NovaBay Pharmaceuticals, Inc.
Form 10-K
March 29, 2019

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, 2018

OR

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

For the transition period from to

Commission file number 001-33678

NOVABAY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**68-0454536**

(State or other jurisdiction of incorporation or organization)

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

2000 Powell Street, Suite 1150, Emeryville, California 94608

(Address of principal executive offices) (Zip Code)

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

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

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

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes No

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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	

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, 2018, 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 $12,878,993. This figure excludes an aggregate of 11,937,707 shares of common stock held by affiliates, including officers and directors, as of June 30, 2018. 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 24, 2019, there were 17,089,304 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

NOVABAY PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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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 overall 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. However, the Company recently announced a refocus to strategically shift its commercialization strategy to focus on high performing territories and territories identified as having significant prescription volume potential along with favorable health plan coverage while continuing to focus on contracting with additional mail-order pharmacies as channel partners. 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 new sales and marketing strategy intended to increase product margin and profitability; (2) maintaining low expenses and continuing to optimize sales force efficiency, including strategic 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 U.S. distribution partners and an international distribution partner in China. We currently do not sell or distribute CelleRx, although we are looking into several distribution possibilities.

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 proprietary solution with hypochlorous acid that acts as an antimicrobial preservative in solution and has been shown to neutralize bacterial toxins in laboratory tests. Because it is a gentle isotonic solution, we believe that it is well 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 (commonly referred to as blepharitis), 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, Philadelphia, Chicago, 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. These agreements with partner pharmacies give us greater control over the patient experience and ensure patients obtain the product at the best possible price. Avenova is also 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 and 2018, although we recently decreased this number to 15 high-performing field sales representatives at the end of the first quarter of 2019 to conserve cash**.**

We expect that our prescription business will continue to be an important part of total Avenova sales. Although we are seeking new distribution channels, we continue to focus our primary sales efforts on building our prescription business under a value pricing model. We maintain 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. Our partner pharmacies ensure that proper insurance reimbursement occurs, and that our patients are receiving the best possible price.

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, partner 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 they 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 equity

awards.

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 these 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. This program will require a partner willing to invest in phase 3 clinical studies in order to move this program forward and 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 have paused all development work on *intelli*-Case until we find an outside partner 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 may begin to explore market opportunities for this product in the coming year.

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 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 180,000 prescriptions in the United States for Avenova in 2018. Although the number of prescribing physicians who write more than 10 scripts per month has risen dramatically, no individual doctor represented in excess of 10% of our revenues for the year ended December 31, 2018.

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 31, 2018, we owned 100 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, 2018 and 2017, we incurred total research and development expenses of approximately $0.3 million and $0.4 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 (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. Most importantly, we have received notices from several national payors that Avenova will not be covered in 2019. 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, 2018, we had a total of 70 employees, all of whom were full-time employees. After the reduction in force in March 2019, the Company currently has 33 employees, half of which are field sales representatives dedicated solely to the sale of Avenova. 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 31, 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 February 2019, in connection with a $1.0 million loan to the Company facilitated by China Kington (the "February 2019 Loan"), we issued a promissory note payable to Pioneer Pharma (Hong Kong) Company Limited ("Pioneer Hong Kong"), which has a perfected security interest in all tangible and intangible assets of the Company. The February 2019 Loan includes an interest payment of $150,000 which along with the entire principal sum is payable in full upon our next financing with Pioneer Hong Kong, but in no event later than July 27, 2019. In connection with the February 2019 Loan, the Company must pay China Kington a 2% fee for brokering the transaction and enter into a

consulting agreement with China Kington for the term of one year to facilitate closer oversight of the Company's expenses and strategic direction by the Board of Directors. Bob Wu, acting in a dual role as a member of the Company's Board of Directors and as principal of China Kington, will be paid $100,000 pursuant to this consulting agreement.

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

See the above description under "Borrowings" regarding our loan from Pioneer Hong Kong.

Triton Funds LP Term Sheet

On March 25, 2019, the Company entered into a Term Sheet (the "Term Sheet") with Triton Funds LP, a Delaware company ("Triton"). Pursuant to the Term Sheet, upon the transaction closing, Triton will have the right to purchase shares of common stock of the Company up to a value of $3,000,000 (the "Shares") at a purchase price equal to 90% of the lowest trading price of the Company's common stock for the five business days prior to the closing date. In addition, the Term Sheet requires a donation of 150,000 shares of common stock to Triton Funds LLC (the "Donation Shares") and a document preparation fee of $15,000. The Term Sheet also requires that a Form S-3 be filed by April 1, 2019 to register the Shares and Donation Shares with the Securities and Exchange Commission.

Securities Purchase Agreement and Convertible Promissory Note

On March 26, 2019 (the “Closing Date”), the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with Iliad Research and Trading, L.P. (the “Lender”), pursuant to which the Company issued a Secured Convertible Promissory Note (the “Convertible Note”) to the Lender dated as of the Closing Date. The Convertible Note has an original principal amount of $2,215,000, bears interest at a rate of 10% per annum and will mature on September 26, 2020, unless earlier paid, redeemed or converted in accordance with its terms. The Company received proceeds of $2,000,000 after an original issue discount and payment of Lender’s legal fees.

The Convertible Note provides the Lender with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's Common Stock at a conversion price of $1.65 per share ("Lender Conversion Price") or the Market Price. The Market Price is defined as 85% of the lowest closing bid price during the twenty (20) Trading Days immediately preceding the applicable measurement date.

Pursuant to a Security Agreement between the Company and the Lender, repayment of the Convertible Note is secured by all of the assets of the Company. The assets covered by the Security Agreement are currently encumbered by that certain lien of up to $1,000,000, plus accrued and unpaid interest and fees, in favor of Pioneer Pharma Hong Kong as described under "Borrowings" above.

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"). The SEC also maintains an Internet site that contains reports, proxy, information statements and other information regarding issuers at http://www.sec.gov.

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 sustained operating losses for the majority of our corporate history and expect that our 2019 expenses will exceed our 2019 revenues, as we continue to invest in our Avenova commercialization efforts. Our operating cash flow is not sufficient to support our ongoing operations, and we expect to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. The February 2019 Loan only covers our operating expenses for approximately thirty (30) days. Any additional loans, such as the convertible loan with Chicago Venture Partners, or equity fundraising that we are able to secure in the near-term will be limited and will only provide working capital sufficient for the second quarter of 2019. As such, additional funding will be needed in both the short- and long-term in order to pursue our business plan, which includes maintaining a small salesforce in the U.S. for Avenova, 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.

In 2017 and prior years, we have periodically been notified by the NYSE American that we did not comply with the exchange's minimum stockholders' equity requirements. Although we were able to regain compliance in the past, we cannot guarantee that we will be able to continue to comply with the listing standards of NYSE American, and therefore our common stock could 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. Our stock price, by way of example, reached a high in 2018 of $4.20 per share and a low of $0.73 per share. 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 December 31, 2018, each of China Pioneer, Mr. Fu and OP Financial Investments Limited own approximately 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.

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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 other 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. Subsequently, Mr. Henry Liu was replaced by Mr. Yanbin "Lawrence" Liu in connection with the closing of the OP Private Placement. 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. Additionally, China Kington facilitated the February 2019 Loan from Pioneer Hong Kong. As a condition of this loan, they have oversight of our operations, in addition to their presence on our Board of Directors.

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 other 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 seven (7) of our eight (8) directors are either nominees of China Pioneer, Pioneer Hong Kong, OP Financial Investments Limited or China Kington after our 2020 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 constituted approximately 98% of our revenue for 2018. 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. The 510(k) status of Avenova also affects our ability to obtain formal insurance reimbursement by payors, and affects our ability to obtain Medicare coverage.

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 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 actions 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 reputational 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. Effective as of September 28, 2018, our Chief Executive Officer, Mark M. Sieczkarek, was replaced by John J. McGovern, who was serving as our Chief Financial Officer and Treasurer. On March 7, 2019, Mr. McGovern resigned as the Interim President and Chief Executive Officer, Chief Financial Officer and Treasurer. Effective March 8, 2019, the Board appointed (i) Justin Hall to serve as Interim President and Chief Executive Officer in addition to his role as General Counsel and Chief Compliance Officer and (ii) Jason Raleigh to serve as the Interim Chief Financial Officer and Treasurer, who previously served as the Company's Corporate Controller. No assurance can be given that we will be able to timely locate replacements or that such replacements will be effective in our growth.

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 the 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, the 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. California law prevents 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 be issued 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.

Significant disruptions of information technology systems or breaches of information security could adversely affect our businesses.

We rely to a large extent upon information technology systems to operate our businesses. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property), and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us. For example, we distribute our products in the United States primarily through three pharmaceutical wholesalers, and a security breach that impairs the distribution operations of our wholesalers could significantly impair our ability to deliver our products to healthcare providers.

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 31, 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."

Holders

As of March 29, 2019, 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.

	12/13	12/14	12/15	12/16	12/17	12/18
NovaBay Pharmaceuticals, Inc.	**100.00**	**51.22**	**6.57**	**10.73**	**12.52**	**2.51**
NYSE American	**100.00**	**101.45**	**72.08**	**86.50**	**85.89**	**75.60**
RDG MicroCap Biotechnology	**100.00**	**98.36**	**79.08**	**31.65**	**26.32**	**16.07**

(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,				
	2018	2017	2016	2015	2014
	(in thousands, except per share data)				
Statements of Operations Data:					
Sales:					
Product Revenue, net	$12,474	$18,127	$11,617	$4,146	$684
Other Revenue, net	34	103	280	235	370
Total Sales, net	12,508	18,230	11,897	4,381	1,054
Product Cost of Goods Sold	1,503	2,784	2,464	1,261	486
Gross Profit	11,005	15,446	9,433	3,120	568
Operating expenses:					
Research and development	259	410	1,371	5,728	9,483
Sales and marketing	12,789	13,711	11,809	10,523	1,754
General and administrative	5,828	8,636	7,235	8,006	6,235
Total operating expenses	18,876	22,757	20,415	24,257	17,472
Operating loss	(7,871)	(7,311)	(10,982)	(21,137)	(16,904)
Non-cash gain (loss) on changes in fair value of warrant liability	1,311	(101)	(2,099)	2,149	1,664
Other income (expense), net	19	12	(68)	17	48
Loss before provision for income taxes	(6,541)	(7,400)	(13,149)	(18,971)	(15,192)
Provision for income taxes	(4)	(3)	(2)	(2)	(2)
Net loss	$(6,545)	$(7,403)	$(13,151)	$(18,973)	$(15,194)
Loss per share:					
Basic	$(0.39)	$(0.48)	$(1.40)	$(6.82)	$(7.65)
Diluted	$(0.46)	$(0.48)	$(1.40)	$(6.82)	$(7.65)
Shares used in computing net loss per share:					

Basic (after 1 for 25 reverse stock split)	16,921	15,324	9,408	2,784	1,985
Diluted (after 1 for 25 reverse stock split)	17,058	15,324	9,408	2,784	1,985

	2018	2017	2016	2015	2014
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$3,183	$3,199	$9,512	$2,385	$5,429
Working capital	4,761	4,016	10,148	(106)	3,607
Total assets	9,361	10,079	15,381	5,077	7,537
Deferred revenue—current and non-current	41	3,375	4,053	2,418	2,425
Common stock and additional paid-in capital	119,935	113,668	110,772	85,422	73,395
Total stockholders' equity (deficit)	4,954	2,594	7,101	(5,098)	1,848

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 overall 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. However, the Company recently announced a refocus to strategically shift its commercialization strategy to focus on high performing territories and territories identified as having significant prescription volume potential along with favorable health plan coverage while continuing to focus on contracting with additional specialty pharmacies as channel partners. 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 new sales and marketing strategy intended to maintain current product margin and target profitability; (2) maintaining low expenses and continuing to optimize sales force efficiency, including strategic geographical reach; 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, 2018 and 2017, management had reserved $10 thousand and $13 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, 2018 and 2017, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $104 thousand and $140 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

Beginning January 1, 2018, we have followed the provisions of Topic 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized.

We generate product revenue through product sales to our major distribution partners, a limited number of distributors and via our webstore. Product supply is the only performance obligation contained in these arrangements and we recognize product revenue upon transfer of control to our major distribution partners at the amount of consideration that we expect to be entitled to, generally upon shipment to the distributor on a "sell-in" basis.

Other revenue is primarily generated through commercial partner agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include more than one performance obligation and generally contain non-refundable upfront fees, payments based upon achievement of certain milestones and royalties on net product sales.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under these agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Topic 606. Our performance obligations include:

- Product supply
- Exclusive distribution rights in the product territory
- Regulatory submission and approval services
- Development services
- Sample supply
- Incremental discounts and product supply prepayments considered material rights to the customer

We have optional additional items in our contracts, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future commercial product supply and optional research and development services at the customer's or our discretion are generally considered options. We assess if these options provide a material right to the licensee and if so, such material rights are accounted for as separate performance obligations.

Transaction Price

We have both fixed and variable consideration. Under our license arrangements, non-refundable upfront fees are considered fixed, while milestone payments are identified as variable consideration when determining the transaction price. Product supply selling prices are identified as variable consideration subject to the constraint on variable consideration for estimated discounts, rebates, chargebacks and product returns. Funding of research and development activities are considered variable payments until such costs are reimbursed at which point they are considered fixed. We allocate the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

For product supply under our distribution arrangements, contract liabilities are recorded for invoiced amounts that are subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. Because we do not have sufficient historical data to compute our own return rate, the return rate used to estimate the constraint on variable consideration for product returns is based on an average of peer and competitor company historical return rates. We update the return rate assumption quarterly and apply it to the inventory balance that is held at the distributor and has not yet been sold through to the end customer. Payment for product supply is typically due 30 days after control transfers to the customer. At any point in time there is generally one month of inventory in the sales channel, therefore uncertainty surrounding constraints on variable consideration is generally resolved after one month from when control is transferred.

