,077)	(4,638)
Provision for income tax	-	(2)
Net loss and comprehensive loss	$(5,077)	$(4,640)
Loss per share attributable to common stockholders (basic and diluted)	$(1.24)	$(2.13)
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (basic and diluted)	4,086	2,175

The accompanying notes are an integral part of these consolidated financial statements.

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$(5,077)	$(4,640)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	40	41
Gain on disposal of property and equipment	—	(1)
Stock-based compensation expense for options and stock issued to employees and directors	74	265
Stock-based compensation expense for options and stock issued to non-employees	19	20
Stock-based compensation expense for issuance of restricted stock units to employees	133	—
Stock-based compensation expense for issuance of restricted stock units to non-employees	21	—
Allowance for doubtful accounts	31	70
Note receivable impairment	91	—
Non-cash loss (gain) on change in fair value of warrants	385	(34)
Changes in operating assets and liabilities:		
Accounts receivable	(992)	(117)
Inventory	144	29
Prepaid expenses and other assets	(107)	(491)
Accounts payable and accrued liabilities	(580)	357
Deferred revenue	886	(6)
Net cash used in operating activities	(4,932)	(4,507)
Cash flows from investing activities:		
Purchases of property and equipment	(16)	(14)
Proceeds from disposal of property and equipment	—	37
Net cash provided (used) by investing activities	(16)	23
Cash flows from financing activities:		
Proceeds from common stock issuances, net	2,628	—
Proceeds from borrowings	1,365	—
Proceeds from shelf offering, net	—	4,653
Net cash provided by financing activities	3,993	4,653
Net increase (decrease) in cash and cash equivalents	(955)	169
Cash and cash equivalents, beginning of period	2,385	5,429
Cash and cash equivalents, end of period	$1,430	$5,598

Supplemental disclosure of non cash information		
Stock issued to consultants for services included in accounts payable and accrued liabilities	$1	$—

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company focused on commercializing prescription Avenova® daily lid and lash hygiene in the domestic eye care market.

The Company was incorporated under the laws of the State of California on January 19, 2000, as NovaCal Pharmaceuticals, Inc. It had no operations until July 1, 2002, on which date it acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, it changed its name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, it formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which was formed to conduct research and development in Canada and was dissolved in July 2012, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which may explore and pursue dermatological opportunities. In June 2010, the Company changed the state in which it is incorporated (the "Reincorporation"), and is now incorporated under the laws of the State of Delaware. All references to "the Company" herein refer to the California corporation prior to the date of the Reincorporation, and to the Delaware corporation on and after the date of the Reincorporation**.** Historically, the Company operated as four business segments. At the direction of its Board of Directors, the Company is focused primarily on commercializing prescription Avenova for managing hygiene of the eyelids and lashes in the United States and is now managed as a single business and not four segments.

Effective December 18, 2015, we effected a 1-for-25 reverse split of our outstanding common stock (the "Reverse Stock Split") (See Note 10). The accompanying financial statements and related notes give retroactive effect to this reversal stock split.

Need to Raise Additional Capital

The Company has incurred significant losses from operations since inception and expects losses to continue for the foreseeable future. As of March 31, 2016, the Company had cash and cash equivalents of $1.4 million. The Company's operating plans call for cash expenditures to exceed $18.0 million over the next twelve months. The Company plans to raise additional capital to fund its operations. The Company plans to finance its operations through the sale of equity securities, debt arrangements or partnership or licensing collaborations. Such funding may not be available or may be on terms that are not favorable to the Company. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and its ability to continue as a going concern. If the Company becomes unable to continue as a going concern, it may have to liquidate its assets and might realize significantly less than the values at which such assets are carried on its financial statements, and stockholders may lose all or part of their investment in Company common stock.

The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying interim condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America ("GAAP") and with the instructions for Form 10-Q and Regulation S-X. Accordingly, they do not include all of the information and notes required for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 26, 2015. The unaudited condensed consolidated financial statements include the accounts of the Company and its consolidated subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Reclassifications

Prior period amounts in the accompanying consolidated balance sheets have been reclassified to conform to current period presentation. The reclassifications did not change total assets, total liabilities, or total stockholders' equity.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, DermaBay, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization periods for payments received from product development and license agreements as they relate to revenue recognition, assumptions for valuing options and warrants, and income taxes. Actual results could differ from those estimates.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements and related disclosures are unaudited, have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the results of operations for the periods presented.

The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. The condensed consolidated results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period.

Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid instruments with a stated maturity of three months or less at the date of purchase to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates their fair value. As of March 31, 2016, the Company's cash and cash equivalents were held in financial institutions in the United States.

The Company classifies all highly liquid investments with a stated maturity of greater than three months at the date of purchase as short-term investments. Short-term investments generally consist of municipal and corporate debt securities. The Company has classified its short-term investments as available-for-sale. The Company does not intend to hold securities with stated maturities greater than twelve months until maturity. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value below cost of any available-for-sale security that is determined to be other-than-temporary results in a revaluation of its carrying amount to fair value and an impairment charge to earnings, resulting in a new cost basis for the security. No such impairment charges were recorded for the periods presented. The interest income and realized gains and losses are included in other (expense), net within the consolidated statements of operations and comprehensive loss. Interest income is recognized when earned.

Concentrations of Credit Risk and Major Partners

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains deposits of cash, cash equivalents and short-term investments with three highly-rated, major financial institutions in the United States.

Deposits in these banks may exceed the amount of federal insurance provided on such deposits. The Company does not believe it is exposed to significant credit risk due to the financial position of the financial institutions in which these deposits are held. Additionally, the Company has established guidelines regarding diversification and investment maturities, which are designed to maintain safety and liquidity.

During the three months ended March 31, 2016, revenues were derived primarily from sales of Avenova directly to doctors through the Company's webstore and to three distribution partners. During the three months ended March 31, 2015, revenues were derived from one collaboration partner, service revenues and sales of NeutroPhase.

As of March 31, 2016, 33%, 24% and 10% of accounts receivable were derived from the Company's three primary distribution partners. As of December 31, 2015, 41% and 18% of accounts receivable were derived from the Company's two primary distribution partners.

Fair Value of Financial Assets and Liabilities

Financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. Our warrant liability is carried at fair value.

The Company measures the fair value of financial assets and liabilities based on U.S. GAAP guidance which defines fair value, establishes a framework for measuring fair value, and requires disclosures about fair value measurements.

Under U.S. GAAP, fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A fair value hierarchy is also established, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair

value. There are three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities;

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable;

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions).

Allowance for Doubtful Accounts

We charge bad debt expense and record an allowance for doubtful accounts when management believes it to be unlikely that specific invoices will be collected. Management identified amounts due that are in dispute and it believes are unlikely to be collected at the end of March 31, 2016. At March 31, 2016, management had reserved $71 thousand, primarily based on specific amounts that are in dispute and are over 120 days past due.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes, and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods.

