2017 ANNUAL REPORT

NovaBay® PHARMA

To My Fellow Stockholders:

I am pleased to provide you with this update on the progress of NovaBay Pharmaceuticals, Inc. and our continued success in establishing the Avenova® brand. In 2017 we began to execute on a strategy to capitalize on third-party insurance reimbursement to secure higher per-unit pricing for Avenova, which serves the dual purposes of driving revenue growth and expanding gross margin.

Our continued success is evidenced by 2017 revenue of more than $18 million, which represents growth of 53% from the prior year, and by gross margin on Avenova sales of 91%, which is up from 86% in 2016.

Avenova continues to represent a significant commercial opportunity for our company. Our physicians have found that this product addresses the sizable and largely untapped market of millions of Americans who suffer from blepharitis and dry eye, as well as those undergoing ophthalmic procedures such as LASIK, retinal and cataract surgeries, or those who experience contact lens tolerance issues. Avenova is formulated with our proprietary pure hypochlorous acid, which is a significant advantage over other hypochlorous-based products that contain bleach particles.

Clinical and laboratory research by NovaBay proves that Avenova attacks the bacteria that is the underlying cause of over 80% of dry eye conditions, rather than simply addressing the symptoms. We are benefitting from the awareness being created by heavy consumer advertising and the promotion of dry eye products by other, much larger companies. Our marketing message is focused on Avenova's ability to reduce the underlying bacterial cause of dry eye, which makes Avenova complementary to these other dry eye products.

I'm proud of our organization's significant accomplishments since the commercial launch of Avenova about two and a half years ago. We have gained the support of leaders in the fields of ophthalmology and optometry, which is critical to our product's adoption in this market. We have captured the attention of eye care specialists and patients across the country, establishing a base of more than 10,000 prescribers and 350,000 patients This is a significant achievement for a product that represents a paradigm shift in the management of dry eye. We have secured distribution agreements that make Avenova available in more than 90% of the retail pharmacies across the U.S. Above all, we have developed a following of loyal customers who have found that Avenova brings them relief for chronic dry eye and blepharitis.

Looking toward the future, we anticipate refining our strategy with the objective of generating profitable growth by improving insurance reimbursement while optimizing our sales and marketing resources. We expect to use detailed data collection to develop a list of high prescribers in regions with high reimbursement. Rather than having our sales representatives call on a broad group of eye care specialists, they will now spend their time on a more efficient approach of calling on targeted high prescribers. We eliminated direct sales coverage in certain lower-reimbursement territories and reduced the size of our field sales organization to align with this tighter focus, while continuing to service uncovered territories through our inside sales team.

We are also working to expand and improve insurance reimbursement by obtaining new or improved coverage for Avenova from major health plans. We have engaged a highly regarded managed care consultancy to support a process that begins with collecting substantial amounts of information in support of Avenova's role in managing dry eye. The next step is to initiate contact with key plans to present our case, which we expect will begin in the next several months. As we systematically obtain reimbursement, we will look to expand our sales organization.

We are excited by the opportunity ahead. We have a product in Avenova that offers important advantages to a market that has ample room for growth. We have doctors and patients who discovered and understand the anti-microbial advantages of using Avenova in managing the chronic conditions of blepharitis and dry eye. We are implementing a financially efficient sales strategy based on analytics aimed at producing more profitable growth, while we continue to manage expenses. As always, we are firmly focused on enhancing stockholder value.

On behalf of the NovaBay board of directors and my hard-working colleagues, I thank you for your continued support.

Sincerely,

Mark M. Sieczkarek
Chairman, Chief Executive Officer
and President

April 2018

This 2017 Annual Report to Stockholders of NovaBay Pharmaceuticals, Inc. contains forward looking statements that are subject to risks and uncertainties. These forward looking statements may include statements about the commercialization of Avenova, the success of our current strategies, and our future financial results. Words such as "continue", "expect", "will", "anticipate", and variations of these words that imply future events and opinions, identify these statements as forward looking statements. Actual results may differ materially from those implied by the forward looking statements due to a number of risks and uncertainties. Please see the information under the caption "Item 1A Risk Factors" in Part I of the Annual Report on Form 10-K included in this 2017 Annual Report to Stockholders for factors that could cause actual results to differ materially from those anticipated in the forward looking statements.

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 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	**68-0454536**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2000 Powell Street, Suite 1150, Emeryville, California 94608
(Address of principal executive offices) (Zip Code)

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	NYSE American

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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	☐	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	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 June 30, 2017, the aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the last sale price of such stock as of such date on the NYSE American, was approximately $19,499,665. This figure excludes an aggregate of 10,244,327 shares of common stock held by officers and directors as of June 30, 2017. Exclusion of shares held by any of these persons should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

As of March 13, 2018, there were 17,089,304 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the Proxy Statement for the 2018 Annual Meeting of Stockholders expected to be held in May 31, 2018.

NOVABAY PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017

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Unless the context requires otherwise, all references in this report to "we," "our," "us," the "Company" and "NovaBay" refer to NovaBay Pharmaceuticals, Inc. and its subsidiaries. Further, all references to "we," "us," "our," "the Company," or "NovaBay" herein refer to the California corporation prior to the date of the Reincorporation (as defined below) and to the Delaware corporation on and after the date of the Reincorporation.

On December 18, 2015, the Company effected a 1-for-25 reverse split of its common stock. The accompanying financial statements and related notes give retroactive effect to this reverse stock split.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. These forward-looking statements include, but are not limited to, statements regarding our product candidates, market opportunities, competitions, strategies, anticipated trends and challenges in our business and the markets in which we operate, and anticipated expenses and capital requirements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," *"plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that* may *cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" in Item 1A of this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. You should read this report and the documents that we reference and have filed as exhibits thoroughly and with the understanding that our actual future results* may *be materially different from what we expect. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this report. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.*

PART I

ITEM 1. BUSINESS

Overview

NovaBay Pharmaceuticals, Inc. is a medical device company predominately focused on eye care. We are currently focused primarily on commercializing Avenova®, a prescription product sold in the United States for cleansing and removing foreign material including microorganisms and debris from skin around the eye, including the eyelid.

Avenova is an eye care product formulated with our proprietary, stable and pure form of hypochlorous acid. Avenova has proven in laboratory testing to have broad antimicrobial properties as a preservative in solution as it removes foreign material including microorganisms and debris from the skin on the eyelids and lashes without burning or stinging.

Our business strategy remains the same since November 2015, when we restructured our business to focus our resources on growing sales of Avenova in the United States. Our current three-part business strategy is comprised of: (1) focusing our resources on growing the U.S. commercial sales of Avenova, including implementation of a sales and marketing strategy intended to increase product margin and profitability; (2) maintaining low expenses and continuing to optimize sales force efficiency, including expansion of geographical reach and efforts directed to maintain and increase insurance reimbursement for Avenova; 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.

Pursuant to our business strategy, we have developed additional products containing our proprietary, stable and pure form of hypochlorous acid, including NeutroPhase® for the wound care market and CelleRx® for the dermatology market. Since the launch of NeutroPhase in 2013, we have established a U.S. distribution partner, and an international distribution partner in China. We currently do not sell or distribute CelleRx.

Avenova, NeutroPhase, and CelleRx are medical devices cleared by the U.S. Food and Drug Administration ("FDA") under the Food and Drug Administration Act Section 510(k). The products are intended for use under the supervision of healthcare professionals for the cleansing and removal of foreign material, including microorganisms and debris. For wound treatment, NeutroPhase® is also intended for use under the supervision of healthcare professionals for moistening absorbent wound dressings and cleansing minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening and debriding acute and chronic dermal lesions.

Avenova

Prescription Avenova is a saline solution with hypochlorous acid that acts as an antimicrobial preservative in solution and has been shown to neutralize bacterial toxins in laboratory tests, and therefore, we believe that it is suited for daily eyelid hygiene. We have received approximately 700,000 new prescriptions or reorders for Avenova since the launch of the product in 2014. We believe that Avenova offers distinct advantages, when compared to alternative regimens that contain soaps, bleach, and other impurities, as it removes unwanted microorganisms from the skin without the use of harmful ingredients such as detergents and bleach.

We currently believe our target market to be the millions of Americans who suffer from minor irritation of the skin around the eye, making it prudent to utilize a cleanser with the advantages of Avenova. To access our target market, our salesforce is calling on a base of prescribers that includes the approximately 18,000 ophthalmologists and approximately 40,000 optometrists in the U.S. Our sales and marketing campaign targets major urban areas such as New York, Los Angeles, Boston, Atlanta, and San Francisco.

We began selling Avenova in the United States in 2014. Since then, we have consistently reported increases in key metrics, including the total number of prescribers, as well as growth in prescription volume as reported by distributors and the number of retail pharmacies ordering Avenova (both of which have been confirmed by third-party prescription data providers). We have distribution agreements with McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation that make Avenova accessible nationwide in nearly all retail pharmacies across the United States, and we have entered into certain agreements directly with some preferred pharmacy networks. Avenova also is marketed through numerous ophthalmology and optometry networks, including some specialty pharmacy groups that specialize in obtaining patient refills and maintaining patient compliance.

Based on consistent positive sales performance, we incrementally grew our salesforce to approximately 50 medical sales representatives in 2016 and maintained a similar number throughout 2017. Having previously been managed through a professional employer organization, we transitioned our contract salesforce to direct employees in January 2017.

We expect that our prescription business will be the main driver of long-term Avenova sales growth and gross margin expansion. We are focusing our primary sales efforts on building our prescription business under a value pricing model. Our strategy is supported by clear evidence of insurance reimbursement, with many of Avenova prescriptions filled at pharmacies covered by some form of commercial insurance at the end of 2017. We are working to improve insurance reimbursement coverage for Avenova, and we are aligning our product pricing accordingly. Furthermore, we have instituted a rebate program for electronic payment transactions and in the form of instant rebate cards. The rebate cards are intended to be used by patients who either do not have insurance coverage or whose insurance coverage does not cover Avenova, thereby lowering the price for the patient at the pharmacy.

We also expect to invest in systems that support prescribing physicians' efforts to educate their patients. We believe we have made it easier for doctors to get Avenova into the hands of patients by providing availability through well-known national pharmacy chains, specialty pharmacies, or directly through the practitioners' office.

Certain key opinion leaders in the field of ophthalmology and optometry have embraced Avenova as a tool for cleansing and removing foreign material including microorganisms and debris from skin like the eyelid, and have joined our Ophthalmic and Optometry Advisory Boards (the "Advisory Boards") to promote its use among their peers. We have entered into written agreements with these key opinion leaders for their services, which include potential stock options.

Competitors for Avenova

There are many companies that sell lid and lash scrubs, most of which, to the best of our knowledge, are surfactant (soap) based. Unlike its competitors, Avenova consists solely of saline and 0.01% pure hypochlorous acid, without the bleach impurities included in competitive offerings. While newer over-the-counter products have recently been commercially launched, they all include bleach or other impurities. Because it lacks these impurities, we believe that physicians and their patients will choose Avenova over other competitive prescription products or over-the-counter soap products. While antibacterial soaps are commonly used to reduce or prevent bacterial contamination on the skin, we do not view them as effective competitors of Avenova.

Strategic Alternatives and Other Assets

In addition to our hypochlorous acid family of products, we have synthesized and developed a second category of novel compounds also aimed at addressing the global, topical anti-infective markets. We are also in the process of seeking

additional sources of revenue by licensing or selling select non-core assets in urology, dermatology and wound care, as described in more detail below.

Aganocide Compounds

This second product category includes auriclosene, our lead clinical-stage Aganocide compound, which is a patented, synthetic molecule with a broad spectrum of uses against bacteria, viruses and fungi. Our Aganocide compound is a derivative of the naturally occurring dichlorotaurine, mimicking the anti-infective chemistry and mechanism of action that human white blood cells, known as leukocytes, use against infections. Our Aganocide compound possesses a significantly reduced likelihood of bacteria or viruses developing resistance, which is critical for advanced anti-infectives. The World Health Organization has issued the international nonproprietary name ("INN") "auriclosene" for our lead Aganocide® compound NVC-422. Each INN is a globally recognized unique name, and we believe INNs facilitate the identification of active pharmaceutical ingredients. Auriclosene is a novel chemical entity and was granted composition of matter patent protection to 2024 by the U.S. Patent Office. Although we conducted clinical trials using the Aganocide compounds from 2007 to 2015, none have received FDA approval and we therefore cannot commercialize the compounds in the United States.

AIS (Urology)

Our urology program utilizes the technology of our Aganocide compounds and is in an advanced stage of clinical development. Statistically significant and clinically meaningful results have been reported from two Phase 2 clinical studies with our Auriclosene Irrigation Solution ("AIS") in urinary catheter blockage and encrustation ("UCBE"). We announced the results of a Phase 2b clinical study in September 2016 which demonstrated that AIS, when compared to a sodium citrate buffer, proved more effective in reducing urinary blockage in patients with chronic indwelling urinary catheters who have repeat history of blockage. This study enrolled a population of 36 chronically catheterized patients with spinal cord injury and other neurological disorders. The primary efficacy endpoint comparing percent flow rate reduction of AIS-treated catheters to buffer-treated catheters was achieved with statistical significance (p values < 0.05). The clinical efficacy endpoint was also achieved with statistical significance, with no blockage in subjects in the AIS arm versus clinical blockage in 28% of the subjects treated with vehicle. No serious adverse events were reported, and overall tolerability was considered good. We are currently seeking partners to invest in phase 3 clinical studies and moving this program forward to seek FDA approval.

intelli-Case

While a majority of the approximately 40 million contact lens wearers in the United States disinfect their contact lenses with a multipurpose disinfection system to prevent potentially serious infections, we estimate that approximately 12% of the contact lens wearers use hydrogen peroxide as a disinfection solution. Many ophthalmologists and optometrists are known to favor the use of hydrogen peroxide for its disinfection ability and lens material compatibility, yet, to the best of our knowledge, side effects associated with misuse and non-compliance discourage peroxide system use. For example, hydrogen peroxide in too low of a concentration does not fully disinfect lenses and in too high of a concentration can severely irritate the eye.

We have developed a contact lens case that improves the safety of those contact lens wearers who use hydrogen peroxide solution to disinfect their lenses. In June 2015, we received FDA-clearance for the *intelli*-Case, an easy-to-use device for use with hydrogen peroxide disinfection solutions for soft and rigid gas permeable contact lenses. The *intelli*-Case monitors the neutralization of hydrogen peroxide during the disinfection cycle with sophisticated microprocessor electronics embedded in the cap of what otherwise looks like a standard peroxide lens case. The LED indicators on the case inform the user if the lenses are safe to insert into the eyes, resulting in a disinfection system that is safe yet simple to use.

We are actively looking for a company with its own branded hydrogen cleansing solution to license *intelli*-Case and brand the *intelli*-Case and their solution together. Because the cost of manufacturing the *intelli*-Case is relatively high, we are seeking potential partners with the resources to make this device broadly available in the market.

CelleRx (Dermatology)

Created for cosmetic procedures, CelleRx (0.015% hypochlorous acid as a preservative in solution) is a cleansing solution intended for use after laser resurfacing, chemical peels and other cosmetic surgery procedures. We believe that CelleRx is superior to Dakin solution, which contains bleach impurities.

Because our main focus is on Avenova and the eyecare market, we currently do not sell or distribute CelleRx. Initial proof of concept studies have shown promising results, and we are seeking established dermatological companies to bring this to market.

NeutroPhase (Wound Care)

Consisting of 0.03% hypochlorous acid, NeutroPhase is used to cleanse and remove microorganisms from any type of acute or chronic wound, and can be used with any type of wound care modality.

NeutroPhase is intended to treat the millions of patients in the United States who suffer from chronic non-healing wounds, such as pressure, venous stasis and diabetic ulcers. NeutroPhase is used by some physicians as an irrigation solution as part of the adjunct treatment for Necrotizing Fasciitis ("NF").

NeutroPhase is competing in a crowded wound cleanser market with many older and lower-priced products with similar uses, such as Vashe and Betadine Surgical Scrub. However, we believe NeutroPhase has distinct competitive advantages in a market where there is currently no dominant product. NeutroPhase is distributed through commercial partners in the United States and internationally: Principle Business Enterprise distributes NeutroPhase in the United States and Pioneer Pharma Co. Ltd., a Shanghai-based company, distributes NeutroPhase in mainland China.

Customers, Manufacturing and Suppliers

Our salesforce calls on primarily ophthalmologists, optometrists, and other eye care professionals who can prescribe Avenova. There are currently approximately 10,000 doctors prescribing Avenova in the United States. These doctors have written over 200,000 prescriptions in the United States for Avenova in 2017. No individual doctor represented in excess of 10% of our revenues for the year ended December 31, 2017.

We currently outsource manufacturing of all our products to two contract manufacturers with facilities located in the United States. We believe that our contract manufacturers have adequate manufacturing capacity to satisfy our demands and that additional contract manufacturers are also available should they be required.

All raw materials and other supplies utilized in the manufacturing process of our contract manufacturers are available from various third party suppliers in quantities adequate to meet our needs.

Intellectual Property

We believe that patents and other proprietary rights are important to our business. We also rely on trade secrets and know-how to maintain our competitive position. We seek to protect our intellectual property rights by a variety of means, including obtaining patents, maintaining trade secrets and proprietary know-how and technological innovation to operate, without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights. In order to maintain our trade secrets, we have entered into confidentiality/invention rights agreements with all our employees and confidentiality agreements with our contract manufacturers.