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

	Wholesaler/ Pharmacy fees	**Cash discounts**	**Rebate**	**Returns**	**Total**
Balance at December 31, 2017	$ (530)	$ (31)	$ 818	$ -	$ 257
Effect of ASC 606 Adoption	(27)	35	(573)	(42)	(607)
Current provision related to sales made during current period	(2,611)	(470)	(643)	(9,992)	(13,716)
Payments	2,568	405	69	9,592	12,634
Balance at December 31, 2018	$ (600)	$ (61)	$ (329)	$ (442)	$ (1,432)

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, and achievement is in our control (such as a regulatory submission by us), the value of the associated milestone is included in the transaction price. Milestone payments that are not within our control, such as approvals from regulators, are not considered probable of being achieved until those approvals are received.

For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

As part of the accounting for arrangements that contain multiple performance obligations, we must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. When a contract contains more than one performance obligation, we use key assumptions to determine the stand-alone selling price of each performance obligation. The estimated stand-alone selling prices for distribution rights and material rights for incremental discounts on product supply are calculated using an income approach discounted cash flow model and can include the following key assumptions: forecasted commercial partner sales, product life cycle estimates, costs of product sales, commercialization expenses, annual growth rates and margins, discount rates and probabilities of technical and regulatory success. For all other performance obligations, we use a cost-plus margin approach. We allocate the total transaction price to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or service underlying each performance obligation.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under each arrangement. If we cannot reasonably estimate when performance obligations either are completed or become inconsequential, then revenue recognition is deferred until we can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. Revenue is recognized for products at a point in time and for licenses of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time proportionate to the costs that we have incurred to perform the services using the cost-to-cost input method.

Our intellectual property in the form of distribution rights is determined to be distinct from the other performance obligations identified in the arrangements and considered "right to use" licenses which the customer can benefit from at a point in time. We recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license.

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 actual costs 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, 2018 and 2017

	Year Ended December 31,		Dollar	Percent
	2018	2017	Change	Change
Statement of Operations				
Sales:				
Product revenue, net	$12,474	$18,127	$(5,653)	-31 %
Other revenue	34	103	(69)	-67 %
Total sales, net	12,508	18,230	(5,722)	-31 %
Product cost of goods sold	1,503	2,784	(1,281)	-46 %
Gross profit	11,005	15,446	(4,441)	-29 %
Research and development	259	410	(151)	-37 %
Sales and marketing	12,789	13,711	(922)	-7 %
General and administrative	5,828	8,636	(2,808)	-33 %
Total operating expenses	18,876	22,757	(3,881)	-17 %
Operating loss	(7,871)	(7,311)	(560)	8 %
Non cash gan (loss) on changes in fair value of warrant liability	1,311	(101)	1,412	-1398 %
Other income, net	19	12	7	58 %
Loss before provision for income taxes	(6,541)	(7,400)	859	-12 %
Provision for income tax	(4)	(3)	(1)	33 %
Net loss and comprehensive loss	$(6,545)	$(7,403)	$858	-12 %

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

Product revenue, net, decreased by $5.7 million, or 31%, to $12.5 million for the year ended December 31, 2018, from $18.1 million for the year ended December 31, 2017. The decrease in product revenue, net, is primarily the result of a decrease in the net selling price of Avenova products, along with a $1.8 million decrease in non-Avenova product sales. The decrease in the net selling price of Avenova was largely due to the decrease in insurance coverage of the product by national payors. The decrease in non-Avenova product sales was largely due to the loss of a significant customer.

Other revenue, net, decreased by $69 thousand, or 67%, to $34 thousand for the year ended December 31, 2018, from $103 thousand for the year ended December 31, 2017.

Product cost of goods sold decreased by $1.3 million, or 46%, to $1.5 million for the year ended December 31, 2018, from $2.8 million for the year ended December 31, 2017. The decrease in product cost of goods sold was primarily the result of a decrease in product revenue, along with product mix.

Gross profit decreased by $4.4 million, or 29%, to $11.0 million for the year ended December 31, 2018, from $15.4 million for the year ended December 31, 2017. The decrease in gross profit was primarily the result of decreased product revenue, net.

Research and Development

Research and development expenses decreased by $0.1 million, or 37%, to $0.3 million for the year ended December 31, 2018, from $0.4 million for the year ended December 31, 2017. The decrease is primarily the result of our strategic shift of capital resources from research and development to the commercialization of Avenova.

Sales and marketing

Sales and marketing expenses decreased by $0.9 million, or 7%, to $12.8 million for the year ended December 31, 2018, from $13.7 million for the year ended December 31, 2017. The decrease is primarily due to the decrease in sales headcount and employee related costs, partly offset by an increase in providing samples.

General and administrative

General and administrative expenses decreased by $2.8 million, or 33%, to $5.8 million for the year ended December 31, 2018, from $8.6 million for the year ended December 31, 2017. The decrease is primarily a result of lower stock-based compensation awards, including the CFO retirement package recorded in 2017, and other employee related costs, along with a decrease in professional services and consulting fees.

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

The adjustments to the fair value of warrants was a gain of $1.3 million for the year ended December 31, 2018, compared to a loss of $0.1 million for the year ended December 31, 2017.

For additional information regarding the warrants and their valuation, please see Note 10 in the Notes to Consolidated Financial Statements (Warrant Liability) included in Part II, Item 8 of this report. For the year ended December 31, 2018, non-cash gain on changes in fair values of warrants was caused by the reduction in the price of the Company's common stock during the year. For 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.

Other income, net

Other income, net, was income of $19 thousand compared to income of $12 thousand for the years ended December 31, 2018 and December 31, 2017, respectively.

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 gain (loss) on changes in fair value of warrants

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 (Warrant Liability) included in Part II, Item 8 of this report. For 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. For 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 income of $12 thousand compared to 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.

Liquidity and Capital Resources

As of December 31, 2018 and December 31, 2017, our cash and cash equivalents were $3.2 million. The Company has sustained operating losses for most of its corporate history and expects to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. The Company's operating cash flow is not sufficient to support its ongoing operations.

Cash Used in Operating Activities

For the year ended December 31, 2018, cash used in operating activities was $5.6 million compared to $6.3 million for the year ended December 31, 2017. The change was primarily due to the decrease of net loss by $0.9 million, a decrease in stock-based compensation by $1.9 million, an increase in depreciation of $0.2 million, favorable changes in working capital of $2.9 million and change of the warrant liability fair value by $1.4 million.

For the year ended December 31, 2017, cash used in operating activities was $6.3 million compared to $11.7 million for the year ended December 31, 2016. The change was primarily due to the decrease of net loss by $5.8 million, increase in stock-based compensation by $0.5 million and stock option modification expense by $0.5 million and favorable changes in working capital of $1.2 million offset by the decrease in the gain on change of the warrant liability fair value by $2.0 million, the decrease of warrant modification expense by $0.3 million and the decrease of other adjustments for non-cash items by $0.3 million.

Cash Used in Investing Activities

For the years ended December 31, 2018, 2017 and 2016, cash used in investing activities was for the purchase of property and equipment of $44 thousand, $244 thousand and $160 thousand, respectively.

Cash Provided by Financing Activities

Net cash provided by financing activities of $5.6 million for the year ended December 31, 2018 was primarily attributable to the net proceeds from issuance of common stock related to the OP Private Placement. See Note 11 in the Notes to Consolidated Financial Statements (Stockholders' Equity (Deficit)) in Part II, Item 8 of this report for further information regarding the OP Private Placement.

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

Net cash provided by financing activities of $19.4 million for the year ended December 31, 2016 was primarily attributable to the net sale of $13.6 million of our common stock in our financings in February, May and August 2016, and Warrants exercised in a net amount of $7.4 million in August, September, October, and November 2016, and the borrowing of $1.4 million in connection with the final tranche of the Bridge Loan, fully offset by the full repayment of $3.0 million of our Bridge Loan. See Note 11 in the Notes to Consolidated Financial Statements (Stockholders' Equity (Deficit)) in Part II, Item 8 of this report for further information regarding these activities.

Quarterly Results of Operations (unaudited)

The following table presents unaudited quarterly results of operations for the eight most recent quarters ending with the quarter ended December 31, 2018. This information has been derived from our unaudited consolidated financial statements and has been prepared by us on a basis consistent with our audited annual consolidated financial statements and includes all adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the information for the periods presented.

	Quarter Ended							
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
	(in thousands, except per share data)							
Statements of Operations Data:								
Sales:								
Product Revenue, net	$3,604	$ 3,142	$2,794	$2,934	$ 6,259	$ 4,080	$4,094	$3,694
Other Revenue, net	21	-	-	13	57	11	28	7
Total Sales, net	3,625	3,142	2,794	2,947	6,316	4,091	4,122	3,701
Product Cost of Goods Sold	441	332	479	251	977	521	698	588
Gross Profit	3,184	2,810	2,315	2,696	5,339	3,570	3,424	3,113
Operating expenses:								
Research and development	107	45	61	46	146	132	70	62
Sales and marketing	3,186	3,230	2,977	3,396	3,299	3,296	3,376	3,740
General and administrative	1,502	1,344	1,360	1,622	1,502	2,311	1,735	3,088
Total operating expenses	4,795	4,619	4,398	5,064	4,947	5,739	5,181	6,890
Operating income (loss)	(1,611)	(1,809)	(2,083)	(2,368)	392	(2,169)	(1,757)	(3,777)
Non-cash gain (loss) on change in fair value of warrant liability	340	267	490	214	400	(281)	15	(235)
Other income (expense), net	6	4	5	4	3	3	4	2
Income (Loss) before provision for income taxes	(1,265)	(1,538)	(1,588)	(2,150)	795	(2,447)	(1,738)	(4,010)
Provision for income tax	(3)	-	(1)	-	(2)	—	—	(1)
Net income (loss)	$(1,268)	$ (1,538)	$(1,589)	$(2,150)	$ 793	$ (2,447)	$(1,738)	$(4,011)

Net income (loss) per share:								
Basic	$(0.07)	$ (0.09)	$(0.09)	$(0.13)	$ 0.05	$ (0.16)	$(0.11)	$(0.26)
Diluted	$(0.07)	$ (0.11)	$(0.12)	$(0.14)	$ 0.02	$ (0.16)	$(0.11)	$(0.26)
Shares used in computing net income (loss) per share:								
Basic (after effect of 1-for-25 reverse stock split)	17,089	17,089	17,089	16,406	15,376	15,324	15,308	15,284
Diluted (after effect of 1-for-25 reverse stock split)	17,089	17,148	17,292	16,670	16,018	15,324	15,308	15,284

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2018, we had net operating loss carryforwards for federal and state income tax purposes of $100.1 million and $84.1 million, respectively. The federal net operating loss carryforwards consist of $94.9 million generated before January 1, 2018, which will begin to expire in 2024 and $5.2 million that will carryforward indefinitely but are subject to the 80% taxable income limitation. The state net operating loss carryforwards will begin to expire in 2028. As of December 31, 2018, we also had tax credit carryforwards for federal income tax purposes of $1.3 million and $0.3 million for state tax purposes. If not utilized, the federal tax credits will begin expiring in 2026. The state tax credits have an indefinite carryover period.

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

Inflation

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

Off -Balance Sheet Arrangements

We did not have any off-balance sheet arrangements at December 31, 2018 and December 31, 2017 as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Seasonality

Consistent with our peers in the United States pharmaceutical industry, our business experiences seasonality with the first quarter of each year typically being the lowest revenue quarter. This annual phenomenon is due to consumers facing the need to satisfy health insurance deductibles and changes to copays as each new insurance year begins. For the year ended December 31, 2018, the second quarter had the lowest revenue due to the decrease in sales force.

Contractual Obligations

Our contractual cash commitments as of December 31, 2018, were as follows (in thousands):

Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than

					5 years
Facility leases	$2,654	$1,116	$ 1,463	$ 75	$ —
Vehicle leases	176	163	13	—	—
	$2,830	$1,279	$ 1,476	$ 75	$ —

Our commitments as of December 31, 2018 consist of two operating facility leases, the Lease and the lease for EmeryStation, and 54 operating vehicle leases.

The total commitment for the Lease as of December 31, 2018 was $1.4 million due over the lease term, compared to $1.8 million as of December 31, 2017.

The total commitment of the EmeryStation lease as of December 31, 2018 was $1.3 million due over such lease term, compared to $2.0 million as of December 31, 2017. On July 11, 2016, we entered into a Sublease Agreement to sublease our former corporate headquarters at EmeryStation. Sublease rental reimbursement is not deducted from the above table. We anticipate collecting $690 thousand and $577 thousand in the years ending December 31, 2019 and 2020, respectively, under the Sublease Agreement for the lease of EmeryStation.

Additionally, we have operating leases for a fleet of 54 vehicles, which commenced upon the delivery of the vehicles during the first quarter of 2017. The total commitment for these leases as of December 31, 2018 was $176 thousand due over the lease terms, compared to $340 thousand as of December 31, 2017.

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risk consists principally of interest rate risk on our cash, cash equivalents, and short-term investments. Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in interest rates, particularly because our current liquid assets at December 31, 2018 are held in cash and cash equivalents.

Our investment policy restricts our investments to high-quality investments and limits the amounts invested with any one issuer, industry, or geographic area. The goals of our investment policy are as follows: preservation of capital, assurance of liquidity needs, best available return on invested capital, and minimization of capital taxation. Some of the securities in which we invest may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with an interest rate fixed at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. To minimize this risk, in accordance with our investment policy, we maintain our cash and cash equivalents in short-term marketable securities, including money market mutual funds, Treasury bills, Treasury notes, certificates of deposit, commercial paper, and corporate and municipal bonds. The risk associated with fluctuating interest rates is limited to our investment portfolio. Due to the short-term nature of our investment portfolio, we believe we have minimal interest rate risk arising from our investments. As of December 31, 2018 and 2017, a 10% change in interest rates would have had an immaterial effect on the value of our investment portfolio. We do not use derivative financial instruments in our investment portfolio. We do not hold any instruments for trading purposes.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors

NovaBay Pharmaceuticals, Inc.