Inventory is stated at the lower of cost or market value determined by the first-in, first-out method.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets of five to seven years for office and laboratory equipment, three years for software and seven years for furniture and fixtures. Leasehold improvements are depreciated over the shorter of seven years or the lease term.

The costs of normal maintenance, repairs, and minor replacements are charged to operations when incurred.

Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with U.S. GAAP, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets. During the three months ended March 31, 2016, the Company impaired a note receivable which was deemed to no longer be collectable, as the originator of the loan is not in business and the collateral held against the loan did not possess value in an amount sufficient to satisfy the loan. As a result, a $91 thousand impairment charge was recorded to research and development expense for the three months ended March 31, 2016. There were no impairments during the three months ended March 31, 2015. Determination of recoverability is based on the estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values and the loss is recognized in the statements of operations.

Comprehensive (Loss)

ASU No. 2011-05, *Comprehensive Income (Topic 220),* requires that an entity's change in equity or net assets during a period from transactions and other events from non-owner sources be reported. The Company reports unrealized gains and losses on its available-for-sale securities as other comprehensive (loss).

Revenue Recognition

The Company sells products through a limited number of distributors and via its webstore. The Company generally records product sales upon shipment to the final customer for its webstore sales and upon shipment from its distributor to the final customers for its major distribution partners.

The Company recognizes product revenue when: (i) persuasive evidence that an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. Revenue from sales transactions where the customer has the right to return the product is recognized at the time of sale only if: (i) the Company's price to the customer is substantially fixed or determinable at the date of sale, (ii) the customer has paid the Company, or the customer is obligated to pay the Company and the obligation is not contingent on resale of the product, (iii) the customer's obligation to the Company would not be changed in the event of theft or

physical destruction or damage of the product, (iv) the customer acquiring the product for resale has economic substance apart from that provided by the Company, (v) the Company does not have significant obligations for future performance to directly bring about resale of the product by the customer, and (vi) the amount of future returns can be reasonably estimated.

Product Revenue Allowances

Product revenue is recognized, net of cash consideration paid to our customers and wholesalers, for services rendered by wholesalers in accordance with such wholesaler's agreements and includes both a fixed rate per prescription shipped and monthly program management and data fees. These services are not deemed sufficiently separable from the customers' purchase of the product; therefore, they are recorded as a reduction of revenue at the time of revenue recognition.

Other product revenue allowances include certain prompt pay discounts and allowances offered to our customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue or as a selling expense at the later of the date at which the related revenue is recognized or the date at which the allowance is offered.

Other Revenue

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, and payments based upon achievement of certain milestones and royalties on net product sales. In accordance with authoritative guidance, the Company analyzes its multiple element arrangements to determine whether the elements can be separated. The Company performs its analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting, and revenue is recognized over the performance obligation period. Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured. If these factors were to vary, the resulting change could have a material effect on our revenue recognition and on the Company's results of operations.

Cost of Goods Sold

Cost of goods sold includes third party manufacturing costs, shipping costs, and other costs of goods sold. Cost of goods sold also includes any necessary allowances for excess inventory that may expire and become unsalable. The Company recorded an allowance for obsolete inventory of $45 thousand during 2015, but did not record an allowance for excess inventory as of December 31, 2015. During the three months ended March 31, 2016, the Company disposed of the obsolete inventory and eliminated the allowance for obsolete inventory of $45 thousand.

Research and Development Costs

The Company charges research and development costs to expense as incurred. These costs include salaries and benefits for research and development personnel, costs associated with clinical trials managed by contract research organizations, and other costs associated with research, development and regulatory activities. Research and development costs may vary depending on the type of item or service incurred, location of performance or production, level of availability of the item or service, and specificity required in production for certain compounds. The Company uses external service providers to conduct clinical trials, to manufacture supplies of product candidates and to provide various other research and development-related products and services. The Company's research, clinical and development activities are often performed under agreements it enters into with external service providers. The Company estimates and accrues the costs incurred under these agreements based on factors such as milestones achieved, patient enrollment, estimates of work performed, and historical data for similar arrangements. As actual costs are incurred, the Company adjusts its accruals. Historically, the Company's accruals have been consistent with management's estimates, and no material adjustments to research and development expenses have been recognized. Subsequent changes in estimates may result in a material change in the Company's expenses, which could also materially affect its results of operations.

Patent Costs

Patent costs, including legal expenses, are expensed in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of ASU No. 2014-12, *Compensation-Stock Compensation (Topic 718)*. Under the fair value recognition provisions, stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model. See Note 11for further information regarding stock-based compensation expense and the assumptions used in estimating that expense. The Company accounts for restricted stock unit awards issued to employees and non-employees based on the fair market value of the Company's common stock at the date of issuance.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recognized if it is more likely than not that some portion or the entire deferred tax asset will not be recognized.

Common Stock Warrant Liabilities

For warrants that are issued or modified and there is a deemed possibility that the Company may have to settle the warrants in cash, or for warrants the Company issues or modifies that contain an exercise price adjustment feature that reduces the exercise price of the Company's common stock eligible for purchase thereunder in the event that the Company subsequently issues equity instruments at a price lower than the exercise price of the warrants, the Company records the fair value of the issued or modified warrants as a liability at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss on the consolidated statements of operations and comprehensive loss. The fair values of these warrants have been determined using the Binomial Lattice ("Lattice") valuation model, which provides for assumptions regarding volatility, call and put features and risk-free interest rates within the total period to maturity. These values are subject to a significant degree of the Company's judgment.

Net (Loss) per Share

The Company computes net (loss) per share by presenting both basic and diluted (loss) per share ("EPS").

Basic EPS is computed by dividing net (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the applicable period, including stock options and warrants, using the treasury stock method**.** In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted EPS computation in net loss periods since their effect would be anti-dilutive. During the three months ended March 31, 2016 and March 31, 2015, there was no difference between basic and diluted net loss per share due to the Company's net losses. The following table sets forth the calculation of basic EPS and diluted EPS:

	Three Months Ended March 31,	
	2016	2015
Net loss	$(5,077)	$(4,640)
Basic Shares	4,086	2,175
Add: shares issued upon assumed exercise of stock options and warrants	—	—
Diluted shares	4,086	2,175
Basic and diluted net loss per share	$(1.24)	$(2.13)

The following outstanding stock options and stock warrants were excluded from the diluted net loss per share computation as their effect would have been anti-dilutive:

	Three Months Ended	
	March 31,	
	2016	2015
Stock options	300	337
Stock warrants	1,458	854
	1,758	1,191

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. ASU No. 2014-09 uses a five-step model to determine revenue recognition in contracts with customers. The Company is currently evaluating the potential impact of this standard on its financial statements. ASU No. 2014-09 is effective for the Company in the first quarter of fiscal year 2019 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU No. 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU No. 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU No. 2014-09. Early adoption in the first quarter of fiscal year 2018 is permitted. The Company is evaluating the effects of the adoption of this guidance to its financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. ASU No. 2015-03 changes the presentation of debt issuance costs in financial statements. Under the new guidance, an entity presents such costs in the balance sheet as a direct deduction from the related debt liability, rather than as an asset. Amortization of the costs is reported as interest expense. This guidance became effective beginning in the first quarter of 2016. The Company's adoption of this guidance did not result in a material impact to our consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*, which changes the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. ASU No. 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new guidance must be

applied on a prospective basis and is effective for the Company in the first quarter of fiscal year 2017, with early adoption permitted. The Company does not believe the implementation of this guidance will result in a material impact to its consolidated financial statements.

