

NovaBay Pharmaceuticals, Inc.  
Form 10-Q  
May 11, 2017  
**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, 2017

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  
(State or other jurisdiction of incorporation or organization)

68-0454536  
(I.R.S. Employer Identification No.)

**2000 Powell Street, Suite 1150, 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, 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. (Check one):

Large accelerated filer  
Non-accelerated filer

Accelerated filer

Emerging growth company

Smaller reporting company

(Do not check if a smaller reporting 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 Exchange Act).  
Yes No

As of May 9, 2017, there were 15,309,175 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 subsidiary, as applicable.

NovaBay®, NovaBay Pharma®, Avenova™, NeutroPhase®, CelleRx®, intelli-Case™, AgaNa®e Aganocide®, AgaDerm®, Neutrox™ and Going Beyond Antibiotics™ are trademarks of NovaBay Pharmaceuticals, Inc. All other trademarks and trade names are the property of their respective owners.

**PART I****FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****NOVABAY PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS****(In thousands)**

|   | <b>March 31,<br/>2017</b> | <b>December<br/>31,<br/>2016</b> |
|---|---------------------------|----------------------------------|
|   | (Unaudited)               | Footnote<br>2                    |
| <b>ASSETS</b>   |                           |                                  |
| Current assets:   |                           |                                  |
| Cash and cash equivalents   | \$7,399                   | \$9,512                          |
| Accounts receivable, net of allowance for doubtful accounts (\$52 and \$10 at March 31, 2017 and December 31, 2016, respectively)   | 2,331                     | 2,120                            |
| Inventory, net of allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of \$273 and \$196 at March 31, 2017 and December 31, 2016, respectively) | 765                       | 873                              |
| Prepaid expenses and other current assets   | 1,036                     | 1,966                            |
| Total current assets  | 11,531                    | 14,471                           |
| Property and equipment, net   | 421                       | 371                              |
| Other assets long-term  | 730                       | 539                              |
| <b>TOTAL ASSETS</b>   | <b>\$12,682</b>           | <b>\$15,381</b>                  |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>   |                           |                                  |
| Liabilities:  |                           |                                  |
| Current liabilities:  |                           |                                  |
| Accounts payable  | \$798                     | \$455                            |
| Accrued liabilities   | 1,831                     | 2,007                            |
| Deferred revenue  | 1,673                     | 1,861                            |
| Total current liabilities   | 4,302                     | 4,323                            |
| Deferred revenues - non-current   | 1,807                     | 1,986                            |
| Deferred rent   | 314                       | 327                              |
| Warrant liability   | 1,681                     | 1,446                            |
| Other liabilities   | 222                       | 198                              |
| Total liabilities   | 8,326                     | 8,280                            |
| Stockholders' equity :  |                           |                                  |

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|  |                 |                 |
|--|-----------------|-----------------|
| Preferred stock: 5,000 shares authorized; none outstanding at March 31, 2017 and December 31, 2016   | —               | —               |
| Common stock, \$0.01 par value; 240,000 shares authorized; 15,288 and 15,269 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively | 153             | 153             |
| Additional paid-in capital   | 111,885         | 110,619         |
| Accumulated deficit  | (107,682 )      | (103,671 )      |
| Total stockholders' equity   | 4,356           | 7,101           |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>  | <b>\$12,682</b> | <b>\$15,381</b> |

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)**

|  | Three Months<br>Ended<br>March 31, |            |
|--|------------------------------------|------------|
|  | 2017                               | 2016       |
| Sales:   |                                    |            |
| Product revenue, net   | \$3,694                            | \$1,655    |
| Other revenue, net   | 7                                  | 64         |
| Total sales, net   | 3,701                              | 1,719      |
| Product cost of goods sold   | 588                                | 611        |
| Gross profit   | 3,113                              | 1,108      |
| Research and development   | 62                                 | 933        |
| Sales and marketing  | 3,740                              | 3,144      |
| General and administrative   | 3,088                              | 1,682      |
| Total operating expenses   | 6,890                              | 5,759      |
| Operating Loss   | (3,777 )                           | (4,651 )   |
| Non cash loss on changes in fair value of warrant liability  | (235 )                             | (385 )     |
| Other income (expense), net  | 2                                  | (41 )      |
| Loss before provision for income taxes   | (4,010 )                           | (5,077 )   |
| Provision for income tax   | (1 )                               | —          |
| Net loss and comprehensive loss  | \$(4,011 )                         | \$(5,077 ) |
| Net loss per share attributable to common stockholders (basic and diluted)                               | \$(0.26 )                          | \$(1.24 )  |
| Weighted-average shares of common stock outstanding used in computing net loss per share of common stock | 15,284                             | 4,086      |

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



**NOVABAY PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)****(In thousands)**

|  | <b>Three Months<br/>Ended<br/>March 31,<br/>2017      2016</b> |                |
|--|--|----------------|
| <b>Operating activities:</b>   |  |                |
| Net loss   | \$(4,011)  | \$(5,077)      |
| Adjustments to reconcile net loss to net cash used in operating activities:              |  |                |
| Depreciation and amortization  | 18   | 40             |
| Stock-based compensation expense for options and stock issued to employees and directors | 1,157  | 74             |
| Stock-based compensation expense for options and stock issued to non-employees           | 36   | 19             |
| Issuance of RSUs to employees  | —  | 133            |
| Issuance of RSUs to non-employees  | —  | 21             |
| Note receivable impairment   | —  | 91             |
| Non-cash loss on change in fair value of warrant liability                               | 235  | 385            |
| Changes in operating assets and liabilities:   |  |                |
| Increase in accounts receivable  | (211 )   | (961 )         |
| Decrease in inventory  | 108  | 144            |
| (Increase) decrease in prepaid expenses and other assets                                 | 921  | (107 )         |
| Increase in other assets long-term   | (181 )   | —              |
| Increase (decrease) in accounts payable and accrued liabilities                          | 234  | (476 )         |
| Increase in deferred rent  | 56   | —              |
| Increase (decrease) in deferred revenue  | (368 )   | 781            |
| <b>Net cash used in operating activities</b>   | <b>(2,006)</b>   | <b>(4,933)</b> |
| <b>Investing activities:</b>   |  |                |
| Purchases of property and equipment  | (59 )  | (16 )          |
| <b>Net cash used in investing activities</b>   | <b>(59 )</b>   | <b>(16 )</b>   |
| <b>Financing activities:</b>   |  |                |
| Proceeds from common stock issuances, net  | —  | 2,628          |
| Proceeds from restricted stock sold to cover taxes                                       | —  | 12             |
| Settlement of restricted stock for tax withholding                                       | (48 )  | (11 )          |
| Proceeds from borrowings   | —  | 1,365          |
| Net cash provided (used) in financing activities   | <b>(48)</b>  | <b>3,994</b>   |
| <b>Net decrease in cash and cash equivalents</b>   | <b>(2,113)</b>   | <b>(955 )</b>  |
| Cash and cash equivalents, beginning of period   | 9,512  | 2,385          |
| <b>Cash and cash equivalents, end of period</b>  | <b>\$7,399</b>   | <b>\$1,430</b> |

**Supplemental disclosure of non cash information:**

|  |      |     |
|--|------|-----|
| Stock issued to consultants for services, included in accounts payable and accrued liabilities | \$1  | \$1 |
| Fixed asset purchases, included in accounts payable and accrued liabilities                    | \$9  | \$— |
| Severance paid in RSU to non-employee  | \$69 | \$— |

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

## NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. (the “Company”) is a pharmaceutical 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 (“DermaBay”). In June 2010, it 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, the Company effected a 1-for-25 reverse split of its outstanding common stock (the “Reverse Stock Split”) (See Note 11). The accompanying financial statements and related notes give retroactive effect to the Reverse Stock Split.

### *Liquidity*

Based primarily on the funds available at March 31, 2017, the Company believes these resources will be sufficient to fund its operations into May 2018. The Company has sustained operating losses for the majority of its corporate history and expects that its 2017 expenses will exceed its 2017 revenues, as the Company continues to re-invest in our Avenova commercialization efforts. The Company expects to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. Accordingly, the Company’s planned operations raise doubt about its ability to continue as a going concern. The Company’s liquidity needs will be largely determined by the success of operations in regards to the commercialization of Avenova. The Company’s plans to alleviate the doubt of its going concern, which are being implemented to mitigate these conditions, primarily include its ability to control the timing and spending on its sales and marketing programs and raising additional funds through equity financings. The Company also may consider other plans to fund operations including: (1) out-licensing rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestones or an upfront fee; (2) raising additional capital through debt financings or from other sources; (3) reducing spending on one or more of its sales and marketing programs; and/or (4) restructuring operations to change its overhead

structure. The Company may issue securities, including common stock and warrants through private placement transactions or registered public offerings, which would require the filing of a Form S-1 or Form S-3 registration statement with the Securities and Exchange Commission (“SEC”). The Company’s future liquidity needs, and ability to address those needs, will largely be determined by the success of the commercialization of Avenova. 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 its 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 23, 2017. The unaudited condensed consolidated financial statements include the accounts of the Company and its consolidated subsidiaries, as applicable. 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. Additionally, prior period amounts in the accompanying consolidated statement of operations and comprehensive loss have been reclassified to conform to current period presentation. The reclassifications did not change the net loss or loss per share.

### ***Principles of Consolidation***

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, DermaBay, Inc., as applicable. DermaBay, Inc. was dissolved by the Company in April 2016. All inter-company accounts and transactions have been eliminated in consolidation.

### ***Use of Estimates***

The preparation of financial statements in accordance with 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 and Cash Equivalents***

The Company considers all highly-liquid instruments with a stated maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents are stated at cost, which approximates fair value. As of March 31, 2017, and December 31, 2016, the Company's cash and cash equivalents were held in three highly-rated, major financial institutions in the United States.

***Concentrations of Credit Risk and Major Partners***

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits of cash and cash equivalents 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.

During the three months ended March 31, 2017 and 2016 revenues were derived primarily from sales of Avenova directly to doctors through the Company's webstore and to three major distribution partners.

During the three months ended March 31, 2017 and 2016 revenues from our major distribution or collaboration partners greater than 10% are as follows:

| Major distribution or collaboration partner | March 31, 2017 |   | March 31, 2016 |   |
|---|----------------|---|----------------|---|
|   |                |   |                |   |
| Distributor A                               | 23             | % | 20             | % |
| Distributor B                               | 25             | % | *              |   |
| Distributor C                               | 21             | % | *              |   |
| Collaborator                                | *              |   | 14             | % |

\* not greater than 10%

As of March 31, 2017 and December 31, 2016, accounts receivable from our major distribution partners greater than 10% are as follows:

| Major distribution partner | March 31, 2017 |   | December 31, 2016 |   |
|----------------------------|----------------|---|-------------------|---|
|                            |                |   |                   |   |
| Distributor A              | 25             | % | 22                | % |
| Distributor B              | 25             | % | 24                | % |
| Distributor C              | 28             | % | 31                | % |

The Company relies on two contract sole source manufacturers to produce its finished goods. The Company does not have any manufacturing facilities and intends to continue to rely on third parties for the supply of finished goods. Third party manufacturers may not be able to meet the Company's needs with respect to timing, quantity or quality.