As of December 15, 2017, we owned 99 issued patents worldwide. Our issued patents are within two patent families: Neutrox hypochlorous acid and Aganocide compounds. The Neutrox hypochlorous acid patents underlay our Avenova products, which is our primary business. Within our Neutrox hypochlorous acid patent family, we own two issued U.S. patents and eight issued foreign patents. The Aganocide compound patent family underlay products that are still in clinical stages, which we are not currently developing and are instead focused almost exclusively on Avenova. Within our Aganocide compound patent family, we own eight issued U.S. patents and 81 issued foreign patents.

Research and Development

For the years ended December 31, 2017 and 2016, we incurred total research and development expenses of approximately $0.4 million and $1.4 million, respectively. Pursuant to our business strategy focusing our resources on growing the commercial sales of Avenova and maintaining low expenses, we are currently not conducting any substantive research and development. Any substantial research and development costs incurred in the future would be related to our urology program, which we do not expect to move forward without outside investment.

Government Regulation

We are subject to extensive government regulation, principally by the FDA and state and local authorities in the United States and by comparable agencies in foreign countries. Governmental authorities in the United States extensively regulate the pre-clinical and clinical testing, safety, efficacy, research, development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution, among other things, of pharmaceutical and medical device products under various federal laws including the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and under comparable laws by the states and in most foreign countries. We also hold our CE Mark and ISO 13485 certifications. To maintain these certifications, we undergo significant quality control audits with the relevant European authorities every year.

FDA Approval/Clearance Requirements

Unless an exemption applies, each medical device that we wish to market in the U.S. must receive 510(k) clearance. It has been the Company's experience thus far that the FDA's 510(k) clearance process usually takes from four to twelve months, but can last significantly longer. We cannot be sure that 510(k) clearance will ever be obtained for any product we propose to market. We have obtained the required FDA clearance for all of our current products that require such clearance.

The FDA decides whether a device line must undergo either the 510(k) clearance or premarket approval ("PMA"). PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The PMA process is based on statutory criteria. These criteria include the level of risk that the agency perceives is associated with the device and a determination of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II, which requires the manufacturer to submit a premarket notification ("PMN") requesting 510(k) clearance, unless an exemption applies. The PMN must demonstrate that the proposed device is "substantially equivalent" in intended use and in safety and effectiveness to a legally marketed predicate device, which is a pre-existing medical device to which equivalence can be drawn, that is either in Class I, Class II, or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA application.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, or the General Controls, which include compliance with the applicable portions of the FDA's quality system regulations, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) PMN process described below. Avenova is classified as a Class I device.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) PMN procedure. Pursuant to the Medical Device User Fee and Modernization Act of 2002, or MDUFMA, as of October 2002 unless a specific exemption applies, 510(k) PMN submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process. intelli-Case is classified as a Class II device.

Class III devices are those devices which have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the PMA process described below. PMA applications (and supplemental PMA applications) are subject to significantly higher user fees under MDUFMA than are 510(k) PMNs. None of our products are Class III devices.

A clinical trial may be required in support of a 510(k) submission. These trials generally require an Investigational Device Exemption, or IDE, application approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin if the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites.

Pervasive and Continuing FDA Regulation

A host of regulatory requirements apply to our marketed devices, including the quality system regulation (which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures), the Medical Reporting Regulations regulations (which require that manufacturers report to the FDA specified types of adverse events involving their products), labeling regulations, and the FDA's general prohibition against promoting products for unapproved or "off-label" uses. Class II devices also can have special controls such as performance standards, post-market surveillance, patient registries and FDA guidelines that do not apply to Class I devices. Unanticipated changes in existing regulatory requirements or adoption of new cGMP requirements could hurt our business, financial condition and results of operations.

Health Care Fraud and Abuse

In the United States, there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other health-related business. For example, the federal Anti-Kickback Law (42 U.S.C. §1320a-7b(b)) prohibits anyone from, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the referral of patients for, or the purchase, order or recommendation of, health care products and services reimbursed by a federal health care program (including Medicare and Medicaid). Recognizing that the federal Anti-Kickback Law is broad and potentially applicable to many commonplace arrangements, the Office of Inspector General within the Department of Health and Human Services, or OIG, has issued regulations, known as the safe harbors, which identify permissible practices. If all of the requirements of an applicable safe harbor are met, an arrangement will not be prosecuted under this law. Safe harbors exist for a number of arrangements relevant to our business, including, among other things, payments to bona fide employees, certain discount arrangements, and certain payment arrangements involving GPOs. The failure of an arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal. However, conduct that does not fully satisfy each requirement of an applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG or the Department of Justice. Violations of this federal law can result in significant penalties, including imprisonment, monetary fines and assessments, and exclusion from Medicare, Medicaid and other federal health care programs. Exclusion of a manufacturer would preclude any federal health care program from paying for its products. In addition to the federal anti-kickback law, many states have their own kickback laws. Often, these state laws closely follow the language of the federal law. Some state anti-kickback laws apply regardless of whether a federal health care program payment is involved. Federal and state anti-kickback laws may affect our sales, marketing and promotional activities, and relationships with health care providers or pharmacies by limiting the kinds of arrangements we may have with them.

Federal and state false claims laws prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payors that are false or fraudulent. For example, the federal False Claims Act (31 U.S.C. §3729 et seq.) imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program (including Medicaid and Medicare). Manufacturers, like us, can be held liable under false claims laws, even if they do not submit claims to the government, where they are found to have caused submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging in kickback arrangements with customers that file claims. A number of states also have false claims laws, and some of these laws may apply to claims for items or services reimbursed under Medicaid and/or commercial insurance. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, and imprisonment.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created certain criminal statutes relating to health care, including health care fraud and false statements related to healthcare matters. The health care fraud statute prohibits, among others, knowingly and willingly executing a scheme to defraud any health care benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, health care benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

The federal Physician Payments Sunshine Act requires certain pharmaceutical and medical device manufacturers to monitor and report certain payments and other transfers of value to physicians and other healthcare providers to the Centers for Medicare and Medicaid Services, or CMS, for disclosure to the public. Failure to submit required information may result in significant civil monetary penalties. In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, medical directorships, and other purposes. Some states mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians, and some states limit or prohibit such gifts.

Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws or the adoption of new federal or state laws or regulations could adversely affect many of the arrangements we have with customers and physicians. Our risk of being found in violation of these laws is increased by the fact that some of these laws are open to a variety of interpretations. If our past or present operations are found to be in violation of any of these laws, we could be subject to civil and criminal penalties, which could hurt our business, results of operations and financial condition.

Foreign Regulation

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ.

Third-Party Reimbursement

Customers that are prescribed our product generally rely on third-party payors, such as indemnity insurers and managed care plans, to cover and reimburse all or part of the cost of our product. As a result, demand for our product is dependent in part on the coverage and reimbursement policies of these payors.

Private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that private third-party payors will cover and reimburse our products in whole or in part in the future or that payment rates will be adequate. Currently, none of our products are reimbursed by federal healthcare programs, such as Medicare and Medicaid, and we do not anticipate that they will be reimbursed by such programs in the future.

CMS, the federal agency responsible for administering the Medicare program, frequently changes product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that private third-party payors will cover and reimburse our products in whole or in part in the future or that payment rates will be adequate. Further, in the U.S., there have been, and we expect that there will continue to be, federal and state proposals to lower expenditures for medical products and services, which may adversely affect reimbursement for our products.

Other U.S. Regulation

We must also comply with numerous federal, state and local laws relating to matters such as environmental protection, safe working conditions, manufacturing practices, healthcare reform, patient privacy and information, fire hazard control and, among other things, the generation, handling, transportation and disposal of hazardous substances.

Employees

As of December 31, 2017, we had a total of 86 full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our principal executive office and administrative operations are located in Emeryville, California. 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. We believe that our office and administration facilities are suitable and adequate for our current operations but we may require additional space and facilities as our business expands.

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.

Borrowings

In January 2016, in connection with a bridge loan (the "Bridge Loan") facilitated by China Kington, we issued five (5) promissory notes to certain lenders between December 2015 and January 2016 for an aggregate amount of $3.0 million.

After the closing of the first tranche of the April 2016 Financing (as defined below), in May 2016, we used $2.5 million of the proceeds to repay the principal on the promissory notes outstanding under the $3.0 million Bridge Loan.

After the closing of the second tranche of the April 2016 Financing, in August 2016 we repaid the final $0.5 million outstanding under the Bridge Loan and all liens on our property and assets associated with the Bridge Loan were released.

Recent Events

Equity

On November 13, 2017, we entered into a share purchase agreement (the "Original Agreement" and, as amended and restated on November 20, 2017, the "Purchase Agreement") with Ch-gemstone Capital (Beijing) Co., Ltd., a company organized in China ("CG Capital"), subject to customary closing conditions. Under the Purchase Agreement, we agreed to issue and sell to CG Capital a total of 2,400,000 shares of our common stock for an aggregate purchase price of $10,320,000 (the "Private Placement") and China Kington Asset Management ("China Kington") agreed to serve as placement agent in exchange for a commission equal to six percent (6%) of the total purchase price upon the closing of the Private Placement. On January 31, 2018, the Purchase Agreement was terminated upon written notification by CG Capital to us that it was unable to meet the closing condition to obtain the approval of the applicable regulatory authorities in China.

Concurrently with the execution of the Original Agreement, CG Capital entered into share transfer agreements (the "Share Transfer Agreements") with two of our existing stockholders, Pioneer Pharma (Hong Kong) Company Limited ("Pioneer Hong Kong" and, together with its parent, China Pioneer Pharma Holdings Limited ("China Pioneer"), "Pioneer Group") and Jian Ping Fu, to purchase 216,696 shares and 3,983,304 shares of our common stock, respectively. In connection with the termination of the Purchase Agreement for the Private Placement, the Share Transfer Agreements were also terminated.

After the termination of the Purchase Agreement with CG Capital, we entered into a share purchase agreement with OP Financial Investments Limited on February 5, 2018 for the sale of an aggregate of 1,700,000 shares of the Company's common stock, par value $0.01 per share, for an aggregate purchase price of $5,984,000 (the "OP Private Placement"). The OP Private Placement closed on February 8, 2018. OP Financial Investments Limited is an investment firm based in Hong Kong focused on cross-border investment opportunities and listed on the Hong Kong Stock Exchange. China Kington served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $359,040.

For more information on the equity transactions, please see Note 11 to our consolidated financial statements.

NYSE American Compliance

On December 7, 2017, the Company received a letter from the NYSE American informing it that the Company is back in compliance with the NYSE American continued listing standards set forth in Part 10 of the NYSE MKT Company Guide (the "Company Guide"). Specifically, the Company had resolved the continued listing deficiencies with respect to Sections 1003(a)(ii) and 1003(a)(iii) of the Company Guide referenced in the NYSE American's letters dated May 16, 2017 and September 14, 2017. The Company is subject to ongoing review for compliance with NYSE American requirements as part of the NYSE American's routine monitoring. For more information, please see Item 1A. "Risk Factors."

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our corporate website, located at *www.novabay.com,* as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (the "SEC").

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

There is uncertainty about our ability to continue as a going concern.

We have a limited number of commercial products, which are still in their early stage of commercialization, and we are focusing our commercialization efforts almost exclusively on Avenova. As a result, we have sustained operating losses for the majority of our corporate history and expect that our 2018 expenses will equal or exceed our 2018 revenues, as we continue to invest in our Avenova commercialization efforts. We expect to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. Additional funding beyond the OP Private Placement may be needed in order to pursue our business plan, which includes increasing market penetration for our existing commercial products, research and development for additional product offerings, seeking regulatory approval for these product candidates, and pursuing their commercialization in the United States, Asia, and other markets. These circumstances raise doubt about our ability to continue as a going concern, which depends on our ability to raise capital to fund our current operations.

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 our stockholders' equity does not meet the minimum standards of the NYSE American, we* may *be subject to delisting procedures.

On May 16, 2017, we received a letter from the NYSE American notifying us that our stockholders' equity as of March 31, 2017 was below the minimum requirements of Section 1003(a)(iii) of the NYSE American Company Guide (the "Company Guide") (requiring stockholders' equity of $6.0 million or more if a company has reported losses from continuing operations and/or net losses in its five most recent fiscal years). In order to maintain our listing, we submitted a plan of compliance, addressing how we intend to regain compliance with the Company Guide within 12 months, or by May 16, 2018. On September 14, 2017, we were further notified by the NYSE American that our common stock no longer satisfied the requirements of Company Guide Section 1003(a)(ii) (requiring stockholders' equity of $4.0 million or more if a company has reported losses from continuing operations and/or net losses in three of the four most recent fiscal years).

On December 7, 2017, we were notified by the NYSE American that we have regained compliance with all of the NYSE American continue listing standards by maintaining a market capitalization in excess of $50 million over the past two quarters.

We are now subject to NYSE American's normal continued listing monitoring. However, in accordance with Section 1009(h) of the Company Guide, if we are again determined to be below any of the continued listing standards within 12 months of December 7, 2017, NYSE American will examine the relationship between the above two incidents of noncompliance and re-evaluate our method of financial recovery. In addition, should our market capitalization fall below $50 million on a 30 trading day average, NYSE American can deem us to be incompliant and may truncate the compliance procedures described in Section 1009 of the Company Guide or immediately initiate delisting proceedings.

We cannot guarantee that our market capitalization will not fall below $50 million on a 30 trading day average or that we will be able to comply with the continued listing standards of NYSE American, and therefore our common stock may be subject to delisting. If our common stock is delisted, this could, among other things, substantially impair our ability to raise additional funds; result in a loss of institutional investor interest and fewer financing opportunities for us; and/or result in potential breaches of representations or covenants of our warrants, subscription agreements or other agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, 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 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 544,695 shares of our common stock, of which the warrants exercisable for 260,093 shares will expire on March 6, 2020, and the warrants exercisable for 284,602 shares will expire on 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 or conversion 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, Pioneer Hong Kong as a wholly-owned subsidiary of China Pioneer and the recipient of all of the previous holdings of Pioneer Pharma (Singapore) Pte. Ltd. pursuant to an internal corporate reorganization of China Pioneer, Mr. Jian Ping Fu and OP Financial Investments Limited. As of February 28, 2018 each of China Pioneer, Mr. Fu and OP Financial Investments Limited own 31%, 23% and 10% 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, 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, OP Financial Investments Limited and/or China Kington might influence our corporate matters in a manner that is not in the best interest of our general stockholders.

After the OP Private Placement, China Pioneer beneficially owned approximately 31% of our outstanding common stock. Our director Mr. Xinzhou "Paul" Li is the chairman of China Pioneer. Pursuant to the arrangement of our Bridge Loan, facilitated by China Kington in January 2016, 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 23% of our common stock, and OP Financial Investments Limited owns approximately 10%. China Kington and its affiliates have served as placement agent for three purchases of Company securities by Mr. Fu during 2016 and one purchase of Company securities by OP Financial Investments Limited in 2018.

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. 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, Mr. Fu and/or OP Financial Investments Limited to cooperate, they could eventually unilaterally elect all of their preferred director nominees at a Company Annual Meeting of Stockholders. Even with our classified board, China Pioneer, Pioneer Hong Kong, Mr. Fu and/or OP Financial Investments Limited could ensure that four (4) of our eight (8) directors are either nominees of China Pioneer, Pioneer Hong Kong or China Kington after the Company's annual meeting of stockholders this year, or six (6) after our 2019 annual meeting of stockholders. In the interim, China Pioneer, Pioneer Hong Kong, China Kington, Mr. Fu and/or OP Financial Investments Limited 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 our formation, our 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, which has a limited commercial history but constitutes approximately 90% of our revenue for 2017. We are dedicating a substantial amount of our resources to advance Avenova as aggressively as possible. If we are unsuccessful in Avenova's broad 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. While we believe we are creating an efficient commercial organization, 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, which could cause our commercialization efforts to be unprofitable or less profitable than expected.

We expect to generate revenue from sales of Avenova, which is classified as a cleared medical device by the FDA, but we cannot guarantee that the FDA will continue to allow us to market and sell Avenova as a cleared medical device, which would halt our sales and marketing of Avenova and cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

Our ability to generate product sales will depend on the commercial success of Avenova. Our ability to continue to commercialize Avenova and generate revenue depends upon, among other things:

- FDA allowing us to continue marketing Avenova as an FDA clearance;
- acceptance in the medical community;
- the safety of Avenova's predicate devices;
- the number of patients who use Avenova for the intended target;
- sufficient coverage or reimbursement by third party payors;
- our ability to successfully market Avenova; and
- the amount and nature of competition from competing companies with similar products and procedures.

The sale of Avenova will be subject to among other things, regulatory and commercial and market uncertainties that may be outside of our control. Products that are approved or cleared for marketing by the FDA may be materially adversely impacted by the emergence of new industry standards and practices or regulations that could render Avenova as well as our other cleared products less competitive or obsolete. We cannot guarantee that Avenova, our other cleared products, or products that may be approved or cleared for marketing in the future will not be materially adversely impacted by a change in industry standards or regulations. If changes to Avenova or our other cleared products that may market and sell in the future cause a delay in continued commercialization or if we cannot make a change to satisfy the industry standards and practices or regulations, we may not be able to meet market demand which may have a materially adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, the FDA may request that we submit another 510(k) premarket submission that compares to another predicate device. If we are unable to find an adequate predicate device that is substantially equivalent to Avenova for the treatment claims that we use to sell and market Avenova, we may not be able to obtain the necessary FDA clearance to continue to market and sell Avenova without performing comprehensive clinical trials. In such event, we would need to seek premarket approval from the FDA for the applicable product before we could continue to sell and market Avenova in the United States, which would be significantly more time consuming, expensive, and uncertain.