Emeryville, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of NovaBay Pharmaceuticals, Inc. (the "Company") as of December 31, 2018 and 2017 and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018**,** in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the accompanying financial statements, the Company has changed its method of accounting for revenue in 2018 due to the adoption of Financial Accounting Standards Board (United States) Accounting Standard Codification Topic No. 606, *Revenue from Contracts with Customers.*

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has experienced operating losses for most of its history and expects expenses to exceed revenues in 2019. The Company also has recurring negative cash flows from operations and an accumulated deficit. All of these matters raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ OUM & CO. LLP

San Francisco, California

March 29, 2019

We have served as the Company's auditor since 2010.

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands except par value amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$3,183	$3,199
Accounts receivable, net of allowance for doubtful accounts ($10 and $13 at December 31, 2018 and December 31, 2017, respectively)	3,385	3,629
Inventory, net of allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $104 and $140 at December 31, 2018 and December 31, 2017, respectively)	280	504
Prepaid expenses and other current assets	1,760	1,663
Total current assets	8,608	8,995
Property and equipment, net	201	471
Other assets	552	613
TOTAL ASSETS	$9,361	$10,079
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$551	$466
Accrued liabilities	3,255	1,672
Deferred revenue	41	2,841
Total current liabilities	3,847	4,979
Deferred revenues - non-current	-	534
Deferred rent	184	286
Warrant liability	178	1,489
Other liabilities	198	197
Total liabilities	4,407	7,485
Stockholders' equity :		
Preferred stock: 5,000 shares authorized; none outstanding at December 31, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value; 50,000 and 240,000 shares authorized; 17,089 and 15,385 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	171	154
Additional paid-in capital	119,764	113,514

Accumulated deficit	(114,981)	(111,074)
Total stockholders' equity	4,954	2,594
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$9,361	$10,079

As the Company adopted the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2018*, using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 8.

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

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands except per share data)

	Year Ended December 31,		
	2018	2017	2016
Sales:			
Product revenue, net	$12,474	$18,127	$11,617
Other revenue	34	103	280
Total sales, net	12,508	18,230	11,897
Product cost of goods sold	1,503	2,784	2,464
Gross profit	11,005	15,446	9,433
Research and development	259	410	1,371
Sales and marketing	12,789	13,711	11,809
General and administrative	5,828	8,636	7,235
Total operating expenses	18,876	22,757	20,415
Operating loss	(7,871)	(7,311)	(10,982)
Non-cash gain (loss) on changes in fair value of warrant liability	1,311	(101)	(2,099)
Other income (expense), net	19	12	(68)
Loss before provision for income taxes	(6,541)	(7,400)	(13,149)
Provision for income tax	(4)	(3)	(2)
Net income loss and comprehensive loss	$(6,545)	$(7,403)	$(13,151)
Net loss per share attributable to common stockholders (basic)	$(0.39)	$(0.48)	$(1.40)
Net loss per share attributable to common stockholders (diluted)	(0.46)	$(0.48)	$(1.40)
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (basic)	16,921	15,324	9,408
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (diluted)	17,058	15,324	9,408

As the Company adopted the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2018*, using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 8.

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

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2015	3,486	$ 35	$ 85,387	$ -	$ (90,520)	(5,098)
Net loss	-	-	-	-	(13,151)	(13,151)
Issuance of stock and warrants, net of offering costs	7,692	77	13,571	-	-	13,648
Issuance of common stock in connection with exercise of warrants, net of offering costs	3,977	40	7,389	-	-	7,429
Fair market value of warrants transferred to equity upon exercise	-	-	2,103	-	-	2,103
Warrant modification	-	-	270	-	-	270
Issuance of stock to consultants for services	2	-	8	-	-	8
Vesting of employee restricted stock awards	73	1	173	-	-	174
Vesting of non-employee restricted stock awards	41	-	133	-	-	133
Shares retired as result of reverse stock split	(2)	-	-	-	-	-
Stock-based compensation expense related to employee and director stock options	-	-	1,316	-	-	1,316
Stock-based compensation expense related to non-employee and director stock options	-	-	269	-	-	269
Balance at December 31, 2016	15,269	153	110,619	-	(103,671)	7,101
Net loss					(7,403)	(7,403)
Issuance of common stock in connection with exercise of warrants, net of offering costs	21	-	97	-	-	97
Issuance of stock for option exercises	68	1	184	-	-	185
Issuance of stock to consultants for services	1	-	-	-	-	-
Vesting of non-employee restricted stock awards	26	-	106	-	-	106
Stock-based compensation expense related to employee and director stock options	-	-	1,867	-	-	1,867
Stock-based compensation expense related to non-employee and director stock options	-	-	137	-	-	137

Stock option modification	-	-	504	-	-	504
Balance at December 31, 2017	15,385	154	113,514	-	(111,074)	2,594
Net loss	-	-	-	-	(6,545)	(6,545)
Issuance of common stock in connection with offering	1,700	17	5,967	-	-	5,984
Offering costs	-	-	(399)	-	-	(399)
Issuance of stock for option exercises	4	-	11	-	-	11
Cumulative retrospective adjustment related to adoption of ASC 606	-	-	-	-	2,638	2,638
Stock-based compensation expense related to employee and director stock options	-	-	594	-	-	594
Stock option modification	-	-	77	-	-	77
Balance at December 31, 2018	17,089	$ 171	$ 119,764	$ -	$ (114,981)	$ 4,954

As the Company adopted the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2018*, using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 8.

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

NOVABAY PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
Operating activities:			
Net loss	$(6,545)	$(7,403)	$(13,151)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	266	95	114
Loss (gain) on disposal of property and equipment	1	—	(219)
Stock-based compensation expense for options and stock issued to employees and directors	594	1,867	1,316
Stock-based compensation expense for options and stock issued to non-employees	—	137	129
Issuance of RSUs to employees	—	—	173
Issuance of RSUs to non-employees	—	34	133
Warrant modification	—	—	270
Stock option modification expense	77	504	—
Note receivable impairment	—	—	91
Leasehold improvements impairment	—	—	70
Non-cash (gain) loss on change in fair value of warrant liability	(1,311)	101	2,099
Changes in operating assets and liabilities:			
Accounts receivable	774	(1,509)	(1,585)
Inventory	198	369	472
Prepaid expenses and other assets	(97)	313	(1,470)
Other assets long-term	62	(73)	—
Accounts payable and accrued liabilities	516	(260)	(2,356)
Deferred rent	(69)	27	327
Deferred revenue	(34)	(472)	1,641
Deferred taxes	—	—	87
Long-term obligations	—	—	198
Net cash used in operating activities	(5,568)	(6,270)	(11,661)
Investing activities:			
Purchases of property and equipment	(44)	(244)	(160)
Net cash used by investing activities	(44)	(244)	(160)
Financing activities:			
Proceeds from common stock issuances, net	5,585	—	13,648
Proceeds from exercise of warrants, net	—	38	7,429

Proceeds from exercise of options, net	11	185	—
Proceeds from stock options & RSUs sold to cover taxes	1	26	—
Settlement of restricted stock for tax withholding	—	(48)	—
Proceeds from borrowings	—	—	1,365
Repayment of borrowings	—	—	(3,020)
Net cash provided by financing activities	5,597	201	19,422
Net increase (decrease) in cash, cash equivalents, and restricted cash	(15)	(6,313)	7,601
Cash, cash equivalents and restricted cash, beginning of period	3,673	9,986	2,385
Cash, cash equivalents and restricted cash, end of period	$3,658	$3,673	$9,986

	Year Ended December 31,		
	2018	**2017**	**2016**
Supplemental disclosure of cash flow information:			
Interest paid	$—	$—	$51
Supplemental disclosure of non cash information:			
Cumulative effect of adoption of new accounting standard	$2,638	—	—
Stock issued to consultants for services, included in accounts payable and accrued liabilities	$—	$1	$8
Fixed asset purchases included in accounts payable and accrued liabilities	$(49)	$(49)	$60
Equity transferred to warrant liability	$—	$58	$2,103
Exchange of equipment for services	$—	$—	$279
Severance paid in RSU to non-employee	$—	$69	$140

As the Company adopted the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2018*, using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 8.

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

NOVABAY PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION

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

The Company was incorporated under the laws of the State of California on January 19, 2000, as NovaCal Pharmaceuticals, Inc. It had no operations until July 1, 2002, on which date it acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, it changed its name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In June 2010, the Company changed the state in which it is incorporated (the "Reincorporation") and is now incorporated under the laws of the State of Delaware. All references to "the Company" herein refer to the California corporation prior to the date of the Reincorporation and to the Delaware corporation on and after the date of the Reincorporation. In April 2016, the Company dissolved DermaBay, a wholly-owned U.S. subsidiary that was formed to explore dermatological opportunities. Historically, the Company operated as four business segments. At the direction of its Board of Directors, the Company is now focused primarily on commercializing prescription Avenova for managing hygiene of the eyelids and lashes in the United States and is managed as a single segment.

Effective December 18, 2015, the Company effected a 1-for-25 reverse split of its outstanding common stock (the "Reverse Stock Split") (See Note 11). The accompanying financial statements and related notes give retroactive effect to the Reverse Stock Split.

Liquidity

Based primarily on the funds available at December 31, 2018, the Company believes these resources will be sufficient to fund its operations into the second quarter of 2019. The Company has sustained operating losses for the majority of

its corporate history and expects that its 2018 expenses will exceed its 2018 revenues, as the Company continues to re-invest in its Avenova commercialization efforts. The Company expects to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. Accordingly, the Company's planned operations raise substantial doubt about its ability to continue as a going concern. The Company's liquidity needs will be largely determined by the success of operations in regard to the commercialization of Avenova. The Company also may consider other plans to fund operations including: (1) out-licensing rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestones or an upfront fee; (2) raising additional capital through debt and equity financings or from other sources; (3) reducing spending on one or more of its sales and marketing programs; and/or (4) restructuring operations to change its overhead structure. The Company may issue securities, including common stock and warrants through private placement transactions or registered public offerings, which would require the filing of a Form S-1 or Form S-3 registration statement with the Securities and Exchange Commission ("SEC"). In the absence of the Company's completion of one or more of such transactions, there will be substantial doubt about the Company's ability to continue as a going concern within one year after the date these financial statements are issued, and the Company will be required to scale back or terminate operations and/or seek protection under applicable bankruptcy laws. The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to its ability to continue as a going concern.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Reclassifications

Prior period amounts in the accompanying consolidated balance sheets have been reclassified to conform to current period presentation. The reclassifications did not change total assets, total liabilities, or total stockholders' equity. Prior period amounts in the accompanying consolidated statements of operations and comprehensive loss have also been reclassified to conform to current period presentation. The reclassifications did not change the net loss or loss per share.

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

Use of Estimates

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

Cash and Cash Equivalents

The Company considers all highly-liquid instruments with a stated maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents are stated at cost, which approximates fair value. As of December 31, 2018, and December 31, 2017, the Company's cash and cash equivalents were held in two highly-rated, major financial institutions in the United States.

Beginning fiscal 2018, the Company adopted Accounting Standards Update ("ASU") No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires the statement of cash flows to explain the change during the period relating to total cash, cash equivalents, and restricted cash. The Company adopted this standard using the retrospective transition method by restating its consolidated statements of cash flows to include restricted cash of $474 thousand in beginning and ending cash, cash equivalents, and restricted cash for the period ended December 31, 2017, and $475 thousand in the ending cash, cash equivalents, and restricted cash balances for the period ended December 31, 2018. Net cash flows for years ended December 31, 2018 and 2017, did not change as a result of including restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period amounts presented on the statements of cash flows.

The following table provides a reconciliation of the cash, cash equivalents, and restricted cash reported in the consolidated balance sheet that sum to the total of the same reported in the consolidated statement of cash flows:

	Year Ended December 31,	
	2018	**2017**
Cash and cash equivalents	$3,183	$3,199
Restricted cash included in Other assets	475	474
Total cash, cash equivalents, and restricted cash in the statement of cash flows	$3,658	$3,673

The restricted cash amount included in Other assets on the consolidated balance sheet represents amounts held as certificate of deposit for long-term financing and lease arrangements as contractually required by our financial institution and landlord.

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

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

Deposits in these banks may exceed the amount of federal insurance provided on such deposits. The Company does not believe it is exposed to significant credit risk due to the financial position of the financial institutions in which these deposits are held.

During the years ended December 31, 2018, 2017 and 2016 revenues were derived primarily from sales of Avenova directly to three major distribution partners and to doctors through the Company's webstore.

As of December 31, 2018, December 31, 2017 and December 31, 2016 revenues from our major distribution or collaboration partners greater than 10% are as follows:

	Year Ended December 31,		
Major distribution or collaboration partner	**2018**	**2017**	**2016**
Distributer A	23%	22 %	20 %
Distributer B	26%	23 %	22 %
Distributer C	25%	21 %	16 %
Collaborator D	*	10 %	*

***Not greater than 10%**

As of December 31, 2018, and December 31, 2017 accounts receivable from our major distribution or collaboration partners greater than 10% are as follows:

	Year Ended December 31,	
Major distribution or collaboration partner	**2018**	**2017**
Distributer A	32 %	25 %
Distributer B	31 %	18 %
Distributer C	23 %	23 %
Collaborator D	*	23 %

***Not greater than 10%**

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

Fair Value of Financial Assets and Liabilities

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

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

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

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

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

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

Allowance for Doubtful Accounts

The Company charges bad debt expense and records an allowance for doubtful accounts when management believes it unlikely a specific invoice will be collected. Management identifies amounts due that are in dispute, and it believes are unlikely to be collected at the end of each reporting period. At December 31, 2018 and December 31, 2017, management had reserved $10 thousand and $13 thousand, respectively, primarily based on specific amounts that are in dispute or were over 120 days past due.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. At December 31, 2018 and 2017, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $104 thousand and $140 thousand, respectively.