#### *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 GAAP guidance, which defines fair value, establishes a framework for measuring fair value, and requires disclosures about fair value measurements.

Under 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; and

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

#### ***Allowance for Doubtful Accounts***

The Company charges bad debt expense and records an allowance for doubtful accounts when management believes it to be unlikely that specific invoices will be collected. Management identifies amounts due that are in dispute and it believes are unlikely to be collected. As of March 31, 2017 and December 31, 2016, management reserved \$52 thousand and \$10 thousand, respectively, primarily based on specific amounts that were in dispute and were over 120 days past due at those dates.

#### ***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 estimated net realizable value determined by the first-in, first-out method. The inventory allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of \$273 thousand and \$196 thousand at March 31, 2017, and December 31, 2016, respectively.





### ***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 computer equipment and 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 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 first quarter of fiscal year 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 during the three months ended March 31, 2016. There were no impairments during the three months ended March 31, 2017. Determination of recoverability is based on an 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 Income (Loss)***

Accounting Standards Codification (“ASC”) 220, *Comprehensive Income* 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 income (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 a sale 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. If these factors were to vary, the resulting change could have a material effect on the Company's revenue recognition and on the Company's results of operations.

#### ***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 wholesalers' 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. The Company recognizes other revenue 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 the Company's revenue recognition and 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 allowance for excess and obsolete inventory along with lower of cost and estimated net realizable value.

### ***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 Accounting Standards Update (“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 12 for 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 (consultants and advisory board members) based on the fair market value of the Company’s common stock as of 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 Liability***

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 earnings (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 period, including stock options and warrants, using the treasury stock method, using the if-converted 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, 2017 and 2016, there was no difference between basic and diluted EPS due to the Company's net losses. The following table sets forth the calculation of basic EPS and diluted EPS:

| <b>(in thousands)</b>  | <b>Three Months<br/>Ended<br/>March 31,</b> |             |
|--|---|-------------|
|  | <b>2017</b>                                 | <b>2016</b> |
| Net loss   | \$ (4,011 )                                 | \$ (5,077 ) |
| Basic Shares   | 15,284                                      | 4,086       |
| Add: shares issued upon assumed exercise of stock options and warrants | —   | —           |
| Diluted shares   | \$ 15,284                                   | \$ 4,086    |
| Basic and diluted net loss per share                                   | \$ (0.26 )                                  | \$ (1.24 )  |

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:

| <b>(in thousands)</b>                             | Three Months<br>Ended<br>March 31, |       |
|---|------------------------------------|-------|
|   | 2017                               | 2016  |
| Period end stock options to purchase common stock | 2,134                              | 300   |
| Period end common stock warrants                  | 565                                | 1,458 |
|   | 2,699                              | 1,758 |

### ***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606). In August 2015 and March, April, May and December 2016, the FASB issued additional amendments to the new revenue guidance relating to reporting revenue on a gross versus net basis, identifying performance obligations, licensing arrangements, collectability, noncash consideration, presentation of sales tax, transition, and clarifying examples. This new standard will replace all current GAAP guidance on this topic and eliminate all industry-specific guidance. The new revenue recognition guidance provides a unified model to determine how revenue is recognized. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under today’s guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each performance obligation. ASU 2014-09 as amended is effective for interim and annual reporting periods beginning after December 15, 2017 and permits companies to adopt the standard early. The Company plans to adopt the new standard effective January 1, 2018 with a modified retrospective transition applying the new guidance to the most current period presented with the cumulative effect of changes reflected in the opening balance of retained earnings in the most current period presented.

While the Company is still in the process of assessing the potential impact of this new standard on its consolidated financial statements, the Company has identified that transactions which under current guidance are recognized upon shipment from its distributor to the final customers for its major distribution partners will be recognized upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to. As a result, the Company will record contract liabilities for the invoiced amounts that are estimated to be subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. The constraint on variable consideration for product returns will be a new estimation resulting from the earlier recognition under the new guidance.

The Company has also identified that license and collaboration revenue that is currently accounted for as a combined unit of accounting because products or services are not separable, may be identified as separate performance obligations that are capable of being distinct under the new guidance. As a result, the transaction price under these arrangements, including upfront fees and milestone payments, may be allocated differently to performance obligations, which may each be recognized at earlier points in time or with a different pattern of performance over time.

The Company is still evaluating its major distribution agreements and its license and collaboration agreements and assessing the impact of adoption of the new standard to its consolidated financial statements. The Company will continue to monitor additional modifications, clarifications or interpretations undertaken by the FASB that may impact its current conclusions, and will expand its analysis to include any new or modified revenue arrangements prior to adoption. The Company expects to complete such efforts by the fourth quarter of 2017.



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 Company previously adopted ASU 2014-15. For adoption impact, see Note 1 to the financial statements under “*Liquidity*.”

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 adoption and implementation of ASU 2015-11 did not result in a material impact to the Company’s consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments – 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 consolidated 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 on its consolidated 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 such interim period. The adoption and implementation of ASU 2016-09 did not result in a material impact to the Company’s consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments (Topic 230)*, which addresses eight specific issues regarding the treatment of cash flow. This update is effective for the Company for its fiscal year 2018. The Company is currently evaluating the effects of the adoption of ASU 2016-15 to its consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230)*, that will require entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. This update is effective for the Company for its fiscal year 2018. The Company is currently evaluating the effects of the adoption of ASU 2016-18 to its consolidated 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, 2017:

| <b>(in thousands)</b> | <b>Fair Value Measurements Using</b> |                    |                    |
|-----------------------|--------------------------------------|--------------------|--------------------|
|                       | <b>Quoted</b>                        | <b>Significant</b> | <b>Significant</b> |

|  | <b>Balance at</b> | <b>Prices in</b> | <b>Other</b>      | <b>Unobservable</b> |
|--|-------------------|------------------|-------------------|---------------------|
|  | <b>March</b>      | <b>Active</b>    | <b>Observable</b> | <b>Inputs</b>       |
|  | <b>31,</b>        | <b>Markets</b>   | <b>Inputs</b>     | <b>(Level 3)</b>    |
|  | <b>2017</b>       | <b>for</b>       | <b>(Level 2)</b>  |                     |
|  |                   | <b>Identical</b> |                   |                     |
|  |                   | <b>Items</b>     |                   |                     |
|  |                   | <b>(Level 1)</b> |                   |                     |
| <b>Assets</b>                                    |                   |                  |                   |                     |
| Cash equivalents                                 | \$100             | \$ 100           | \$ —              | \$ —                |
| Restricted cash held as a certificate of deposit | 324               | 324              | —                 | —                   |
| Deposit held as a certificate of deposit         | 150               | 150              | —                 | —                   |
| Total assets                                     | \$574             | \$ 574           | \$ —              | \$ —                |
| <b>Liabilities</b>                               |                   |                  |                   |                     |
| Warrant liability                                | \$1,681           | \$ —             | \$ —              | \$ 1,681            |
| Total liabilities                                | \$1,681           | \$ —             | \$ —              | \$ 1,681            |

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

| (in thousands)                                   | Fair Value Measurements Using |           |             |              |
|--|-------------------------------|-----------|-------------|--------------|
|  | Quoted                        |           |             |              |
|  | Prices in                     |           | Significant | Significant  |
|  | Balance Active                | Markets   | Other       | Unobservable |
|  | at                            | for       | Observable  | Inputs       |
|  | December                      | Identical | Inputs      | (Level 3)    |
|  | 31,                           | Items     | (Level 2)   |              |
|  | 2016                          | (Level 1) |             |              |
| <b>Assets</b>                                    |                               |           |             |              |
| Cash equivalents                                 | \$100                         | \$ 100    | \$ —        | \$ —         |
| Restricted cash held as a certificate of deposit | 324                           | 324       | —           | —            |
| Deposit held as a certificate of deposit         | 150                           | 150       | —           | —            |
| Total assets                                     | \$574                         | \$ 574    | \$ —        | \$ —         |
| <b>Liabilities</b>                               |                               |           |             |              |
| Warrant liability                                | \$1,446                       | \$ —      | \$ —        | \$ 1,446     |
| Total liabilities                                | \$1,446                       | \$ —      | \$ —        | \$ 1,446     |

For the three-month period ended March 31, 2017, as a result of the fair value adjustment of the warrant liability, the Company recorded a non-cash expense on an increase in the fair value of the warrants of \$235 thousand, in its consolidated statement of operations and comprehensive loss. See Note 10 for further discussion of the calculation of the fair value of the warrant liability.

| (in thousands)                                       | Warrant   |
|--|-----------|
|  | liability |
| Fair value of warrant liability at December 31, 2016 | \$ 1,446  |
| Increase in fair value at March 31, 2017             | 235       |
| Fair value of warrant liability at March 31, 2017    | \$ 1,681  |

#### NOTE 4. PREPAID EXPENSES AND OTHER ASSETS

Prepaid expenses and other current assets consisted of the following:

| <b>(in thousands)</b>                           | <b>March<br/>31,</b> | <b>December<br/>31,</b> |
|---|----------------------|-------------------------|
|   | <b>2017</b>          | <b>2016</b>             |
| Prepaid outsourced sales team                   | \$—                  | \$ 606                  |
| Prepaid sales rebate                            | 340                  | 658                     |
| Prepaid rent                                    | 33                   | 120                     |
| Prepaid research and development services       | 121                  | 123                     |
| Rent receivable                                 | 87                   | 165                     |
| Other   | 455                  | 294                     |
| Total prepaid expenses and other current assets | \$1,036              | \$ 1,966                |

#### **NOTE 5. INVENTORY**

Inventory consisted of the following:

| <b>(in thousands)</b>   | <b>March<br/>31,</b> | <b>December<br/>31,</b> |
|---|----------------------|-------------------------|
|   | <b>2017</b>          | <b>2016</b>             |
| Raw materials and supplies  | \$ 559               | \$ 514                  |
| Finished goods  | 479                  | 555                     |
| Less allowance for excess and obsolete inventory and lower of cost or estimate net realizable value adjustments | (273 )               | (196 )                  |
| Total inventory, net  | \$ 765               | \$ 873                  |

**NOTE 6. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

| <b>(in thousands)</b>                           | <b>March<br/>31,</b> | <b>December<br/>31,</b> |
|---|----------------------|-------------------------|
|   | <b>2017</b>          | <b>2016</b>             |
| Office and laboratory equipment                 | \$ 24                | \$ 24                   |
| Furniture and fixtures                          | 153                  | 153                     |
| Computer equipment and software                 | 231                  | 170                     |
| Production equipment                            | 105                  | 105                     |
| Leasehold improvements                          | 74                   | 68                      |
| Total property and equipment, at cost           | 587                  | 520                     |
| Less: accumulated depreciation and amortization | (166 )               | (149 )                  |
| Total property and equipment, net               | \$ 421               | \$ 371                  |

Depreciation and amortization expense was \$18 thousand and \$40 thousand for the three months ended March 31, 2017 and 2016, respectively.