Our commercialized product Avenova, like our other cleared products, are not approved by the FDA as a drug, and we rely solely on the 510(k) clearance of our products 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, we may only legally make very limited claims that pertain to our products' cleared intended use. Without claims of efficacy, market acceptance of our products may be slow.

There is significant risk that the FDA or other federal or state law enforcement authorities may determine that the nature and scope of our sales and marketing activities constitutes the promotion of our products for a non-FDA-approved uses in violation of applicable law and as the sale of unapproved drugs, which is prohibited under applicable law. We face the risk that the FDA may take enforcement action against us for the way that we promote and sell our products. 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 unapproved drug products, 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 limit and change our sales, promotion, grant and educational activities.

We have only limited experience in regulatory affairs, which* may *affect our ability or the time required to navigate complex regulatory requirements and obtain necessary regulatory clearance or approvals, if such clearances or approvals are received at all. Regulatory delays or denials* may *increase our costs, cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory clearances or approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only three employees. As a result, we may experience delays in connection with obtaining regulatory clearances or approvals for our products, if such clearances or approvals are obtained at all.

In addition, the products we currently have FDA clearance and/or approval or clearance in other countries as well as the products that we are developing and intend to market are subject to complex regulatory requirements, particularly in the United States, Europe and Asia, which can be costly and time-consuming. With respect to the products that we have FDA clearance, there can be no assurances that the FDA will continue to allow us to market those products without further clinical trials. With respect to products that we are currently developing but have no regulatory clearances or approvals, there can be no assurance that necessary regulatory clearances or approvals will be granted on a timely basis, if at all. Furthermore, there can be no assurance of continued compliance with all regulatory requirements necessary for the manufacture, marketing and sale of the products we will offer in each market where such products are expected to be sold, or that products we have commercialized will continue to comply with applicable regulatory requirements. If a government regulatory agency were to conclude that we were not in compliance with applicable laws or regulations, the agency could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or employees, and could recommend criminal prosecution. Furthermore, regulators may proceed to ban, or request the recall, repair, replacement or refund of the cost of, any device manufactured or sold by us.

Developments after a product reaches the market* may *adversely affect sales of our products.

Even after obtaining regulatory clearances, certain developments may decrease demand for our products, including the following:

- the re-review of products that are already marketed;
- new scientific information and evolution of scientific theories;
- the recall or loss of regulatory clearance of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater scrutiny in advertising and promotion.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of a product, it could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. In addition, some health authorities appear to have become more cautious when examining new products and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the United States, on advertising, and promotion (in particular, direct to consumer advertising) and pricing of pharmaceutical products. Certain regulatory changes or decisions could make it more difficult for us to sell our products. If any of the above occurs to Avenova, our business, results of operations, financial condition and cash flows could be materially adversely affected.

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.

The FDA and other governmental authorities require that all of our products be manufactured in strict compliance with federal Quality Systems Regulations and other applicable government regulations and corresponding foreign standards. We do not currently operate manufacturing facilities for production of our products. As a result, we have partnered with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute our products and help us meet legal requirements. As we have limited control over our commercial partners, any performance failure on their part (including failure to deliver compliant, quality components or finished goods on a timely basis) could affect the commercialization of our products, producing additional losses and reducing or delaying product revenues. If any of our commercial partners or manufacturers have violated or is alleged to have violated any laws or regulations during the performance of their obligations to us, it is possible that we could suffer financial and reputation harm or other negative outcomes, including possible legal consequences.

Our products 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. Accordingly, we and our third-party manufacturers are also subject to periodic unannounced inspections by the FDA to determine compliance with the FDA's requirements, including primarily current Good Manufacturing Practice ("cGMP"), the Quality Systems Regulations ("QSR"), medical device reporting regulations, and other applicable government regulations and corresponding foreign standards, including ISO 13485.

The results of these inspections can include inspectional observations on FDA's Form 483, untitled letters, warning letters, or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our FDA-cleared products are ineffective, make additional therapeutic claims that are not commensurate to the accepted labeling claims, or pose an unreasonable health risk, the FDA could take a number of regulatory actions, including but not limited to, preventing us from manufacturing any or all of our devices or performing laboratory testing on human specimens, which could materially adversely affect our business.

Avenova's FDA-clearance and our other products that have been cleared by the FDA or products that we may obtain FDA-clearance in the future, if at all, are subject to limitations on the intended uses for which the product may be marketed, which can reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearance to one or all of our products that may be cleared in the future, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

If we were to lose, or have restrictions imposed on, FDA clearances we may receive in the future, our business, operations, financial condition and results of operations would likely be materially adversely impacted.

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 June 1, 2018. If we are unable to extend our agreement with Mr. Sieczkarek, no assurance can be given that we will be able to timely locate a replacement or that such replacement will be as effective in our growth as Mr. Sieczkarek has been.

We 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. We rely on our distribution agreements with McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation to fill Avenova prescriptions at most of the retail pharmacies in the United States. If they are not able to ensure consistent availability of our product at retail pharmacies, our revenues will suffer.

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 products. 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 are subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we* 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 products.

The clearance that we have received from the FDA for our products is subject to strict limitations on the indicated uses for which the products may be marketed. The labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for are products are subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the products or the withdrawal of the products from the market. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory clearance, product recalls, seizure of products, operating restrictions, injunctions, warning letters and other enforcement actions, and criminal prosecution. Any of these events could prevent us from marketing our products and our business may not be able to continue past such concerns.

Our products* may *in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If we experience unanticipated problems with the products, if or once approved or cleared for marketing, our products could be subject to restrictions or withdrawal from the market which* may *have a materially adverse impact on our business, financial condition, results of operations, and prospects.

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for our cleared medical devices, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our current suppliers and suppliers that we may have relationships with in the future are required to comply with FDA's Quality Systems Regulations ("QSR") including for the manufacture, testing, control, quality assurance, labeling, shipping, storage, distribution and promotion of our products. The FDA enforces the QSR and similarly, other regulatory bodies with similar regulations enforce those regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions against us: (1) untitled letters, Form 483 observation letters, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for 510(k) clearance of new products or modified products; (7) operating restrictions; (8) withdrawing 510(k) clearances that have already been granted; (9) refusal to grant export clearance for our products; or (10) criminal prosecution.

If any of these actions were to occur it could harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, if any of our key component suppliers are not in compliance with all applicable regulatory requirements we may be unable to produce our products on a timely basis and in the required quantities, if at all.

If our product or products cause a reaction in a patient that causes serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that our device or a similar device has likely caused or would likely cause or contribute to death. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

If our product or products cause an unexpected reaction to a patient or patients in certain ways that* may *have caused or contributed to serious injury, we will be subject to product liability claims.

We cannot make assurances that any liability insurance coverage that we qualify for, if at all, will fully satisfy any liabilities brought for any event or injury that is attributed to our product or products. Even if our liability insurance satisfies any and all products liabilities brought against us, any product liability claims may significantly harm our reputation and delay market acceptance of our product or products that may be cleared or approved in the future, if at all.

We expect to rely on third parties to conduct any future studies of our technologies that* may *be required by the FDA, and those third parties* may *not perform satisfactorily.

Though we do not anticipate conducting further clinical trials in the near future, should we decide otherwise, we may not have the ability to independently conduct the clinical or other studies that will be required to obtain FDA clearance for one or all of our products currently in development or products that we may develop in the future. Should we conduct clinical trials, those trials may be performed by third parties that may not perform satisfactorily, which may have a materially adverse impact on our business, financial condition, results of operations, and prospects.

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 or suspended 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 products or 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.

We operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products could become obsolete or uncompetitive.

The medical device market is highly competitive. We compete with many medical device companies globally in connection with our cleared products and would be also competing with our products under development, if those products are cleared or approved. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we develop. If our technologies or products become obsolete or uncompetitive, our related product sales would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

Avenova faces substantial competition in the eye care markets in which we operate.

We face intense competition in the eye care market, which is focused on cost-effectiveness, price, service, product effectiveness and quality, patient convenience and technological innovation. Avenova faces substantial competition in the eye care market from companies of all sizes in the United States and abroad, including, among others, large companies such as Allergan plc and Shire plc, against products such as Restasis, Xiidra, eye wipes, baby shampoo and soap. These products are not saline with hydrochlorous acid as a preservative in solution and they are prescribed for eyelid and lash disease symptom management. There are also over-the-counter products that contain hypochlorous acid that compete with Avenova. Competition may increase further as existing competitors enhance their offerings or additional companies enter our markets or modify their existing products to compete directly with our products. The hypochlorous acid is used as only a preservative and Avenova relies on the 99.99% saline solution as its active ingredient. Many of our competitors have substantially more resources and a greater marketing scale than we do. We may not be able to sustain our current levels of growth as competitive pressures, including pricing pressure from competitors, increase. If our competitors respond more quickly to new or emerging technologies and changes in customer requirements, our products may be rendered obsolete or non-competitive. In addition, if our competitors develop more effective or affordable products, or achieve earlier patent protection or product commercialization than we do, our operating results will materially suffer.

We* may *not be able to enhance the capabilities of our current and new products to keep pace with our industry's rapidly changing technology and customer requirements.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our future success will depend significantly on our ability to keep pace with technological developments and evolving industry standards as well as respond to changes in customer needs. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we currently sell, Avenova in particular, and products that we plan to sell. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

Demands of third-party payors, cost reduction pressures among our customers, restrictive reimbursement practices, and cost-saving and other financial measures* may *adversely affect our business.

Currently, none of our products are reimbursed by federal healthcare programs, such as Medicare and Medicaid, and we do not anticipate that they will be reimbursed by such programs in the future. Our ability to negotiate favorable contracts with non-governmental payors, including managed-care plans or group purchasing organizations ("GPOs"), even if facilitated by our distributors, may significantly affect revenue and operating results. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for some of our products, to negotiate reduced fees or other concessions or to delay payment. In addition, third-party payors may reduce or limit reimbursement for our products in the future, such as by withdrawing their coverage policies, canceling any future contracts with us, reviewing and adjusting the rate of reimbursement, or imposing limitations on coverage. Furthermore, the increasing leverage of organized buying groups among non-governmental payors may reduce market prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers, lower pricing for our products to new customers, or limitations or reductions in reimbursement could have a material adverse effect on the financial position, cash flows and results of operations.

Federal and state healthcare reform legislation, including the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the "Affordable Care Act," may also adversely affect our business. The Affordable Care Act contains provisions aimed at improving quality and decreasing costs in the Medicare program, such as value-based payment programs and reduced hospital payments for avoidable readmissions and hospital acquired conditions. The Affordable Care Act has been, and continues to be, subject to judicial and legislative challenges seeking to modify, limit, replace, or repeal the legislation. While we cannot predict what additional healthcare programs and regulations will be implemented at the federal or state level, or the effect of any future legislation or regulation on our business, any changes that lower potential reimbursement for our products, impose additional costs, reduce the potential number of people eligible for reimbursement for the use of our products, or otherwise reduce demand for our products, could adversely affect our business, financial condition and results of operations.

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 and because patent applications are not published for a period of time, or in some cases at all, 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 a dispute involving our proprietary technology were resolved against us, it could mean the earlier entry of some or all third parties seeking to compete in the marketplace for a given product, and a consequent significant decrease in the price we could charge for our product. If such a dispute alleging that our technology or operations infringed third party patent rights 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 Avenova or NeutroPhase or products that we currently do not sell but may sell in the future such as 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 in-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, obtain 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 withstand an invalidity challenge or 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 products 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 commercial 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.

Failure to comply with laws and regulations governing the sales and marketing of our products could materially impact our revenues.

We engage in various marketing, promotional and educational activities pertaining to, as well as the sale of, pharmaceutical products and/or medical devices in the United States and in certain other jurisdictions outside of the United States. The promotion, marketing and sale of pharmaceutical products and medical devices is highly regulated and the sales and marketing practices of market participants, such as us, have been subject to increasing supervision by governmental authorities, and we believe that this trend will continue.

In the United States, our sales and marketing activities are regulated by a number of regulatory authorities and law enforcement agencies, including the U.S. Department of Health and Human Services, the FDA, the Federal Trade Commission, the U.S. Department of Justice, the SEC, and state regulatory authorities. These authorities and agencies and their equivalents in countries outside the United States have broad authority to investigate market participants for potential violations of laws relating to the sale, marketing and promotion of pharmaceutical products and medical devices, including the False Claims Act, the Anti-Kickback Statute, the UK Bribery Act of 2010 and the Foreign Corrupt Practices Act, and their state equivalents, among others, for alleged improper conduct, including corrupt payments to government officials, improper payments, inducements, and financial relationships with and to medical professionals, patients, and sales personnel, off-label marketing of pharmaceutical products and medical devices, and the submission of false claims for reimbursement by the federal government. Healthcare companies and providers may also be subject to enforcement actions or prosecution for such improper conduct. Any inquiries or investigations into our operations, or enforcement or other regulatory action

against us, by such authorities could result in significant defense costs, fines, penalties and injunctive or administrative remedies, distract management to the detriment of the business, result in the exclusion of certain products, or us, from government reimbursement programs or subject us to regulatory controls or government monitoring of our activities in the future.

Failure to obtain and/or maintain required licenses or registrations could reduce revenue.

Our business is subject to a variety of licensing or registration requirements by the FDA, certain states and foreign jurisdictions where our products are distributed. Failure to obtain or maintain required licenses could result in the termination of the sale of certain products in the application states or foreign jurisdictions, or the termination of such products. We may also be subject to fines and other penalties imposed by the relevant government authorities for non-compliance.

The process for obtaining licenses or registrations can be lengthy and expensive and the results sometimes are unpredictable. If we are unable to obtain licenses or registrations needed to produce, market and sell our products in a timely fashion, or at all, our revenues could be materially and adversely affected.

We are subject to U.S. healthcare fraud and abuse and health information privacy and security laws, and the failure to comply with such laws* may *adversely affect our business.

We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The U.S. laws that may affect our ability to operate include, but are not limited to: (i) the federal Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies, and relationships with healthcare providers or other persons and entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third party payers that are false or fraudulent, and from offering or transferring remuneration to a Medicare or state healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state healthcare program; (iii) the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, among other things, created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; (iv) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information and places restrictions on the use of such information for marketing communications; (v) the Physician Payments Sunshine Act, which among other things, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under a federal healthcare program to report annually information related to "payments or other transfers of value" made to physicians and teaching hospitals, and ownership and investment interests held by certain healthcare professionals and their immediate family members; (vi) the government pricing rules and price reporting laws applicable to the Medicaid, Medicare Part B, 340B Drug Pricing Program, the U.S. Department of Veterans Affairs program, and the TRICARE program; and (vii) state and foreign law equivalents of each of the above laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, and state and foreign price and payment reporting and disclosure laws, many of which differ from each other in significant ways and often are not preempted by their federal counterparts, thus complicating compliance efforts. Violations of the health information privacy and fraud and abuse laws may result in severe penalties against us and/or our responsible employees, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Defense of litigation claims and government investigations can be costly, time consuming, and distract management, and it is possible that we could incur judgments or enter into settlements that would require us to change the way we operate our business. Certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with health information privacy or fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that may govern our activities, such as federal and state anti-kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn. Due to the breadth of these statutory provisions, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the U.S. Department of Justice, and other agencies have increased their enforcement activities and scrutiny with respect to sales, marketing, research, financial relationships with healthcare providers, rebate or copay arrangements, discounts, and similar activities and relationships of pharmaceutical and medical device companies in recent years, and many companies have been subject to government investigations related to these practices and relationships. A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacture and/or distribution, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs, and other sanctions.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audit reports to stockholders causes our expenses to be higher than they would be if we were a privately-held company. The increased costs associated with operating as a public company may decrease our net income or increase our net loss, and may cause us to reduce costs in other areas of our business or increase the prices of our product to offset the effect of such increased costs. Additionally, if these requirements divert our management's attention from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations.

A failure of our internal control over financial reporting could materially impact our business or stock price.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. An internal control system, no matter how well designed 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. Because of the inherent limitations in all internal control systems, internal control over financial reporting may not prevent or detect misstatements. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud, and could expose us to litigation or adversely affect the market price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2. PROPERTIES

Our principal executive offices and administrative operations are located at 2000 Powell Street, Suite 1150, Emeryville, California. In total, we lease approximately 7,799 square feet of office space in the facility pursuant to the Lease expiring on February 28, 2022.

The Company also leases 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 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, as amended, for the EmeryStation premises is October 31, 2020), unless earlier terminated pursuant to any provision of the Company's master lease for EmeryStation, or the Sublease Agreement.

ITEM 3. LEGAL PROCEEDINGS

We are currently not a party to, nor is our property the subject matter of, any pending or, to our knowledge, contemplated material legal proceedings. From time to time, we may become party to litigation and subject to claims arising in the ordinary course of our business.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the NYSE American, under the symbol "NBY." The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported by the NYSE American, after giving effect to the 1 for 25 reverse stock split:

	2017		2016	
	High	Low	High	Low
First Quarter	$ 4.35	$ 3.20	$ 3.42	$ 1.77
Second Quarter	$ 4.05	$ 2.25	$ 3.42	$ 1.90
Third Quarter	$ 5.00	$ 3.37	$ 5.29	$ 2.12
Fourth Quarter	$ 4.80	$ 2.75	$ 5.09	$ 3.25

Holders

As of March 15, 2018, there were approximately 110 holders of record of our common stock. This figure does not reflect persons or entities that hold their stock in nominee or "street" name through various brokerage firms.