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

Property and Equipment

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

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

Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with U.S. GAAP, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets. There were no impairment charges during the years ended December 31, 2018 and 2017. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values and the loss is recognized in the statements of operations.

Comprehensive Income (Loss)

ASC 220, *Comprehensive Income,* requires that an entity's change in equity or net assets during a period from transactions and other events from non-owner sources be reported. The Company reports unrealized gains and losses on its available-for-sale securities as other comprehensive income (loss).

Revenue Recognition

Beginning January 1, 2018, the Company has followed the provisions of ASC Topic 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized.

The Company generates product revenue through product sales to its major distribution partners, a limited number of other distributors and via its webstore. Product supply is the only performance obligation contained in these arrangements, and the Company recognizes product revenue upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to, generally upon shipment to the distributor on a "sell-in" basis.

Other revenue is primarily generated through commercial partner agreements with strategic partners for the development and commercialization of the Company's product candidates. The terms of the agreements typically include more than one performance obligation and generally contain non-refundable upfront fees, payments based upon achievement of certain milestones and royalties on net product sales.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. The Company's performance obligations include:

Product supply

Exclusive distribution rights in the product territory

Regulatory submission and approval services
Development services
Sample supply
Incremental discounts and product supply prepayments considered material rights to the customer

The Company has optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future commercial product supply and optional research and development services at the customer's or the Company's discretion are generally considered options. The Company assesses if these options provide a material right to the licensee and if so, such material rights are accounted for as separate performance obligations.

Transaction Price

The Company has both fixed and variable consideration. Under the Company's license arrangements, non-refundable upfront fees are considered fixed, while milestone payments are identified as variable consideration when determining the transaction price. Product supply selling prices are identified as variable consideration subject to the constraint on variable consideration for estimated discounts, rebates, chargebacks and product returns. Funding of research and development activities are considered variable payments until such costs are reimbursed, at which point they are considered fixed. The Company allocates the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

For product supply under the Company's distribution arrangements, contract liabilities are recorded for invoiced amounts that are subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. Because the Company does not have sufficient historical data to compute its own return rate, the return rate used to estimate the constraint on variable consideration for product returns is based on an average of peer and competitor company historical return rates. The Company updates the return rate assumption quarterly and applies it to the inventory balance that is held at the distributor and has not yet been sold through to the end customer. Payment for product supply is typically due 30 days after control transfers to the customer. At any point in time there is generally one month of inventory in the sales channel, therefore uncertainty surrounding constraints on variable consideration is generally resolved one month from when control is transferred.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur and achievement is in the control of the Company (such as a regulatory submission by the Company), the value of the associated milestone is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are

received.

For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

As part of the accounting for arrangements that contain multiple performance obligations, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. When a contract contains more than one performance obligation, the Company uses key assumptions to determine the stand-alone selling price of each performance obligation. The estimated stand-alone selling prices for distribution rights and material rights for incremental discounts on product supply are calculated using an income approach discounted cash flow model and can include the following key assumptions: forecasted commercial partner sales, product life cycle estimates, costs of product sales, commercialization expenses, annual growth rates and margins, discount rates and probabilities of technical and regulatory success. For all other performance obligations, the Company uses a cost-plus margin approach. The Company allocates the total transaction price to each performance obligation based on the estimated relative stand-alone selling prices of the promised goods or services underlying each performance obligation.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. Revenue is recognized for products at a point in time and for licenses of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time proportionate to the costs that the Company has incurred to perform the services using the cost-to-cost input method.

The Company's intellectual property in the form of distribution rights are determined to be distinct from the other performance obligations identified in the arrangements and considered "right to use" licenses which the customer can benefit from at a point in time. The Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license.

Cost of Goods Sold

Cost of goods sold includes third party manufacturing costs, shipping costs, and other costs of goods sold. Cost of goods sold also includes any necessary allowance for excess and obsolete inventory along with lower of cost and estimated net realizable value.

Research and Development Costs

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

Patent Costs

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

Stock-Based Compensation

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

Income Taxes

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

Common Stock Warrant Liabilities

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

Net Income (Loss) per Share

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

Basic EPS is computed by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period, including stock options and warrants, using the treasury stock method. In computing, diluted EPS, the average stock price for the period is used to determine the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted EPS computation in net loss periods because their effect would be anti-dilutive.

During the year ended December 31, 2018, the basic EPS was a net loss of $0.39 per share and the diluted EPS was a net loss of $0.46 per share due to the gain on changes in fair value of warrant liability.

The following table sets forth the calculation of basic EPS and diluted EPS:

	Year Ended December 31,		
	2018	**2017**	**2016**
Numerator			
Net loss	$(6,545)	$(7,403)	$(13,151)
Less gain on changes in fair value of warrant liability	(1,311)	—	—
Net loss, diluted	$(7,856)	$(7,403)	$(13,151)
Denominator			
Weighted average shares outstanding, basic	16,921	15,324	9,408
Net loss per share, basic	$(0.39)	$(0.48)	$(1.40)
Weighted average shares outstanding, basic	16,921	15,324	9,408
Effect of dilutive warrants	137	—	—
Weighted average shares outstanding, diluted	17,058	15,324	9,408
Net loss per share, diluted	$(0.46)	$(0.48)	$(1.40)

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

(in thousands)	Year Ended December 31, 2018	2017	2016
Stock options	3,374	2,960	1,489
Stock warrants	—	544	565
	3,374	3,504	2,054

Recent Accounting Pronouncements

In 2014, the Financial Accounting Standards Board (the "FASB") issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("Topic 606"). In 2015 and 2016, the FASB issued additional amendments to the new revenue guidance relating to reporting revenue on a gross versus net basis, identifying performance obligations, licensing arrangements, collectability, noncash consideration, presentation of sales tax, transition, and clarifying examples. Collectively, these are referred to as Topic 606, which replaces all legacy U.S. GAAP guidance on revenue recognition and eliminates all industry-specific guidance. The new revenue recognition guidance provides a unified model to determine how revenue is recognized. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In applying Topic 606, companies need to use more judgment and make more estimates than under the legacy guidance. This includes identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, allocating the transaction price to each distinct performance obligation, the level of effort required to satisfy performance obligations, and the period over which we expect to complete our performance obligations under the arrangement. As a result, the timing of recognition of revenue has more variability under the new revenue standard due to significant estimates involved in the new accounting. Topic 606, as amended, is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted one year earlier.

On January 1, 2018, the Company adopted Topic 606 using the modified retrospective method applied to those contracts that were not completed as of January 1, 2018. In addition, the Company has accounted for all contract modifications retrospectively for contracts in transition at the date of adoption by electing the contract modification practical expedient. Contract consideration has not been adjusted for the effects of a significant financing component if the time between the transfer of the good or service and payment timing is one year or less. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under Topic 605. See Note 8 for further information.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, to address the diversity in the classification and presentation of changes in restricted cash in the statement of cash flows by requiring entities to combine the changes in cash and cash equivalents and restricted cash in one line. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash in the statement of cash flows. Additionally, if more than one-line item is recorded on the balance sheet for cash and cash equivalents and restricted cash, a reconciliation between the statement of cash flows and balance sheet is required. The Company adopted the standard effective January 1, 2018 using the retrospective transition method. The impact of the adoption was not material to the consolidated statement of cash flows.

In February 2016, the FASB issued ASU 2016-02, *Financial Accounting for Leases.* Under this update, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a

lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP, which requires only capital leases to be recognized on the balance sheet, this ASU will require both types of leases to be recognized on the balance sheet. This ASU will also require disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements, providing additional information about the amounts recorded in the financial statements. In July 2018, the FASB issued ASU 2018-11, *Targeted Improvements*, which allows a transition option for entities to not apply the new lease standard in comparative periods presented in the financial statements in the year of adoption. The update also provides a practical expedient to allow lessors the option to combine lease and non-lease components. In December 2018, the FASB issued ASU 2018-20, *Leases (Topic 842)*, which provides narrow-scope improvements for lessors. These updates are effective for annual periods beginning after December 15, 2018, and interim periods thereafter. Early adoption is permitted. The Company plans to elect the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification, lease term and initial direct costs as well as the practical expedient to choose not to separate nonlease components from lease components and instead account for each as a single lease component for all classes of its assets. The Company also plans to elect ASU 2018-11 and as a result will not adjust the comparative period financial information or make the new required lease disclosures for periods before the effective date. The Company has updated its inventory of real estate, equipment, and automobile leases for attributes required by these standards, and anticipates the adoption of these standards will result in operating lease-related assets and liabilities of approximately $2.2 million and $2.5 million, respectively, recorded on the Consolidated Balance Sheets as of January 1, 2019 and no material impact to the Company's results of operations and cash flows.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception.* Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II simply replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. This ASU is effective for public companies for the annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company plans to adopt ASU 2017 -11 effective January 1, 2019 by applying the standards retrospectively to the Company's warrants with down round features by means of a cumulative-effect adjustment to the Company's accumulated deficit. The Company does not expect the adoption to have a material impact on the Company's financial position, results of operations and cash flows.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting (Topic 718),* that expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for certain specified exemptions. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company is currently evaluating the effects of the adoption of ASU 2018-07 to its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. This amendment modifies the disclosure requirements on fair value measurements. The guidance is effective for fiscal years ending after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company does not expect the adoption to have a material impact on the Company's financial position, results of operations and cash flows.

NOTE 3. FAIR VALUE MEASUREMENTS

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

The Company's cash equivalents and investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities and certificates of deposit. The types of investments that are generally classified within Level 2 of the fair value hierarchy include corporate securities and U.S. government securities.

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

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2018:

		Fair Value Measurements Using		
(in thousands)	**Balance at December 31, 2018**	**Quoted Prices in Active Markets for Identical Items (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Assets				
Cash equivalents	$103	$ 103	$ —	$ —
Restricted cash held as a certificate of deposit	324	324	—	—
Deposit held as a certificate of deposit	151	151	—	—
Total assets	$578	$ 578	$ —	$ —
Liabilities				
Warrant liability	$178	$ —	$ —	$ 178
Total liabilities	$178	$ —	$ —	$ 178

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2017:

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

For the year ended December 31, 2018, as a result of the fair value adjustment of the warrant liability, the Company recorded a non-cash gain on a change in the fair value of $1.3 million in its consolidated statements of operations and comprehensive loss. See Note 10 for further discussion on the calculation of the fair value of the warrant liability.

(in thousands)	**2018**	**2017**
Fair value of warrant liability at January 1	$1,489	$1,446
Fair value of warrants issued	—	—
Fair value of warrants transferred (to) from equity upon exercise	—	(58)
Decrease in fair value on exercise date and December 31	(1,311)	101
Fair value of warrant liability at December 31	$178	$1,489

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

(in thousands)	December 31, 2018	December 31, 2017
Prepaid sales rebates	$ 925	$ 923
Rent receivable	108	86
Prepaid rent	130	123
Prepaid employees' benefits	113	112
Prepaid fleet leasing costs	75	61
Prepaid dues and subscription	130	4
Other	279	354
Total prepaid expenses and other current assets	$ 1,760	$ 1,663

NOTE 5. INVENTORY

Inventory consisted of the following:

(in thousands)	December 31, 2018	December 31, 2017
Raw materials and supplies	$ 217	$ 298
Finished goods	167	346
Less: Reserve for excess and obsolete inventory	(104)	(140)
Total inventory, net	$ 280	$ 504

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

(in thousands)	December 31, 2018	December 31, 2017
Office and laboratory equipment	$ 24	$ 24
Furniture and fixtures	157	157
Computer equipment and software	385	354
Production equipment	65	105
Leasehold improvements	79	74
Total property and equipment, at cost	710	714
Less: accumulated depreciation and amortization	(509)	(243)
Total property and equipment, net	$ 201	$ 471

Depreciation and amortization expense was $266 thousand, $95 thousand and $114 thousand for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 7. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(in thousands)	December 31, 2018	December 31, 2017
Employee payroll and benefits	$ 708	$ 761
Severance/retirement pay	—	347
Distributer fees and discounts	—	185
Sales rebates	—	106
Avenova contract liabilities (see Note 8)	2,282	—
Deferred rent	101	69
Other	164	204
Total accrued liabilities	$ 3,255	$ 1,672

NOTE 8. ADOPTION OF TOPIC 606, "REVENUE FROM CONTRACTS WITH CUSTOMERS"

On January 1, 2018, the Company adopted Topic 606 using the modified retrospective method applied to those contracts that were not completed as of January 1, 2018. In addition, the Company has accounted for all contract modifications retrospectively for contracts in transition at the date of adoption by electing the contract modification practical expedient. Contract consideration has not been adjusted for the effects of a significant financing component if the time between the transfer of the good or service and payment timing is one year or less. Results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under Topic 605.

Transactions under the Company's major distribution agreements, which under prior guidance, were recognized upon shipment from its distributors to the final customers, are now recognized upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to. As a result, the Company now records contract liabilities for the invoiced amounts that are estimated to be subject to significant reversal, including product revenue allowances for cash consideration paid to customers for services, discounts, rebate programs, chargebacks, and product returns. The constraint on variable consideration for product returns is a new estimation resulting from the earlier recognition under the new guidance. Based on this change, the entire deferred revenue and deferred cost of goods sold balances related to its distribution agreements were allocated to either contract liabilities and other liabilities associated with invoicing in periods prior to adoption or included in the cumulative adjustment to retained earnings upon adoption.