In August 2014, FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This new standard provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosure if substantial doubt exists. The new standard is effective for annual periods ending after December 15, 2016 and for annual periods and interim periods thereafter. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial statements

In January 2016, the FASB issued ASU 2016-01, *Financial Instructions – Overall (Subtopic 825-10)*: *Recognition and Measurement of Financial Assets and Financial Liabilities*, which provides guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. This guidance will be effective for the Company beginning in the first quarter of fiscal year 2018. The Company is evaluating the effects of the adoption of this guidance to its financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes the lease accounting requirements in *Leases (Topic 840)*. ASU 2016-02 requires a dual approach for lessee accounting under which a lessee would account for leases as finance leases or operating leases. Both finance leases and operating leases will result in the lessee recognizing a right-of-use asset and a corresponding lease liability. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset, and for operating leases, the lessee would recognize a straight-line total lease expense. The guidance also requires qualitative and specific quantitative disclosures to supplement the amounts recorded in the financial statements so that users can understand more about the nature of an entity's leasing activities, including significant judgments and changes in judgments. This guidance is effective beginning in the first quarter of fiscal year 2019. The Company is evaluating the effects of the adoption of this guidance to its financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,* which is intended to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This guidance is effective beginning in the first quarter of fiscal year 2017 and early adoption is permitted in an interim period with any adjustments reflected as of the beginning of the fiscal year that includes that interim period. The Company is evaluating the effects of the adoption of this guidance to its financial statements.

NOTE 3. FAIR VALUE MEASUREMENTS

The Company measures the fair value of financial assets and liabilities based on authoritative guidance which defines fair value, establishes a framework consisting of three levels for measuring fair value, and requires disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company's warrant liability is classified within Level 3 of the fair value hierarchy because the value is calculated using significant judgment based on the Company's own assumptions in the valuation of this liability.

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2016:

(in thousands)	Balance at March 31, 2016	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities				
Warrant liability	$ 1,835	$ —	$ —	$ 1,835
Total liabilities	$ 1,835	$ —	$ —	$ 1,835

For the three months ended March 31, 2016 the Company recorded a non-cash loss of $385 thousand in its consolidated statement of operations and comprehensive loss, as a result of the fair value adjustment of its warrant liability. See Note 9 for further discussion on the calculation of the fair value of the Company's warrant liability.

(in thousands)	Warrant liability
Fair value of warrants at December 31, 2015	$ 1,450
Increase in fair value at March 31, 2016	385
Total warrant liability at March 31, 2016	$ 1,835

NOTE 4. INVENTORY

Inventory consisted of the following:

(in thousands)	March 31, 2016	December 31, 2015
Raw materials and supplies	$824	$ 660
Goods in process	114	248
Finished goods	263	482
Less Reserve for obsolete inventory	-	(45)
Total inventory	$1,201	$ 1,345

NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

(in thousands)	March 31, 2016	December 31, 2015
Office and laboratory equipment	$1,639	$ 1,633
Furniture and fixtures	257	254
Software	37	37
Leasehold improvements	179	173
Total property and equipment, at cost	2,112	2,097
Less: accumulated depreciation	(1,742)	(1,702)
Net property and equipment	$370	$ 395

Depreciation and amortization expense was $40 thousand and $41 thousand for the three months ended March 31, 2016 and 2015, respectively.

NOTE 6. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(in thousands)	March 31, 2016	December 31, 2015
Research and development	$451	$ 394
Employee payroll and benefits	514	614
Severance pay	591	590
Sales rebate	64	150
Other	399	232
Total accrued liabilities	$2,019	$ 1,980

NOTE 7. RELATED PARTY NOTES PAYABLE

Beginning on December 30, 2015, the Company entered into a series of agreements pursuant to a loan (the "*Loan*") facilitated by China Kington Asset Management Co. Ltd. ("*China Kington*"). In connection with the Loan, the Company issued five (5) promissory notes (the "*Notes*") payable to Mr. Mark Sieczkarek, the Gail J. Maderis Revocable Trust, Dr. T. Alex McPherson, Mr. Jian Ping Fu, and Pioneer Pharma (Singapore) Pte. Ltd. ("*Pioneer Singapore*") (collectively, the "*Lenders*"), loaning the Company an aggregate of $3.0 million. Specifically, Mr. Sieczkarek, Chairman of the Board of the Company (the "*Board*") and Interim President and Chief Executive Officer of the Company, loaned the Company $199 thousand; the Gail J. Maderis Revocable Trust, on behalf of Ms. Maderis, a Director of the Company, loaned the Company $71 thousand; Dr. McPherson, a Director of the Company, loaned the Company $20 thousand; Pioneer Singapore loaned the Company $1.4 million; and Mr. Fu loaned the Company $1.4 million. All Notes were issued on December 30, 2015 except the Note payable to Mr. Fu, which was issued on January 12, 2016.

The proceeds from the Notes are being used for general corporate purposes. Minimum quarterly payments of principal and interest began on March 31, 2016 and will continue on the last day of each June, September, December and March thereafter. The entire principal sum and any and all accrued and unpaid interest is payable in full upon the Company's next financing, but in no event shall the term of the Loan extend beyond December 30, 2018, except for the loan by Mr. Fu, the term of which shall extend three (3) years from the date of issuance of the Note payable to Mr. Fu. The Notes will pay interest at a rate of six percent (6%) per annum and may be prepaid in whole or in part at any time without premium or penalty.

In connection with the Notes, China Kington has agreed to act as collateral agent for the benefit of the Lenders, in accordance with the terms of a collateral agency and intercreditor agreement (the "*Collateral Agency Agreement*"), which was entered into on December 30, 2015 between China Kington and the Lenders. To secure the Notes, China Kington has a perfected security interest in all tangible and intangible assets of the Company, pursuant to a security agreement (the "*Security Agreement*") between the Company and China Kington, which was entered into on December 30, 2015.