Dividend Policy

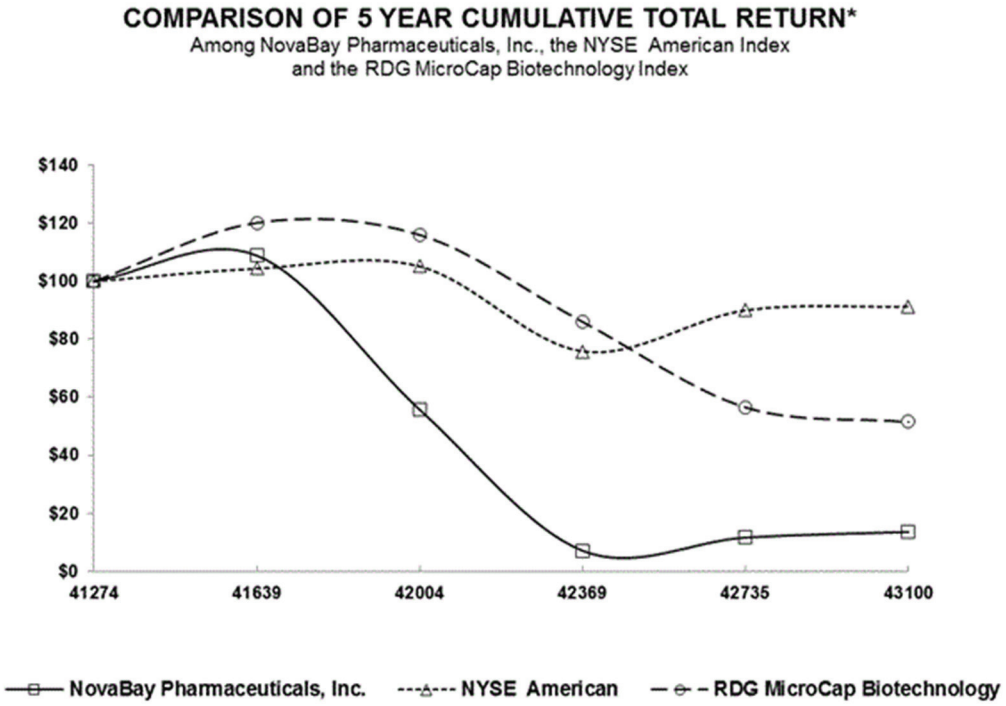
We have not paid cash dividends on our common stock since our inception. We currently expect to retain earnings primarily for use in the operation and expansion of our business, therefore, we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements, restrictions under any existing indebtedness and other factors the Board of Directors deems relevant.

Performance Graph (1)

The following graph compares our total stockholder returns for the past five years to two indices: the NYSE American Composite Index and the RDG MicroCap Biotechnology Index. The total return for each index assumes the reinvestment of all dividends, if any, paid by companies included in these indices and is calculated as of December 31 of each year.

As a member of the NYSE American Composite Index, we are required under applicable regulations to use this index as a comparator, and we believe it is relevant since it is composed of peer companies in lines of business similar to ours.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



	12/12	12/13	12/14	12/15	12/16	12/17
NovaBay Pharmaceuticals, Inc.	**100.00**	**108.85**	**55.75**	**7.15**	**11.68**	**13.63**
NYSE American Composite Index	**100.00**	**104.47**	**105.23**	**75.69**	**89.97**	**91.27**
RDG MicroCap Biotechnology Index.....	**100.00**	**120.14**	**115.98**	**86.00**	**56.59**	**51.54**

(1) This section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

ITEM 6. SELECTED FINANCIAL DATA

The following table presents selected financial information as of and for the dates and periods indicated below which have been derived from our audited consolidated financial statements and other information. The information set forth below is not necessarily indicative of results of future operations, and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this report and our consolidated financial statements and related notes included elsewhere in this report.

	Year Ended December 31,				
	2017	2016	2015	2014	2013
	(in thousands, except per share data)				
Statements of Operations Data:					
Sales:					
Product Revenue, net	$ 18,127	$ 11,617	$ 4,146	$ 684	$ 223
Other Revenue, net	103	280	235	370	3,254
Total Sales, net	18,230	11,897	4,381	1,054	3,477
Product Cost of Goods Sold	2,784	2,464	1,261	486	162
Gross Profit	15,446	9,433	3,120	568	3,315
Operating expenses:					
Research and development	410	1,371	5,728	9,483	12,461
Sales and marketing	13,711	11,809	10,523	1,754	—
General and administrative	8,636	7,235	8,006	6,235	6,366
Total operating expenses	22,757	20,415	24,257	17,472	18,827
Operating Loss	(7,311)	(10,982)	(21,137)	(16,904)	(15,512)
Non-cash gain (loss) on changes in fair value of warrant liability	(101)	(2,099)	2,149	1,664	(555)
Other income (expense), net	12	(68)	17	48	27
Loss before provision for income taxes	(7,400)	(13,149)	(18,971)	(15,192)	(16,040)
Provision for income taxes	(3)	(2)	(2)	(2)	(2)
Net loss	$ (7,403)	$ (13,151)	$ (18,973)	$ (15,194)	$ (16,042)
Loss per share:					
Basic	$ (0.48)	$ (1.40)	$ (6.82)	$ (7.65)	$ (10.51)
Diluted	$ (0.48)	$ (1.40)	$ (6.82)	$ (7.65)	$ (10.51)
Shares used in computing net loss per share:					
Basic (after 1 for 25 reverse stock split)	15,324	9,408	2,784	1,985	1,527
Diluted (after 1 for 25 reverse stock split)	15,324	9,408	2,784	1,985	1,527

	2017	2016	2015	2014	2013
			(in thousands)		
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 3,199	$ 9,512	$ 2,385	$ 5,429	$ 13,053
Working capital	4,016	10,148	(106)	3,607	11,163
Total assets	10,079	15,381	5,077	7,537	15,650
Deferred revenue—current and non-current	3,375	4,053	2,418	2,425	1,871
Common stock and additional paid-in capital	113,668	110,772	85,422	73,395	64,884
Total stockholders' equity (deficit)	2,594	7,101	(5,098)	1,848	8,516

ITEM 7. 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 II, Item 8 of this report. This discussion contains forward-looking statements that involve risks and uncertainties. Words such as "expects," "anticipated," "will," "may," *"goals," "plans," "believes," "estimates," "concludes," determines," variations of these words, and similar expressions are intended to identify these forward-looking statements. As a result of many factors, including those set forth under the section entitled "Risk Factors" in 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 medical device company predominantly focused on eye care. We are currently focused primarily on commercializing Avenova®, a prescription product sold in the United States for cleansing and removing foreign material including microorganisms and debris from skin around the eye, including the eyelid.

Avenova is an eye care product formulated with our proprietary, stable and pure form of hypochlorous acid. Avenova has proven in laboratory testing to have broad antimicrobial properties as a preservative in solution as it removes foreign material including microorganisms and debris from the skin on the eyelids and lashes without burning or stinging.

Our business strategy remains the same since November 2015, when we restructured our business to focus our resources on growing sales of Avenova in the United States. Our current three-part business strategy is comprised of: (1) focusing our resources on growing the U.S. commercial sales of Avenova, including implementation of a sales and marketing strategy intended to increase product margin and profitability; (2) maintaining low expenses and continuing to optimize sales force efficiency, including expansion of geographical reach and efforts directed to maintain and increase insurance reimbursement for Avenova; 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.

Pursuant to our business strategy, we have developed additional products containing our proprietary, stable and pure form of hypochlorous acid, including NeutroPhase® for the wound care market and CelleRx® for the dermatology market. Since the launch of NeutroPhase in 2013, we have established a U.S. distribution partner and an international distribution partner in China. We currently do not sell or distribute CelleRx.

Avenova, NeutroPhase, and CelleRx are medical devices cleared by the FDA under the Food and Drug Administration Act Section 510(k). The products are intended for use under the supervision of healthcare professionals for the cleansing and removal of foreign material, including microorganisms and debris. For wound treatment, NeutroPhase® is also intended for use under the supervision of healthcare professionals for moistening absorbent wound dressings and cleansing minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening and debriding acute and chronic dermal lesions.

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 II, Item 8 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 December 31, 2017 and 2016, management had reserved $13 thousand and $10 thousand, respectively, primarily based on specific amounts that were in dispute or 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 and 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 December 31, 2017 and 2016, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $140 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.

We adopted the new revenue recognition standard effective January 1, 2018 under the modified retrospective transition method. While the Company is still in the process of assessing the impact of this new standard on its consolidated financial statements, the evaluation of its license and collaboration arrangements is complete, and is the Company is now working on finalizing its assessment of the quantitative impact from the adoption of the new standard on its consolidated financial statements including the new presentation and disclosure requirements. For license and collaboration revenue for which contract deliverables are currently accounted for as a combined unit of accounting because products or services are not separable, the Company has identified that under the new guidance the separate performance obligations are capable of being distinct. As a result, the transaction price under these arrangements, including upfront fees and milestone payments, will be allocated differently to each performance obligation and may be recognized at earlier points in time or with a different pattern of performance over time.

The Company identified the following performance obligations during its review of the license and collaboration agreements:

- Exclusive distribution rights in the product territory
- Regulatory submission and approval services
- Development services
- Sample supply, free of charge
- Incremental discounts and product supply prepayments representing a material right to the customer

The Company has found that based upon the relative estimated selling prices of each performance obligation, the licenses typically make up approximately 90% to 95% of the total transaction price allocation for each contract. Because the licenses have been classified under the new guidance as a "right to use" the intellectual property, for which the customers right to use the intellectual property is transferred at a point in time, under the new rules the revenue for each license will be recognized at contract inception when the licenses are granted. Based on these findings, the Company currently estimates that approximately 96% or $2.0 million of the current deferred revenue balance related to its license and collaboration arrangements will be allocated to performance obligations that were satisfied in periods prior to adoption and included in the cumulative adjustment to retained earnings upon adoption.

As the Company finalizes its evaluation of the new standard, new information may arise that could change the Company's understanding of the impact on its 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.

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 payment discounts and allowances offered to our customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue 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 revenue allowances (in thousands):

	Wholesaler/ Pharmacy fees	Cash discounts	Rebate	Total
Balance at December 31, 2014	—	—	—	—
Current provision related to sales made during current period	(28)	(38)	—	(66)
Payments	28	38	—	66
Balance at December 31, 2015	—	—	—	—
Current provision related to sales made during current period	(1,350)	(222)	(4,379)	(5,951)
Payments	1,019	222	4,871	6,112
Balance at December 31, 2016	(331)	—	492	161
Current provision related to sales made during current period	(2,916)	(485)	(8,779)	(12,180)
Payments	2,717	454	9,105	12,276
Balance at December 31, 2017	$ (530)	$ (31)	$ 818	$ 257

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 allowances for excess and obsolete inventory, along with the 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 differ, or are expected to differ, from the previous estimate. See Note 12 of the Notes to Consolidated Financial Statements (Equity-Based Compensation) 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 II, Item 8 of this report for information on recent accounting pronouncements.

Results of Operations

Comparison of Years Ended* December 31, 2017 *and 2016

	Year Ended December 31,		Dollar	Percent
	2017	2016	Change	Change
Statement of Operations				
Sales:				
Product revenue, net	$ 18,127	$ 11,617	$ 6,510	56%
Other revenue	103	280	(177)	(63)%
Total sales, net	18,230	11,897	6,333	53%
Product cost of goods sold	2,784	2,464	320	13%
Gross profit	15,446	9,433	6,013	64%
Research and development	410	1,371	(961)	(70)%
Sales and marketing	13,711	11,809	1,902	16%
General and administrative	8,636	7,235	1,401	19%
Total operating expenses	22,757	20,415	2,342	11%
Operating Loss	(7,311)	(10,982)	3,671	(33)%
Non cash loss on changes in fair value of warrant liability	(101)	(2,099)	1,998	(95)%
Other income (expense), net	12	(68)	80	(118)%
Loss before provision for income taxes	(7,400)	(13,149)	5,749	(44)%
Provision for income tax	(3)	(2)	(1)	50%
Net loss and comprehensive loss	$ (7,403)	$ (13,151)	$ 5,748	(44)%

Total Net Sales, Product Cost of Goods Sold and Gross Profit

Product revenue, net, increased by $6.5 million, or 56%, to $18.1 million for the year ended December 31, 2017, from $11.6 million for the year ended December 31, 2016. The change in product revenue, net, was primarily the result of increased sales of Avenova in connection with our planned shift of sales to the higher-margin reimbursed pharmacy channel from our legacy in-office direct sales channel and our focus on product commercialization driven by unit growth and price increases, as well as the significant growth of non-Avenova products.

Other revenue, net, decreased by $177 thousand, or 63%, to $103 thousand for the year ended December 31, 2017, from $280 thousand for the year ended December 31, 2016. Other revenue decreased primarily due to recognition of deferred revenue upon the termination of a collaboration agreement in the third quarter of 2016.

Product cost of goods sold increased by $320 thousand, or 13%, to $2.8 million for the year ended December 31, 2017, from $2.5 million for the year ended December 31, 2016. The change in product cost of goods sold was primarily the result of the product mix and the continuing shift in sales mix toward the reimbursed pharmacy channel which maintains a higher selling price.

Gross profit increased by $6.0 million, or 64%, to $15.4 million for the year ended December 31, 2017, from $9.4 million for the year ended December 31, 2016. The increase in gross profit was primarily the result of increased sales of Avenova and the continuing shift in sales mix toward the higher margin reimbursed pharmacy channel.

Research and Development

Research and development expenses decreased by $1.0 million, or 70%, to $0.4 million for the year ended December 31, 2017, from $1.4 million for the year ended December 31, 2016. The reduction is primarily the result of our previously-announced change in business strategy, as reflected by our reduced spending on clinical trials and our shift of capital resources from research and development to the commercialization of Avenova.

Sales and marketing

Sales and marketing expenses increased by $1.9 million, or 16%, to $13.7 million for the year ended December 31, 2017, from $11.8 million for the year ended December 31, 2016. The increase was primarily due to the increase in sales representative headcount, along with increased sampling and marketing programs.

General and administrative

General and administrative expenses increased by $1.4 million, or 19%, to $8.6 million for the year ended December 31, 2017, from $7.2 million for the year ended December 31, 2016. The increase was primarily a result of higher stock-based compensation, recording of the previous CFO's retirement package, and an increase in legal fees and employees' administrative expenses to support the sales team brought in-house at the end of January 2017. This was partly offset by the Company's operations moving to a smaller headquarters and subleasing our former headquarters.

Non-cash loss on changes in fair value of warrant liability

The adjustments to the fair value of warrants was a loss of $0.1 million for the year ended December 31, 2017, compared to a loss of $2.1 million for the year ended December 31, 2016.

For additional information regarding the warrants and their valuation, please see Note 10 in the Notes to Consolidated Financial Statements included in Part II, Item 8 of this report. In the year ended December 31, 2017, non-cash loss on changes in fair value of warrants was caused by the increase in the price of the Company's common stock above the warrants' exercise prices. In the year ended December 31, 2016, non-cash loss on changes in fair value of warrants was caused by a reduction in the exercise price of the warrants pursuant to the price protection provision in such warrants, along with an increase in the price of the Company's common stock above the warrants' exercise prices.

Other income (expense), net

Other income (expense), net, was an income of $12 thousand compared to an expense of $68 thousand for the years ended December 31, 2017 and December 31, 2016, respectively. The decrease in expense was a result of the elimination of the interest due on the notes the Company entered into in December 2015 and January 2016 as part of our Bridge Loan, which was 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 (Related Party Notes Payable) included in Part II, Item 8 of this report.

Comparison of Years Ended* December 31, 2016 *and 2015

	Year Ended December 31,		Dollar	Percent
	2016	2015	Change	Change
	(in thousands)			
Statement of Operations:				
Sales:				
Product revenue, net	$ 11,617	$ 4,146	$ 7,471	180 %
Other revenue	280	235	45	19 %
Total sales, net	11,897	4,381	7,516	172 %
Product cost of goods sold	2,464	1,261	1,203	95 %
Gross profit	9,433	3,120	6,313	202 %
Research and development	1,371	5,728	(4,357)	(76)%
Sales and marketing	11,809	10,523	1,286	12 %
General and administrative	7,235	8,006	(771)	(10)%
Total operating expenses	20,415	24,257	(3,842)	(16)%
Operating Loss	(10,982)	(21,137)	10,155	(48)%
Non-cash gain (loss) on changes in fair value of warrant liability	(2,099)	2,149	(4,248)	(198)%
Other income (expense), net	(68)	17	(85)	(500)%
Loss before provision for income taxes	(13,149)	(18,971)	5,822	(31)%
Provision for income tax	(2)	(2)	—	— %
Net loss	$ (13,151)	$ (18,973)	$ 5,822	(31)%

Total Net Sales, Product Cost of Goods Sold and Gross Profit

Product revenue, net, increased by $7.5 million, or 180%, to $11.6 million from $4.1 million and other revenue, net, increased by $45 thousand, or 19%, to $280 thousand from $235 thousand for the year ended December 31, 2016, compared to the year ended December 31, 2015. 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 increased primarily due to the recognition of deferred revenue upon the termination of a collaboration agreement.

Product cost of goods sold increased by $1.2 million, or 95%, to $2.5 million from $1.3 million for the year ended December 31, 2016, compared to the year ended December 31, 2015. The increase in product cost of goods sold was primarily the result of increased sales of Avenova, along with increased reserves for excess and obsolete inventory.