**NOTE 7. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following:

| <b>(in thousands)</b>          | <b>March<br/>31,</b> | <b>December<br/>31,</b> |
|--------------------------------|----------------------|-------------------------|
|                                | <b>2017</b>          | <b>2016</b>             |
| Research and development       | \$10                 | \$ 2                    |
| Employee payroll and benefits  | 603                  | 763                     |
| Severance pay                  | —                    | 250                     |
| Inventory                      | 68                   | 75                      |
| Legal                          | 242                  | —                       |
| Sales rebates                  | 225                  | 166                     |
| Outsourced sales team          | 280                  | 333                     |
| Distributor fees and discounts | 203                  | 206                     |
| Other                          | 200                  | 212                     |

Total accrued liabilities           \$1,831   \$ 2,007

#### **NOTE 8. 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 Directors of the Company (the “Board”) and 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. China Pioneer, with its wholly-owned subsidiary, Pioneer Hong Kong (which now holds all of the holdings of Pioneer Singapore due to a recent internal corporate reorganization) and Mr. Fu are the Company's two largest stockholders. 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 were used for general corporate purposes. Minimum quarterly payments of principal and interest began on March 31, 2016 and were scheduled to continue on the last day of each of June, September, December and March thereafter. The entire principal sum and any and all accrued and unpaid interest was payable in full upon the Company's next financing, subsequent to the dates of the Notes, but in no event would the term of the Loan extend beyond December 30, 2018, except for the loan by Mr. Fu, the term of which was to extend three (3) years from the date of issuance. The Notes carried an interest rate of six percent (6%) per annum and could be prepaid in whole or in part at any time without premium or penalty.

In connection with the Notes, China Kington 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 perfected a 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 the financing; (3) the participation of the Board, management and investors that the Board 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 Board, respectively. Because Bob Wu is the Managing Director of China Kington, China Kington became a related party upon his appointment to the Board.

Upon closing the first tranche of an \$11.8 million private placement on May 6, 2016 and by agreement with the Lenders, the Company used \$2.5 million of the proceeds from the private placement to repay the principal on the Notes issued to the Lenders.

Upon closing the second tranche of such \$11.8 million private placement on August 1, 2016, the Company repaid the remaining principal on the Notes in the amount of \$520 thousand.

As of March 31, 2017, and December 31, 2016, outstanding amounts under these Notes was zero.

## **NOTE 9. COMMITMENTS AND CONTINGENCIES**

### ***Operating Leases***

### **Facility Leases**

On August 24, 2016, we entered into an Office Lease (the "Lease"), pursuant to which we leased approximately 7,799 rentable square feet of real property located on the eleventh floor (Suite 1150) at 2000 Powell Street, Emeryville, California 94608 from KBSIII Towers at Emeryville, LLC (the "Landlord"), for our new principal executive offices. The expiration date of the Lease is February 28, 2022, unless earlier terminated pursuant to any provision of the Lease. The Company has the option to extend the term of the Lease for one five (5)-year period upon written notice to



the Landlord due no earlier than twelve (12) months and no later than nine (9) months prior to the expiration of the Lease.

The Company still has a lease commitment for the laboratory facilities and office space at Suite 550, EmeryStation North Building, 5980 Horton Street, Emeryville, California (“EmeryStation”) under an operating lease which will expire on October 21, 2020. On July 11, 2016, the Company entered into a Sublease Agreement to sublease all 16,465 rentable square feet of real property at EmeryStation (the “Sublease Agreement”). The commencement date under the Sublease Agreement was September 8, 2016. The expiration date of the Sublease Agreement is October 21, 2020, as amended (while the expiration date of the Company’s master lease for the EmeryStation premises is October 31, 2020), unless earlier terminated pursuant to the Company terminating its master lease for EmeryStation or the Sublease Agreement.

Rent expense for the above two facility leases was approximately \$99 thousand and \$253 thousand, net for the three months ended March 31, 2017 and 2016, respectively.

The Company’s monthly rent payments fluctuate under the various leases and sublease agreements. In accordance with GAAP, the Company recognizes rent expense on a straight-line basis. The Company records deferred rent and sublease future minimum payments receivable for the difference between the amounts paid and recorded as expense.

#### **Vehicle Fleet Leases**

During the three months ended March 31, 2017, the Company leased 54 vehicles under a master fleet lease agreement. Each lease is for a period of 36 months, which commenced upon the delivery of the vehicle. As of March 31, 2017, the aggregate monthly lease payment for all 54 vehicles is \$14 thousand, including a management fee of \$15 per vehicle. In addition, the Company made an initial payment of \$2,750 per vehicle, which it is amortizing over the 36 month lease period.

Lease expense for the vehicle fleet was \$17 thousand and zero for the three months ended March 31, 2017 and 2016, respectively.

#### *Directors and Officers Indemnity*

As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving at the Company's 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 it to recover a portion of any future payments. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, it has not recorded any liabilities for these agreements as of December 31, 2016.

In the normal course of business, the Company provides indemnification of varying scope under its agreements with other companies, typically its clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, it 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, it believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of March 31, 2017.

#### *Legal Matters*

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. On December 19, 2016, Liam Kozma ("Plaintiff"), claiming to be a stockholder of the Company, filed a putative derivative action (the "Complaint") against the Company and the Board of Directors (the "Board") in the United States District Court for the District of Delaware (the "Court") alleging that the Board breached its fiduciary duty and made materially false and misleading statements in the Company's proxy statement filed with the SEC on April 18, 2016, as supplemented on May 17, 2016 (collectively, the "2016 Proxy Statement"), related to the Company's amendment of the 2007 Omnibus Incentive Plan (the "Plan"). The Company is in discussion with Plaintiff's counsel regarding settlement. The Company has reserved an amount in connection with the Complaint that is immaterial to its results of operations or financial condition. Such litigation and threatened litigation actions necessarily involve substantial uncertainty and it is not possible at this time to predict the ultimate resolution or to determine whether, or to what extent, any loss with respect to these legal proceedings may exceed the amounts reserved by the Company.

There are no matters as of March 31, 2017, that, in the opinion of management, would ultimately result in liability that would have a material adverse effect on the Company's financial position, results of operations or cash flows.

#### **NOTE 10. 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 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 and comprehensive loss. 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 “2015 Securities Purchase 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 (which expired March 3, 2016). The Company entered into these agreements to enable it to expeditiously raise capital in the October 2015 Offering (as described below) and future offerings. As consideration for these agreements, the Company amended certain provisions of both the warrants with a 15-month term (the “Short-Term Warrants”) and warrants with a five-year term (the “Long-Term Warrants”) issued pursuant to the 2015 Securities Purchase Agreement (together, the “March 2015 Warrants”) and the warrants issued pursuant to the placement agent agreement dated June 29, 2011 (the “July 2011 Warrants”). Specifically, the amendments decreased the exercise price for both the March 2015 Warrants and the July 2011 Warrants to \$5.00 per share. In addition, the amendments extended the exercise expiration date for the Short-Term Warrants and the July 2011 Warrants to March 6, 2020. A price protection provision also was added to both the July 2011 Warrants and 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 (the “October 2015 Warrants”) with an exercise price of \$5.00 per share (the “October 2015 Offering”). 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 the October 2015 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 the Company sold common stock to Mr. Jian Ping Fu at that price.

The key assumptions used to value the July 2011 Warrants as of March 31, 2017 and December 31, 2016 were as follows:

| <b>Assumption</b>         | <b>Period Ended</b>   |                          |
|---------------------------|-----------------------|--------------------------|
|                           | <b>March 31, 2017</b> | <b>December 31, 2016</b> |
| Expected price volatility | 103.00%               | 102.00 %                 |
| Expected term (in years)  | 2.93                  | 3.18                     |
| Risk-free interest rate   | 1.48 %                | 1.51 %                   |

|   |        |   |         |   |
|---|--------|---|---------|---|
| Dividend yield                          | 0.00   | % | 0.00    | % |
| Weighted-average fair value of warrants | \$2.97 |   | \$ 2.55 |   |

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 Company's agreement to modify the terms of the March 2015 Warrants and July 2011 Warrants in October 2015, 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 and comprehensive loss.

The key assumptions used to value the Short-Term Warrants as of March 31, 2017 and December 31, 2016 were as follows:

| <b>Assumption</b>                       | <b>Period Ended</b>           |                                  |         |   |
|---|-------------------------------|----------------------------------|---------|---|
|   | <b>March<br/>31,<br/>2017</b> | <b>December<br/>31,<br/>2016</b> |         |   |
| Expected price volatility               | 103.00%                       | 102.00                           | %       |   |
| Expected term (in years)                | 2.93                          | 3.18                             |         |   |
| Risk-free interest rate                 | 1.48                          | %                                | 1.51    | % |
| Dividend yield                          | 0.00                          | %                                | 0.00    | % |
| Weighted-average fair value of warrants | \$2.97                        |                                  | \$ 2.47 |   |

The key assumptions used to value the Long-Term Warrants as of March 31, 2017 and December 31, 2016 were as follows:

| <b>Assumption</b>                       | <b>Period Ended</b>           |                                  |   |   |
|---|-------------------------------|----------------------------------|---|---|
|   | <b>March<br/>31,<br/>2017</b> | <b>December<br/>31,<br/>2016</b> |   |   |
| Expected price volatility               | 103.00%                       | 102.00                           | % |   |
| Expected term (in years)                | 2.93                          | 3.18                             |   |   |
| Risk-free interest rate                 | 1.48                          | 1.51                             | % | % |
| Dividend yield                          | 0.00                          | 0.00                             | % | % |
| Weighted-average fair value of warrants | \$2.80                        | \$ 2.55                          |   |   |

As noted above, the Company issued warrants in connection with the October 2015 Offering. The Company evaluated the terms of the October 2015 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 and comprehensive loss. The fair value of the warrants at issuance on October 27, 2015 was \$1.3 million.

The key assumptions used to value the warrants as of March 31, 2017, and December 31, 2016 were as follows:

| <b>Assumption</b>                       | <b>Period Ended</b>           |                                  |   |   |
|---|-------------------------------|----------------------------------|---|---|
|   | <b>March<br/>31,<br/>2017</b> | <b>December<br/>31,<br/>2016</b> |   |   |
| Expected price volatility               | 98.00%                        | 96.00                            | % |   |
| Expected term (in years)                | 3.58                          | 3.83                             |   |   |
| Risk-free interest rate                 | 1.62                          | 1.66                             | % | % |
| Dividend yield                          | 0.00                          | 0.00                             | % | % |
| Weighted-average fair value of warrants | \$3.05                        | \$ 2.60                          |   |   |

During the third quarter of 2016, a total of 3,613,284 warrants to purchase 3,613,284 shares of common stock were exercised related to warrants issued during July 2011, March 2015 and October 2015, resulting in gross proceeds of \$6.9 million. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the

date of exercise of \$1.6 million, with any change in fair value recorded in the consolidated statement of operations and comprehensive loss. The \$1.6 million fair value was subsequently transferred to equity as of the date of exercise.

During the fourth quarter of 2016, a total of 363,523 warrants to purchase 363,523 shares of common stock were exercised related to the October 2011, November 2015 and December 2015 warrants resulting in gross proceeds of \$0.9 million. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of \$0.5 million, with any change in fair value recorded in the consolidated income statement and comprehensive loss. The \$0.5 million fair value was subsequently transferred to equity as of the date of exercise.