As consideration to China Kington for facilitating the Loan, the Company agreed to the following: (1) the grant of a first right of refusal for China Kington (or its designee that shall be acceptable to the Company in its reasonable discretion) to lead financings for the Company for a period that is the shorter of two (2) years or the day that the Company's cash flow has been equal to or greater than $0 in each month for three (3) consecutive months, subject to certain limitations; (2) the participation of Mr. Sieczkarek as a Lender in this financing; (3) the participation of the Company's Board of Directors, management and investors that the Board of Directors and management provide, to contribute an aggregate nine percent (9%) of funds in the Company's next financing; (4) the appointment of two new members to the Company's Board by China Kington; and (5) the Company's agreement to reasonably cooperate with reasonable requests made by an auditor engaged, and paid for, by China Kington, subject to certain limitations. Upon the recommendation of China Kington, and after reviewing their relevant experiences and background and discussing the same, on January 26, 2016 the Board of Directors unanimously appointed Mr. Mijia "Bob" Wu and Mr. Xiaoyan "Henry" Liu to serve as Class I and Class III members of the Company's Board of Directors, respectively.

As of March 31, 2016, outstanding amounts under the Notes were $3.1 million, including accrued interest.

See the *Neutrophase Distribution Agreements* section of Note 12 for a description of the Company's relationship with Pioneer Pharma Co., Ltd.

NOTE 8. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases laboratory facilities and office space under an operating lease which will expire on October 31, 2020. Rent expense was approximately $253 thousand and $256 thousand for the three months ended March 31, 2016 and 2015, respectively.

The Company's monthly rent payments fluctuate under the master lease agreement. In accordance with U.S. GAAP, the Company recognizes rent expense on a straight-line basis. The Company records deferred rent for the difference between the amounts paid and amounts recorded as expense.

Directors and Officers Indemnity

As permitted under Delaware law and in accordance with its bylaws, the Company shall indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving at its request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director or officer insurance policy that limits its exposure and may enable the Company to recover a portion of any future payments. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, no liability has been recorded for these agreements as of March 31, 2016.

In the normal course of business, the Company provides indemnifications of varying scope under agreements with other companies, typically clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, the Company generally indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with use or testing of its products or product candidates or with any U.S. patent or any copyright or other intellectual property infringement claims by any third party with respect to its products. The term of these indemnification agreements is generally perpetual. The potential future payments the Company could be required to make under these indemnification agreements is unlimited. Historically, costs related to these indemnification provisions have been immaterial. The Company also maintains various liability insurance policies that limit its exposure. As a result, the Company believes the fair value of these indemnification agreements is minimal. Accordingly, no liabilities have been recorded for these agreements as of March 31, 2016.

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. There are no matters at March 31, 2016, that, in the opinion of management, would have a material adverse effect on the Company's financial position, results of operations or cash flows.

NOTE 9. WARRANT LIABILITY

In July 2011, the Company sold common stock and warrants in a registered direct financing. As part of this transaction, 139,520 warrants were issued with an exercise price of $33.25 and were exercisable from January 1, 2012 to July 5, 2016. The terms of the warrants require registered shares to be delivered upon each warrant's exercise and also require possible cash payments to the warrant holders (in lieu of the warrant's exercise) upon specified fundamental transactions involving the Company's common stock, such as in an acquisition of the Company. Under ASC 480, *Distinguishing Liabilities from Equity*, the Company's ability to deliver registered shares upon an exercise of the warrants and the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company's control. The warrants contain a provision according to which the warrant holder would have the option to receive cash, equal to the Black-Scholes-Merton fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. In addition, after January 5, 2012, and if the closing bid price per share of the common stock in the principal market equals or exceeds $66.50 for any ten trading days (which do not have to be consecutive) in a period of fifteen consecutive trading days, the Company has the right to require the exercise of one-third of the warrants then held by the warrant holders.

In October 2015, the holders of all warrants issued pursuant to the Company's securities purchase agreement dated March 3, 2015 (the "Agreement") agreed to reduce the length of notice required to such investors prior to the Company's issuance of new securities from twenty business days to two business days, for the remainder of such investors' pre-emptive right period (expiring March 3, 2016). The Company entered into these agreements to enable it to expeditiously raise capital in its October 2015 offering (as described below) and future offerings. As consideration for these agreements, the Company amended certain provisions of both warrants issued with a 15-month term (the "Short-Term Warrants") and warrants issued with a 60-month term (the "Long-Term Warrants") pursuant to the Agreement (together, the "March 2015 Warrants") and the warrants issued pursuant to the placement agent agreement dated June 29, 2011 (the "2011 Warrants"). Specifically, the amendments decreased the exercise price for both the March 2015 Warrants and the 2011 Warrants to $5.00 per share. In addition, the amendments extended the exercise expiration date for the Short-Term Warrants and the 2011 Warrants to March 6, 2020. A price protection provision also was added to both the 2011 Warrants and the March 2015 Warrants, such that if the Company subsequently sells or otherwise disposes of Company common stock at a lower price per share than $5.00 or any securities exchangeable

for common stock with a lower exercise price than $5.00, the exercise price of such warrants will be reduced to that lower price.

In October 2015, the Company also entered into an underwriting agreement with Roth Capital Partners, LLC, relating to the public offering and sale of up to (i) 492,000 shares of the Company's common stock; and (ii) warrants to purchase up to 442,802 shares of the Company's common stock with an exercise price of $5.00 per share.

The shares of common stock and warrants were issued separately. Each warrant was exercisable immediately upon issuance and will expire 60 months from the date of issuance. The price to the public in this offering was $5.00 per share of common stock and related warrant. The net proceeds to the Company were approximately $2.1 million after deducting underwriting discounts and commissions and offering expenses.

In February 2016, the strike price of the July 2011, March 2015 and October 2015 warrants was reduced to $1.81 per share, pursuant to the price protection provisions in such warrants, because of the Company sold common stock to Mr. Jian Ping Fu at that price.

The Company evaluated the change in terms of the July 2011 warrants and noted that the change in terms resulted in a revaluation at the time of the change. The warrants were re-issued and valued as of October 27, 2015 at $361 thousand with the new terms, and a modification expense was recorded for the difference between the fair value of the warrants at their new terms after modification on October 27, 2015 and the fair value of the warrants at their original terms prior to modification as of October 27, 2015. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations.

The key assumptions used to value the warrants after the modification at October 27, 2015 were as follows:

Assumption	
Expected price volatility	80.00%
Expected term (in years)	4.36
Risk-free interest rate	1.23 %
Dividend yield	0.00 %
Weighted-average fair value of warrants	$2.60

The key assumptions used to value the warrants after the modification at March 31, 2016, and December 31, 2015 were as follows:

Assumption	**Period Ended**	
	March 31, 2016	**December 31, 2015**
Expected price volatility	86.00%	80.00 %
Expected term (in years)	3.93	4.18
Risk-free interest rate	1.03 %	1.58 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of warrants	$1.44	$ 1.10

In March 2015, the Company issued both the Short-Term Warrants ($15.00 per share exercise price) and the Long-Term Warrants ($16.25 per share exercise price). At that time, the Company determined that these warrants qualified for equity accounting and did not contain embedded derivatives that required bifurcation. After the Agreement noted above, the Company evaluated the change in terms of the March 2015 Warrants and noted that the change in terms resulted in liability classification of both the Short-Term and Long-Term Warrants. The March 2015 Warrants were re-issued and valued as of October 27, 2015 at a total of $1.8 million with the new terms and a modification expense was recorded at the difference between the fair value of the warrants on their new terms after modification as of October 27, 2015 and the fair value of the warrants on their original terms prior to modification as of October 27, 2015. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations.