Gross Profit increased by $6.3 million, or 202%, to $9.4 million from $3.1 million for the year ended December 31, 2016, compared to the year ended December 31, 2015. The increase in gross profit was primarily the result of increased sales of Avenova, along with the recognition of deferred revenue upon the termination of a collaboration agreement.

Research and Development

Research and development expenses decreased by $4.3 million, or 76%, to $1.4 million for the year ended December 31, 2016, from $5.7 million for the year ended December 31, 2015. The reduction is primarily the result of our previously-announced change in business strategy, as reflected by our reduced spending on clinical trials and our shift of capital resources from research and development to the commercialization of Avenova. Also contributing to the decrease was a gain recognized on the sale of laboratory equipment of $232 thousand during the third quarter of 2016.

Sales and marketing

Sales and marketing expenses increased by $1.3 million, or 12%, to $11.8 million for the year ended December 31, 2016, from $10.5 million for the year ended December 31, 2015. The increase was primarily due to our previously-announced change in business strategy, as reflected by our increase in sales representative headcount and sales and marketing activities, partially offset by reduced expenses associated with our out-sourced sales team.

General and administrative

General and administrative expenses decreased by $0.8 million, or 10%, to $7.2 million for the year ended December 31, 2016, from $8.0 million for the year ended December 31, 2015. The decrease was primarily a result of our overall cost reduction efforts, including a reduction in staff-related expense and reductions in consulting and outside services, partially offset by the modification of the exercise price of the warrants issued in May 2015, higher stock-based compensation, and costs associated with the subleasing of our former headquarters.

Non-cash gain (loss) on changes in fair value of warrants

The adjustments to the fair value of warrants was a loss of $2.1 million and a gain of $2.1 million for the years ended December 31, 2016 and December 31, 2015, respectively.

For additional information regarding the warrants and their valuation, please see Note 10 in the Notes to Consolidated Financial Statements (Warrant Liability) included in Part II, Item 8 of this report. In the year ended December 31, 2016, non-cash loss on changes in fair value of warrants was caused by a reduction in the exercise price of the warrants pursuant to the price protection provision in such warrants, along with an increase in the price of the Company's common stock above the warrants' exercise prices. During the year ended December 31, 2015, we incurred a non-cash gain resulting from the re-valuation of the pre-modified July 2011 warrants to zero.

Other income (expense), net

Other income (expense), net, was an expense of $68 thousand compared to income of $17 thousand for the years ended December 31, 2016 and December 31, 2015, respectively. The increase in 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 was 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 (Related Party Notes Payable) included in Part II, Item 8 of this report.

Liquidity and Capital Resources

As of December 31, 2017, our cash and cash equivalents were $3.2 million, compared to $9.5 million as of December 31, 2016. The Company has sustained operating losses for most of its corporate history and expects to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. We believe that based on our current business plan and revenue prospects and our anticipated cash flows, our existing cash balances will be sufficient to meet our working capital and operating resource expenditure requirements for at least the next twelve months.

Cash Used in Operating Activities

For the year ended December 31, 2017, cash used in operating activities was $6.3 million compared to $12.1 million for the year ended December 31, 2016. The change was primarily due to the decrease of net loss by $5.8 million, increase in stock-based compensation by $0.5 million and stock option modification expense by $0.5 million and favorable changes in working capital of $1.6 million offset by the decrease in the gain on change of the warrant liability fair value by $2.0 million, the decrease of warrant modification expense by $0.3 million and the decrease of other adjustments for non-cash items by $0.3 million.

For the year ended December 31, 2016, cash used in operating activities was $12.1 million compared to $18.6 million for the year ended December 31, 2015. The decrease was primarily due to increased sales of Avenova and a decrease in operating expenses, partially offset by an increase in cost of sales.

Cash Used in Investing Activities

For the years ended December 31, 2017, 2016 and 2015, cash used in investing activities was for the purchase of property and equipment of $0.2 million, $0.2 million and $0.1 million, respectively.

Cash Provided by Financing Activities

Net cash provided by financing activities of $0.2 million for the year ended December 31, 2017 was primarily attributable to the proceeds from the exercise of options and Warrants.

Net cash provided by financing activities of $19.4 million for the year ended December 31, 2016 was primarily attributable to the net sale of $13.6 million of our common stock in our financings in February, May and August 2016, and Warrants exercised in a net amount of $7.4 million in August, September, October, and November 2016, and the borrowing of $1.4 million in connection with the final tranche of the Bridge Loan, fully offset by the full repayment of $3.0 million of our Bridge Loan.

Net cash provided by financing activities of $15.6 million for the year ended December 31, 2015, was primarily attributable to proceeds from the sale of common stock and Warrants in March, May and October, the sale of our common stock under our ATM agreement and the proceeds from the Bridge Loan.

Quarterly Results of Operations (unaudited)

The following table presents unaudited quarterly results of operations for the eight most recent quarters ending with the quarter ended December 31, 2017. This information has been derived from our unaudited consolidated financial statements and has been prepared by us on a basis consistent with our audited annual consolidated financial statements and includes all adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the information for the periods presented.

	Quarter Ended							
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017	December 31, 2016	September 30, 2016	June 30, 2016	March 31, 2016
	(in thousands, except per share data)							
Statements of Operations Data:								
Sales:								
Product Revenue, net	$ 6,259	$ 4,080	$ 4,094	$ 3,694	$ 4,046	$ 3,262	$ 2,654	$ 1,655
Other Revenue, net	57	11	28	7	31	176	9	64
Total Sales, net	6,316	4,091	4,122	3,701	4,077	3,438	2,663	1,719
Product Cost of Goods Sold	977	521	698	588	808	566	479	611
Gross Profit	5,339	3,570	3,424	3,113	3,269	2,872	2,184	1,108
Operating expenses:								
Research and development	146	132	70	62	156	4	278	933
Sales and marketing	3,299	3,296	3,376	3,740	3,149	2,663	2,853	3,144
General and administrative	1,502	2,311	1,735	3,088	1,994	2,266	1,293	1,682
Total operating expenses	4,947	5,739	5,181	6,890	5,299	4,933	4,424	5,759
Operating income (loss)	392	(2,169)	(1,757)	(3,777)	(2,030)	(2,061)	(2,240)	(4,651)
Non-cash gain (loss) on change in fair value of warrant liability	400	(281)	15	(235)	381	(1,671)	(424)	(385)
Other income (expense), net	3	3	4	2	1	(4)	(24)	(41)
Income (Loss) before provision for income taxes	795	(2,447)	(1,738)	(4,010)	(1,648)	(3,736)	(2,688)	(5,077)
Provision for income tax	(2)	—	—	(1)	—	—	(2)	—
Net income (loss)	$ 793	$ (2,447)	$ (1,738)	$ (4,011)	$ (1,648)	$ (3,736)	$ (2,690)	$ (5,077)
Net income (loss) per share:								
Basic	$ 0.05	$ (0.16)	$ (0.11)	$ (0.26)	$ (0.11)	$ (0.34)	$ (0.36)	$ (1.24)
Diluted	$ 0.02	$ (0.16)	$ (0.11)	$ (0.26)	$ (0.13)	$ (0.34)	$ (0.36)	$ (1.24)
Shares used in computing net income (loss) per share:								
Basic (after effect of 1-for-25 reverse stock split)	15,376	15,324	15,308	15,284	15,148	10,913	7,407	4,086
Diluted (after effect of 1-for-25 reverse stock split)	16,018	15,324	15,308	15,284	15,459	10,913	7,407	4,086

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2017, we had net operating loss carryforwards for federal and state income tax purposes of $94.8 million and $78.5 million, respectively. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2024 and 2037. As of December 31, 2017, we also had tax credit carryforwards for federal income tax purposes of $1,316,000 and $282,000 for state tax purposes. If not utilized, the federal tax credits will begin expiring in 2026. The state tax credits have an indefinite carryover period.

Current federal and California tax laws include substantial restrictions on the utilization of net operating loss carryforwards in the event of an ownership change of a corporation. Accordingly, our ability to utilize net operating loss carryforwards may be limited as a result of such ownership changes. Such a limitation could result in the expiration of carryforwards before they are utilized.

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 did not have any off-balance sheet arrangements at December 31, 2017 and December 31, 2016 as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

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 December 31, 2017, were as follows (in thousands):

Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Facility leases	$ 3,737	$ 1,083	$ 2,141	$ 513	$ —
Vehicle leases	340	163	177	—	—
	$ 4,077	$ 1,246	$ 2,318	$ 513	$ —

Our commitments as of December 31, 2017 consist of two operating facility leases, the Lease and the lease for EmeryStation, and 54 operating vehicle leases.

The total commitment for the Lease as of December 31, 2017 was $1.8 million due over the lease term, compared to $2.1 million as of December 31, 2016.

The total commitment of the EmeryStation lease as of December 31, 2017 was $2.0 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 at EmeryStation. Sublease rental reimbursement is not deducted from the above table. We anticipate collecting $610 thousand, $690 thousand, and $575 thousand, in the years ending December 31, 2018, 2019, and 2020, respectively, under the Sublease for the lease of EmeryStation.

Additionally, we have operating leases for a fleet of 54 vehicles, which commenced upon the delivery of the vehicles during the first quarter of 2017. The total commitment for these leases as of December 31, 2017 was $340 thousand due over the lease terms, compared to zero as of December 31, 2016.

See Note 9 in the Notes to Consolidated Financial Statements (Commitments and Contingencies) in Part II, Item 8 of this report for further information regarding these leases.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risk consists principally of interest rate risk on our cash, cash equivalents, and short-term investments. Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in interest rates, particularly because our current liquid assets at December 31, 2017 are held in cash and cash equivalents.

Our investment policy restricts our investments to high-quality investments and limits the amounts invested with any one issuer, industry, or geographic area. The goals of our investment policy are as follows: preservation of capital, assurance of liquidity needs, best available return on invested capital, and minimization of capital taxation. Some of the securities in which we invest may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with an interest rate fixed at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. To minimize this risk, in accordance with our investment policy, we maintain our cash and cash equivalents in short-term marketable securities, including money market mutual funds, Treasury bills, Treasury notes, certificates of deposit, commercial paper, and corporate and municipal bonds. The risk associated with fluctuating interest rates is limited to our investment portfolio. Due to the short-term nature of our investment portfolio, we believe we have minimal interest rate risk arising from our investments. As of December 31, 2017 and 2016, a 10% change in interest rates would have had an immaterial effect on the value of our investment portfolio. We do not use derivative financial instruments in our investment portfolio. We do not hold any instruments for trading purposes.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item 8 are set forth below. Our quarterly financial information is set forth in Item 7 of this report and is hereby incorporated into this Item 8 by reference.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
NovaBay Pharmaceuticals, Inc.
Emeryville, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of NovaBay Pharmaceuticals, Inc. (the "Company") as of December 31, 2017 and 2016 and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ OUM & CO. LLP

San Francisco, California
March 21, 2018
We have served as the Company's auditor since 2010.

NOVABAY PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands except par value amounts)

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,199	$ 9,512
Accounts receivable, net of allowance for doubtful accounts ($13 and $10 at December 31, 2017 and December 31, 2016, respectively)	3,629	2,120
Inventory, net of allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $140 and $196 at December 31, 2017 and December 31, 2016, respectively)	504	873
Prepaid expenses and other current assets	1,663	1,966
Total current assets	8,995	14,471
Property and equipment, net	471	371
Other assets	613	539
TOTAL ASSETS	$ 10,079	$ 15,381
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$ 466	$ 455
Accrued liabilities	1,672	2,007
Deferred revenue	2,841	1,861
Total current liabilities	4,979	4,323
Deferred revenues - non-current	534	1,986
Deferred rent	268	327
Warrant liability	1,489	1,446
Other liabilities	215	198
Total liabilities	7,485	8,280
Commitments and Contingencies (Note 9)		
Stockholders' equity :		
Preferred stock: 5,000 shares authorized; none outstanding at December 31, 2017 and December 31, 2016	—	—
Common stock, $0.01 par value; 240,000, shares authorized; 15,385 and 15,269 shares issued and outstanding at December 31, 2017 and December 31, 2016 , respectively	154	153
Additional paid-in capital	113,514	110,619
Accumulated deficit	(111,074)	(103,671)
Total stockholders' equity	2,594	7,101
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 10,079	$ 15,381

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

NOVABAY PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands except per share data)

	Year Ended December 31,		
	2017	**2016**	**2015**
Sales:			
Product revenue, net	$ 18,127	$ 11,617	$ 4,146
Other revenue	103	280	235
Total sales, net	18,230	11,897	4,381
Product cost of goods sold	2,784	2,464	1,261
Gross profit	15,446	9,433	3,120
Research and development	410	1,371	5,728
Sales and marketing	13,711	11,809	10,523
General and administrative	8,636	7,235	8,006
Total operating expenses	22,757	20,415	24,257
Operating Loss	(7,311)	(10,982)	(21,137)
Non cash gain (loss) on changes in fair value of warrant liability	(101)	(2,099)	2,149
Other income (expense), net	12	(68)	17
Loss before provision for income taxes	(7,400)	(13,149)	(18,971)
Provision for income tax	(3)	(2)	(2)
Net loss and comprehensive loss	$ (7,403)	$ (13,151)	$ (18,973)
Net loss per share attributable to common stockholders (basic and diluted)	$ (0.48)	$ (1.40)	$ (6.82)
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock	15,324	9,408	2,784

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

NOVABAY PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balance at December 31, 2014	2,066	21	73,374	—	(71,547)	1,848
Net loss	—	—	—	—	(18,973)	(18,973)
Issuance of common stock in connection with shelf offering, net of offering costs	85	1	1,176	—	—	1,177
Issuance of stock and warrants, net of offering costs	1,328	13	11,505	—	—	11,518
Equity transferred to warrant liability	—	—	(2,175)	—	—	(2,175)
Issuance of stock to consultants for services	4	—	63	—	—	63
Employee bonus paid in common stock	3	—	62	—	—	62
Stock-based compensation expense related to employee and director stock options	—	—	1,194	—	—	1,194
Stock-based compensation expense related to non-employee stock options	—	—	188	—	—	188
Balance at December 31, 2015	3,486	35	85,387	—	(90,520)	(5,098)
Net loss	—	—	—	—	(13,151)	(13,151)
Issuance of stock and warrants, net of offering costs	7,692	77	13,571	—	—	13,648
Issuance of common stock in connection with exercise of warrants, net of offering costs	3,977	40	7,389	—	—	7,429
Fair market value of warrants transferred to equity upon exercise	—	—	2,103	—	—	2,103
Warrant modification	—	—	270	—	—	270
Issuance of stock to consultants for services	2	—	8	—	—	8
Vesting of employee restricted stock awards	73	1	173	—	—	174
Vesting of non-employee restricted stock awards	41	—	133	—	—	133
Shares retired as a result of reverse stock split	(2)	—	—	—	—	—
Stock-based compensation expense related to employee and director stock options	—	—	1,316	—	—	1,316
Stock-based compensation expense related to non-employee stock options	—	—	269	—	—	269
Balance at December 31, 2016	15,269	$ 153	$ 110,619	$ —	$ (103,671)	$ 7,101
Net loss	—	—	—	—	(7,403)	(7,403)
Issuance of common stock in connection with exercise of warrants, net of offering costs	21	—	97	—	—	97
Issuance of stock for option exercises	68	1	184	—	—	185
Issuance of stock to consultants for services	1	—	—	—	—	—
Vesting of non-employee restricted stock awards	26	—	106	—	—	106
Stock-based compensation expense related to employee and director stock options	—	—	1,867	—	—	1,867
Stock-based compensation expense related to non-employee stock options	—	—	137	—	—	137
Stock option modification	—	—	504	—	—	504
Balance at December 31, 2017	15,385	$ 154	$ 113,514	$ -	$ (111,074)	$ 2,594

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

NOVABAY PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2017	**2016**	**2015**
Operating activities:			
Net loss	$ (7,403)	$ (13,151)	$ (18,973)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	95	114	164
Loss (gain) on disposal of property and equipment	-	(219)	(1)
Stock-based compensation expense for options and stock issued to employees and directors	1,867	1,316	1,194
Stock-based compensation expense for options and stock issued to non-employees	137	129	188
Issuance of RSUs to employees	-	173	-
Issuance of RSUs to non-employees	34	133	-
Warrant modification	-	270	-
Stock option modification expense	504	-	-
Note receivable impairment	-	91	-
Property and equipment impairment	-	70	-
Non-cash loss (gain) on change in fair value of warrant liability	101	2,099	(2,149)
Changes in operating assets and liabilities:			
(Increase) Accounts receivable	(1,509)	(1,585)	(299)
Decrease (Increase) Inventory	369	472	(751)
Decrease (Increase) Prepaid expenses and other assets	313	(1,470)	402
(Increase) Other assets long-term	(73)	(474)	-
(Decrease) Increase Accounts payable and accrued liabilities	(260)	(2,356)	1,643
Increase Deferred rent	27	327	17
(Decrease) Increase Deferred revenue	(472)	1,641	6
Increase Deferred taxes	-	87	-
Increase Long-term obligations	-	198	-
Net cash used in operating activities	(6,270)	(12,135)	(18,559)
Investing activities:			
Purchases of property and equipment	(244)	(160)	(123)
Proceeds from disposal of property and equipment	-	-	37
Net cash used in investing activities	(244)	(160)	(86)
Financing activities:			
Proceeds from common stock issuances, net	-	13,648	11,519
Proceeds from exercise of warrants, net	38	7,429	1,250
Proceeds from exercise of options , net	185	-	-
Proceeds from stock options & RSUs sold to cover taxes	26	-	-
Settlement of restricted stock for tax withholding	(48)	-	-
Proceeds from borrowings	-	1,365	1,655
Repayment of borrowings	-	(3,020)	-
Proceeds from shelf offering, net	-	-	1,177
Net cash provided by financing activities	201	19,422	15,601
Net increase (decrease) in cash and cash equivalents	(6,313)	7,127	(3,044)
Cash and cash equivalents, beginning of period	9,512	2,385	5,429
Cash and cash equivalents, end of period	$ 3,199	$ 9,512	$ 2,385

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

NOVABAY PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS, continued
(in thousands)

	Year Ended December 31,		
	2017	**2016**	**2015**
Supplemental disclosure of non cash information			
Stock issued to consultants for services, included in accounts payable and accrued liabilities	$ 1	$ 8	$ 63
Fixed asset purchases, included in accounts payable and accrued liabilities	$ (49)	$ 60	$ -
Interest paid	$ -	$ 51	$ -
Bonus paid in stock	$ -	$ -	$ 62
Options exercised	$ -	$ -	$ (4)
Equity transferred to warrant liability	$ 58	$ 2,103	$ (2,175)
Exchange of equipment for services	$ -	$ 279	$ -
Severance paid in RSU to non-employee	$ 69	$ 140	$ -
Proceeds from stock options and restricted stock sold to cover taxes, in accounts payable and accrued liabilities	$ (26)	$ -	$ -

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

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. is a biopharmaceutical company focusing on commercializing and developing its non-antibiotic anti-infective products to address the unmet therapeutic needs of the global, topical anti-infective market with its two distinct product categories: the NEUTROX® family of products and the AGANOCIDE® compounds. The Neutrox family of products includes AVENOVA® for the eye care market, NEUTROPHASE® for wound care market, and CELLERX® for the aesthetic dermatology market. The Aganocide compounds, still under development, have target applications in the dermatology and urology markets.