The details of all outstanding warrant liability as of March 31, 2017, were as follows:

| Shares and dollars in thousands | Warrant |           |
|---------------------------------|---------|-----------|
|                                 | Shares  | Liability |
| July 2011 Warrants              | 49      | \$ 147    |
| Long-Term Warrants              | 105     | 312       |
| Short-Term Warrants             | 127     | 354       |
| October 2015 Warrants           | 284     | 868       |
|                                 | 565     | \$ 1,681  |

## NOTE 11. STOCKHOLDERS' EQUITY (DEFICIT)

### *Amendments to Articles of Incorporation—Reverse Stock Split*

Effective December 18, 2015, the Company amended its Certificate of Incorporation to affect a 1-for-25 reverse split of its outstanding common stock (the "Reverse Stock Split"). The Reverse Stock Split was approved by the Company's 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 March 31, 2017, and December 31, 2016, there were no shares of Company preferred stock outstanding.

### *Common Stock*

In February 2016, the Company 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. The Company 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. The Company entered into the second purchase agreement with Pioneer Singapore (the "Pioneer Agreement"), pursuant to which the Company 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. The Company 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.

China Kington Asset Management Co. Ltd. served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds received by the Company upon closing pursuant to the purchases by Pioneer



Singapore and Mr. Fu. The amount of such commission was approximately \$155 thousand.

On April 4, 2016, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) for the sale of an aggregate 6,173,299 shares of Common Stock, par value \$0.01 per share and warrants (the “April 2016 Warrants”) exercisable for 3,086,651 Shares to accredited investors for an aggregate purchase price of \$11.8 million (the “Private Placement”). The warrants have a 4-year term and an exercise price of \$1.91, callable by the Company if the closing price of the Common Stock, as reported on the NYSE MKT, is \$4.00 or greater for five sequential trading days. The Private Placement closed in two tranches, the first of which closed on May 5, 2016, resulting in proceeds to the Company of \$7.8 million (the “Primary Closing”), and the second of which closed on August 1, 2016, resulting in proceeds of \$4.0 million to the Company (the “Secondary Closing”). In the Primary Closing, the Company issued 4,079,058 shares of Common Stock and April 2016 Warrants exercisable for 2,039,530 shares of Common Stock. In the Secondary Closing, the Company issued 2,094,241 shares of Common Stock and April 2016 Warrants exercisable for 1,047,121 shares of Common Stock. Both the Primary Closing and the Secondary Closing were subject to the same terms, containing customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Purchasers (as defined below) and other obligations of the parties and termination provisions.

China Kington Asset Management Co. Ltd. served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds received by the Company upon closing pursuant to the purchases by certain investors. The amount of such commission was approximately \$618 thousand.

Also on April 4, 2016, the Company entered into a separate registration rights agreement (the “Registration Rights Agreement”) with Messrs. Andros and Geckler, Dr. Rider, and the Children’s Brain Disease Foundation (the “Participating Purchasers”), pursuant to which the Company agreed to file as many registration statements with the SEC as may be necessary to cover the resale of the shares and the April 2016 Warrants held by the Participating Purchasers, to use its commercially reasonable efforts to have all such registration statements declared effective within the time frames set forth in the Securities Purchase Agreement and the Registration Rights Agreement, and to keep such registration statements effective for the terms defined therein. The Company filed such Registration Statement to cover the resale of the shares and April 2016 Warrants held by the Participating Purchasers with the SEC on June 9, 2016 and received effectiveness of such Registration Statement on June 20, 2016 (Registration Number 333-211943).

During the third quarter of 2016, the Company recorded \$6.6 million in net proceeds upon the exercise of 3,613,284 of the Company's warrants for 3,613,284 shares of the Company's Common Stock, including all of the warrants issued in May 2016 and August 2016. As consideration for the facilitation of the exercise of certain of these warrants held by non-U.S. citizens domiciled outside of the United States, China Kington received a six percent (6%) commission on the aggregate proceeds to the Company pursuant to such exercises. The amount of such commission was approximately \$338 thousand.

During the fourth quarter of 2016, the Company recorded \$0.9 million in net proceeds upon the exercise of 363,523 of the Company's warrants for 363,523 shares of the Company's Common Stock. As consideration for the facilitation of the exercise of certain of these warrants held by non-U.S. citizens domiciled outside of the United States, China Kington received a six percent (6%) commission on the aggregate proceeds to the Company pursuant to such exercises. The amount of such commission was approximately \$32 thousand.

### ***Stock Warrants***

In February 2016, the strike prices of the July 2011, March 2015 Short-Term and Long-Term, and October 2015 warrants were 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.

In May 2016, the Company issued 2,039,530 warrants at the Primary Closing pursuant to the Securities Purchase Agreement. Please see the preceding subsection, "Common Stock," for further details.

In August 2016, the Company issued 1,047,121 warrants at the Secondary Closing pursuant to the Securities Purchase Agreement. Please see the preceding subsection, "Common Stock," for further details.

Effective September 29, 2016, the Company modified the exercise price of all warrants issued pursuant to the securities purchase agreement, dated May 18, 2015, from \$19.50 to \$3.15 per share, which reflected a discount of approximately sixteen percent (16%) to the closing price of the Company's Common Stock on September 27, 2016. The Company has estimated the value of warrant modification as of the date of the modification by applying the Black-Scholes-Merton option pricing model using the single-option valuation approach. As a result of this modification, the Company recorded a non-cash loss of \$270 thousand in general and administrative expense in the consolidated statement of operation and comprehensive loss.

The details of all outstanding warrants as of March 31, 2017, are as follows:

| <b>(in thousands, except for exercise price)</b> | Warrants | Weighted-<br>Average<br>Exercise<br>Price |
|--|----------|---|
| Warrants outstanding December 31, 2016           | 565      | \$ 1.81                                   |
| Warrants granted                                 | —        | —   |
| Warrants exercised                               | —        | —   |
| Warrants expired                                 | —        | —   |
| Warrants outstanding March 31, 2017              | 565      | \$ 1.81                                   |

## **NOTE 12. EQUITY-BASED COMPENSATION**

### *Equity Compensation Plans*

In October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the “2007 Plan”) to provide for the granting of equity 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. At the inception of the 2007 Plan, 40,000 shares were reserved for issuance under the 2007 Plan.

For the years from 2009 to 2012, the number of shares of common stock authorized for issuance under the 2007 Plan increased annually in an amount equal to the lesser of (a) 40,000 shares; (b) 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding year; or (c) such lesser number as determined by the Board. Accordingly, an additional 40,000, 37,427, and 37,207 shares of common stock were authorized for issuance under the 2007 Plan in January 2012, 2011 and 2010, respectively. Beginning in 2013, the shareholders voted to remove the 40,000 share cap and the 2007 Plan increases annually by 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding year. Accordingly, an additional 32,646 and 59,157 shares of common stock were authorized for issuance under the 2007 Plan in January 2014 and 2013, respectively. On March 30, 2015, the Company filed a registration statement to add an additional 82,461 shares to the 2007 Plan. In January 2016, the Company added 139,449 shares to the 2007 Plan, per the 2007 Plan's evergreen provision. On May 26, 2016, the stockholders of the Company approved an amendment to the 2007 Plan to increase the number of shares of Company common stock reserved for issuance thereunder by 1,124,826 shares. In January 2017, the Company added 610,774 shares to the 2007 Plan, per the 2007 Plan's evergreen provision. The aggregate reserved number of shares available under the 2007 Plan is 2,318,486 shares. As of March 31, 2017, there were 15,889 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, then not less than 110% of the fair market value of the common stock on the date of grant. 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, 2017, and activity during the three-month period then ended:

| (in thousands, except years and per share data) | Options | Weighted- | Weighted-    | Aggregate |
|---|---------|-----------|--------------|-----------|
|   |         | Average   | Average      |           |
|   |         | Exercise  | Remaining    | Intrinsic |
|   |         | Price     | Contractual  | Value     |
|   |         |           | Life (years) |           |
| Outstanding at December 31, 2016                | 1,489   | \$ 8.38   | 8.7          | \$ 702    |

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|   |       |            |     |          |
|---|-------|------------|-----|----------|
| Options granted                               | 661   | \$ 3.53    |     |          |
| Restricted stock units granted                | 31    | \$ —       |     |          |
| Options exercised                             | -     | \$ —       |     |          |
| Restricted stock units vested                 | (31   | ) \$ —     |     |          |
| Options forfeited/cancelled                   | (16   | ) \$ 35.12 |     |          |
| Outstanding at March 31, 2017                 | 2,134 | \$ 6.68    | 8.9 | \$ 1,505 |
| Vested and expected to vest at March 31, 2017 | 2,116 | \$ 6.70    | 8.9 | \$ 1,494 |
| Vested at March 31, 2017                      | 1,214 | \$ 9.13    | 8.4 | \$ —     |
| Exercisable at March 31, 2017                 | 1,214 | \$ 9.13    | 8.4 | \$ —     |

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, 2017. There were no stock option awards exercised for the three months ended March 31, 2017 or 2016. The Company received no cash payments for the exercise of stock options during the three months ended March 31, 2017 or 2016.

As of March 31, 2017, total unrecognized compensation cost related to unvested stock options and restricted stock units was approximately \$2 million. 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 1.47 years.

***Stock Option 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 applies to value its stock-based awards.

During the three months ended March 31, 2017 and 2016, the Company granted options to purchase an aggregate of 631 thousand and 91 thousand shares of common stock, respectively, to employees and directors.

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

| <b>Assumption</b>  | <b>Three Months<br/>Ended March<br/>31,</b> |             |
|--|---|-------------|
|  | <b>2017</b>                                 | <b>2016</b> |
| Expected price volatility  | 87.92%                                      | 87.00%      |
| Expected term (in years)   | 6.83  | 7.76        |
| Risk-free interest rate  | 2.27%                                       | 2.09%       |
| Dividend yield   | 0.00%                                       | 0.00%       |
| Weighted-average fair value of options granted during the period | \$2.71                                      | \$1.60      |

**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**—We have not made any dividend payments nor do we 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, 2017, the Company did not issue common stock to employees. During the three months ended March 31, 2016, the Company issued 64 thousand shares of common stock to employees.

For the three months ended March 31, 2017 and 2016, the Company recognized stock-based compensation expense of \$1,157 thousand and \$207 thousand, respectively, for stock based awards to employees and directors.

***Stock-Based Awards to Non-Employees***

During the three months ended March 31, 2017 and 2016, the Company granted options to purchase an aggregate of 30 thousand and 17 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:

| <b>Assumption</b>  | <b>Three Months<br/>Ended March 31,</b> |             |
|--|---|-------------|
|  | <b>2017</b>                             | <b>2016</b> |
| Expected price volatility  | 88.17%                                  | 87.00%      |
| Expected term (in years)   | 10.00                                   | 9.99        |
| Risk-free interest rate  | 2.51%                                   | 2.04%       |
| Dividend yield   | 0.00%                                   | 0.00%       |
| Weighted-average fair value of options granted during the period | \$3.08                                  | \$2.64      |

The Company granted 19 thousand shares of fully vested registered stock to non-employees in the three months ended March 31, 2017, as part of the settlement agreement for Dr. Ron Najafi as described below. 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.