The key assumptions used to value the warrants after the modification at October 27, 2015 were as follows:

Assumption	
Expected price volatility	80.00%
Expected term (in years)	4.36
Risk-free interest rate	1.23 %
Dividend yield	0.00 %
Weighted-average fair value of warrants	$2.78

The key assumptions used to value the Short-Term warrants after the modification at March 31, 2016, and December 31, 2015 were as follows:

Assumption	**Period Ended**	
	March 31, 2016	**December 31, 2015**
Expected price volatility	86.00%	80.00 %
Expected term (in years)	3.93	4.18
Risk-free interest rate	1.03 %	1.58 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of warrants	$1.43	$ 1.16

The key assumptions used to value the Long-Term warrants after the modification at March 31, 2016, and December 31, 2015 were as follows:

Assumption	**Period Ended**	
	March 31, 2016	**December 31, 2015**
Expected price volatility	86.00%	80.00 %
Expected term (in years)	3.93	4.18
Risk-free interest rate	1.03 %	1.58 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of warrants	$1.40	$ 1.16

As noted above, in October 2015, the Company issued warrants in connection with an underwriting agreement. The Company evaluated the terms of the warrants and noted that under ASC 480, the Company’s potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company’s control.

Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations. The fair value of the warrants at issuance was $1.3 million.

The key assumptions used to initially value the warrants at October 27, 2015 were as follows:

Assumption	
Expected price volatility	75.50%
Expected term (in years)	5.00
Risk-free interest rate	1.38 %
Dividend yield	0.00 %
Weighted-average fair value of warrants	$2.82

The key assumptions used to value the warrants after the modification at March 31, 2016, and December 31, 2015 were as follows:

Assumption	**Period Ended**	
	March 31, 2016	**December 31, 2015**
Expected price volatility	82.00%	77.50 %
Expected term (in years)	4.53	4.83
Risk-free interest rate	1.14 %	1.72 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of warrants	$1.59	$ 1.21

The details of all outstanding warrant liability as of March 31, 2016, are as follows:

	Shares	Warrant Liability
July 2011 Warrants	138,621	$199,537
Long-Term Warrants	285,619	400,428
Short-Term Warrants	370,934	529,232
October 2015 Warrants	442,802	705,794
	1,237,976	$1,834,991

NOTE 10. STOCKHOLDERS' EQUITY

Amendments to Articles of Incorporation – Reverse Stock Split

Effective December 18, 2015, we amended our Certificate of Incorporation to effect a 1-for-25 reverse split of our outstanding common stock (the "Reverse Stock Split"). The Reverse Stock Split was approved by our stockholders on December 11, 2015. The accompanying financial statements and related notes give retroactive effect to this Reverse Stock Split.

Preferred Stock

Under the Company's amended articles of incorporation, the Company is authorized to issue up to 5,000,000 shares of preferred stock in such series and with such rights and preferences as may be approved by the Board of Directors. As of December 31, 2015, there were no shares of preferred stock outstanding.

Common Stock

In February 2016, we entered into three securities purchase agreements (the "Purchase Agreements") for the sale of an aggregate of 1,518,567 shares of the Company's common stock (the "Common Stock") to accredited investors for a total of $2.8 million. We entered into the first purchase agreement with Mr. Jian Ping Fu (the "Fu Agreement"), pursuant to which the Company agreed to issue and sell to Mr. Fu 696,590 shares of Common Stock, at a per share price of $1.81, which was a five percent (5%) discount to the closing price of the Common Stock on February 16, 2016, the

date of the Fu Agreement. We entered into the second purchase agreement with Pioneer Singapore (the "Pioneer Agreement"), pursuant to which we agreed to issue and sell to Pioneer Singapore 696,590 shares of Common Stock, at a per share price of $1.91, which was the closing price of the Common Stock on February 16, 2016 with no discount. We entered into a third purchase agreement with Mark M. Sieczkarek (the "Sieczkarek Agreement"), pursuant to which the Company agreed to issue and sell to Mr. Sieczkarek 125,387 shares of Common Stock, at a per share price of $1.91, which was the closing price of the Common Stock on February 16, 2016 with no discount. The Common Stock issued by the Company pursuant to the Purchase Agreements has not been registered under the Securities Act and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

Stock Warrants

In February 2016, the strike prices of the July 2011, March 2015 and October 2015 warrants was reduced to $1.81 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Mr. Jian Ping Fu at that price.

The details of all outstanding warrants as of March 31, 2016, are as follows:

(in thousands, except per share data)	**Warrants**	**Weighted-Average Exercise Price**
Outstanding at December 31, 2015	1,458	$ 5.19
Warrants granted	-	-
Warrants exercised	-	-
Warrants expired	-	-
Outstanding at March 31, 2016	1,458	$ 4.58

NOTE 11. EQUITY-BASED COMPENSATION

Equity Compensation Plans

Prior to its Initial Public Offering (the "IPO"), the Company had two equity plans in place: the 2002 Stock Option Plan and the 2005 Stock Option Plan. Upon the closing of the IPO in October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the "2007 Plan") to provide for the granting of stock awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants as determined by the board of directors. In conjunction with the adoption of the 2007 Plan, no further option awards may be granted from the 2002 or 2005 Stock Option Plans, and any option cancellations or expirations from the 2002 or 2005 Stock Option Plans may not be reissued. As of March 31, 2016, there were 26,039 shares available for future grant under the 2007 Plan.

Under the terms of the 2007 Plan, the exercise price of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and, if granted to an owner of more than 10% of the Company's stock, not less than 110%. Stock options granted under the 2007 Plan expire no later than ten years from the date of grant. Stock options granted to employees generally vest over four years, while options granted to directors and consultants typically vest over a shorter period, subject to continued service. All of the options granted prior to October 2007 include early exercise provisions that allow for full exercise of the option prior to the option vesting, subject to certain repurchase provisions. The Company issues new shares to satisfy option exercises under the plans.

Stock Option Summary

The following table summarizes information about the Company's stock options outstanding at March 31, 2016, and activity during the three-month period then ended:

(in thousands, except years and per share data)	**Options**	**Weighted-Average Exercise Price**	**Weighted-Average Remaining Contractual Life (years)**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2015	388	$ 32.03	6.2	19
Options granted	108	$ 2.20		
Restricted stock units granted	73	$ —		

Restricted stock units vested	(72)	$ —			
Options forfeited/cancelled/expired	(36)	$ 31.80			
Outstanding at March 31, 2016	461	$ 24.93	11.0	$ 31	
Vested and expected to vest at March 31, 2016	456	$ 25.04	11.0	$ 31	
Vested at March 31, 2016	300	$ 34.63	5.4	$ —	
Exercisable at March 31, 2016	300	$ 34.63	5.4	$ —	

For options that have a quoted market price in excess of the exercise price (“in-the-money options”), the aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of the Company’s common stock as quoted on the NYSE MKT as of March 31, 2016. There were no stock option awards exercised for the three months ended March 31, 2016. The Company received no cash payments for the exercise of stock options during the three months ended March 31, 2016. The aggregate intrinsic value of stock option awards exercised was $4 thousand for the three months ended March 31, 2015, as determined at the date of option exercise.