Milestone payments, which under the prior milestone recognition methodology were not recognized until they were substantively achieved, are included in the estimated transaction price when they are considered probable of being achieved. This may result in earlier recognition of revenue for the portion of milestone payments deemed probable which are allocated to performance obligations that are satisfied before the milestones are achieved. For license and collaboration revenue for which contract deliverables were previously accounted for as a combined unit of accounting because products or services were 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, are 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 following table shows the reconciliation of assets and liabilities disclosed in the Form 10-K for the year ended December 31, 2017, as adjusted, due to the modified retrospective adoption of Topic 606 on January 1, 2018 (in thousands):

		Effect of

	As Reported Under Topic 605	Change	As Adjusted Under Topic 606
Accounts receivable	$3,629	$530	$4,159
Inventory	$504	$(25)	$479
Accrued liabilities	$1,672	$1,166	$2,838
Deferred revenue	$2,841	$(2,766)	$75
Deferred revenue, non-current	$534	$(534)	$-
Accumulated deficit	$(111,074)	$2,638	$(108,436)

As a result of adopting Topic 606 using the modified retrospective approach, the following table shows the financial statement line items for the year ended December 31, 2018, as if revenue from contracts with customers had been accounted for under Topic 605 (in thousands, except per share data):

	As Reported Under Topic 606	Effect of Change	As Revised Under Topic 605
Consolidated Balance Sheet:			
Accounts receivable	$3,385	$(358)	$3,027
Inventory	$280	$36	$316
Accrued liabilities	$3,255	$(1,979)	$1,276
Deferred revenue	$41	$3,853	$3,894
Accumulated deficit	$(114,981)	$(2,196)	$(117,177)
Total net sales	$12,508	$431	$12,939
Cost of product sales	$1,503	$(11)	$1,492
Loss from operations	$(7,871)	$442	$(7,429)
Net loss	$(6,545)	$442	$(6,103)
Basic net loss per share	$(0.39)	$0.03	$(0.36)
Diluted net loss per share	$(0.46)	$0.03	$(0.43)
Consolidated Statement of Cash Flows:			
Net loss	$(6,545)	$442	$(6,103)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accounts receivable	$774	$(172)	$602
Inventory	$198	$(11)	$187
Accounts payable and accrued liabilities	$516	$(844)	$(328)
Deferred revenue	$(34)	$584	$550

At December 31, 2018, approximately $41 thousand of transaction prices were allocated to unsatisfied performance obligations that the Company expects to be recognized during 2019.

For additional detail on the Company's accounting policy regarding revenue recognition, refer to Note 2 above.

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The following table presents changes in the Company's contract assets and liabilities for the year ended December 31, 2018:

	Balance at Beginning of the year	Additions	Deductions	Balance at the end of the year
	(in thousands)			
Contract Liabilities: Deferred Revenue	$75	$ -	$ (34)	$41
Contract Liabilities: Accrued Liabilities	1,458	13,716	(12,817)	2,357
Total	$1,533	$ 13,716	$ (12,851)	$2,398

During the year ended December 31, 2018, the Company recognized the following revenue (in thousands):

Revenue recognized in the year from:	
Amounts included in contract liabilities at the beginning of the year:	
Performance obligations satisfied	$1,453
New activities in the year:	
Performance obligations satisfied	11,055
Total revenue	$12,508

License Collaboration and Distribution Agreements

In January 2012, the Company entered into a distribution agreement with China Pioneer, a Shanghai-based company that markets high-end pharmaceutical products into China and an affiliate of Pioneer Pharma (Singapore) Pte. Ltd. ("Pioneer Singapore"), for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, NovaBay received an upfront payment of $312,500. NovaBay also received $312,500 in January 2013 related to the submission of the first marketing approval for the product to the Chinese Food and Drug Administration ("CFDA"). The deferred revenue was recognized as the purchase discounts were earned, with the remaining deferred revenue recognized ratably over the product distribution period. During the year ended December 31, 2014, NovaBay received $625,000 upon receipt of a marketing approval of the product from the CFDA.

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

Pursuant to the terms of the Distribution Agreement, China Pioneer has the right to distribute NeutroPhase, upon a marketing approval from a Regulatory Authority (as defined in the Distribution Agreement) in certain territories in Asia (other than China). Upon execution of the Distribution Agreement, the Company received an upfront payment, which was recorded as deferred revenue. China Pioneer is also obligated to make certain additional payments to the Company upon receipt of the marketing approval. The Distribution Agreement further provides that China Pioneer is entitled to a cumulative purchase discount not to exceed $500,000 upon the purchase of NeutroPhase products, payable in NovaBay unregistered restricted common stock.

Pursuant to the Purchase Agreement, the Company also received $2.5 million from China Pioneer for the purchase of restricted units (with each restricted unit comprising one share of common stock and a warrant for the purchase of one share of common stock). The unit purchase was completed in two tranches: (1) 800,000 units in September 2012; and (2) 1,200,000 units in October 2012, with both tranches at a purchase price of $1.25 per unit. The fair value of the total units sold was $3.5 million, based upon the trading price of our common stock on the dates the units were purchased and the fair value of the warrants based on the Black-Scholes Merton option pricing model. Because the aggregate fair value of the units on the dates of purchase exceeded the $2.5 million in proceeds received from the unit purchase by approximately $1 million, we reallocated $600,000 from deferred revenue to stockholders' equity as consideration for the purchase of the units.

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

On February 7, 2012, the Company entered into a distribution agreement with Integrated Healing Technologies, LLC ("IHT") to distribute NeutroPhase. NovaBay received an upfront payment of $750,000.

In April 2013, the Company entered into a collaboration and license agreement with Virbac. Under this agreement, Virbac acquired exclusive worldwide rights to develop the Company's proprietary compound, auriclosene (NVC-422), for global veterinary markets for companion animals. The Company received an upfront payment of $250,000.

On June 1, 2013, the Company entered into a distribution agreement with Principal Business Enterprise Inc. ("PBE") to distribute NeutroPhase. NovaBay received an upfront payment of $200,000.

Revenue has been recognized under these agreements as follows:

	Year Ended December 31,	
(in thousands)	**2018**	**2017**
Amortization of upfront technology and access fees	$34	$103
Product revenue	169	1,956
Total revenue recognized	$203	$2,059

The Company had a deferred revenue balance of $2.0 million at December 31, 2017 related to these agreements, which consisted of the unamortized balances from upfront technology and access fees. Upon the adoption of Topic 606, deferred revenue decreased by $1.96 million and was recorded as part of the cumulative adjustment to the accumulated deficit. The decrease in deferred revenue related primarily to the identification of the licenses as "right of use" licenses under the current guidance for which control transferred to the customer at the onset of each contract. At December 31, 2018, the Company had deferred revenue of $41 thousand that relates to unsatisfied performance obligations of sample supply due to Pioneer China and PBE and an incremental discount on future product sales due to Pioneer China.

Avenova Distribution Agreements

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

Company also signed a distribution agreement with AmerisourceBergen to distribute Avenova nationwide.

During the years ended December 31, 2018 and 2017, the Company earned $11.0 million and $13.6 million, respectively, in sales revenue for its Avenova product from its distribution agreements.

The Company had a deferred revenue balance of $1.3 million at December 31, 2017 related to these agreements, which consisted of product sales that our customers had not resold to end users (sell-through approach). Upon the adoption of Topic 606, deferred revenue decreased by $1.3 million, with a portion associated with the constraint on variable consideration related to service fees/chargebacks, prompt payment discounts, rebates and returns in the amount of $0.6 million being reclassified as a contract liability. The remaining $0.7 million, including the net effect of deferred cost of goods sold, was recorded as part of the cumulative adjustment to the accumulated deficit. With the adoption of Topic 606, we recognize product sales as revenue when our products are sold to our customers.

At December 31, 2018, under the Avenova product distribution arrangements, the Company had a contract liability balance of $2.4 million. The contract liability is included in accounts payable and accrued liabilities in the balance sheet (see Note 7).

NOTE 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

On August 24, 2016, we entered into an Office Lease (the "Lease"), pursuant to which we leased approximately 7,799 rentable square feet of real property located on the eleventh floor (Suite 1150) at 2000 Powell Street, Emeryville, California 94608 from KBSIII Towers at Emeryville, LLC (the "Landlord"), for our new principal executive offices. The expiration date of the Lease is February 28, 2022, unless earlier terminated pursuant to any provision of the Lease. The Company has the option to extend the term of the Lease for one five (5)-year period upon written notice to the Landlord due no earlier than twelve (12) months and no later than nine (9) months prior to the expiration of the Lease.

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

Rent expense, net was $385 thousand, $389 thousand and $938 thousand for the years ended December 31, 2018, 2017 and 2016, respectively. The future minimum lease payments under these non-cancellable operating leases were as follows as of December 31, 2018:

(in thousands)	**Lease Commitment**
Year ending December 31:	
2019	$ 1,116
2020	1,025
2021	438
2022	75
2023	-
Thereafter	-
Total lease commitment	$ 2,654

The Company's monthly rent payments fluctuate under the master lease agreements. In accordance with U.S. GAAP, the Company recognizes rent expense on a straight-line basis, and records deferred rent for the difference between the amounts paid and recorded as expense. At December 31, 2018 and 2017, the Company had $286 thousand and $355 thousand of deferred rent, respectively.

Sub-lease rental reimbursement is not deducted from the above table. The Company anticipates collecting $690 thousand, and $577 thousand in the years ending December 31, 2019 and 2020, respectively.

Vehicle Fleet Leases

During the year ended December 31, 2018, the Company leased 54 vehicles under a master fleet lease agreement. Each lease is for a period of 36 months, which commenced upon the delivery of the vehicle. As of December 31, 2018, the aggregate monthly lease payment for all 54 vehicles is $14 thousand, including a management fee of $15 per vehicle. In addition, the Company made an initial payment of $3 thousand per vehicle, which it is amortizing over the 36-month lease period.

Lease expense, net, for the vehicle fleet was approximately $120 thousand and $94 thousand for the years ended December 31, 2018 and 2017, respectively.

Directors and Officers Indemnity

As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director or officer insurance policy that limits its exposure and may enable it to recover a portion of any future payments. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, it has not recorded any liabilities for these agreements as of December 31, 2018.

In the normal course of business, the Company provides indemnifications of varying scope under its agreements with other companies, typically its clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, it generally indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with use or testing of its products or product candidates or with any U.S. patent or any copyright or other intellectual property infringement claims by any third party with respect to its products. The term of these indemnification agreements is generally perpetual. The

potential future payments the Company could be required to make under these indemnification agreements is unlimited. Historically, costs related to these indemnification provisions have been immaterial. The Company also maintains various liability insurance policies that limit its exposure. As a result, it believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2018.

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. There are no matters as of December 31, 2018 that, in the opinion of management, would ultimately result in liability that would have a material adverse effect on the Company' financial position, results of operations or cash flows.

NOTE 10. WARRANT LIABILITY

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

In October 2015, the holders of all warrants issued pursuant to the Company's securities purchase agreement dated March 3, 2015 (the "2015 Securities Purchase Agreement") agreed to reduce the length of notice required to such investors prior to the Company's issuance of new securities from twenty business days to two business days, for the remainder of such investors' pre-emptive right period (which expired March 3, 2016). The Company entered into these agreements to enable it to expeditiously raise capital in the October 2015 Offering (as described below) and future offerings. As consideration for these agreements, the Company amended certain provisions of both the warrants with a 15-month term (the "Short-Term Warrants") and warrants with a five-year term (the "Long-Term Warrants") issued pursuant to the 2015 Securities Purchase Agreement (together, the "March 2015 Warrants") and the warrants issued pursuant to the placement agent agreement dated June 29, 2011 (the "July 2011 Warrants"). Specifically, the

amendments decreased the exercise price for both the March 2015 Warrants and the July 2011 Warrants to $5.00 per share. In addition, the amendments extended the exercise expiration date for the Short-Term Warrants and the July 2011 Warrants to March 6, 2020. A price protection provision also was added to both the July 2011 Warrants and March 2015 Warrants, such that if the Company subsequently sells or otherwise disposes of Company common stock at a lower price per share than $5.00 or any securities exchangeable for common stock with a lower exercise price than $5.00, the exercise price of such warrants will be reduced to that lower price.

In October 2015, the Company also entered into an underwriting agreement with Roth Capital Partners, LLC, relating to the public offering and sale of up to (i) 492,000 shares of the Company's common stock; and (ii) warrants to purchase up to 442,802 shares of the Company's common stock (the "October 2015 Warrants") with an exercise price of $5.00 per share (the "October 2015 Offering"). The shares of common stock and warrants were issued separately. Each warrant was exercisable immediately upon issuance and will expire 60 months from the date of issuance. The price to the public in the October 2015 Offering was $5.00 per share of common stock and related warrant. The net proceeds to the Company were approximately $2.1 million after deducting underwriting discounts and commissions and offering expenses.

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

The key assumptions used to value the July 2011 Warrants as of December 31, 2018 and December 31, 2017 were as follows:

	Year Ended December 31,	
Assumption	**2018**	**2017**
Expected price volatility	77 %	91 %
Expected term (in years)	1.18	2.18
Risk-free interest rate	2.60%	1.91%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$0.29	$2.72

In March 2015, the Company issued both the Short-Term Warrants ($15.00 per share exercise price) and the Long-Term Warrants ($16.25 per share exercise price). At that time, the Company determined that these warrants qualified for equity accounting and did not contain embedded derivatives that required bifurcation. After the Company's agreement to modify the terms of the March 2015 Warrants and July 2011 Warrants in October 2015, the Company evaluated the change in terms of the March 2015 Warrants and noted that the change in terms resulted in liability classification of both the Short-Term and Long-Term Warrants. The March 2015 Warrants were re-issued and valued as of October 27, 2015 at a total of $1.8 million with the new terms, and a modification expense was recorded at the difference between the fair value of the warrants on their new terms after modification as of October 27, 2015 and the fair value of the warrants on their original terms prior to modification as of October 27, 2015. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss.