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 June 2010, the Company changed the state in which it is incorporated (the "Reincorporation") and is now incorporated under the laws of the State of Delaware. All references to "the Company" herein refer to the California corporation prior to the date of the Reincorporation and to the Delaware corporation on and after the date of the Reincorporation. In April 2016, the Company dissolved DermaBay, a wholly-owned U.S. subsidiary that was formed to explore dermatological opportunities. Historically, the Company operated as four business segments. At the direction of its Board of Directors, the Company is now focused primarily on commercializing prescription Avenova for managing hygiene of the eyelids and lashes in the United States and is managed as a single segment.

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.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and are expressed in U.S. dollars.

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. Prior period amounts in the accompanying consolidated statements of operations and comprehensive loss have also been reclassified to conform to current period presentation. The reclassifications did not change the net loss or loss per share.

Additionally, prior period amounts in the accompanying consolidated statements of cash flow have also been reclassified to conform to current period presentation. The reclassifications did not change net cash used in operating activities, net cash used in investing activities, or net cash provided by financing activities.

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.

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 December 31, 2017, and December 31, 2016, the Company's cash and cash equivalents were held in two highly-rated, major financial institutions in the United States.

Concentrations of Credit Risk, Major Partners and Customers, and Suppliers

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 two 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 years ended December 31, 2017, 2016 and 2015 revenues were derived primarily from sales of Avenova directly to three major distribution partners and to doctors through the Company's webstore.

As of December 31, 2017, December 31, 2016 and December 31, 2015 revenues from our major distribution or collaboration partners greater than 10% are as follows:

	Year Ended December 31,		
Major distribution or collaboration partner	**2017**	**2016**	**2015**
Distributer A	22%	20%	*
Distributer B	23%	22%	*
Distributer C	21%	16%	*
Collaborator D	10%	*	*

***Not greater than 10%**

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

	Year Ended December 31,	
Major distribution or collaboration partner	**2017**	**2016**
Distributer A	25%	22%
Distributer B	18%	24%
Distributer C	23%	31%
Collaborator D	23%	*

***Not greater than 10%**

The Company relies on two third party 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 U.S. GAAP guidance, which defines fair value, establishes a framework for measuring fair value, and requires disclosures about fair value measurements.

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

Level 1 – quoted prices in active markets for identical assets or liabilities;
Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable;
Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions).

Allowance for Doubtful Accounts

The Company charges bad debt expense and records an allowance for doubtful accounts when management believes it unlikely a specific invoice will be collected. Management identifies amounts due that are in dispute, and it believes are unlikely to be collected at the end of fiscal 2017. At December 31, 2017 and December 31, 2016, management had reserved $13 thousand and $10 thousand, respectively, primarily based on specific amounts that are in dispute or were over 120 days past due.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. At December 31, 2017 and 2016, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $140 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.

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 amortized 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.

In September 2016, the Company sub-leased its former headquarters and determined that its leasehold improvements were impaired. This resulted in a $66 thousand impairment charge recorded to general and administrative expense for the third quarter of 2016, and is reflected in the results for the year ended December 31, 2016.

Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with U.S. GAAP, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets. During the 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 for the first quarter of fiscal year 2016 and is reflected in the results for the year ended December 31, 2016. There were no impairment charges during the year ended December 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)

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 our revenue recognition and on the Company's results of operations.

We adopted the new revenue recognition standard effective January 1, 2018 under the modified retrospective transition method. While the Company is still in the process of assessing the impact of this new standard on its consolidated financial statements, the evaluation of its license and collaboration arrangements is complete, and is the Company is now working on finalizing its assessment of the quantitative impact from the adoption of the new standard on its consolidated financial statements including the new presentation and disclosure requirements. For license and collaboration revenue for which contract deliverables are currently accounted for as a combined unit of accounting because products or services are not separable, the Company has identified that under the new guidance the separate performance obligations are capable of being distinct. As a result, the transaction price under these arrangements, including upfront fees and milestone payments, will be allocated differently to each performance obligation and may be recognized at earlier points in time or with a different pattern of performance over time.

The Company identified the following performance obligations during its review of the license and collaboration agreements:

- Exclusive distribution rights in the product territory
- Regulatory submission and approval services
- Development services
- Sample supply, free of charge
- Incremental discounts and product supply prepayments representing a material right to the customer

The Company has found that based upon the relative estimated selling prices of each performance obligation, the licenses typically make up approximately 90% to 95% of the total transaction price allocation for each contract. Because the licenses have been classified under the new guidance as a "right to use" the intellectual property, for which the customers right to use the intellectual property is transferred at a point in time, under the new rules the revenue for each license will be recognized at contract inception when the licenses are granted. Based on these findings, the Company currently estimates that approximately 96% or $2.0 million of the current deferred revenue balance related to its license and collaboration arrangements will be allocated to performance obligations that were satisfied in periods prior to adoption and included in the cumulative adjustment to retained earnings upon adoption.

As the Company finalizes its evaluation of the new standard, new information may arise that could change the Company's understanding of the impact on its 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.

Product Revenue Allowances

Product revenue is recognized, net of cash consideration paid to the Company's customers and wholesalers, for services rendered by wholesalers in accordance with such wholesalers' agreements and includes 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 the Company's customers, program rebates and chargebacks. These product revenue allowances are recognized as a reduction of revenue 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, 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. Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured. If these factors were to vary the resulting change could have a material effect on our revenue recognition and on our 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, or lack 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 Updates ("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 Liabilities

For warrants that are newly issued or modified and there is a deemed possibility that the Company may have to settle them in cash, or for warrants it issues or modifies that contain an exercise price adjustment feature, 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 in the consolidated statements of operations and comprehensive loss. The fair values of these warrants have been determined using the Binomial Lattice ("Lattice") valuation model. 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.

Net Income (Loss) per Share

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

Basic EPS is computed by dividing net income (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. In computing, diluted EPS, the average stock price for the period is used to determine 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 because their effect would be anti-dilutive.

During years ended December 31, 2017, 2016 and 2015, there is no difference between basic and diluted net loss per share. The following table sets forth the reconciliation between basic EPS and diluted EPS, after giving effect to the reverse stock split.

(in thousands, except per share data)	Year Ended December 31, 2017	2016	2015
Net loss	$ (7,403)	$ (13,151)	$ (18,973)
Basic shares	15,324	9,408	2,784
Add: shares issued upon assumed exercise of stock options and warrants	—	—	—
Diluted shares	15,324	9,408	2,784
Basic EPS	$ (0.48)	$ (1.40)	$ (6.82)
Diluted EPS	$ (0.48)	$ (1.40)	$ (6.82)

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

(in thousands)	Year Ended December 31, 2017	2016	2015
Stock options	2,960	1,489	388
Stock warrants	544	565	1,458

Liquidity

As of December 31, 2017, our cash and cash equivalents were $3.2 million, compared to $9.5 million as of December 31, 2016. The Company has sustained operating losses for most of its corporate history and expects to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations.

On February 5, 2018, we entered into a share purchase agreement with OP Financial Investments Limited for the sale of an aggregate of 1,700,000 shares of the Company's common stock, par value $0.01 per share, for an aggregate purchase price of $5,984,000. See Note 17, "Subsequent Events" for additional information regarding the OP Private Placement.

We believe that based on our current business plan and revenue prospects and our anticipated cash flows, our existing cash balances will be sufficient to meet our working capital and operating resource expenditure requirements for at least the next twelve months from the date of this filing.

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, allocating the transaction price to each performance obligation, the level of effort required to satisfy performance obligations, and the period over which we expect to complete our performance obligations under the arrangement. As a result, the timing of recognition of revenue has more variability under the new revenue standard due to significant estimates involved in the new accounting. 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.

The Company has identified that transactions under its major distribution agreements, which under current guidance are recognized upon shipment from its distributors to the final customers, 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. Based on these findings, the Company expects the entire deferred revenue and deferred cost of goods sold balances related to its distribution agreements to be allocated to either contract liabilities associated with invoicing in periods prior to adoption or included in the cumulative adjustment to retained earnings upon adoption.

The Company has identified that milestone payments, which under the current milestone recognition methodology, are not recognized until they are substantively achieved, will be included in the estimated transaction price when they are considered probable of being achieved. This may result in earlier recognition of revenue for the portion of milestone payments deemed probable which are allocated to performance obligations that are satisfied before the milestones are achieved.

The Company's license and collaboration arrangements include sales-based royalties, including milestone payments based on the level of sales. Under the new guidance, since the licenses are deemed to be the predominant item to which the royalties relate, the sales-based royalties will be recognized at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied), which may be slightly earlier than under the old guidance.

While the Company is still in the process of assessing the impact of this new standard on its consolidated financial statements, the evaluation of its license and collaboration arrangements is complete, and is the Company is now working on finalizing its assessment of the quantitative impact from the adoption of the new standard on its consolidated financial statements including the new presentation and disclosure requirements. For license and collaboration revenue for which contract deliverables are currently accounted for as a combined unit of accounting because products or services are not separable, the Company has identified that under the new guidance the separate performance obligations are capable of being distinct. As a result, the transaction price under these arrangements, including upfront fees and milestone payments, will be allocated differently to each performance obligation and may be recognized at earlier points in time or with a different pattern of performance over time.

The Company identified the following performance obligations during its review of the license and collaboration agreements:

- Exclusive distribution rights in the product territory
- Regulatory submission and approval services
- Development services
- Sample supply, free of charge
- Incremental discounts and product supply prepayments representing a material right to the customer

The Company has found that based upon the relative estimated selling prices of each performance obligation, the licenses typically make up approximately 90% to 95% of the total transaction price allocation for each contract. Because the licenses have been classified under the new guidance as a "right to use" the intellectual property, for which the customers right to use the intellectual property is transferred at a point in time, under the new rules the revenue for each license will be recognized at contract inception when the licenses are granted. Based on these findings, the Company currently estimates that approximately 96% or $2.0 million of the current deferred revenue balance related to its license and collaboration arrangements will be allocated to performance obligations that were satisfied in periods prior to adoption and included in the cumulative adjustment to retained earnings upon adoption.

As the Company finalizes its evaluation of the new standard, new information may arise that could change the Company's understanding of the impact on its 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.

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 was effective for the Company in the first quarter of fiscal year 2017. 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 was effective beginning in the first quarter of fiscal year 2017. Upon adoption, the Company recognized an increase of approximately $1.1 million of net tax operating losses, which had an impact of $0.4 million on our deferred tax assets before our full valuation allowance established against the related deferred tax assets, which did not result in a net impact to retained earnings.

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.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic* 260*), Distinguishing Liabilities from Equity (Topic* 480*), Derivatives and Hedging (Topic* 815*): I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II simply replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within Accounting Standards Codification (ASC) Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. This ASU is effective for public companies for the annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the effects of the adoption of ASU 2017-11 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 that 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 cash equivalents and investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities and certificates of deposit. The types of investments that are generally classified within Level 2 of the fair value hierarchy include corporate securities and U.S. government securities.

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 our 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 December 31, 2017:

		Fair Value Measurements Using		
(in thousands)	**Balance at December 31, 2017**	**Quoted Prices in Active Markets for Identical Items (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Assets				
Cash equivalents	$ 101	$ 101	$ —	$ —
Restricted cash held as a certificate of deposit	324	324	—	—
Deposit held as a certificate of deposit	150	150	—	—
Total assets	$ 575	$ 575	$ —	$ —
Liabilities				
Warrant liability	$ 1,489	$ —	$ —	$ 1,489
Total liabilities	$ 1,489	$ —	$ —	$ 1,489

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

		Fair Value Measurements Using		
(in thousands)	**Balance at December 31, 2016**	**Quoted Prices in Active Markets for Identical Items (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Assets				
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	$ —	$ —
Liabilities				
Warrant liability	$ 1,446	$ —	$ —	$ 1,446
Total liabilities	$ 1,446	$ —	$ —	$ 1,446

For the year ended December 31, 2017, as a result of the fair value adjustment of the warrant liability, the Company recorded a non-cash loss on a change in the fair value of $0.1 million in its consolidated statements of operations and comprehensive loss. See Note 10 for further discussion on the calculation of the fair value of the warrant liability.

(in thousands)	**2017**	**2016**
Fair value of warrant liability at January 1	$ 1,446	$ 1,450
Fair value of warrants issued	—	—
Fair value of warrants transferred (to) from equity upon exercise	(58)	(2,103)
Increase in fair value on exercise date and December 31	101	2,099
Fair value of warrant liability at December 31	$ 1,489	$ 1,446

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

(in thousands)	December 31, 2017	December 31, 2016
Prepaid sales rebates	$ 923	$ 658
Prepaid outsourced sales team	—	606
Rent receivable	86	165
Prepaid research and development services	11	123
Prepaid rent	123	120
Prepaid employees' benefits	112	—
Prepaid fleet leasing costs	61	—
Other	347	294
Total prepaid expenses and other current assets	$ 1,663	$ 1,966

NOTE 5. INVENTORY

Inventory consisted of the following:

(in thousands)	December 31, 2017	December 31, 2016
Raw materials and supplies	$ 298	$ 514
Goods in process	—	—
Finished goods	346	555
Less: Reserve for excess and obsolete inventory	(140)	(196)
Total inventory, net	$ 504	$ 873

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

(in thousands)	December 31, 2017	December 31, 2016
Office and laboratory equipment	$ 24	$ 24
Furniture and fixtures	157	153
Computer equipment and software	354	170
Production equipment	105	105
Leasehold improvements	74	68
Total property and equipment, at cost	714	520
Less: accumulated depreciation and amortization	(243)	(149)
Total property and equipment, net	$ 471	$ 371

Depreciation and amortization expense was $95 thousand, $114 thousand and $164 thousand for the years ended December 31, 2017, 2016 and 2015, respectively.

In the quarter ended September 30, 2016, the Company sub-leased its prior headquarters and determined that its leasehold improvements were impaired. This resulted in a $66 thousand impairment charge recorded to general and administrative expense in the consolidated statement of operation and comprehensive loss for the year ended December 31, 2016.

In the quarter ended September 30, 2016, the Company transferred title to a significant portion of its lab equipment in exchange for research and development services. As a result, the Company recognized a $232 thousand gain on the sales of these assets, which was recorded to research and development expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2016.

In the quarter ended December 31, 2016, the Company disposed of damaged, unusable and fully depreciated property and equipment. As a result, the Company recognized a $13 thousand loss on the disposal of these assets, and a $4 thousand impairment charge, which were recorded to general and administrative expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2016.

NOTE 7. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(in thousands)	December 31, 2017	December 31, 2016
Employee payroll and benefits	$ 761	$ 763
Severance/retirement pay	347	250
Distributer fees and discounts	185	206
Sales rebates	106	166
Outsourced sales team	-	333
Inventory	-	75
Deferred Rent	59	-
Other	214	214
Total accrued liabilities	$ 1,672	$ 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. 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 at the time, loaned the Company $20 thousand; Pioneer Singapore loaned the Company $1.4 million; and Mr. Fu loaned the Company $1.4 million. Pioneer Hong Kong (who now holds all of the holdings of Pioneer Singapore due to an 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 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 December 31, 2017 and December 31, 2016, outstanding amounts under these Notes was zero.