As of March 31, 2016, total unrecognized compensation cost related to unvested stock options and restricted stock units was $882 thousand. This amount is expected to be recognized as stock-based compensation expense in the Company's consolidated statements of operations and comprehensive loss over the remaining weighted average vesting period of 2.02 years.

Stock Options and Awards to Employees and Directors

The Company grants options to purchase common stock to its employees and directors at prices equal to or greater than the market value of the stock on the dates the options are granted. The Company has estimated the value of stock option awards as of the date of grant by applying the Black-Scholes-Merton option pricing model using the single-option valuation approach. The application of this valuation model involves assumptions that are judgmental and subjective in nature. See Note 2 for a description of the accounting policies that the Company applied to value its stock-based awards.

During the three months ended March 31, 2016 and 2015, the Company granted options to purchase an aggregate of 91 thousand and 24 thousand shares of common stock, respectively, to employees and directors.

The weighted-average assumptions used in determining the value of options are as follows:

	Three months ended March 31,	
Assumption	**2016**	**2015**
Expected price volatility	87%	73%
Expected term (in years)	7.76	5.11
Risk-free interest rate	2.09%	1.61%
Dividend yield	0.00%	0.00%
Weighted-average fair value of options granted during the period	$1.60	$9.75

Expected Price Volatility—This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. The computation of expected volatility was based on the historical volatility of our own stock and comparable companies from a representative peer group selected based on industry and market capitalization data.

Expected Term—This is the period of time over which the options granted are expected to remain outstanding. The expected life assumption is based on the Company's historical data.

Risk-Free Interest Rate—This is the U.S. Treasury rate for the week of the grant having a term approximating the expected life of the option.

Dividend Yield—The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future.

Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Additionally, during the three months ended March 31, 2016 and 2015, the Company issued 64 thousand and 4 thousand shares of common stock, respectively, to employees.

For the three months ended March 31, 2016 and 2015, the Company recognized stock-based compensation expense of $207 thousand and $265 thousand, respectively, for stock based awards to employees and directors.

Stock-Based Awards to Non-Employees

During the three months ended March 31, 2016 and 2015, the Company granted options to purchase an aggregate of 17 thousand and 2 thousand shares of common stock, respectively, to non-employees in exchange for advisory and consulting services.

The stock options are recorded at their fair value on the measurement date and recognized over the respective service or vesting period. The fair value of the stock options granted was calculated using the Black-Scholes-Merton option pricing model based upon the following assumptions:

	Three Months Ended March 31,	
Assumption	**2016**	**2015**
Expected price volatility	87%	79%
Expected term (in years)	9.99	9.6
Risk-free interest rate	2.04%	1.91%
Dividend yield	0.00%	0.00%
Weighted-average fair value of options granted during the period	$2.64	$13.50

The Company granted restricted stock to non-employees totaling 10 thousand shares of common stock in the three months ended March 31, 2016 in exchange for advisory and consulting services. The Company did not grant any restricted stock to non-employees in the three months ended March 31, 2015.

For the three months ended March 31, 2016 and 2015, the Company recognized stock-based compensation expense of $40 thousand and $20 thousand, respectively, related to non-employee stock and option grants.

Summary of Stock-Based Compensation Expense

A summary of the stock-based compensation expense included in the consolidated statement of operations and comprehensive loss for the options and stock discussed above is as follows (the amounts that would have been charged to cost of goods sold are not material and have been included in general and administrative below.):

	Three Months Ended March 31,	
(in thousands)	**2016**	**2015**
Research and development	$31	$130
Sales and marketing	2	1
General and administrative	214	154
Total stock-based compensation expense	$247	$285

Since the Company continues to operate at a net loss, it does not expect to realize any current tax benefits related to stock options.

NOTE 12. LICENSE, COLLABORATION AND DISTRIBUTION AGREEMENTS

Virbac Agreement

In April 2012, the Company entered into a feasibility and option agreement with Virbac, a global animal health company for the development and potential commercialization of Aganocides for a number of veterinary uses for companion animals. Under the terms of the agreement, the Company received an upfront payment and is entitled to additional support for research and development. Virbac conducted veterinary studies using the Company's Aganocide compounds to assess feasibility for treating several veterinary indications.

In April 2013, the option was exercised, and the Company entered into a collaboration and license agreement with Virbac. Under this agreement, Virbac acquired exclusive worldwide rights to develop the Company's proprietary compound, auriclosene (NVC-422), for global veterinary markets for companion animals. The Company received an option exercise fee and may receive future development and pre-commercial milestone payments as a result of the collaboration. The Company also expects to receive royalties on the sale of any commercial products in the companion animal field. Virbac's option exercise follows its extensive testing of auriclosene for veterinary uses during the 12-month option period. The Company is recognizing the option exercise fee over its expected performance period of 10 years based on actual sales during this period.

The Company did not recognize any revenue under the Virbac agreement during three months ended March 31, 2016 and 2015, respectively.

The Company had a deferred revenue balance of $246 thousand at March 31, 2016 and December 31, 2015, respectively, related to this agreement, which consisted of the unamortized balances on the upfront technology access fee and option fee and the support for ongoing research and development.

NeutroPhase Distribution Agreements

In January 2012, the Company entered into a distribution agreement with Pioneer Pharma Co., Ltd. ("Pioneer"), a Shanghai-based company that markets high-end pharmaceutical products into China, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, the Company received an upfront payment of $313 thousand. NovaBay also received $313 thousand in January 2013, related to the submission of the first marketing approval for the product to the China Food and Drug Administration ("CFDA") (formerly the SFDA, State Food and Drug Administration), which was submitted in December 2012. The distribution agreement provides that Pioneer is entitled to receive cumulative purchase discounts of up to $500 thousand upon the purchase of NeutroPhase product. The deferred revenue will be recognized as the purchase discounts are earned, with the remaining deferred revenue recognized ratable over the product distribution period. During the year ended December 31, 2014, NovaBay received $625 thousand upon receipt of a marketing approval of the product from the CFDA.

In September 2012, the Company entered into two agreements with Pioneer: (1) an international distribution agreement ("Distribution Agreement") and (2) a unit purchase agreement ("Purchase Agreement"). These agreements were combined and accounted for as one arrangement with one unit of accounting for revenue recognition purposes.