The key assumptions used to value the Short-Term Warrants as of December 31, 2018, and December 31, 2017 were as follows:

	Year Ended December 31,	
Assumption	**2018**	**2017**
Expected price volatility	77 %	91 %
Expected term (in years)	1.18	2.18
Risk-free interest rate	2.60%	1.91%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$0.24	$2.42

The key assumptions used to value the Long-Term Warrants as of December 31, 2018, and December 31, 2017 were as follows:

Assumption	Year Ended December 31, 2018	2017
Expected price volatility	77 %	91 %
Expected term (in years)	1.18	2.18
Risk-free interest rate	2.60%	1.91%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$0.29	$2.72

As noted above, the Company issued warrants in connection with the October 2015 Offering. The Company evaluated the terms of the October 2015 Warrants and noted that under ASC 480, the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company's control. Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss. The fair value of the warrants at issuance on October 27, 2015 was $1.3 million.

The key assumptions used to value the October 2015 warrants as of December 31, 2018, and December 31, 2017 were as follows:

	Year Ended December 31,	
Assumption	**2018**	**2017**
Expected price volatility	73 %	90 %
Expected term (in years)	1.83	2.83
Risk-free interest rate	2.51%	1.96%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$0.38	$2.86

During the third quarter of 2016, a total of 3,613,284 warrants to purchase 3,613,284 shares of common stock were exercised related to the July 2011, March 2015 and October 2015 warrants resulting in gross proceeds of $6.9 million. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $1.6 million, with any change in fair value recorded in the consolidated statements of operations and comprehensive loss. The $1.6 million fair value was subsequently transferred to equity as of the date of their exercise.

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

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

The details of all outstanding warrant liability as of December 31, 2018, were as follows:

Shares and dollars in thousands	Shares	Warrant Liability
July 2011 Warrants	49	$ 15
Long-Term Warrants	96	28

Short-Term Warrants	115	28
October 2015 Warrants	284	107
	544	$ 178

NOTE 11. STOCKHOLDERS' EQUITY (DEFICIT)

Amendments to Certificate of Incorporation – Reverse Stock Split

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

After approval by the Company's stockholders, the Company decreased the number of authorized shares from 240 million to 50 million effective June 4, 2018.

Preferred Stock

Under the Company's Amended and Restated Certificate of Incorporation, the Company is authorized to issue up to 5,000,000 shares of preferred stock in such series and with such rights and preferences as may be approved by the Board of Directors. As of December 31, 2018 and December 31, 2017, there were no shares of preferred stock outstanding.

Common Stock

In February 2016, the Company entered into three securities purchase agreements (the "Purchase Agreements") for the sale of an aggregate of 1,518,567 shares of the Company's common stock (the "Common Stock") to accredited investors for a total of $2.8 million. The Company entered into the first purchase agreement with Mr. Jian Ping Fu (the "Fu Agreement"), pursuant to which the Company agreed to issue and sell to Mr. Fu 696,590 shares of Common Stock, at a per share price of $1.81, which was a five percent (5%) discount to the closing price of the Common Stock on February 16, 2016, the date of the Fu Agreement. The Company entered into the second purchase agreement with Pioneer Singapore (the "Pioneer Agreement"), pursuant to which the Company agreed to issue and sell to Pioneer Singapore 696,590 shares of Common Stock, at a per share price of $1.91, which was the closing price of the Common Stock on February 16, 2016 with no discount. The Company entered into a third purchase agreement with Mark M. Sieczkarek (the "Sieczkarek Agreement"), pursuant to which the Company agreed to issue and sell to Mr. Sieczkarek 125,387 shares of Common Stock, at a per share price of $1.91, which was the closing price of the Common Stock on February 16, 2016 with no discount. The Common Stock issued by the Company pursuant to the Purchase Agreements has not been registered under the Securities Act and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

China Kington Asset Management Co. Ltd. served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds received by the Company upon closing pursuant to the purchases by Pioneer Singapore and Mr. Fu. The amount of such commission was approximately $155 thousand.

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

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

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

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

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

During the first quarter of 2018, we entered into a share purchase agreement with OP Financial Investments Limited for the sale of an aggregate of 1,700,000 shares of the Company's common stock, par value $0.01 per share, for an aggregate purchase price of $5.984 million (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 thousand. The Company also paid $34 thousand to NYSE American for the listing of the additional shares.

Stock Warrants

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

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

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

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

The following table summarizes information about the Company's warrants outstanding at December 31, 2018, 2017 and 2016, and activity during the three years then ended.

(in thousands)	**Warrants**	**Weighted-Average Exercise Price**
Outstanding at December 31, 2015	1,458	$ 5.19
Warrants granted	3,087	$ 1.91
Warrants exercised	(3,977)	$ 1.95
Warrants expired	(3)	$ 78.13
Outstanding at December 31, 2016	565	$ 1.81

Warrants granted	-	$ -
Warrants exercised	(21)	$ 1.81
Warrants expired	-	$ -
Outstanding at December 31, 2017	544	$ 1.81
Warrants granted	-	$ -
Warrants exercised	-	$ -
Warrants expired	-	$ -
Outstanding at December 31, 2018	544	$ 1.81

NOTE 12. EQUITY-BASED COMPENSATION

Equity Compensation Plans

In October 2007, the Company adopted the 2007 Omnibus Incentive Plan (the "2007 Plan") to provide for the granting of equity awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants, as determined by the Board of Directors. At the inception of the 2007 Plan, 40,000 shares were reserved for awards under the 2007 Plan.

For the years from 2009 to 2012, the number of shares of common stock authorized for awards under the 2007 Plan increased annually in an amount equal to the lesser of (a) 40,000 shares; (b) 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding year; or (c) such lesser number as determined by the Board. Accordingly, an additional 40,000, 37,427, and 37,207 shares of common stock were authorized for awards under the 2007 Plan in January 2012, 2011 and 2010, respectively. Beginning in 2013, the shareholders voted to remove the 40,000 share cap and the 2007 Plan's shares authorized for awards increased annually by 4% of the number of shares of the Company's common stock outstanding on the last day of the preceding year. Accordingly, an additional 32,646 and 59,157 shares of common stock were authorized for awards under the 2007 Plan in January 2014 and 2013, respectively. On March 30, 2015, the Company filed a registration statement to add an additional 82,461 shares to the 2007 Plan's shares authorized for awards. In January 2016, the Company added 139,449 shares to the 2007 Plan's shares authorized for awards, per the 2007 Plan's evergreen provision. On May 26, 2016, the stockholders of the Company approved an amendment to the 2007 Plan to increase the number of shares of Company common stock authorized for awards thereunder by 1,124,826 shares. In January 2017, the Company added 610,774 shares to the 2007 Plan's shares authorized for awards, per the 2007 Plan's evergreen provision. As a result of the foregoing, the aggregate number of shares authorized for awards under the 2007 Plan was 2,318,486 shares, prior to its expiration on March 15, 2017 (after taking into account prior awards under the 2007 Plan).

Upon expiration of the 2007 Plan, new awards cannot be issued pursuant to the 2007 Plan, but awards outstanding as of its March 15, 2017 plan expiration date will continue to be governed by its terms. Under the terms of the 2007 Plan, the exercise price of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and, if granted to an owner of more than 10% of the Company's stock, then not less than 110% of the fair market value of the common stock on the date of grant. Stock options granted under the 2007 Plan expire no later than ten years from the date of grant. Stock options granted to employees generally vest over four years, while options granted to directors and consultants typically vest over a shorter period, subject to continued service.

In March 2017, the Company adopted the 2017 Omnibus Incentive Plan (the "2017 Plan"), which was approved by shareholders on June 2, 2017, to provide for the granting of equity awards, such as nonqualified stock options

("NQSOs"), incentive stock options ("ISOs"), restricted stock, performance shares, stock appreciation rights ("SARs"), restricted stock units ("RSUs") and other share-based awards to employees, directors, and consultants, as determined by the Board of Directors. The new 2017 Plan will not affect awards previously granted under the 2007 Plan. The 2017 Plan allows for awards of up to 2,318,486 shares of the Company's common stock, plus an automatic annual increase in the number of shares authorized for awards on the first day of each of the Company's fiscal years beginning January 1, 2018 through January 1, 2027 equal to (i) four percent of the number of shares of Common Stock outstanding on the last day of the immediately preceding fiscal year or (ii) such lesser number of shares of Common Stock than provided for in Section 4(a)(i) of the 2017 Plan as determined by the Board. As of December 31, 2018, there were 1,188,485 shares available for future awards under the 2017 Plan.

Under the terms of the 2017 Plan, the exercise price of NQSOs, ISOs and SARs may not be less than 100% of the fair market value of the common stock on the date of grant and, if ISOs are granted to an owner of more than 10% of the Company's stock, then not less than 110% of the fair market value of the common stock on the date of grant. The term of awards will not be longer than ten years, or in the case of ISOs, not longer than five years with respect to holders of more than ten percent of the Company's stock. Stock options granted to employees generally vest over four years, while options granted to directors and consultants typically vest over a shorter period, subject to continued service. The Company issues new shares to satisfy option exercises under the 2007 and 2017 plans.

Stock Option Summary

The following table summarizes information about the Company's stock options and restricted stock outstanding at December 31, 2018, 2017 and 2016, and activity during the three years then ended:

(in thousands, except years and per share data)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2015	388	$ 32.03	6.2	$ 19
Options granted	1,227	$ 2.74		
Restricted stock units granted	104	$ —		
Options exercised	-	$ —		
Restricted stock units vested	(114)	$ —		
Options forfeited/cancelled	(116)	$ 28.27		
Restricted stock units cancelled	-	$ —		
Outstanding at December 31, 2016	1,489	$ 8.38	8.7	$ 702
Options granted	1,616	$ 3.03		
Restricted stock units granted	49	$ —		
Options exercised	(68)	$ 2.72		
Restricted stock units vested	(39)	$ —		
Options forfeited/cancelled	(87)	$ 22.08		
Restricted stock units cancelled	-	$ —		
Outstanding at December 31, 2017	2,960	$ 5.16	8.6	$ 2,586
Options granted	1,118	$ 2.03		
Restricted stock units granted	12	$ —		
Options exercised	(4)	$ 2.35		
Restricted stock units vested	-	$ —		
Options forfeited/cancelled	(701)	$ 5.12		
Restricted stock units cancelled	(11)	$ —		
Outstanding at December 31, 2018	3,374	$ 4.13	8.2	$ 8
Vested and expected to vest at December 31, 2018	2,898	$ 4.40	8.2	$ 8
Vested at December 31, 2018	1,675	$ 5.96	7.4	$ —
Exercisable at December 31, 2018	1,675	$ 5.96	7.4	$ —

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of the Company's common stock as quoted on the NYSE American as of December 31, 2018 for options that have a quoted market price in excess of the exercise price. There were 4 thousand stock option awards exercised for the year ended December 31, 2018 for which the Company received cash payments of $11 thousand. There was no intrinsic value for stock option awards exercised for the year ended December 31, 2018. There were 68 thousand stock option awards exercised for the year ended December 31, 2017 for which the Company received cash payments of $185 thousand. The aggregate intrinsic value of stock option awards exercised was $116 thousand for the year ended December 31, 2017. There were no stock option awards exercised during the year ended December 31, 2016. Accordingly, the Company received no cash payments for the exercise of stock options during the year ended December 31, 2016. As of December 31, 2018, total unrecognized compensation cost related to unvested stock options and restricted stock was approximately $1.7 million. This amount is expected to be recognized as stock-based compensation expense in the Company's consolidated statements of operations and comprehensive loss over the remaining weighted average vesting period of 3.01 years.

Stock Option Awards to Employees and Directors

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

During the years ended December 31, 2018, 2017 and 2016, the Company granted options to employees and directors to purchase an aggregate of 1,085,000, 1,529,000, and 1,139,000 shares of common stock, respectively.

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

	Year Ended December 31,		
Assumption	**2018**	**2017**	**2016**
Expected price volatility	89.30%	87.78%	84.47%
Expected term (in years)	5.98	6.90	7.03
Risk-free interest rate	2.80 %	2.12 %	1.57 %
Dividend yield	0.00 %	0.00 %	0.00 %
Weighted-average fair value of options granted during the period	$1.51	$2.34	$2.06

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

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

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

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

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

In addition, the Company granted restricted stock to employees totaling 12,000, 10,000, and 64,000 shares of common stock in the years ended December 31, 2018, 2017 and 2016, respectively.

For the years ended December 31, 2018, 2017 and 2016, we recognized stock-based compensation expense of $671 thousand, $2,371 thousand, and $1,489 thousand, respectively, for option awards to employees and directors.

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

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

In March 2018, the Company modified stock options held by Mr. Liu, who resigned as a director of the Company, effective March 21, 2018. The option exercise period for Mr. Liu was extended from three months to three years, calculated from his date of resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $26 thousand.