For the three months ended March 31, 2017 and 2016, the Company recognized stock-based compensation expense of \$36 thousand and \$40 thousand, respectively, related to non-employee stock and option grants.

In November 2015, Dr. Ron Najafi resigned from his position as President and CEO of the Company. As part of his separation agreement, in December 2016, the Company paid him a portion of the amount due under the agreement via a combination of registered shares and cash during fiscal year 2016. The expense related to this separation agreement was accrued for and expensed in the year ended December 31, 2015, and the shares were issued to him via fully vested registered stock in December 2016. In January 2017, the remaining portion of the amount due under the agreement was paid via a combination of registered shares and cash.

In March 2016, Roy Wu left the Company as Senior Vice President of Business Development. As part of his separation agreement, in March 2016, the Company paid him a combination of stock and cash. The expense related to this separation agreement was accrued for and expensed in the year ended December 31, 2015 based upon the known terms, and the shares were issued to him via fully vested restricted stock in March 2016.

#### ***Summary of Stock-Based Compensation Expense***



A summary of the stock-based compensation expense included in results of operations for the option and stock awards discussed above is as follows:

| <b>(in thousands)</b>                  | <b>Three<br/>Months<br/>Ended<br/>March 31,</b> |             |
|--|---|-------------|
|  | <b>2017</b>                                     | <b>2016</b> |
| Research and development               | \$21  | \$31        |
| Sales and Marketing                    | 37  | 2           |
| General and administrative             | 1,135   | 214         |
| Total stock-based compensation expense | \$1,193   | \$247       |

Since the Company has operating losses and net operating loss carryforwards, there are no tax benefits associated with stock-based compensation expense.

#### **NOTE 13. 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, NovaBay received an upfront payment and is entitled to additional support for research and development.

In April 2013, the Company entered into a collaboration and license agreement with Virbac. Under this new 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.

No revenue was recognized in the three months ended March 31, 2017 and 2016, related to these agreements.

The Company had deferred revenue balances of \$246 thousand at March 31, 2017 and December 31, 2016, related to these agreements, which consisted of the unamortized balances on the upfront technology and access fee and the support for ongoing research and development.

### *NeutroPhase Distribution Agreements*

In January 2012, the Company entered into a distribution agreement with China Pioneer Pharma Holdings, Ltd. (“China Pioneer”), a Shanghai-based company that markets high-end pharmaceutical products into China and an affiliate of Pioneer Singapore, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, NovaBay received an upfront payment of \$312,500. NovaBay also received \$312,500 in January 2013, related to the submission of the first marketing approval for the product to the CFDA. The deferred revenue was recognized as the purchase discounts were earned, with the remaining deferred revenue recognized ratably over the product distribution period. During the year ended December 31, 2014, NovaBay received \$625,000 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 a 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 the marketing approval. The Distribution Agreement further provides that Pioneer is entitled to a cumulative purchase discount not to exceed \$500,000 upon the purchase of NeutroPhase product, payable in NovaBay 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) 800,000 units in September 2012; and (2) 1,200,000 units in October 2012, with both tranches at a purchase price of \$1.25 per unit. 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 \$600,000 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, which were developed internally by NovaBay. The expanded partnership agreement covers the commercialization and distribution of these products in China and 11 countries in Southeast Asia.

Revenue has been recognized under these agreements as follows:

| <b>(in thousands)</b>                         | <b>Three<br/>Months<br/>Ended<br/>March<br/>31,<br/>2017</b> |      | <b>2016</b> |  |
|---|--|------|-------------|--|
| Amortization of upfront technology access fee | \$6  | \$51 |             |  |
| Product sales                                 |  | —    | 236         |  |
|   | \$6  |      | \$287       |  |

The Company had deferred revenue balances of \$1.0 million at March 31, 2017 and December 31, 2016, related to these agreements, which consisted of the unamortized balances on the upfront technology and access fee and the support for ongoing research and development.

On February 7, 2012, the Company entered into a distribution agreement with Integrated Healing Technologies, LLC, (“IHT”) to distribute NeutroPhase. NovaBay received an upfront payment of \$750 thousand.

Revenue has been recognized under this agreement as follows:

| <b>(in thousands)</b>                         | <b>Three<br/>Months<br/>Ended<br/>March<br/>31,<br/>2012</b> | <b>2016</b> |
|---|--|-------------|
| Amortization of upfront technology access fee | \$—  | \$13        |
| Product sales                                 | —  | 92          |
|   | \$—  | \$105       |

The Company had deferred revenue balances of \$653 at March 31, 2017 and March 31, 2016, related to these agreements, which consisted of the unamortized balances on the upfront technology and access fee and the support for ongoing research and development.

On June 1, 2013, the Company entered into a distribution agreement with Principal Business Enterprise Inc. (“PBE”) to distribute NeutroPhase. NovaBay received an upfront payment of \$200 thousand.

Revenue has been recognized under this agreement as follows:

| <b>(in thousands)</b>                         | <b>Three<br/>Months<br/>Ended<br/>March 31,<br/>2017</b> |      | <b>2016</b> |
|---|--|------|-------------|
| Amortization of upfront technology access fee | \$1  | \$ — | —           |
| Product sales                                 | 73   | —    | —           |
|   | \$74   | \$ — | —           |

The Company had deferred revenue balances of \$194 thousand, at March 31, 2017 and December 31, 2016, related to these agreements, which consisted of the unamortized balances on the upfront technology and 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 also signed a nationwide distribution agreement with AmerisourceBergen to market Avenova. Since December 2015, the Company has signed nationwide distribution agreements with Willow Pharmacy, Allure Pharmacy, Smith Drug Company and Dakota Drug to market Avenova.

During the three months ended March 31, 2017 and 2016, the Company earned \$2.8 million and \$0.6 million, respectively, in sales revenue for its Avenova product from its distribution agreements.

The Company had a deferred revenue balance of \$1.6 million and \$1.9 million as of March 31, 2017 and December 31, 2016, respectively, for its Avenova product from its distribution agreements.

### **NOTE 14. 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 made no contributions during the three months ended March 31, 2017.

### **NOTE 15. RELATED PARTY TRANSACTIONS**

#### *Related Party Loans*

See Note 8, “Related Party Notes Payable” for a description of the Loan with the following related parties: Mr. Siczek, Chairman of the Board, President and Chief Executive Officer of the Company; the Gail J. Maderis Revocable Trust, on behalf of Ms. Maderis, a Director of the Company; Dr. McPherson, a Director of the Company; and Pioneer Singapore and Mr. Fu, the Company’s two largest stockholders. The Loan was fully paid off on

August 1, 2016.

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### *Related Party Financing*

See Note 11, “Stockholders’ Equity (Deficit)” – “Common Stock” for a description of the February 2016 Purchase Agreements and April 2016 Securities Purchase Agreement. The following related parties participated in both transactions: Mr. Sieczkarek, Chairman of the Board, President and Chief Executive Officer of the Company; and Pioneer Singapore and Mr. Fu, the Company’s two largest stockholders.

### *Related Party Revenue*

The Company recognized related party revenues from product sales and license and collaboration fees of \$6 thousand and \$287 thousand for the three months ended March 31, 2017 and 2016, respectively. There were no related party accounts receivable as of March 31, 2017 and December 31, 2016. See Note 13, “License, Collaboration and Distribution Agreements - NeutroPhase Distribution Agreements,” for additional information regarding the Company’s distribution agreements with Pioneer, which is an affiliate of Pioneer Singapore, the Company’s largest stockholder.

### *Related Party Expenses*

The Company recognized related party commission fees of zero and \$155 thousand for the three months ended March 31, 2017 and 2016, respectively. These fees were paid to China Kington, representing the commission on sale of the Company’s common stock. See Note 11, “Stockholders’ Equity (Deficit)” – “Common Stock” for additional information regarding such commissions.

## **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, 2016, which was filed with the Securities and Exchange Commission (the “SEC”) on March 23, 2017. 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 made 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 pharmaceutical company predominantly focused on eye care. We develop, manufacture and market innovative anti-infective products for a multitude of uses; however, we are currently focused primarily on commercializing prescription Avenova for the domestic eye care market in the United States.

Avenova is the only eye care product formulated with our proprietary, stable and pure form of hypochlorous acid (marketed as Neutrox). By replicating the antimicrobial chemicals used by white blood cells to fight infection, Avenova has proven in laboratory testing to have broad antimicrobial properties. It removes microorganisms and debris from the skin on the eyelids and lashes without burning or stinging. It also is the only commercial product clinically validated to reduce bacterial load on ocular skin surface, the build-up of which can cause the chronic eye condition blepharitis.

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. This new strategy allowed us to achieve our goal of reaching adjusted positive cash flow from operations (excluding working capital changes) by the end of 2016. Our current 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 also developed additional commercial products containing Neutrox, including NeutroPhase for the wound care market 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 synthesized and developed a second category of novel compounds also aimed at harnessing the power of white blood cell chemistry to address the global, topical anti-infective market. This second product category includes Auriclosene<sup>®</sup>, our lead clinical-stage Aganocide<sup>®</sup> compound, which is a patented, synthetic molecule with a broad spectrum of activity against bacteria, viruses and fungi.

### **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 (Summary of Significant Accounting Policies), 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 set up an “Allowance for Doubtful Accounts” when management identifies amounts due that are in dispute and believes it unlikely a specific invoice will be collected. At March 31, 2017 and December 31, 2016, management reserved \$52 thousand and \$10 thousand, respectively, primarily based on specific amounts that were in dispute and were over 120 days past due as of those dates.

#### ***Inventory***

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes, pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. At March 31, 2017 and December 31, 2016, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of \$273 thousand and \$196 thousand, respectively.

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

### ***Revenue Recognition***

We sell products through a limited number of distributors, direct medical sales representatives, and via our webstore. We generally record product sales upon shipment to the final customer for our webstore sales and upon shipment from our distributor to the final customers for our major distribution partners.

We recognize 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) our price to the customer is substantially fixed or determinable at the date of sale, (ii) the customer has paid us, or the customer is obligated to pay us and the obligation is not contingent on resale of the product, (iii) the customer's obligation to us 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 us, (v) we do 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. 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.

**Product Revenue Allowances**

Product revenue is recognized net of cash consideration paid to our customers and wholesalers, for services rendered by the wholesalers in accordance with the wholesalers agreements, and include 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. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates or chargebacks. We review the adequacy of product revenue allowances on a quarterly basis. Amounts accrued for product revenue allowances are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience.

The following table summarizes the activity in the accounts related to product allowances (in thousands):

|   | <b>Wholesaler/<br/>Pharmacy<br/>fees</b> | <b>Cash<br/>discounts</b> | <b>Rebate</b> | <b>Total</b> |
|---|--|---------------------------|---------------|--------------|
| Balance at December 31,2016                                   | \$ (331 )                                | \$ —                      | \$492         | \$161        |
| Current provision related to sales made during current period | (517 )                                   | (97 )                     | (2,305)       | (2,919)      |
| Payments  | 630                                      | 97                        | 1,928         | 2,655        |
| Balance at March 31,2017                                      | \$ (218 )                                | \$ —                      | \$115         | \$(103 )     |

**Other Revenue**

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of certain milestones and royalties on net product sales. In accordance with authoritative guidance, we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our 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.