NOTE 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

On August 24, 2016, the Company entered into an Office Lease (the "Lease"), pursuant to which the Company leased approximately 7,799 rentable square feet of real property located on the eleventh floor (Suite 1150) at 2000 Powell Street, Emeryville, California 94608 (the "Premises") from KBSIII Towers at Emeryville, LLC (the "Landlord"), for the Company's 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 also has the option to extend the term of the Lease for one five (5)-year period upon written notice to the Landlord which is no earlier than twelve (12) months and no later than nine (9) months prior to the expiration of the then current term. The effective monthly base rental rate for the first twelve (12) months of the Lease is $4.15 per square foot ($338,390 annually), and increases approximately three percent (3%) every eleven (11) months thereafter beginning with the thirteenth (13^{th}) month of the Lease, with a maximum monthly rental rate of $4.81 per square foot ($450,250 annually) for months sixty-one (61) to sixty-three (63) of the Lease. The Company will also be responsible for its share of the direct expenses of the Premises, or 2.16%, which includes certain additional operating expenses, utilities costs and tax expenses. The Landlord has agreed to abate all of the Company's monthly base rental payments for the first three (3) full calendar months of the Lease. The Company was also required to provide a standby letter of credit (the "Letter of Credit") as security for performance of its obligations and for all losses and damages the Landlord may suffer as a result of any default by the Company under the Lease in the initial amount of $323,658, which is secured by a certificate of deposit and is recorded in other assets. Provided that no default occurs under the terms of the Lease, and certain financial requirements are met, the Company will be entitled to periodically reduce the amount of the Letter of Credit down to a maximum of approximately $151,823 as of the last day of the sixtieth (60^{th}) full calendar month of the Lease.

The Company also leases 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") that the Company currently leases at EmeryStation. The commencement date under the Sublease Agreement was September 8, 2016. The expiration date of the Sublease Agreement is October 21, 2020, the expiration date of the Company's lease for the EmeryStation Premises, unless earlier terminated pursuant to any provision of the Company's lease for EmeryStation, as amended, or the Sublease Agreement. As a result of the sublease, the Company recorded a non-cash loss of $40 thousand, and an impairment to leasehold improvements of $66 thousand, which were recorded to general and administrative expense.

Rent expense, net was $389 thousand, $938 thousand and $1,008 thousand for the years ended December 31, 2017, 2016 and 2015, respectively. The future minimum lease payments under these non-cancellable operating leases were as follows as of December 31, 2017:

(in thousands)	Lease Commitment
Year ending December 31:	
2018	$ 1,083
2019	1,116
2020	1,025
2021	438
2022	75
Thereafter	-
Total lease commitment	$ 3,737

The Company's monthly rent payments fluctuate under the master lease agreements. In accordance with U.S. GAAP, the Company recognizes rent expense on a straight-line basis, and records deferred rent for the difference between the amounts paid and recorded as expense. At December 31, 2017 and 2016, the Company had $355 thousand and $327 thousand of deferred rent, respectively.

Sub-lease rental reimbursement is not deducted from the above table. The Company anticipates collecting $610 thousand, $690 thousand, and $575 thousand in the years ending December 31, 2018, 2019, and 2020, respectively.

Vehicle Fleet Leases

During the year ended December 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 December 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 $3 thousand per vehicle, which it is amortizing over the 36-month lease period.

Lease expense, net, for the vehicle fleet was approximately $94 thousand and zero for the years ended December 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, 2017.

In the normal course of business, the Company provides indemnifications 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 December 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 parties agreed to settle the litigation conditioned upon approval by the Court. The court approved the settlement by final order dated December 18, 2017 and this matter is now considered resolved.

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").

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 Company evaluated the change in terms of the July 2011 Warrants and noted that the change in terms resulted in a revaluation at the time of the change. The warrants were re-issued and valued as of October 27, 2015 at $360,821 with the new terms, and a modification expense was recorded for the difference between the fair value of the warrants at their new terms after modification on October 27, 2015 and the fair value of the warrants at their original terms prior to modification

as of October 27, 2015. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss.

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

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

The 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.

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

	Year Ended December 31,	
Assumption	**2017**	**2016**
Expected price volatility	91.00%	102.00%
Expected term (in years)	2.18	3.18
Risk-free interest rate	1.91%	1.51%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$ 2.72	$ 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 and Long-Term Warrants after modification at October 27, 2015 were as follows:

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

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

	Period Ended	
Assumption	**December 31, 2017**	**December 31, 2016**
Expected price volatility	91.00%	102.00%
Expected term (in years)	2.18	3.18
Risk-free interest rate	1.91%	1.51%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$ 2.42	$ 2.47

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

	Period Ended	
Assumption	**December 31, 2017**	**December 31, 2016**
Expected price volatility	91.00%	102.00%
Expected term (in years)	2.18	3.18
Risk-free interest rate	1.91%	1.51%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$ 2.72	$ 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 initially value the October 2015 warrants at October 27, 2015 were as follows:

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

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

	Period Ended	
Assumption	**December 31, 2017**	**December 31, 2016**
Expected price volatility	90.00%	96.00%
Expected term (in years)	2.83	3.83
Risk-free interest rate	1.96%	1.66%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$ 2.86	$ 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 the July 2011, March 2015 and October 2015 warrants 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 statements of operations and comprehensive loss. The $1.6 million fair value was subsequently transferred to equity as of the date of their 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 statements of operations and comprehensive loss. The $0.5 million fair value was subsequently transferred to equity as of the date of their exercise.

During the second quarter of 2017, a total of 21,000 warrants to purchase 21,000 shares of common stock were exercised related to the March 2015 Short-Term and Long-Term warrants resulting in gross proceeds of $38 thousand. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $58 thousand, with any change in fair value recorded in the consolidated statements of operations and comprehensive loss. The $58 thousand fair value was subsequently transferred to equity as of the date of exercise.

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

Shares and dollars in thousands	Shares	Warrant Liability
July 2011 Warrants	49	$ 135
Long-Term Warrants	96	261
Short-Term Warrants	115	278
October 2015 Warrants	284	815
	544	$ 1,489

NOTE 11. STOCKHOLDERS' EQUITY (DEFICIT)

Amendments to Certificate of Incorporation – Reverse Stock Split

Effective December 11, 2015, the Company amended its Certificate of Incorporation to effect a 1-for-25 reverse split of its outstanding common stock which was approved by our stockholders on December 11, 2015. The accompanying financial statements and related notes give retroactive effect to this reverse stock split.

Preferred Stock

Under the Company's Amended and Restated Certificate of Incorporation, the Company is authorized to issue up to 5,000,000 shares of preferred stock in such series and with such rights and preferences as may be approved by the Board of Directors. As of December 31, 2017 and December 31, 2016, there were no shares of preferred stock outstanding.

Common Stock

On March 25, 2014, the Company closed a public offering for the sale of 224,000 units, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 6.25 shares of common stock (or a total of 56,000 shares), at a purchase price of $30.00 per unit. The warrants were immediately exercisable for $39.00 per share expired eighteen months from the date of issuance. All of the shares of common stock and warrants issued in the offering (and the shares of common stock issuable upon exercise of the warrants) were offered pursuant to a shelf registration statement filed with, and declared effective by, the Securities and Exchange Commission. The shares of common stock and the warrants were immediately separable and were issued separately, but were purchased together. The Company raised a total of $6.7 million from this offering, or approximately $6.0 million in net proceeds after deducting underwriting commissions of $470 thousand and other offering costs of $211 thousand.

On October 16, 2014, the Company entered into an At-The-Market Offering Agreement (the "2014 ATM Agreement") with Ascendiant under which it may offer and sell its common stock having aggregate sales proceeds of up to $10.0 million from time to time through Ascendiant as its sales agent. Sales of Company common stock through Ascendiant are made by means of ordinary brokers' transactions on the NYSE American or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by the Company and Ascendiant. Ascendiant uses commercially reasonable efforts to sell Company common stock from time to time, based upon instructions from it (including any price, time or size limits or other customary parameters or conditions it may impose). The Company pays Ascendiant a commission of 3.0% of the gross sales proceeds of any common stock sold through Ascendiant under the 2014 ATM Agreement. The Company also provided Ascendiant with customary indemnification rights. In connection with the 2014 ATM Agreement, the Company terminated its existing At-The-Market Offering Agreement with Ascendiant dated November 13, 2013. The Company is not obligated to make any sales of common stock under the 2014 ATM Agreement. The offering of shares of the Company's common stock pursuant to the 2014 ATM Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the 2014 ATM Agreement, or (ii) termination of the 2014 ATM Agreement in accordance with its terms.

Pursuant to the 2014 ATM Agreement, the Company sold 1.3 million shares for gross proceeds of $1.2 million, or approximately $1.1 million in net proceeds after deducting offering costs and commissions of $81 thousand.

On March 6, 2015, the Company closed a private placement offering of an aggregate of 370,993 immediately separable units, which included 370,933 shares of the Company's common stock, 278,200 Long-Term Warrants and 370,933 Short-Term Warrants (the "March Offering"). The per unit purchase price was $12.50 for outside investors and $15.00 for Company insiders, and the exercise prices for the 15-month warrants and 5-year warrants were $15.00 and $16.25 per share, respectively. Also on March 6, 2015, the Company entered into a registration rights agreement with the purchasers, pursuant to which the Company agreed to file as many registration statements with the Securities and Exchange Commission (the "SEC") as may be necessary to cover the resale of the shares of Company common stock issued in the offering, including those shares underlying the March 2015 Warrants, and to keep such registration statements effective for the terms defined therein. The Company raised a total of $4.7 million from this offering, or approximately $4.5 million in net proceeds after deducting offering costs of $200 thousand.

On May 22, 2015, the Company closed a private placement offering of an aggregate of 435,746 shares of the Company's common stock and 217,873 warrants with a 12-month term (the "May Offering"). The purchase price for a share of Company common stock and related warrants was $15.75, and the exercise price for the warrants was $19.50 per share. On May 18, 2015, the Company entered into a registration rights agreement with the purchasers, pursuant to which the Company agreed to use best efforts to file as many registration statements with the SEC as may be necessary to cover the resale of the shares of Company common stock issued in the offering, including those shares underlying the warrants, and to keep such registration statements effective for the terms defined therein. In connection with the May Offering, the Company agreed to enter into an additional definitive securities purchase agreement with the purchasers in the March Offering. In exchange for a waiver of certain pre-emptive rights granted to the purchasers in the March Offering, an additional 635,000 shares of Company common stock were issued to such purchasers (other than entities affiliated with the Company). The Company raised a total of $7.3 million from this offering, or approximately $6.4 million in net proceeds after deducting offering costs of $900 thousand. 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 non-US citizens. The amount of such commission was approximately $408 thousand and was included in the offering costs noted above.

On October 27, 2015, pursuant to an underwriting agreement with Roth Capital Partners, LLC, the Company closed a public offering of (i) 492,000 shares of the Company's common stock; and (ii) warrants to purchase up to 468,280 shares of the Company's common stock with an exercise price of $5.00 per share (the "October 2015 Warrants"). The shares of common stock and October 2015 Warrants were issued separately. Each October 2015 Warrant was exercisable immediately upon issuance and will expire 60 months from the date of issuance. The price to the public in this offering was $5.00 per share of common stock and related October 2015 Warrant. The Company raised a total of $2.3 million from this offering, or approximately $1.9 million in net proceeds after deducting underwriting discounts and offering costs of $400 thousand.

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 "April 2016 Financing"). 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 American, is $4.00 or greater for five sequential trading days. The April 2016 Financing 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 July 2011, 139,520 warrants were issued in connection with our July 2011 registered direct financing. These warrants were issued with an exercise price of $33.25 and were set to expire on July 5, 2016. In October 2015, the exercise expiration date was extended until March 6, 2020. Outstanding warrants were exercisable at December 31, 2016. See Note 10 for further details on these warrants.

In March 2015, the Company issued 278,200 Long-Term Warrants and 370,933 Short-Term Warrants. Outstanding March 2015 Warrants were exercisable at December 31, 2016. See Note 10 for further details on these warrants.

In May 2015, the Company issued 217,873 warrants with a 12-month term and an exercise price of $19.50 per share. The warrants became exercisable at any time on or after November 22, 2015, six months from the date of issuance, and continued to be exercisable for one year thereafter. These outstanding warrants were exercisable at December 31, 2015. See Note 10 for further details on these warrants.

In October 2015, the Company issued warrants to purchase up to 442,800 shares of the Company's common stock with an exercise price of $5.00 per share. Each warrant was exercisable immediately upon issuance and will expire 60 months from the date of issuance. A price protection provision was included in such 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. See Note 10 for further details on these 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 operations and comprehensive loss.

The following table summarizes information about the Company's warrants outstanding at December 31, 2017, 2016 and 2015, and activity during the three years then ended.

(in thousands)	Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2014	197	$ 35.23
Warrants granted	1,317	$ 7.40
Warrants expired	(56)	$ 39.00
Outstanding at December 31, 2015	1,458	$ 5.19
Warrants granted	3,087	$ 1.91
Warrants exercised	(3,977)	$ 1.95
Warrants expired	(3)	$ 78.13
Outstanding at December 31, 2016	565	$ 1.81
Warrants granted	-	$ -
Warrants exercised	(21)	$ 1.81
Warrants expired	-	$ -
Outstanding at December 31, 2017	544	$ 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 awards under the 2007 Plan.

For the years from 2009 to 2012, the number of shares of common stock authorized for awards 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 awards 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's shares authorized for awards increased 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 awards 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's shares authorized for awards. In January 2016, the Company added 139,449 shares to the 2007 Plan's shares authorized for awards, 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 authorized for awards thereunder by 1,124,826 shares. In January 2017, the Company added 610,774 shares to the 2007 Plan's shares authorized for awards, per the 2007 Plan's evergreen provision. As a result of the foregoing, the aggregate number of shares authorized for awards under the 2007 Plan was 2,318,486 shares, prior to its expiration on March 15, 2017 (after taking into account prior awards under the 2007 Plan).

Upon expiration of the 2007 Plan, new awards cannot be issued pursuant to the 2007 Plan, but awards outstanding as of its March 15, 2017 plan expiration date will continue to be governed by its terms. 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.

In March 2017, the Company adopted the 2017 Omnibus Incentive Plan (the "2017 Plan"), which was approved by shareholders on June 2, 2017, to provide for the granting of equity awards, such as nonqualified stock options ("NQSOs"), incentive stock options ("ISOs"), restricted stock, performance shares, stock appreciation rights ("SARs"), restricted stock units ("RSUs") and other share-based awards to employees, directors, and consultants, as determined by the Board of Directors. The new 2017 Plan will not affect awards previously granted under the 2007 Plan. The 2017 Plan allows for awards of up to 2,318,486 shares of the Company's common stock, plus an automatic annual increase in the number of shares authorized for awards on the first day of each of the Company's fiscal years beginning January 1, 2018 through January 1, 2027 equal to (i) four percent of the number of shares of Common Stock outstanding on the last day of the immediately preceding fiscal year or (ii) such lesser number of shares of Common Stock than provided for in Section 4(a)(i) of the 2017 Plan as determined by the Board. As of December 31, 2017, there were 1,383,328 shares available for future awards under the 2017 Plan.

Under the terms of the 2017 Plan, the exercise price of NQSOs, ISOs and SARs may not be less than 100% of the fair market value of the common stock on the date of grant and, if ISOs are 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. The term of awards will not be longer than ten years, or in the case of ISOs, not longer than five years with respect to holders of more than ten percent of the Company's stock. 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. The Company issues new shares to satisfy option exercises under the 2007 and 2017 plans.

Stock Option Summary

The following table summarizes information about the Company's stock options and restricted stock outstanding at December 31, 2017, 2016 and 2015, and activity during the three years then ended:

(in thousands, except years and per share data)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2014	323	$ 38.25	6.3	$ 23
Options granted	85	$ 11.20		
Restricted stock units granted	16	$ —		
Options exercised	-	$ —		
Restricted stock units vested	(6)	$ —		
Options forfeited/cancelled	(28)	$ 30.58		
Restricted stock units cancelled	(2)	$ —		
Outstanding at December 31, 2015	388	$ 32.03	6.2	$ 19
Options granted	1,227	$ 2.74		
Restricted stock units granted	104	$ —		
Options exercised	-	$ —		
Restricted stock units vested	(114)	$ —		
Options forfeited/cancelled	(116)	$ 28.27		
Restricted stock units cancelled	-	$ —		
Outstanding at December 31, 2016	1,489	$ 8.38	8.7	$ 702
Options granted	1,616	$ 3.03		
Restricted stock units granted	49	$ —		
Options exercised	(68)	$ 2.72		
Restricted stock units vested	(39)	$ —		
Options forfeited/cancelled	(87)	$ 22.08		
Restricted stock units cancelled	-	$ —		
Outstanding at December 31, 2017	2,960	$ 5.16	8.6	$ 2,586
Vested and expected to vest at December 31, 2017	2,434	$ 5.64	8.5	$ 2,083
Vested at December 31, 2017	1,389	$ 7.71	8.0	$ —
Exercisable at December 31, 2017	1,389	$ 7.71	8.0	$ —

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 American as of December 31, 2017 for options that have a quoted market price in excess of the exercise price. There were 68 thousand stock option awards exercised for the year ended December 31, 2017 for which the Company received cash payments of $185 thousand. The aggregate intrinsic value of stock option awards exercised was $116 thousand for the year ended December 31, 2017. There were no stock option awards exercised during the years ended December 31, 2016 and 2015. Accordingly, the Company received no cash payments for the exercise of stock options during the years ended December 31, 2016 and December 31, 2015. As of December 31, 2017, total unrecognized compensation cost related to unvested stock options and restricted stock was approximately $2.0 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 2.79 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 applied to value its stock-based awards.

During the years ended December 31, 2017, 2016 and 2015, the Company granted options to employees and directors to purchase an aggregate of 1,529,000, 1,139,000, and 59,000 shares of common stock, respectively.

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

	Year Ended December 31,		
Assumption	**2017**	**2016**	**2015**
Expected price volatility	87.78%	84.47%	77.22%
Expected term (in years)	6.90	7.03	6.8
Risk-free interest rate	2.12%	1.57%	1.76%
Dividend yield	0.00%	0.00%	0.00%
Weighted-average fair value of options granted during the period	$ 2.34	$ 2.06	$ 7.35

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

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

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

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

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

In addition, the Company granted restricted stock to employees totaling 10,000, 64,000, and 16,000 shares of common stock in the years ended December 31, 2017, 2016 and 2015, respectively.