Pursuant to the terms of the Distribution Agreement, Pioneer has the right to distribute NeutroPhase, upon receiving marketing approval from a regulatory authority, in certain territories in Asia (other than China). Upon execution of the Distribution Agreement, the Company received an upfront payment, which was recorded as deferred revenue. Pioneer

is also obligated to make certain additional payments to the Company upon receipt of marketing approval. The Distribution Agreement further provides that Pioneer is entitled to a cumulative purchase discount not to exceed $500 thousand upon the purchase of NeutroPhase product, payable in the Company's unregistered restricted common stock.

Pursuant to the Purchase Agreement, the Company also received $2.5 million from Pioneer for the purchase of restricted units (comprising one share of common stock and a warrant for the purchase of one share of common stock). The unit purchase was completed in two tranches: (1) 32,000 units in September 2012; and (2) 48,000 units in October 2012, with both tranches at a purchase price of $31.25 per share. The fair value of the total units sold was $3.5 million, based upon the trading price of our common stock on the dates the units were purchased and the fair value of the warrants based on the Black-Scholes-Merton option pricing model. Because the aggregate fair value of the units on the dates of purchase exceeded the $2.5 million in proceeds received from the unit purchase by approximately $1 million, we reallocated $600 thousand from deferred revenue to stockholders' equity as consideration for the purchase of the units.

In December 2013, the Company announced it had expanded its NeutroPhase commercial partnership agreement with Pioneer. The expanded agreement includes licensing rights to two new products, Avenova and CelleRx, both developed internally by NovaBay. The expanded partnership agreement covers the commercialization and distribution of these products in China and 11 countries in Southeast Asia.

During the three months ended March 31, 2016, the Company had three other smaller agreements and continues to seek additional distribution agreements.

Revenue has been recognized under these agreements as follows:

	Three Months Ended March 31,	
(in thousands)	**2016**	**2015**
Amortization of Upfront Technology Access Fee	$51	$ 6
Total	$51	$ 6

The Company had a deferred revenue balance of $271 thousand at March 31, 2016 and December 31, 2015, respectively, related to these agreements, which consisted of the unamortized balances on the upfront technology access fee and the support for ongoing research and development.

Avenova Distribution Agreements

In November 2014, the Company signed a nationwide distribution agreement for its Avenova product with McKesson Corporation (“McKesson”) as part of the Company’s commercialization strategy. McKesson makes Avenova widely available in local pharmacies and major retail chains across the U.S., such as Wal-Mart, Costco, CVS and Target. In January 2015, the Company signed a nationwide distribution agreement with Cardinal Health. In April 2015, the Company signed a nationwide distribution agreement with AmerisourceBergen to market Avenova.

During the three months ended March 31, 2016 and March 31, 2015, the Company earned $553 thousand and $39 thousand, respectively, in sales revenue for its Avenova product from its distribution agreements.

NOTE 13. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) plan covering all eligible employees. The Company is not required to contribute to the plan and has made no contributions through March 31, 2016.

NOTE 14. SUBSEQUENT EVENTS

On April 4, 2016, the Company entered into a securities purchase agreement for the sale of an aggregate of 6,173,299 shares of the Company's common stock, par value $0.01 per share (the "Shares"), and warrants exercisable for 3,086,651 Shares to accredited investors for an aggregate purchase price of $11,791,000 (the "Private Placement"). For every one (1) Share purchased at $1.91 per share, each purchaser will receive a warrant to purchase one-half a Share, with such warrants having a four (4)-year term and an exercise price of $1.91, callable by the Company if the closing price of the Company's common stock, as reported on the NYSE MKT, is $4.00 or greater for five (5) sequential trading days.

The Private Placement was designed to close in two tranches, the first of which occurred on May 6, 2016 (the "Primary Closing"), and the second of which is scheduled to occur on July 31, 2016 (the "Secondary Closing"). Both the Primary Closing of $7.8 million of Company securities and the Secondary Closing of $4.0 million of Company securities are subject to the same terms. Upon the Primary Closing, the Company used $2.5 million in proceeds to repay principal on the Notes issued to the Lenders. See Note 7 for additional information regarding the Notes.

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

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included in Part I, Item 1 of this report, and with our consolidated financial statements and related notes, 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, 2015, which was filed with the Securities and Exchange Commission (the "SEC") on March 4, 2016. This discussion contains forward-looking statements that involve risks and uncertainties. Words such as "expects," "anticipated," "will," "may," "goals," "plans," "believes," "estimates," variations of these words, and similar expressions are intended to identify these forward-looking statements. As a result of many factors, such as those set forth under the section entitled "Risk Factors" in Part II, Item 1A and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements Readers are cautioned that these forward-looking statements are only predictions based upon assumptions that we believed to be reasonable at the time and are subject to risks and uncertainties. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements.

Overview

We are a biopharmaceutical company developing products for the eye care market. We are currently focused primarily on commercializing prescription Avenova® for managing hygiene of the eyelids and lashes in the United States.

Avenova is the only eye care product formulated with a proprietary, stable and pure form of hypochlorous acid called Neutrox. By replicating the anti-microbial chemicals used by white blood cells to fight infection, Neutrox has proven in laboratory testing to have broad antimicrobial properties. Avenova with Neutrox removes debris from the skin on the eyelids and lashes without burning or stinging.

In November 2015, we introduced a new business strategy to focus on growing sales of Avenova in the U.S. market and to restructure our business with the goal of achieving profitability from operations by the end of 2016. Our three-part business strategy is comprised of: (1) focusing our resources on growing the commercial sales of Avenova in the U.S. eye care market, including the implementation of an innovative sales and marketing strategy to increase product margin and profitability; (2) significantly reducing expenses through the restructuring of our operations and other cost reduction measures; and (3) seeking additional sources of revenue through partnering, divesting and/or other means of monetizing non-core assets in urology, dermatology, and wound care.

We have developed additional commercial products containing Neutrox, including our NeutroPhase Skin and Wound Cleanser for wound care and CelleRx for the dermatology market. We have partnerships for NeutroPhase in the U.S. as well as select overseas markets, most notably China.

In addition to our Neutrox family of products, we have also synthesized and developed a second category of novel compounds aimed at harnessing the power of white blood cell chemistry to address the global, topical anti-infective market. This second product category includes auriclosene, our lead clinical-stage Aganocide compound, which is a patented, synthetic molecule with a broad spectrum of activity against bacteria, viruses and fungi.

Avenova

Prescription Avenova (0.01% Neutrox) is well-suited for daily eyelid and eyelash hygiene by the approximately 30 million Americans who suffer from blepharitis and dry eye. Additionally, we estimate that an additional 11 million patients suffering from other conditions could potentially benefit from the use of Avenova, bringing the total potential market to approximately 41 million patients.

We are targeting a customer base of prescribers that includes the approximately 17,000 ophthalmologists and approximately 37,000 optometrists in the U.S. In August 2014, we launched a dedicated Avenova sales force of 10 direct medical sales representatives in 10 major metropolitan areas across the United States. This sales and marketing campaign initially targeted major urban areas where large numbers of individuals suffer from problems with their eyelids and lashes. These markets included New York, Los Angeles, Boston, Atlanta, and San Francisco.