### ***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 and obsolete inventory, along with lower of cost or estimate net realizable value.

### ***Research and Development Costs***

We charge 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, or lack of availability of the item or service, and specificity required in production for certain compounds. We use 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. Our research, clinical and development activities are often performed under agreements we enter into with external service providers. We estimate and accrue 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, we adjust our accruals. Historically, our 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 our expenses, which could also materially affect our results of operations.

### ***Stock-Based Compensation***

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. 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 (Equity-Based Compensation) differ, or are expected to differ, from the previous estimate. See Note 12 of the Notes to Consolidated Financial Statements for further information regarding stock-based compensation expense and the assumptions used in estimating that expense. For stock options granted to employees, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model.

Stock-based compensation arrangements with non-employees are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model.

### ***Income Taxes***

We account 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 we may have to settle them in cash, or for warrants we issue or modify that contain an exercise price adjustment feature that reduces the exercise price and increases the number of shares of our common stock eligible for purchase thereunder in the event we subsequently issue equity instruments at a price lower than the exercise price of the warrants, we record the fair value of the issued or modified warrants as a liability at each balance sheet date and record 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, and the change in the fair value

are recorded in the consolidated statements of operations and comprehensive gain or loss. The Lattice model 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 our judgment. For additional information regarding the Company's outstanding warrants, see Note 10 of the Notes to Consolidated Financial Statements (Warrant Liability).

### **Recent Accounting Pronouncements**

See Note 2 of the Notes to Consolidated Financial Statements (Summary of Significant Accounting Policies) included in Part I, Item 1 of this report for information on recent accounting pronouncements.

**Results of Operations*****Comparison of the Three Months Ended March 31, 2017 and 2016***

| <b>Statement of Operations</b>                              | Three Months Ended |           | Dollar Change | Percent Change |    |
|---|--------------------|-----------|---------------|----------------|----|
|   | March 31, 2017     | 2016      |               |                |    |
| Sales:  |                    |           |               |                |    |
| Product revenue, net  | \$3,694            | \$1,655   | \$2,039       | 123            | %  |
| Other revenue   | 7                  | 64        | (57 )         | (89            | )% |
| Total sales, net  | 3,701              | 1,719     | 1,982         | 115            | %  |
| Product cost of goods sold                                  | 588                | 611       | (23 )         | (4             | )% |
| Gross profit  | 3,113              | 1,108     | 2,005         | 181            | %  |
| Research and development                                    | 62                 | 933       | (871 )        | (93            | )% |
| Sales and marketing   | 3,740              | 3,144     | 596           | 19             | %  |
| General and administrative                                  | 3,088              | 1,682     | 1,406         | 84             | %  |
| Total operating expenses                                    | 6,890              | 5,759     | 1,131         | 20             | %  |
| Operating Loss  | (3,777)            | (4,651)   | 874           | (19            | )% |
| Non cash loss on changes in fair value of warrant liability | (235 )             | (385 )    | 150           | (39            | )% |
| Other income (expense), net                                 | 2                  | (41 )     | 43            | (105           | )% |
| Loss before provision for income taxes                      | (4,010)            | (5,077)   | 1,067         | (21            | )% |
| Provision for income tax                                    | (1 )               | -         | (1 )          | -              | %  |
| Net loss and comprehensive loss                             | \$(4,011)          | \$(5,077) | \$1,066       | (21            | )% |

***Sales, Product Cost of Goods Sold and Gross Profit***

Product revenue, net, increased by \$2.0 million, or 123%, to \$3.7 million for the three months ended March 31, 2017 from \$1.7 million for the prior year's period and other revenue, net, decreased by \$57 thousand for the three months ended March 31, 2017, or 89%, to \$7 thousand from \$64 thousand for the three months ended March 31, 2016. The change in product revenue, net, was primarily the result of increased sales of Avenova in connection with the focus on product commercialization driven by unit growth and price increases.

Other revenue decreased primarily due to lower non-Avenova sales.

Product cost of goods sold decreased by \$23 thousand, or 4%, to \$588 thousand from \$611 thousand for the three months ended March 31, 2017, compared to the three months ended March 31, 2016. The decrease in product cost of goods sold was primarily the result of lower non-Avenova sales, partly off-set by increased reserves for excess and obsolete inventory, and lower of cost or estimated net realizable value adjustments. Product cost of goods did not increase at the same rate of product revenue due to the continuing shift in sales mix toward the reimbursed pharmacy channel which maintains a higher selling price.

Gross Profit increased by \$2.0 million, or 181%, to \$3.1 million for the three months ended March 31, 2017 from \$1.1 million for the three months ended March 31, 2016. The increase in gross profit was primarily the result of increased sales of Avenova, along with the continuing shift in sales mix toward the reimbursed pharmacy channel.

### ***Research and Development***

Research and development expenses decreased by \$0.9 million, or 93%, to \$62 thousand for the three months ended March 31, 2017, down from \$1.0 million for the three months ended March 31, 2016. The reduction is primarily the result of the Company's previously-announced change in business strategy, as reflected by its reduced spending on clinical trials and its shift of capital resources from research and development to the commercialization of Avenova.



***Sales and marketing***

Sales and marketing expenses increased by \$0.6 million, or 19%, to \$3.7 million for the three months ended March 31, 2017, up from \$3.1 million for the three months ended March 31, 2016. The increase was primarily due to a change from an out-sourced sales team to an in-house sales team and an increase in the number of sales persons.

***General and administrative***

General and administrative expenses increased by \$1.4 million, or 84%, to \$3.1 million for the three months ended March 31, 2017, up from \$1.7 million for the three months ended March 31, 2016. The increase was primarily a result of higher stock-based compensation.

***Non-cash (loss) gain on changes in fair value of warrant liability***

The adjustments to the fair value of warrants resulted in a loss of \$0.2 million for the three months ended March 31, 2017, compared to a loss of \$0.4 million for the three months ended March 31, 2016.

In October 2015, we issued warrants and modified the terms of warrants originally issued in July 2011 and March 2015, resulting in the creation of warrant liabilities. For additional information regarding these warrants and their valuation, please see Note 10 in the Notes to Consolidated Financial Statements in Part I, Item 1 of this report. In the three months ended March 31, 2017, non-cash loss on changes in fair value of warrant liability was caused by a further increase in the price of the Company's common stock above the warrants' exercise price. During the three months ended March 31, 2016, we incurred a non-cash loss resulting from the reduction in the strike price of the July 2011, March 2015 and October 2015 warrants to \$1.81, resulting from the sale of the Company's common stock to Mr. Jian Ping Fu at that price in February 2016.

***Other income (expense), net***

Other income (expense), net, changed to income of \$2 thousand for the three months ended March 31, 2017, as compared to an expense of \$41 thousand for the three months ended March 31, 2016. The decrease in other expense was a result of the interest due on the notes the Company entered into in December 2015 and January 2016 as part of our Bridge Loan, which were fully paid off on August 1, 2016. For additional information regarding the notes and the

Bridge Loan, please see Note 8 in the Notes to Consolidated Financial Statements in Part I, Item 1 of this report.

### **Financial Condition, Liquidity and Capital Resources**

As of March 31, 2017, our cash and cash equivalents were \$7.4 million, compared to \$9.5 million as of December 31, 2016. The Company has sustained operating losses for the majority of its corporate history and expects that its 2017 expenses will exceed its 2017 revenues, as we continue to re-invest in our Avenova commercialization efforts. The Company expects to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. Accordingly, the Company's planned operations raise doubt about its ability to continue as a going concern.

The Company's liquidity needs will be largely determined by the success of operations in regards to the commercialization of Avenova. The Company's plans to alleviate the doubt regarding its ability to continue as a going concern, which are being implemented to mitigate these conditions, primarily include its ability to control the timing and spending on its sales and marketing programs and raising additional funds through equity financings. The Company also may consider other plans to fund operations including: (1) out-licensing rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestones or an upfront fee; (2) raising additional capital through debt financings or from other sources; (3) reducing spending on one or more of its sales and marketing programs; and/or (4) restructuring operations to change its overhead structure. The Company may issue securities, including common stock and warrants through private placement transactions or registered public offerings, which would require the filing of a Form S-1 or Form S-3 registration statement with the SEC. The Company's future liquidity needs, and ability to address those needs, will largely be determined by the success of the commercialization of Avenova. 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 its ability to continue as a going concern.

***Net Cash Used In Operating Activities***

For the three months ended March 31, 2017, net cash used in operating activities was \$2.0 million, compared to \$4.9 million for the three months ended March 31, 2016. The decrease was primarily due to increased sales of Avenova, and an increase in non-cash stock-based compensation expense for options and stock issued to employees and directors, partially offset by an increase in deferred revenue.

***Net Cash Used In Investing Activities***

For the three months ended March 31, 2017, net cash used in investing activities for the purchase of property and equipment was \$59 thousand, compared to \$16 thousand for the three months ended March 31, 2016.

***Net Cash Provided by Financing Activities***

Net cash used in financing activities was \$48 thousand for the three months ended March 31, 2017, was attributable to the settlement of restricted stock for tax withholding. Net cash provided by financing activities of \$4.0 million for the three months ended March 31, 2016, was attributable to the sale of common stock and warrants, and from proceeds received from borrowings.

***Net Operating Losses and Tax Credit Carryforwards***

As of December 31, 2016, we had NOL carryforwards for federal and state income tax purposes of \$90.2 million and \$78.2 million, respectively. If not utilized, the federal and state NOL carryforwards will begin expiring at various dates between 2024 and 2036. As of December 31, 2016, we also had tax credit carryforwards for federal income tax purposes of \$1.3 million and \$0.3 million for state tax purposes. If not utilized, the federal tax credits will begin expiring in 2031. The state tax credits have an indefinite carryover period.

Current federal and California tax laws include substantial restrictions on the utilization of NOL carryforwards in the event of an ownership change of a corporation. Accordingly, our ability to utilize NOL carryforwards may be limited as a result of such ownership changes and result in expiration before utilization.

***Inflation***

We do not believe that inflation has had a material impact on our business and operating results during the periods presented, and we do not expect it to have a material impact in the near future, although there can be no assurances that our business will not be affected by inflation in the future.

***Off-Balance Sheet Arrangements***

We have no off-balance sheet arrangements as of March 31, 2017.

***Seasonality***

Consistent with our peers in the United States pharmaceutical industry, our business experiences seasonality with the first quarter of each year typically being the lowest revenue quarter. This annual phenomenon is due to consumers facing the need to satisfy health insurance deductibles and changes to copays as each new insurance year begins.

***Contractual Obligations***

Our contractual cash commitments as of March 31, 2017, were as follows (in thousands):

| <b>Contractual Obligations</b> | <b>Total</b> | <b>Less than<br/>1 year</b> | <b>1 - 3<br/>years</b> | <b>3 - 5<br/>years</b> | <b>More than<br/>5<br/>years</b> |
|--------------------------------|--------------|-----------------------------|------------------------|------------------------|----------------------------------|
| Facility leases                | \$4,527      | \$1,059                     | \$2,215                | \$1,253                | \$ —                             |
| Vehicle leases                 | 463          | 163                         | 300                    | —                      | —                                |
|                                | \$4,990      | \$1,222                     | \$2,515                | \$1,253                | \$ —                             |

Our commitments as of March 31, 2017 consist of two operating facility leases: the Lease and the lease for Emery Station, and 54 operating vehicle leases.