Stock-Based Awards to Non-Employee Consultants

During the years ended December 31, 2018, 2017 and 2016, the Company granted options to purchase an aggregate of 33,000, 86,000, and 89,000 shares of common stock, respectively, to non-employees in exchange for advisory and consulting services. The stock options are recorded at their fair value on the measurement date and recognized over the respective service or vesting period. The fair value of the stock options granted was calculated using the Black-Scholes-Merton option pricing model based upon the following assumptions:

	Year Ended December 31,		
Assumption	**2018**	**2017**	**2016**
Expected price volatility	85.03%	87.41%	87.68%
Expected term (in years)	10.0	10.0	10.0
Risk-free interest rate	2.94 %	2.27 %	1.61 %
Dividend yield	0.00 %	0.00 %	0.00 %
Weighted-average fair value of options granted during the period	$1.99	$2.40	$2.29

The Company did not grant restricted stock to non-employees in year ended December 31, 2018. The Company granted 31 thousand shares of fully vested registered stock to non-employee Dr. Ron Najafi in the year ended December 31, 2017, as part of his settlement agreement, as described below. In addition, the Company also granted restricted stock to a non-employee consultant totaling 8 thousand shares of common stock in the year ended December 31, 2017, in exchange for advisory and consulting services. Lastly, Company granted restricted stock to non-employees totaling 41,000 shares of common stock in the year ended December 31, 2016, in exchange for advisory and consulting services.

For the years ended December 31, 2018, 2017 and 2016, the Company recognized stock-based compensation expense of $0, $243 thousand, and $262 thousand, respectively, related to non-employee options and restricted stock grants.

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

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

terms, and the shares were issued to him via fully vested restricted stock in March 2016.

Summary of Stock-Based Compensation Expense

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

	Year Ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
Research and development	$32	$113	$195
Sales and Marketing	141	152	132
General and administrative	498	2,277	1,424
Total stock-based compensation expense	$671	$2,542	$1,751

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

NOTE 13. EMPLOYEE BENEFIT PLAN

We have a 401(k) plan covering all eligible employees, and we are not required to contribute to the plan. For the years ended December 31, 2018 and 2017, we made $14 thousand and $0 contributions to the plan, respectively.

NOTE 14. INCOME TAXES

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

	Year Ending December		
(in thousands)	**2018**	**2017**	**2016**
Current			
Federal	$—	$ —	$ —
State	4	3	2
Other	—	—	—
Total current tax expense	4	3	2
Deferred			
Federal	—	—	—
State	—	—	—
Other	—	—	—
Total deferred tax expense	—	—	—
Income tax provision	$4	$ 3	$ 2

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

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

	December 31	
(in thousands)	**2018**	**2017**
Deferred tax assets:		
Net operating losses	$26,790	$25,564
Accruals	446	225
Deferred revenue	10	508
Stock options	1,425	1,556
Other deferred tax assets	716	727
Property and equipment	9	—
Total deferred tax assets	29,396	28,580
Deferred tax liabilities:		
Property and equipment	—	(35)
Total deferred tax liabilities	—	(35)
Valuation allowance	(29,396)	(28,545)
Net deferred taxes	$—	$—

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Act") was signed into law resulting in significant changes to the Internal Revenue Code. The Act, among other things, reduced the federal corporate income tax rate from 35% to 21% effective for tax years beginning after December 31, 2017. Consequently, the Company's net deferred tax assets as of December 31, 2017 were significantly reduced to reflect the estimated impact of the Tax Act. Due to the Company's lack of earnings history and uncertainties surrounding the ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance as mentioned above. The significant reduction in the deferred tax assets are fully offset by a reduction in the valuation allowance.

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

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

2018	2017	2016
$851	$(10,100)	$3,642

Net operating loss and tax credit carryforwards as of December 31, 2018, are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal (Post December 31, 2017)	$5,216	Do Not Expire
Net operating losses, federal (Pre January 1, 2018)	$94,886	2024 - 2037
Net operating losses, state	$84,078	2028 - 2038
Tax credits, federal	$1,316	2026 - 2035
Tax credits, state	$325	Indefinite

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

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

Year Ending December 31

(in thousands)	2018	2017	2016
Income tax provision (benefit) at federal statutory rate	$(1,374)	$(2,516)	$(4,471)
State tax	20	(12)	(157)
Stock based compensation expense for GAAP	283	154	52
Change in valuation allowance	851	(10,484)	3,641
Revaluation of warrant liability	(275)	34	806
Tax credits	—	—	(31)
Other	33	(49)	162
Section 162(m) disallowance	(88)	336	—
Tax Reform - Tax Rate Change	—	12,540	—
Impact of ASC 606	554	—	—
Total	$4	$3	$2

Uncertain Income Tax Positions

The Company adopted the provisions of ASC 740-10, *Accounting for Uncertainty in Income Taxes*, on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the years ended December 31, 2018 and 2017 is as follows:

	Year ended December 31,	
(in thousands)	2018	2017
Unrecognized benefit - beginning of period	$931	$974
Gross increases/ (decreases) - prior/current period tax positions	43	(43)
Unrecognized benefit - end of period	$974	$931

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

NOTE 15. RELATED PARTY TRANSACTIONS

Related Party Revenue

The Company recognized related party revenues from product sales and license and collaboration fees of $77 thousand, $27 thousand, and $418 thousand for the years ended December 31, 2018, 2017 and 2016, respectively. In fulfillment of the performance obligations under this contract, the company supplied product samples with a cost of $426 thousand, $102 thousand, and $0 for the years ended December 31, 2018, 2017 and 2016, respectively. These costs were recorded as a sales and marketing expense. Related party accounts receivable as of December 31, 2018 was $39 thousand. There was no related party accounts receivable as of December 31, 2017. See Note 8, "Adoption of Topic 606, "*Revenue from contracts with customers*", for additional information regarding the Company's distribution agreements with China Pioneer, which is an affiliate of Pioneer Singapore, the Company's largest stockholders.

Related Party Expenses

The Company recognized related party commission fees of $0.4 million, $0, and $1.1 million for the years ended December 31, 2018, 2017 and 2016, respectively. These fees were paid to China Kington, representing the commission on sale of the Company's common stock and the exercise of the Company's warrants. See Note 11, "Stockholders' Equity (Deficit)" – "Common Stock" for additional information regarding such commissions.

Related Party Financing

On February 27, 2019, the Company issued a promissory note payable to Pioneer Pharma (Hong Kong) Company Limited ("Pioneer Hong Kong"). Details regarding the February 2019 Loan are described in Note 16 (Subsequent Events) of the Notes to Consolidated Financial Statements.

NOTE 16. SUBSEQUENT EVENTS

As disclosed in our Current Reports on Form 8-K filed on March 11, 2019 and March 12, 2019, the Company announced a refocus in the Company's business strategy. While continuing to focus on the sales growth of Avenova in the United States, the Company will strategically shift its commercialization strategy to focus on high performing territories and territories identified as having significant prescription volume potential along with favorable health plan coverage while continuing to focus on contracting with additional specialty pharmacies as channel partners. In line with the Company's refocused business strategy, the Company has announced changes in the Company's management team including: (i) Mr. McGovern resigning as the Interim President and Chief Executive Officer, Chief Financial Officer and Treasurer; (ii) the Board appointing Justin Hall to serve as Interim President and Chief Executive Officer in addition to his role as General Counsel and Chief Compliance Officer; and (iii) the Board appointing Jason Raleigh as the Interim Chief Financial Officer and Treasurer, who previously served as the Company's Corporate Controller. Further, Paul E. Freiman, who previously served at the Board's Lead Independent Director, was nominated to lead the Board as Chairman.

On February 27, 2019, the Company issued a promissory note payable to Pioneer Hong Kong, loaning the Company $1.0 million (the “February 2019 Loan”). The loan includes an interest payment of $150 thousand and is payable in full upon the Company's next financing with Pioneer Hong Kong and in no event after July 27, 2019. The loan was facilitated by China Kington Asset Management Co. Ltd. ("China Kington") which has a perfected security interest in all tangible and intangible assets of the Company. In connection with the February 2019 Loan, the Company must pay China Kington a 2% fee for brokering the transaction and enter into a consulting agreement with China Kington for the term of one year to facilitate closer oversight of the Company's expenses and strategic direction by the Board of Directors. Bob Wu, acting in a dual role as a member of the Company’s Board of Directors and as principal of China Kington, will be paid $100,000 pursuant to this consulting agreement.

On March 25, 2019, the Company entered into a Term Sheet (the “Term Sheet”) with Triton Funds LP, a Delaware company (“Triton”). Pursuant to the Term Sheet, upon the transaction closing, Triton will have the right to purchase shares of common stock of the Company up to a value of $3,000,000 (the “Shares”) at a purchase price equal to 90% of the lowest trading price of the Company’s common stock for the five business days prior to the closing date. In addition, the Term Sheet requires a donation of 150,000 shares of common stock to Triton Funds LLC (the “Donation Shares”) and a document preparation fee of $15,000. The Term Sheet also requires that a Form S-3 be filed by April 1, 2019 to register the Shares and Donation Shares with the Securities and Exchange Commission.

On March 26, 2019 (the “Closing Date”), the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with Iliad Research and Trading, L.P. (the “Lender”), pursuant to which the Company issued a Secured Convertible Promissory Note (the “Convertible Note”) to the Lender dated as of the Closing Date. The Convertible Note has an original principal amount of $2,215,000, bears interest at a rate of 10% per annum and will mature on September 26, 2020, unless earlier paid, redeemed or converted in accordance with its terms. The Company received

proceeds of $2,000,000 after an original issue discount and payment of Lender's legal fees.

The Convertible Note provides the Lender with the right to convert, at any time, all or any part of the outstanding principal and accrued but unpaid interest into shares of the Company's common stock at a conversion price of $1.65 per share ("Lender Conversion Price") or the Market Price. The Market Price is defined as 85% of the lowest closing bid price during the twenty (20) Trading Days immediately preceding the applicable measurement date.

Pursuant to a Security Agreement between the Company and the Lender, repayment of the Convertible Note is secured by all of the assets of the Company. The assets covered by the Security Agreement are currently encumbered by that certain lien of up to $1,000,000, plus accrued and unpaid interest and fees, in favor of Pioneer Hong Kong described above.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

Based upon that evaluation at December 31, 2018, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure, at the reasonable assurance level, that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018. Our management utilized the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission to conduct an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2018. Our management has concluded that, as of December 31, 2018, our internal control over financial reporting was effective based on these criteria.

Changes in Internal Control Over Financial Reporting

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

The names of the Company's current directors and nominees, their ages, and positions with us as of March 29, 2019, and biographical information about them, are as follows:

Paul E. Freiman, age 84, has served as a director of the Company since May 2002 and was appointed Chairman of the Company's Board of Directors (the "Board") in March 2019 after serving as the Company's Lead Independent Director. Since January 2009, Mr. Freiman has been an independent pharmaceutical professional and consultant. Currently, he is also board chairman of Chronix Biomedical Inc., a private molecular diagnosis company. Mr. Freiman's prior experience includes serving as the president and chief executive officer of Neurobiological Technologies, Inc. (OTC: NTII) and a member of its board of directors from April 1997 until 2009. Mr. Freiman's prior experience also includes serving as the former chairman and chief executive officer of Syntex from 1989 to 1994. He is credited with much of the marketing success of Syntex's lead product, Naprosyn, and was responsible for moving the product to over-the-counter status, marketed as Aleve. Mr. Freiman served as chairman of the board of Neurotrope, Inc. (OTCBB: BLFL) from 2013 until August 2016. Mr. Freiman served as chairman of Penwest Pharmaceutical Co. (NASDAQ: PPCO) until 2010 and served on the board of directors of Otsuka American Pharmaceuticals, Inc. and Otsuka America, Inc. until 2011, NeoPharm, Inc. (NASDAQCM: NEOL) until 2010 and Calypte Biomedical Corporation (OTC: CBMC) until September 2009. Mr. Freiman also served on the board (including as chairman) of the Pharmaceutical Research and Manufacturers Association of America. He has also served on a number of industry task forces both domestically and internationally. Mr. Freiman received a B.S. in pharmacy from Fordham University and an honorary doctorate from the Arnold & Marie Schwartz College of Pharmacy.

Mark M. Sieczkarek, age 64, has served as a director of the Company since January 2014. Mr. Sieczkarek served as Chairman of the Board from April 2015 till March 2019 and served as Chief Executive Officer ("***CEO***") from June 1, 2016 until September 28, 2018 (including serving as Interim President and CEO of NovaBay from November 2015 to May 31, 2016). Mr. Sieczkarek currently also serves as chief executive officer of Fe3 Medical, Inc., a private company focused on developing a novel transdermal therapy for iron deficiency anemia, since 2015, and chief

executive officer of MarkAnn Inc., LLC, a private real estate holding company. Mr. Sieczkarek has more than 37 years of leadership experience in the pharma, device and diagnostics industries and most recently served as chairman, president and chief executive officer of Solta from April 2016 until it was acquired by Valeant Pharmaceuticals International, Inc. in January 2014. Mr. Sieczkarek was also Lead Director of Solta for seven (7) years and served on the audit committee and as head of the compensation committee. Mr. Sieczkarek also served as president and chief executive officer of Conceptus from 2003 to 2011. Previously, Mr. Sieczkarek was senior vice president and president of Bausch & Lomb's Americas Region, responsible for the commercial operation of all Bausch & Lomb businesses in the United States, Canada and Latin America. Mr. Sieczkarek joined Bausch & Lomb in 1995 as vice president and controller in the Personal Products division and also served as president of Europe, and a vice president in Corporate Business Development. Previously, Mr. Sieczkarek held an executive level position with KOS Pharmaceuticals, several Bristol Myers-Squibb subsidiaries and Sanofi Diagnostics Pasteur. Mr. Sieczkarek received an M.B.A. degree in Finance from Canisius College in Buffalo, New York, and a B.S. degree in Accounting from the State University of New York at Buffalo.

