NovaBay Pharmaceuticals, Inc.
Form 10-K
March 21, 2018

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	**(I.R.S. Employer Identification No.)**

organization)

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.

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

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.

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	Cash	Rebate	Total

	fees	discounts		
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)		