The total commitment for the Lease as of March 31, 2017 was \$2.0 million due over the lease term, compared to \$2.1 million as of December 31, 2016.

The total commitment of the Emery Station lease as of March 31, 2017 was \$2.5 million due over such lease term, compared to \$2.6 million as of December 31, 2016. On July 11, 2016, we entered into a Sublease Agreement to sublease our former corporate headquarters. Sublease rental reimbursement is not deducted from the above table. We anticipate collecting \$654 thousand, \$613 thousand, \$758 thousand, and \$383 thousand in the years ending March 31, 2017, 2018, 2019, and 2020, respectively, under the Sublease for the lease of Emery Station.

Additionally, we have operating leases for a fleet of 54 vehicles, which commenced upon the delivery of the vehicles during the first quarter 2017. The total commitment for these leases as of March 31, 2017 was \$0.5 million due over the lease term, compared to zero as of December 31, 2016.

See Note 9 in the Notes to Consolidated Financial Statements in Part I, Item 1 of this report for further information regarding these leases.

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

Our market risk consists principally of interest rate risk on our cash and cash equivalents.

With most of our focus on Avenova in the domestic U.S. market, we do not have any material exposure to foreign currency rate fluctuations.

### **ITEM 4. CONTROLS AND PROCEDURES**

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 and 15d-15 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Assessing the costs and benefits of such controls and procedures necessarily involves the exercise of judgment by management. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms

and were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

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

There was no change in our internal control over financial reporting during the quarter ended March 31, 2017, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1A. RISK FACTORS**

*Our business is subject to a number of risks, the most important of which are discussed below. You should consider carefully the following risks in addition to the other information contained in this report and our other filings with the SEC before deciding to buy, sell or hold our common stock. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline and you may lose all or part of your investment. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations.*

#### **Risks Relating to Our Liquidity**

*We have a history of losses and we may never achieve or maintain sustained profitability.*

We have historically incurred net losses and we may never achieve or maintain sustained profitability. In addition, at this time:

- we expect to incur substantial marketing and sales expenses as we continue to attempt to increase sales of our Avenova product
- our results of operations may fluctuate significantly
- we may be unable to develop and commercialize our product candidates and
- it may be difficult to forecast accurately our key operating and performance metrics because of our limited operating history.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully market and sell Avenova, either independently or with partners, we will not be able to generate sufficient revenues to achieve or maintain profitability in the future. Our failure to achieve and subsequently maintain profitability could have a material adverse impact on the market price of our common stock.

### **Risks Relating to Owning Our Common Stock**

*If we conduct offerings in the future, the price at which we offer our securities may trigger a price protection provision included in warrants originally issued in July 2011, March 2015 and October 2015, reducing the probability and magnitude of any future share price appreciation.*

As part of our October 2015 offering, we agreed to provide certain price protections affecting currently outstanding warrants exercisable for an aggregate of 565,695 shares of our common stock, of which 281,093 shares must be issued, if at all, by March 6, 2020, and 284,602 shares must be issued, if at all, by October 27, 2020 (the “Warrants”). Specifically, in the event that we undertake a third-party equity financing of either: (1) common stock at a sale price of less than \$5.00 per share or (2) convertible securities with an exercise price of less than \$5.00 per share, we have agreed to reduce the exercise price of all Warrants to such lower price. The exercise price of the Warrants is currently set at \$1.81 as a result of our February 2016 private placement offering. The further reduction of the exercise price for the Warrants would limit the probability and magnitude of future share price appreciation, if any, by placing downward pressure on our stock price if it exceeds such offering sale price. All of the Warrants are currently exercisable and will remain so after any exercise price adjustment. In the past, we have extended the expiration dates or adjusted other terms of the Warrants as consideration for certain offering conditions, and we cannot assure you that we will not do so in the future. Any such modifications would reduce the probability and magnitude of any share price appreciation during the period of the extension. We cannot guarantee that you will receive a return on your investment when you do sell your shares or that you will not lose the entire amount of your investment. If you do receive a return on your investment, it may be lower than the return you would have realized in the absence of the price protection provisions discussed hereof.



***The price of our common stock may fluctuate substantially, which may result in losses to our stockholders.***

The stock prices of many companies in the pharmaceutical and biotechnology industry have generally experienced wide fluctuations, which are often unrelated to the operating performance of those companies. The market price of our common stock is likely to be volatile and could fluctuate in response to, among other things:

the announcement of new products by us or our competitors  
the announcement of partnering arrangements by us or our competitors  
quarterly variations in our or our competitors' results of operations  
announcements by us related to litigation  
changes in our earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earnings estimates  
developments in our industry and  
general, economic and market conditions, including volatility in the financial markets, a decrease in consumer confidence and other factors unrelated to our operating performance or the operating performance of our competitors.

***The volume of trading of our common stock may be low, leaving our common stock open to the risk of high volatility.***

The number of shares of our common stock being actively traded may be very low and any stockholder wishing to sell his, her, or its stock may cause a significant fluctuation in the price of our stock. We have a number of large stockholders, including our principal stockholders China Pioneer Pharma Holdings Limited ("China Pioneer"), Pioneer Pharma (Hong Kong) Company Limited as a wholly-owned subsidiary of China Pioneer and the recipient of all of the holdings of Pioneer Pharma (Singapore) Pte. Ltd. pursuant to an internal corporate reorganization of China Pioneer ("Pioneer Hong Kong") and Mr. Jian Ping Fu. Each of China Pioneer and Mr. Fu own 34% and 26% of our common stock, respectively. The sale of a substantial number of shares of common stock by such large stockholders within a short period of time could cause our stock price to decrease substantially. In addition, low trading volume of a stock increases the possibility that, despite rules against such activity, the price of the stock may be manipulated by persons acting in their own self-interest. We may not have adequate market makers and market making activity to prevent manipulation.

***Our amended and restated certificate of incorporation and bylaws and Delaware law contain provisions that could discourage a third party from making a takeover offer that is beneficial to our stockholders.***

Anti-takeover provisions of our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. The provisions of our charter documents include:

a classified board so that only one of the three classes of directors on our Board of Directors is elected each year;  
elimination of cumulative voting in the election of directors  
procedures for advance notification of stockholder nominations and proposals  
the ability of our Board of Directors to amend our bylaws without stockholder approval and  
the ability of our Board of Directors to issue up to 5,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

In addition, as a Delaware corporation, we are subject to the Delaware General Corporation Law (“DGCL”), which includes provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of our Company. Provisions of the DGCL could make it more difficult for a third party to acquire a majority of our outstanding voting stock by discouraging a hostile bid, or delaying, preventing or deterring a merger, acquisition or tender offer in which our stockholders could receive a premium for their shares, or effect a proxy contest for control of NovaBay or other changes in our management.

***We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.***

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our Board of Directors may consider relevant. If we do not pay dividends, you will experience a return on your investment in our shares only if our stock price appreciates. We cannot assure you that you will receive a return on your investment when you do sell your shares or that you will not lose the entire amount of your investment.

***China Pioneer, Pioneer Hong Kong, Mr. Jian Ping Fu and/or China Kington might influence our corporate matters in a manner that is not in the best interest of our general stockholders.***

As of April 17, 2017, China Pioneer beneficially owns approximately 34% of our common stock. Our director Mr. Xinzhou “Paul” Li is the chairman of China Pioneer. Pursuant to the arrangement of our Bridge Loan, two (2) of our directors were nominated by China Kington, including Mr. Mijia “Bob” Wu, who is the Managing Director of China Kington and Non-Executive Director of Pioneer Hong Kong, and Mr. Xiaoyan “Henry” Liu, who has worked closely with China Kington on other financial transactions in the past. Mr. Jian Ping Fu beneficially owns approximately 26% of our common stock. China Kington and its affiliates have served as placement agent for three purchases of Company securities by Mr. Fu during the last year.

As a result, China Pioneer, Pioneer Hong Kong as a wholly-owned subsidiary of China Pioneer and China Kington have input on all matters before our Board of Directors and may be able to exercise significant influence over all matters requiring board and stockholder approval. Please see the risk factor entitled “*We may be unable to raise additional capital on acceptable terms in the future, which may in turn limit our ability to develop and commercialize products and technologies.*” China Pioneer, Pioneer Hong Kong and China Kington may choose to exercise their influence in a manner that is not in the best interest of our general stockholders.

In addition, were China Pioneer, Pioneer Hong Kong and Mr. Fu to cooperate, they could unilaterally elect all of their preferred director nominees at our 2017 Annual Meeting of Stockholders. Even with our classified board, China Pioneer, Pioneer Hong Kong and Mr. Fu could ensure that five (5) of our eight (8) directors are either nominees of China Pioneer, Pioneer Hong Kong or China Kington. In the interim, China Pioneer, Pioneer Hong Kong, China Kington and/or Mr. Fu could exert significant indirect influence on us and our management.

*Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.*

Under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss (“NOL”) carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. Since our formation, we have raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders’ subsequent disposition of those shares, may have resulted in one or more changes of control, as defined by Section 382 of the Code. We have not currently completed a study to assess whether any change of control has occurred, or whether there have been multiple changes of control since our formation, due to the significant complexity and cost associated with such study. If we have experienced a change of control at any time since its formation, its NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. In addition, since we may need to raise additional funding to finance our operations, we may undergo further ownership changes in the future. If we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

## **Risks Relating to Our Business**

*Our future success is largely dependent on the successful commercialization of Avenova.*

The future success of our business is largely dependent upon the successful commercialization of Avenova. We are dedicating a substantial amount of our resources to advance Avenova as aggressively as possible. If we encounter difficulties in its commercialization, we may not have the resources necessary to continue our business in its current form. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to successfully commercialize our products. We believe we are creating an efficient commercial organization. However, we may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution necessary to be successful. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Such expenses may be disproportionate compared to the revenues we may be able to generate on sales of Avenova.

*Our commercialized products are not approved by the FDA as a drug, so we rely solely on the 510(k) clearance of Neutrox as a medical device.*

Our business and future growth depend on the development, use and sale of products that are subject to FDA regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are

prohibited from promoting our products for off-label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA. As a medical device, our claims regarding efficacy are limited. Without claims of efficacy, market acceptance of our products may be slow.

There is a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales and marketing activities may constitute the promotion of our products for a non-FDA-approved use in violation of applicable law. We also face the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and be required to substantially change our sales, promotion, grant and educational activities. In addition, were any enforcement actions against us or our senior officers to arise, we could be excluded from participation in U.S. government healthcare programs such as Medicare and Medicaid.

***We do not have our own manufacturing capacity, and we rely on partnering arrangements or third-party manufacturers for the manufacture of our products and potential products.***

We do not currently operate manufacturing facilities for production of our product and product candidates. We have no experience in product formulation or manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. As a result, we have partnered and expect to partner with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute product supplies for our clinical trials. Any performance failure on the part of our commercial partners or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and reducing or delaying product revenues.