Based on positive sales performance, we expanded our sales force to 35 direct medical sales representatives in February 2015 and to 43 direct medical sales representatives in August 2015. The sales representatives recruited for this effort have extensive experience with eye care products and medical devices—a skill set critical for rapid adoption of Avenova. Based on extensive market research, we have assigned our sales representatives to the markets across the U.S. representing the highest sales potential. These direct medical sales representatives are calling on targeted ophthalmologists and optometrists in those markets that treat large numbers of blepharitis and dry eye patients. Avenova is a natural addition to their existing lid hygiene regimens.

We have distribution agreements with McKesson Corporation, Cardinal Health and AmerisourceBergen Corporation that make Avenova accessible in 90% of the approximate 67,000 retail pharmacies across the U.S. Avenova also is marketed through the top ophthalmology and optometry networks. These include Vision Source Independent Optometry Network, the largest independent optometry network in the country representing 2,800 independent optometrist offices, and ALLDocs Optometry Group (also known as The Association of LensCrafters Leaseholding Doctors), the second largest independent optometry group in the U.S., which works closely with its LensCrafters partners. Through a partnership with ALPHAEON, Avenova is available to member ophthalmologists on the ShoutMD® Store, the first social commerce store for lifestyle healthcare products. Avenova is also available for order online with a prescription, and we provide an online pharmacy locator to assist patients with filling prescriptions.

We expect that our prescription business will be the main driver of long-term Avenova sales growth. Reimbursement under insurance coverage continues to grow with 68% of Avenova prescriptions covered by insurance plans at the end of 2015. Supported by the high percentage rate of insurance reimbursement, we are focusing our primary sales efforts on building our prescription business under a new value pricing model. We are working to improve insurance reimbursement coverage for Avenova and aligning our product pricing accordingly.

Although we are focusing on our prescription sales, we expect continued growth in the doctor to patient direct sales channel. We also expect to invest in systems that support prescribing physicians' efforts to educate their patients. We have made it easy for doctors to get Avenova into the hands of patients by providing availability through well-known national pharmacy chains, specialty pharmacies, or directly through the practitioners' office. Furthermore, in order to ensure consistent pricing, we have instituted rebate cards to ensure the best price for the patient at the pharmacy. This sales model combined with the prospect for further increases in reimbursement under insurance plans has the potential to provide us with additional revenue upside.

Partnerships to Monetize Other Assets

We intend to seek additional sources of revenue and reduce expenses by licensing or selling select non-core assets, possibly including intelli-Case, NeutroPhase, CelleRx and our Aganocide compounds, including auriclosene.

Currently, the program with the most potential is our urology program. Statistically-significant and clinically-meaningful results from a Phase 2 clinical study of our Auriclosene Irrigation Solution (AIS) used to reduce urinary catheter blockage and encrustation (UCBE), were announced in September 2013. This study, comparing AIS to saline solution, achieved its primary endpoints and showed clear benefits for patients with long-term indwelling catheters. We initiated the next Phase 2 study in the fourth quarter of 2014 and in the fourth quarter of 2015 announced completion of that study. Patients with long-term indwelling urinary catheters were treated with AIS or its Vehicle. The results of this more demanding study showed that AIS was better than its Vehicle in preventing the reduction of flow through catheters due to encrustation, the primary efficacy measure, by a statistically-significant margin. Furthermore, there were no cases of clinical catheter blockage in the AIS arm of the study; all cases of clinical blockage requiring catheter removal occurred only in the Vehicle arm.

NovaClear intelli-Case. In June 2015, we received FDA-clearance for the NovaClear intelli-Case, a highly innovative, easy-to-use device for use with hydrogen peroxide disinfection solutions for soft and rigid gas permeable contact lenses. The intelli-Case monitors the neutralization of hydrogen peroxide during the disinfection cycle with sophisticated microprocessor electronics embedded in the cap of what otherwise looks like a standard peroxide lens case. The LED indicators on the lid inform the user if the lenses are safe to insert into the eyes, resulting in a disinfection system that is safe yet simple to use. We are seeking potential partners with the resources to make this break-through device available to the largest number of contact lens wearers as soon as possible.

Additional Neutrox-based Products

In addition to Avenova, the Neutrox-branded products currently being commercialized as prescription medical devices are NeutroPhase and CelleRx.

NeutroPhase (Wound Care). Since its launch in the U.S. in 2013, NeutroPhase has impacted how wound care is administered. Consisting of 0.03% Neutrox, NeutroPhase is used to cleanse and remove microorganisms from any type of acute or chronic wound and can be used with any type of wound care modality. Recently, NeutroPhase has been found to be an effective irrigation solution as part of the adjunct treatment for Necrotizing Fasciitis ("NF"). Also known as flesh-eating disease, NF typically has high mortality and amputation rates (30% and 70%, respectively), even with aggressive debridement and antibiotic treatment. We believe that NeutroPhase is also well-suited to treat the six million patients in the U.S. who suffer from chronic non-healing wounds, such as pressure, venous stasis and diabetic ulcers.

In the U.S. and internationally, NeutroPhase is distributed through commercial partners. In January 2012, we entered into an exclusive distribution agreement with Pioneer Pharma Company Limited ("Pioneer"), a Shanghai-based company, for the distribution of NeutroPhase throughout Southeast Asia and mainland China. We subsequently expanded the agreement with Pioneer so that it includes the licensing rights to CelleRx and Avenova. In September 2014, China's Food and Drug Administration cleared our NeutroPhase Skin and Wound Cleanser for sale throughout mainland China. In November 2014, Taiwan's Food and Drug Administration cleared our NeutroPhase Skin and Wound Cleanser for sale in Taiwan. We began shipping NeutroPhase to China and Taiwan in the fourth quarter of 2014 to support our launch of NeutroPhase Skin and Wound Cleanser by Pioneer. In the U.S., NeutroPhase is distributed through our partner, Principle Business Enterprise ("PBE").

CelleRx (Dermatology). Created for cosmetic procedures, CelleRx (0.015% Neutrox) is a gentle cleansing solution that is effective for post-laser resurfacing, chemical peels and other cosmetic surgery procedures. Cosmetic surgeons and aesthetic dermatologists have found that CelleRx results in less pain, erythema, and exudate compared to Dakin solution, which contains bleach impurities. CelleRx is a non-alcohol formulation that doesn't dry or stain the skin, and most importantly, has been shown to reduce the patient's downtime post procedure.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the

reporting periods. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts, giving due consideration to materiality. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, research and development costs, patent costs, stock-based compensation, income taxes and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates.

While our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements, included in Part I, Item 1 of this report, we believe that the following accounting policies are most critical to fully understanding and evaluating our reported financial results.

Allowance for Doubtful Accounts

We charge bad debt expense and setup an allowance for doubtful accounts when management believes it to be unlikely that specific invoices will be collected. Management identified amounts due that are in dispute and it believes are unlikely