For the years ended December 31, 2017, 2016 and 2015, we recognized stock-based compensation expense of $2,371 thousand, $1,489 thousand, and $1,193 thousand, respectively, for option awards to employees and directors.

In the second quarter of 2015, the Company modified stock options owned by two of its directors, Mr. Cashion and Mr. Wicks, each of whom retired at the Company's 2015 annual meeting of stockholders in June 2015. All outstanding stock options held by Mr. Cashion and Mr. Wicks became fully vested upon retirement, and the option exercise period for Mr. Cashion and Mr. Wicks was extended from three months to four years, calculated from the date of retirement. Options with an expiration date prior to the end of the exercise period maintained the same expiration date. In connection with the stock option modification, the Company recognized stock-based compensation expense of $185 thousand.

During the second and third quarters of 2016, the Company modified stock options held by two of its directors, Dr. Radaelli and Dr. McPherson, each of whom resigned as directors of the Company, effective May 6, 2016 and August 24, 2016, respectively. All outstanding stock options held by Dr. Radaelli and Dr. McPherson became fully vested upon retirement, and the option exercise period for Dr. Radaelli and Dr. McPherson was extended from three months to four years, calculated from each former director's respective date of resignation. Options with an expiration date prior to the end of the exercise period maintained the same expiration date. In connection with the stock option modification, the Company recognized stock-based compensation expense of $58 thousand.

In July 2017, Mr. Paulson announced his retirement from his position as CFO of the Company as of December 31, 2017. As part of his employment agreement, the Company modified his stock options, effective upon his retirement. All outstanding stock options held by Mr. Paulson became fully vested upon retirement, and the option exercise period was extended from three months to three years, calculated from the date of retirement. Options with an expiration date prior to the end of the exercise period maintained the same expiration date. As this agreement was entered into during the third quarter of 2017 and Mr. Paulson agreed to continue providing service through December 31, 2017, the Company recorded stock-based compensation expense in connection with the stock option modification in both the third and fourth quarters of 2017. In connection with the stock option modification, the Company recognized stock-based compensation expense of $244 thousand during the three months ended September 30, 2017 and $260 thousand during the three months ended December 31, 2017.

Stock-Based Awards to Non-Employee Consultants

During the years ended December 31, 2017, 2016 and 2015, the Company granted options to purchase an aggregate of 86,000, 89,000, and 27,000 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:

	Year Ended December 31,		
Assumption	**2017**	**2016**	**2015**
Expected price volatility	87.41%	87.68%	83.77%
Expected term (in years)	10.0	10.0	9.6
Risk-free interest rate	2.27%	1.61%	2.18%
Dividend yield	0.00%	0.00%	0.00%
Weighted-average fair value of options granted during the period	$ 2.40	$ 2.29	$ 7.15

In addition, the Company granted restricted stock to non-employees totaling 39,000, 41,000, and 500 shares of common stock in the years ended December 31, 2017, 2016 and 2015, respectively, in exchange for advisory and consulting services.

For the years ended December 31, 2017, 2016 and 2015, the Company recognized stock-based compensation expense of $243 thousand, $262 thousand, and $188 thousand, respectively, related to non-employee options and restricted stock 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 separation 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 separation agreement was paid via a combination of registered shares and cash.

In March 2016, Mr. 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 the consolidated statement of operations and comprehensive loss for the options and common stock discussed above is as follows. The amounts that would have been charged to cost of goods sold are not material and have been included in general and administrative expense below.

	Year Ended December 31,		
(in thousands)	**2017**	**2016**	**2015**
Research and development	$ 113	$ 195	$ 449
Sales and Marketing	152	132	-
General and administrative	2,277	1,424	933
Total stock-based compensation expense	$ 2,542	$ 1,751	$ 1,382

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

NOTE 13. LICENSE, COLLABORATION AND DISTRIBUTION AGREEMENTS

Virbac

In April 2012, the Company entered into a feasibility and option agreement with Virbac, a global animal health company, for the development and potential commercialization of Aganocides for a number of veterinary uses for companion animals. Under the terms of the agreement, the Company received an upfront payment and is entitled to additional support for research and development.

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 years ended December 31, 2017, 2016 and 2015 related to these agreements.

The Company had deferred revenue balances of $246 thousand in each of the years ended December 31, 2017, 2016 and 2015, 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, 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 (Chinese Food and Drug Adminstration). 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 China 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, China 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. China Pioneer is also obligated to make certain additional payments to the Company upon receipt of the marketing approval. The Distribution Agreement further provides that China 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, we also received $2.5 million from China 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 China Pioneer. The expanded agreement includes licensing rights to 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:

(in thousands)	Year Ended December 31, 2017	2016	2015
Amortization of upfront technology access fee	$ 25	$ 94	$ 25
Product sales	2	324	70
Total revenue recognized	$ 27	$ 418	$ 95

The Company had deferred revenue balances of $1.0 million, $1.0 million, and $1.1 million, respectively, at December 31, 2017, 2016 and 2015, related to these agreements, which consisted of the unamortized balances on the upfront technology and access fee.

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 $750,000.

Revenue has been recognized under this agreement as follows:

(in thousands)	Year Ended December 31, 2017	2016	2015
Amortization of upfront technology access fee	$ 75	$ 21	$ 5
Product sales	1,705	332	34
Total revenue recognized	$ 1,780	$ 353	$ 39

The Company had deferred revenue balances of $578 thousand, $653 thousand and $674 thousand, respectively, at December 31, 2017, 2016 and 2015, related to these agreements, which consisted of the unamortized balances on the upfront technology and access fee.

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 $200,000.

Revenue has been recognized under this agreement as follows:

(in thousands)	Year Ended December 31, 2017	2016	2015
Amortization of upfront technology access fee	$ 3	$ —	$ 1
Product sales	249	22	66
Total revenue recognized	$ 252	$ 22	$ 67

The Company had deferred revenue balances of $191 thousand, $194 thousand and $195 thousand, respectively, at December 31, 2017, 2016 and 2015, related to these agreements, which consisted of the unamortized balances on the upfront technology and access fee.

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 signed nationwide distribution agreements with Willow Pharmacy, Allure Pharmacy, Smith Drug Company and Dakota Drug to market Avenova.

During the years ended December 31, 2017, 2016 and 2015, the Company earned $13.6 million, $7.3 million and $947 thousand, respectively, in net sales revenue for its Avenova product under its distribution agreements.

The Company had a deferred revenue balance of $1.3 million, $1.7 million and $24 thousand as of December 31, 2017, 2016 and 2015, respectively, for its Avenova product under its distribution agreements.

NOTE 14. EMPLOYEE BENEFIT PLAN

We have a 401(k) plan covering all eligible employees. We are not required to contribute to the plan and have made no contributions through December 31, 2017.

NOTE 15. INCOME TAXES

The federal and state income tax provision is summarized as follows (in thousands):

	Year Ending December 31		
(in thousands)	**2017**	**2016**	**2015**
Current			
Federal	$ —	$ —	$ —
State	3	2	2
Other	—	—	—
Total Current tax expense	3	2	2
Deferred	—	—	—
Federal	—	—	—
State	—	—	—
Other	—	—	—
Total deferred tax expense	—	—	—
Income tax provision	$ 3	$ 2	$ 2

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The tax effects of significant items comprising the Company's deferred taxes as of December 31, are as follows:

(in thousands)	December 31 2017	2016
Deferred tax assets:		
Net operating losses	$ 25,564	$ 34,902
Accruals	225	287
Deferred revenue	508	829
Stock options	1,556	1,894
Other deferred tax assets	727	765
Total deferred tax assets	28,580	38,677
Deferred tax liabilities:		
Property and equipment	(35)	(32)
Total deferred tax liabilities	(35)	(32)
Valuation allowance	(28,545)	(38,645)
Net deferred taxes	$ —	$ —

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Act") was signed into law resulting in significant changes to the Internal Revenue Code. The Act, among other things, reduced the federal corporate income tax rate from 35% to 21% effective for tax years beginning after December 31, 2017. Consequently, the Company's net deferred tax assets as of December 31, 2017 were significantly reduced to reflect the estimated impact of the Tax Act. Due to the Company's lack of earnings history and uncertainties surrounding the ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance as mentioned above. The significant reduction in the deferred tax assets are fully offset by a reduction in the valuation allowance, resulting in no impact to income tax expense.

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting (ASU 2016-09), 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. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We adopted ASU 2016-09 in the first quarter of 2017.

The impact of adopting ASU 2016-09 resulted in the following:

• Classification of excess income tax benefits from stock-based compensation arrangement as a discrete item within income tax expense, rather than recognizing such excess income tax benefits in additional paid-in capital. The adoption of this guidance resulted in an increase of approximately $1.1 million of net operating losses, which has an impact of $0.4 million on our deferred tax assets before our full valuation allowance established against the related deferred tax assets.

The Company records the tax benefit of net operating loss carryforwards and temporary differences as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets is currently not likely to be realized and, accordingly, has provided a valuation allowance.

The valuation allowance (decreased)/increased by the following amounts (in thousands):

2017	2016	2015
$(10,100)	$3,642	$8,101

Net operating loss and tax credit carryforwards as of December 31, 2017, are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal	$ 94,830	2024 - 2037
Net operating losses, state	$ 78,533	2028 - 2037
Tax credits, federal	$ 1,316	2026 - 2035
Tax credits, state	$ 282	do not expire

Under U.S. federal tax law, the amount and availability of tax benefits are subject to a variety of interpretations and restrictive tests. Utilization of the net operating loss (NOL) carryforwards may be subject to a substantial annual limitation due to ownership changes that have occurred previously or that could occur in the future, as provided by Section 382 of the Internal Revenue Code of 1986, and similar state provisions. Ownership changes may limit the amount of NOL carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, the Company has raised capital through the issuance of capital stock on two 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. The Company has not currently completed a study to assess whether any change of control has occurred, or whether there have been multiple changes of control since the Company's formation, due to the significant complexity and cost associated with the study. If the Company has 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. A full valuation allowance has been provided against the Company's NOL carryforwards, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Accordingly, there would be no impact on the consolidated balance sheet or statement of operations if an adjustment is required.

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows:

	Year Ending December 31		
(in thousands)	**2017**	**2016**	**2015**
Income tax provision (benefit) at federal statutory rate	$ (2,516)	$ (4,471)	$ (6,439)
State tax	(12)	(157)	(1,060)
ISO-related expense for GAAP	154	52	164
Change in valuation allowance	(10,484)	3,641	8,101
Revaluation of warrant liability	34	806	(731)
Tax credits	—	(31)	(123)
Other	(49)	162	90
Section 162(m) disallowance	336	—	—
Tax Reform - Tax Rate Change	12,540	—	—
Total	$ 3	$ 2	$ 2

Uncertain Income Tax Positions

The Company adopted the provisions of ASC 740-10, *Accounting for Uncertainty in Income Taxes*, on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the years ended December 31, 2017 and 2016 is as follows:

	Year ended December 31,	
(in thousands)	**2017**	**2016**
Unrecognized benefit - beginning of period	$ 974	$ 957
Gross increases/ (decreases) - prior/current period tax positions	(43)	17
Unrecognized benefit - end of period	$ 931	$ 974

Our policy will be to recognize interest and penalties related to income taxes as a component of income tax expense. We are subject to income tax examinations for U.S. incomes taxes and state income taxes from 2004 and 2006 forward respectively. We do not anticipate that total unrecognized tax benefits will significantly change in the next 12 months.

NOTE 16. 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. Sieczkarek, 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 China Pioneer, Pioneer Singapore as a wholly-owned subsidiary of China Pioneer and recipient of all of the holdings of Pioneer Singapore as a result

of an internal corporate reorganization, and Mr. Fu, the Company's two largest stockholders. The Loan was fully paid off as of August 1, 2016.

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 $27 thousand, $418 thousand and $95 thousand for the years ended December 31, 2017, 2016 and 2015, respectively. There were no related party accounts receivable as of December 31, 2017 and December 31, 2016, respectively. See Note 13, "License, Collaboration and Distribution Agreements - NeutroPhase Distribution Agreements," for additional information regarding the Company's distribution agreements with China Pioneer, one of the Company's largest stockholders.

Related Party Expenses

The Company recognized related party commission fees of $0, $1.1 million and $408 thousand for the years ended December 31, 2017, 2016 and 2015, respectively. These fees were paid to China Kington, representing the commission on sale of the Company's common stock and the exercise of the Company's warrants. See Note 11, "Stockholders' Equity (Deficit)" – "Common Stock" for additional information regarding such commissions.

NOTE 17. SUBSEQUENT EVENTS

On November 13, 2017, we entered into a share purchase agreement (the "Original Agreement" and, as amended and restated on November 20, 2017, the "Purchase Agreement") with Ch-gemstone Capital (Beijing) Co., Ltd., a company organized in China ("CG Capital"), subject to customary closing conditions. Under the Purchase Agreement, we agreed to issue and sell to CG Capital a total of 2,400,000 shares of our common stock for an aggregate purchase price of $10,320,000 (the "Private Placement") and China Kington Asset Management ("China Kington") agreed to serve as placement agent in exchange for a commission equal to six percent (6%) of the total purchase price upon the closing of the Private Placement. On January 31, 2018, the Purchase Agreement was terminated upon written notification by CG Capital to us that it was unable to meet the closing condition to obtain the approval of the applicable regulatory authorities in China.

Concurrently with the execution of the Original Agreement, CG Capital entered into share transfer agreements (the "Share Transfer Agreements") with two of our existing stockholders, Pioneer Pharma (Hong Kong) Company Limited ("Pioneer Hong Kong" and, together with its parent, China Pioneer Pharma Holdings Limited ("China Pioneer"), "Pioneer Group") and Jian Ping Fu, to purchase 216,696 shares and 3,983,304 shares of our common stock, respectively. In connection with the termination of the Purchase Agreement for the Private Placement, the Share Transfer Agreements were also terminated.

After the termination of the Purchase Agreement with CG Capital, we entered into a share purchase agreement with OP Financial Investments Limited on February 5, 2018 for the sale of an aggregate of 1,700,000 shares of the Company's common stock, par value $0.01 per share, for an aggregate purchase price of $5,984,000 (the "OP Private Placement"). The OP Private Placement closed on February 8, 2018. OP Financial Investments Limited is an investment firm based in Hong Kong focused on cross-border investment opportunities and listed on the Hong Kong Stock Exchange. China Kington served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $359,040.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure 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 at December 31, 2017, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure, at the reasonable assurance level, 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.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017. Our management utilized the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2017. Our management has concluded that, as of December 31, 2017, our internal control over financial reporting was effective based on these criteria.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting which has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be included in our Proxy Statement for the 2018 Annual Meeting of Stockholders (the "2018 Proxy Statement") and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in the 2018 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be included in the 2018 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in the 2018 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be included in the 2018 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

(1) *Financial Statements*. The financial statements listed in the Index for Item 8 hereof are filed as part of this report.
(2) *Financial Statement Schedules*. All schedules have been omitted because they are not required or the required information is included in our consolidated financial statements and notes thereto.
(3) *Exhibits*. The following exhibits are filed as part of this Report:

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 21, 2018

By: /s/ Mark M. Sieczkarek

Director and Chief Executive Officer

POWER OF ATTORNEY

We, the undersigned officers and directors of NovaBay Pharmaceuticals, Inc., do hereby constitute and appoint Mark M. Sieczkarek and John J. McGovern, and each of them, our true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby, ratifying and confirming all that each of said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report on Form 10-K has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated:

Signature	Title	Date
/s/ MARK M. SIECZKAREK **Mark M. Sieczkarek, M.B.A.**	Chairman of the Board and Chief Executive Officer (principal executive officer)	March 21, 2018
/s/ JOHN J. MCGOVERN **John J. McGovern**	Chief Financial Officer (principal financial officer)	March 21, 2018
/s/ PAUL E. FREIMAN **Paul E. Freiman**	Lead Independent Director	March 21, 2018
/s/ YONGHAO MA **Yonfhao Ma, Ph.D. (Carl MA)**	Director	March 21, 2018
/s/ GAIL MADERIS **Gail Maderis, M.B.A.**	Director	March 21, 2018
/s/ TODD ZAVODNICK **Todd Zavodnick**	Director	March 21, 2018
/s/ XINZHOU LI **Xinzhou Li (Paul LI)**	Director	March 21, 2018
/s/ MIJIA WU **Mijia Wu, M.B.A. (Bob WU)**	Director	March 21, 2018
/s/ XIAOYAN LIU **Xiaoyan Liu (Henry LIU)**	Director	March 21, 2018

BOARD OF DIRECTORS:

Mark M. Sieczkarek
Chairman and Chief Executive Officer

Paul Freiman
Lead Independent Director, Chair of the Compensation Committee

Gail Maderis
Independent Director, Chair of the Audit Committee

Todd Zavodnick
Independent Director, Chair of the N&CG Committee

Yonghao "Carl" Ma
Independent Director

Mijia "Bob" Wu
Director

Xinzhou "Paul" Li
Director

Yanbin "Lawrence" Liu,
Director

OFFICERS

Mark M. Sieczkarek
Chairman and Chief Executive Officer

Jack J. McGovern
Chief Financial Officer

Justin M. Hall
Senior Vice President, General Counsel and Corporate Secretary

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TRANSFER AGENT AND REGISTRAR

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