Our products and product candidates do and will require precise, high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers and partners often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. These manufacturers and partners are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with Quality Systems Regulations, current Good Manufacturing Practice and other applicable government regulations and corresponding foreign standards. If any of our manufacturers or partners fails to maintain compliance, the production of our products could be interrupted, resulting in delays, additional costs and potentially lost revenues.

In addition, if the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we will need to manufacture them in larger quantities. Significant scale-up of manufacturing will require validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product, the regulatory approval or commercial launch of any products may be delayed or there may be a shortage in supply and our business may be harmed as a result.

***We depend on skilled and experienced personnel and management leadership to operate our business effectively and maintain our investor relationships. If we are unable to retain, recruit and hire such key employees, our ability to manage our business will be harmed, which would impair our future revenue and profitability.***

Our success largely depends on the skills, experience and efforts of our officers and other key employees. The efforts of our officers and other key employees are critical to us as we continue to focus on the commercialization of our Avenova product. The loss of any of our senior management team members could disrupt our business, affect key partnerships and impair our future revenue and profitability. In particular, our Chief Executive Officer, Mark M. Sieczkarek, is critical to our successful commercialization of Avenova, and we have entered into an executive employment agreement with him, expiring on May 31, 2017.

***We intend to rely on a limited number of pharmaceutical wholesalers to distribute Avenova.***

We intend to rely primarily upon a limited number of pharmaceutical wholesalers in connection with the distribution of Avenova. If we are unable to establish or maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability.

***If we grow and fail to manage our growth effectively, we may be unable to execute our business plan.***

Our future growth, if any, may cause a significant strain on our management and our operational, financial and other resources. Our ability to grow and manage our growth effectively will require us to implement and improve our operational, financial and management information systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management information systems could have a material adverse effect on our business, financial condition, and results of operations.

***Government agencies may establish usage guidelines that directly apply to our products or proposed products or change legislation or regulations to which we are subject.***

Government usage guidelines typically address matters such as usage and dose, among other factors. Application of these guidelines could limit the use of our products and products that we may develop. In addition, there can be no assurance that government regulations applicable to our products or proposed products or the interpretation thereof will not change and thereby prevent the marketing of some or all of our products for a period of time or permanently. The FDA's policies may change and additional government regulations may be enacted that could modify, prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U.S. or in other countries.

***We and our collaborators are and will be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and which may limit our ability to commercialize our medical devices and drug products and candidates.***

Any regulatory approvals that we receive may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The FDA may require us to commit to perform lengthy post marketing studies, which would require us to expend additional resources and thus could have an adverse effect on our operating results and financial condition. In addition, if the FDA approves any of our drug product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drugs, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drugs or the withdrawal of the drugs from the market. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing any products we may develop and our business could suffer.

***Our past clinical trials may expose us to expensive liability claims, and we may not be able to maintain liability insurance on reasonable terms or at all.***

Even though we have concluded all our clinical trials, an inherent risk remains. If a claim were to arise in the future based on our past clinical trial activity, we would most likely incur substantial expenses. Our inability to obtain sufficient clinical trial insurance at an acceptable cost to protect us against potential clinical trial claims could prevent or inhibit the commercialization of our product candidates. Our current clinical trial insurance covers individual and aggregate claims up to \$5.0 million. This insurance may not cover all claims and we may not be able to obtain additional insurance coverage at a reasonable cost, if at all, in the future. In addition, if our agreements with any future corporate collaborators entitle us to indemnification against product liability losses and clinical trial liability, such indemnification may not be available or adequate should any claim arise.

***The pharmaceutical and biopharmaceutical industries are characterized by patent litigation, and any litigation or claim against us may impose substantial costs on us, place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.***

There has been substantial litigation in the pharmaceutical and biopharmaceutical industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. For the most part, these lawsuits relate to the validity, enforceability and infringement of patents. Generic companies are encouraged to challenge the patents of pharmaceutical products in the United States because a successful challenger can obtain six months of exclusivity as a generic product under the Hatch-Waxman Act. We expect that we will rely upon patents,



trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position, and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties to produce our products. In addition, future patents may be issued to third parties which our technology may infringe. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe.

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, would divert management's attention from our business and could have a material negative effect on our business, operating results or financial condition. If such a dispute were to be resolved against us, we might be required to pay substantial damages, including treble damages and attorney's fees if we were found to have willfully infringed a third party's patent, to the party claiming infringement, to develop non-infringing technology, to stop selling any products we develop, to cease using technology that contains the allegedly infringing intellectual property or to enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent us from selling any products we develop, which could harm our business.

***If product liability lawsuits are brought against us, they could result in costly litigation and significant liabilities.***

Despite all reasonable efforts to ensure safety, it is possible that we or our collaborators will sell products, including Avenova, NeutroPhase, CelleRx, and intelli-Case, which are defective, to which patients react in an unexpected manner, or which are alleged to have side effects. The manufacture and sale of such products may expose us to potential liability, and the industries in which our products are likely to be sold have been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention, and could have a material adverse effect on our financial condition, business and results of operations.

If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our collaborators and make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend significant financial and managerial resources.

***If we are unable to protect our intellectual property, our competitors could develop and market products similar to ours that may reduce demand for our products.***

Our success, competitive position and potential future revenues will depend in significant part on our ability to protect our intellectual property. We rely on the patent, trademark, copyright and trade secret laws of the U.S. and other countries, as well as confidentiality and nondisclosure agreements, to protect our intellectual property rights. We apply for patents covering our technologies as we deem appropriate.

There is no assurance that any patents issued to us or licensed or assigned to us by third parties will not be challenged, invalidated, found unenforceable or circumvented, or that the rights granted thereunder will provide competitive advantages to us. If we or our collaborators or licensors fail to file, prosecute or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of any products we develop, and demand for our products could decline as a result. Further, although we have taken steps to protect our intellectual property and proprietary technology, third parties may be able to design around our patents or, if they do infringe upon our technology, we may not be successful or have sufficient resources in pursuing a claim of infringement against those third parties. Any pursuit of an infringement claim by us may involve substantial expense and diversion of management attention.

We also rely on trade secrets and proprietary know-how that we seek to protect by confidentiality agreements with our employees, consultants and collaborators. If these agreements are not enforceable, or are breached, we may not have adequate remedies for any breach, and our trade secrets and proprietary know-how may become known or be independently discovered by competitors.

We operate in the State of California. The laws of the State prevent us from imposing a delay before an employee who may have access to trade secrets and proprietary know-how can commence employment with a competing company. Although we may be able to pursue legal action against competitive companies improperly using our proprietary information, we may not be aware of any use of our trade secrets and proprietary know-how until after significant damage has been done to our company.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors, including generic manufacturers, could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

***Our current patent portfolio could leave us vulnerable to larger companies who have the resources to develop and market competing products.***

We aggressively protect and enforce our patent rights worldwide. However, certain risks remain. There is no assurance that patents will issue from any of our applications or, for those patents we have or that do issue, that the claims will be sufficiently broad to protect our proprietary rights, or that it will be economically possible to pursue sufficient numbers of patents to afford significant protection. For example, we do not have any composition of matter patent directed to the Neutrox composition. This relatively weak patent portfolio leaves us vulnerable to competitors who wish to compete in the same marketplace with similar products. If a potential competitor introduces a formulation similar to Avenova or NeutroPhase with a similar composition that does not fall within the scope of the method of treatment/manufacture claims, then we or a potential marketing partner would be unable to rely on the allowed claims to protect its market position for the method of using the Avenova or NeutroPhase composition, and any revenues arising from such protection would be adversely impacted.

***If physicians and patients do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.***

Even if the FDA has cleared or approves product candidates that we develop, physicians and patients may not accept and use them. Acceptance and use of our products may depend on a number of factors including:

perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products

published studies demonstrating the cost-effectiveness of our products relative to competing products  
availability of reimbursement for our products from government or healthcare payers and

effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of any of our products to find market acceptance would harm our business and could require us to seek additional financing.

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

None.

**ITEM 6. EXHIBITS**

See the Exhibit Index which follows the signature page of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

**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 11, 2017 NOVABAY PHARMACEUTICALS, INC.

/s/ Mark M. Sieczkarek  
Mark M. Sieczkarek  
President and Chief Executive Officer

*(principal executive officer)*

Date: May 11, 2017 /s/ Thomas J. Paulson  
Thomas J. Paulson  
Chief Financial Officer

*(principal financial officer)*

## EXHIBIT INDEX

| Exhibit Number | Exhibit Description  | Incorporation by Reference |                                |             | Filed Herewith |
|----------------|--|----------------------------|--------------------------------|-------------|----------------|
|                |  | Form Item                  | Exhibit/<br>Form 8-K Reference | Filing Date |                |
| 3.1            | Amended and Restated Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.   | 8-K                        | 3.1                            | 6/29/2010   |                |
| 3.2            | Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.  | 8-K                        | 3.1                            | 6/04/2014   |                |
| 3.3            | Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.  | 8-K                        | 3.1                            | 10/02/2015  |                |
| 3.4            | Certificate of Amendment to Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.  | 8-K                        | 3.1                            | 12/21/2015  |                |
| 3.5            | Bylaws of NovaBay Pharmaceuticals, Inc.  | 8-K                        | 3.2                            | 6/29/2010   |                |
| 4.1            | Form of Warrant issued in August 2009 offering.  | 8-K                        | 4.3                            | 8/21/2009   |                |
| 4.2            | Form of Warrant issued in July 2011 offering.  | 8-K                        | 4.4                            | 10/27/2015  |                |
| 4.3            | Form of Warrant issued in December 2012 offering.  | 8-K                        | 4.1                            | 12/6/2012   |                |
| 4.4            | Form of Warrant issued in March 2014 offering.   | 8-K                        | 4.1                            | 3/20/2014   |                |
| 4.5            | Form of Warrant issued in March 2015 offering (issued with 15-month term).   | 8-K                        | 4.2                            | 10/27/2015  |                |
| 4.6            | Form of Warrant issued in March 2015 offering (issued with 5-year term).   | 8-K                        | 4.3                            | 10/27/2015  |                |
| 4.7            | Form of Warrant issued in May 2015 offering.   | 10-Q                       | 4.7                            | 8/13/2015   |                |
| 4.8            | Form of Warrant issued in October 2015 offering.   | 8-K                        | 4.1                            | 10/27/2015  |                |
| 4.9            | Form of Warrant issued in May and August 2016 offering.  | 8-K                        | 4.1                            | 4/05/2016   |                |
| 31.1           | Certification of the Principal Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).  |                            |                                |             | X              |
| 31.2           | Certification of the Principal Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a).  |                            |                                |             | X              |
| 32.1‡          | Certification by the Chief Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350). |                            |                                |             | X              |
| 32.2‡          | Certification by the Chief Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350). |                            |                                |             | X              |
| 101.INS        | XBRL Instance Document   |                            |                                |             | X              |

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|--|---|
| 101.SCH XBRL Taxonomy Extension Schema Document                | X |
| 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document  | X |
| 101.DEF XBRL Taxonomy Extension Definition Linkbase            | X |
| 101.LAB XBRL Taxonomy Extension Labels Linkbase Document       | X |
| 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document | X |

\* XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.