Gail Maderis, M.B.A., age 61, has served as a director of the Company since October 2010. Ms. Maderis is currently the president, chief executive officer and a board member of Antiva, a privately held biopharmaceutical company focused on developing topical therapeutics for HPV-based diseases, since July 2015. Previously, Ms. Maderis served as the president and chief executive officer of BayBio, an independent, non-profit trade association serving the life sciences industry in Northern California, from 2009 until its merger with the California Healthcare Institute in early 2015. From 2003 to 2009, Ms. Maderis was president and chief executive officer of FivePrime Therapeutics, Inc., a biotechnology company focused on the discovery and development of innovative protein and antibody drugs, and prior to that, she held general management positions at Genzyme Corporation, including founder and president of Genzyme Molecular Oncology, a publicly traded division of Genzyme Corporation, and corporate vice president of Genzyme Corporation from 1997 to 2003. Ms. Maderis has been a member of several private company boards of directors, and she previously served as a director of Opexa Therapeutics, Inc. Ms. Maderis received a B.S. degree in Business Administration from the University of California at Berkeley and an M.B.A. from Harvard Business School.

Xinzhou (Paul) Li, age 55, has served as a director of the Company since April 2015. Mr. Li has been the Chairman and Executive Director of China Pioneer Pharma since 2013 (also serving in the role of chief executive officer from November 2013 to December 2014) and is also currently Director of China Pioneer Pharma's wholly-owned subsidiary, Pioneer Pharma (Hong Kong) Company Limited ("***Pioneer Hong Kong***"). China Pioneer Pharma, along with its affiliates, is the exclusive distributor of NovaBay's NeutroPhase® Skin and Wound Cleanser in China and Southeast Asia, as well as NovaBay's largest stockholder. Mr. Li has not been appointed to any committees. Mr. Li previously served as the Board's Asia-Pacific advisor for over two (2) years. Mr. Li founded China Pioneer Pharma in July 1996, and is responsible for managing its operations and planning, and for formulating the company's strategies. He has more than 22 years of experience in the pharmaceutical services industry and has more than 24 years of experience in international trading and management. Prior to China Pioneer Pharma, Mr. Li worked at the Hainan branch of Sumitomo Corporation from 1988 to 1995. Mr. Li graduated from Jianghan Petroleum Normal School with a diploma in English and studied at the China Europe International Business School.

Mijia (Bob) Wu, M.B.A., age 44, has served as a director of the Company since January 2016. As a result of the February 2019 Loan, Mr. Wu, in his role as principal of China Kington, will be paid $100,000 pursuant to a consulting agreement with the Company. Since June 2008, Mr. Wu has been the Managing Director of China Kington (an affiliated entity of China Kington Investment Co. Ltd.), which (i) acted as the sole placement agent (and received a commission) for a $6.86 million private placement of NovaBay common stock and warrants to purchase common stock in May 2015; (ii) facilitated a bridge loan for the Company in the aggregate amount of $3.02 million in August 2016, in consideration for which China Kington was granted, among other things, the right to appoint two (2) new members to the Company's Board; (iii) acted as the sole placement agent (and received a commission) for three (3) securities purchase agreements for the sale of 1,518,567 shares of the Company's common stock to accredited investors in February 2016; and (iv) acted as the sole placement agent (and received a commission) for an $11.8 million private placement of NovaBay common stock and warrants to purchase common stock, which closed in two (2) tranches (May 2016 and August 2016). Concurrently, Mr. Wu serves as the Managing Director of Shanghai Ceton Investment Management Co. Ltd. Since October 2013, he has also been the Non-Executive Director of China Pioneer Pharma, the Company's largest stockholder (holding approximately 34.4% of NovaBay's total common stock outstanding) and indirect owner of Pioneer Hong Kong. Previously, Mr. Wu served as Director at UBS AG, Hong Kong Branch, in 2007 and Vice President of BNP Paribas Hong Kong from 2005 to 2006. He was also the Assistant Vice President at ABN AMRO Bank (China) Co., Ltd. from 2002 to 2005. He holds an M.B.A. from Manchester Business School, University of Manchester, and an Executive M.B.A. from Cheung Kong Graduate School of Business.

Todd Zavodnick, M.B.A., age 47, has served as a director of the Company since May 2016. Mr. Zavodnick currently serves as the Chief Commercial Officer and President at Revance Therapeutics, Inc. (NASDAQ: RVNC), a Silicon Valley-based biotechnology company, since September 2017, and a board member for both Allurion, a private company in the bariatric space, and the Children's Skin Disease Foundation, a not-for-profit organization that focuses on children who suffer from skin disease and the families who care for them. Mr. Zavodnick served as the President, International at ZELTIQ from January 2016 until ZELTIQ's sale to Allergan plc in April 2017. ZELTIQ was a medical technology company focused on developing and commercializing products utilizing its proprietary controlled-cooling technology platform. Prior to ZELTIQ, Mr. Zavodnick held several positions from 2012 to 2015 at Galderma Laboratories, L.P. ("***Galderma***") with his most recent position being President and General Manager, North America. Galderma is a pharmaceutical company specializing in the research, development and marketing of dermatological treatments, becoming a wholly-owned subsidiary of Nestlé in 2014. From 1998 to 2012, Mr.

Zavodnick held several positions at Alcon Laboratories ("***Alcon***"), eventually being elevated to President, China & Mongolia from April 2009 to April 2012. Alcon is a global medical company specializing in eye care products and the second largest division of the Novartis companies. Mr. Zavodnick has a Bachelor's of Science degree in Pharmacy from Rutgers University, as well as an M.B.A. in International Business from the University of Texas at Dallas. In July 2015, Mr. Zavodnick was honored in the Dallas Business Journal *Who's Who in Health Care*, which recognizes 30 prominent professionals who are innovating and affecting positive change in Dallas' health care industry.

Yonghao (Carl) Ma, Ph.D., age 62, has served as a director of the Company since August 2016. Dr. Ma is currently the founder, owner and President of PharmStats since September 1997. PharmStats is a Delaware corporation formed in 1997, specializing in statistical consulting and support for pharmaceutical research and development, registration of pharmaceutical products in the United States and Europe, phase IV post-market research, and health outcomes research. Dr. Ma is particularly experienced in the areas of oncology, the central nervous system, dermatology, pain (acute and chronic) management, multiple sclerosis, and HIV infection. Over the course of his career, Dr. Ma has participated in, or managed, many clinical trials with regard to design, statistical conduct, and regulatory filings in the United States and Europe, including new drug applications. From August 1991 to September 1997, Dr. Ma was an Assistant Professor of Mathematics at Texas State University. Dr. Ma has a Ph.D. in Mathematics from the University of Utah (1991).

Yanbin (Lawrence) Liu, age 39, has served as a director of the Company since March 2018. Mr. Liu brings more than 13 years of business experience, including 4 years of experience in cross-border direct investment. Since 2015, Mr. Liu has served as the Joint Chief Operating Officer & Head of Direct Investment of OP Financial Investments Limited ("OP Financial"). OP Financial purchased shares of common stock from the Company pursuant to the Share Purchase Agreement (as defined and described below in Item 13 of this Annual Report). Mr. Liu served as Investment Director of China-ASEAN Capital Advisory Co., Ltd. from 2014 to 2015. From 2011 to 2014, Mr. Liu was the Head of Project Finance & Syndication Department (EMEA Coverage) and from 2006 to 2011 as the Head of M&A and Structured Finance Department, Corporate Banking, both at the Bank of China Limited in London. From 2002 to 2006, Mr. Liu served as the Key Account Manager, Corporate Banking at the Bank of China Limited in Beijing. Mr. Liu received an Executive MBA (Investment & Strategy) from CASS Business School in London and a bachelor's degree in Business and Economics from the University of International Business and Economics in Beijing, China.

None of the Company's directors were selected as a director or nominee pursuant to any arrangement or understanding between the director and any other person, except for Messrs. Li, Wu and Liu who were selected due to their relationship with China Kington and other entities that have provided financing to the Company.

Executive Officers

The names of the Company's current executive officers, their ages, and positions with us as of March 29, 2019, and biographical information about them, are as follows:

Justin M. Hall, Esq., age 41, currently serves as the Company's Interim President and Chief Executive Officer & General Counsel and Chief Compliance Officer. Mr. Hall has served as the Company's Interim President and Chief Executive Officer since March 2019, as the Company's Senior Vice President and General Counsel since December 2015 and as the Company's Corporate Secretary since July 2017. Prior to this, he served as the Company's lead in-house counsel beginning in February 2013. Prior to joining NovaBay, Mr. Hall worked as Corporate Counsel at Accuray Incorporated, a radiation oncology company, which he joined in October 2006, where he reported directly to the GC and provided substantive legal advice on a broad range of complex legal matters with a focus on employment, corporate compliance, and corporate governance. Mr. Hall also worked as an investment advisor and attorney for the 401(k) Resource Center, which he founded in January 2009, which helped plan sponsors manage their retirement plans by providing legal advice. Mr. Hall's prior experience also includes serving as an investment advisor at Sagemark Consulting from 2000 to 2006, and a stock broker at First Security Van Kasper from 1998 to 2001. Mr. Hall received a B.A. in Business Administration and Management from the University of California, San Diego, and a J.D. from the University of San Diego, School of Law.

Jason Raleigh, age 42, currently serves as the Company's Interim Chief Financial Officer and Treasurer since March 2019. Prior to that, Mr. Raleigh served as the Company's Corporate Controller since February 2016, where he oversaw and managed the Company's accounting department and related functions. Prior to joining the Company, Mr. Raleigh worked as Assistant Controller (from July 2011 to February 2016) and Director of Financial Accounting (from July 2011 to October 2013) at Amyris Inc., a global renewable products company providing sustainable alternatives to a variety of non-renewable resources. Mr. Raleigh's prior experience also includes serving Sonic Solutions from April 2006 to July 2011 in the following positions: Assistant Controller, Director of Corporate Accounting, Director of Revenue and Revenue Manager. Mr. Raleigh received a B.A. in Business Economics, with an emphasis in accounting from the University of California at Santa Barbara.

None of the Company's executive officers were selected as such pursuant to any arrangement or understanding between the executive officer and any other person.

There are no family relationships among any of the Company's directors, executive officers or director nominees.

Section 16(a) Beneficial Ownership Reporting Compliance

Under the federal securities laws, the Company's directors and officers and any persons holding more than ten percent (10%) of the Company's common stock are required to report their ownership of the Company's common stock and any changes in that ownership to the SEC. Specific due dates for these reports have been established, and we are required to report in this Annual Report any failure to file by these dates.

In making this statement, we have relied upon examination of the copies of Forms 3, 4 and 5, and amendments to these forms, provided to us and the written representations of the Company's directors, executive officers and ten percent (10%) stockholders. Based solely on the Company's review of copies of the reports on the Section 16(a) forms received by us with respect to the fiscal year ended December 31, 2018, and the written representations received from the reporting persons that no other reports were required, we believe that all directors, executive officers and persons who own more than ten percent (10%) of the Company's common stock have complied with the reporting requirements of Section 16(a) and have filed all reports required by such section, except for the late filing of the following form: the initial Form 3 for Mr. Liu representing no transactions.

Code of Ethics

NovaBay has a longstanding commitment to effective governance of its business and affairs for the benefit of stockholders. The Board's Nominating and Corporate Governance Committee periodically review the Company's Corporate Governance Guidelines to maintain effective and appropriate standards of corporate governance.

The Company has also established a Code of Ethics and Business Conduct (the "Code of Ethics") that establishes standards of conduct and expectations for employees and the overall manner in which the Company conducts business. The Code of Ethics, along with the Company's other policies and business standards, and the Company's overall risk and compliance programs are components of mitigating the risks associated with the operation of the Company's business.

The Company's Internet address, located at www.novabay.com, includes electronic files of the Company's Code of Conduct & Ethics, as well as the Company's other SEC filings. Stockholders may obtain a copy of this Annual Report or any of the Company's other filings with the SEC, without charge, by writing to: Corporate Secretary, NovaBay Pharmaceuticals, Inc., 2000 Powell Street, Suite 1150, Emeryville, California 94608. The Annual Report (including the exhibits thereto) is also available on the SEC's website at www.sec.gov.

Audit Committee and Audit Committee Financial Expert

The Company has a separately designated standing Audit Committee, which currently consists of Mr. Freiman, Mr. Zavodnick and Ms. Maderis, who serves as the Chair of the Audit Committee. The Company's Board has determined that each member of the Audit Committee is independent, as defined in the NYSE American Company Guide and Rule 10A-3 under the Securities Exchange Act of 1934, as amended. Ms. Maderis qualifies as an "audit committee financial expert" as that term is defined in the rules and regulations established by the SEC.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table shows information regarding the compensation earned during the fiscal years ended December 31, 2018 and December 31, 2017 by the Company's (1) Interim President and CEO & General Counsel and Chief Compliance Officer, (2) former Interim President and CEO & Chief Financial Officer and Treasurer, (3) former President and CEO and (4) former Chief Commercial Officer. The Company's Interim Chief Financial Officer and Treasurer, Jason Raleigh, was not a named executive officer during 2018 and, as such, not reflected in the below table.

Name and Principal Position	Fiscal Year	Salary	Bonus	Stock Awards	Option Awards[1]	All Other Compensation[2]	Total
Justin M. Hall, Esq.	2018	$260,000	$–	$–	$311,499	$ 660	$572,159
Interim President and CEO & General Counsel and Chief Compliance Officer	2017	$228,000	$39,330	$–	$396,592	$ 899	$664,821
John J. McGovern, CPA,	2018	$316,000[3]	$–	$–	$422,004	$ 4,356	$742,360
Former Interim President and CEO & CFO and Treasurer	2017	$136,427[6]	$23,660	$–	$293,445	$ 487	$454,019

Mark Sieczkarek,	2018	$330,000[7]	$–	$–	$-	$ 15,052	$345,052
Former President and CEO	2017	$440,000[7]	$33,000	–	$1,113,105	$ 14,377	$1,600,482
Lewis Stuart,	2018	$175,000[8]	$–	$–	$-	$ 15,386	$190,386
Former Chief Commercial Officer	2017	$25,000 [9]	$–	$34,200	$264,384	$ –	$323,584

(1) These amounts represent the aggregate grant date fair value of the equity awards granted to the Company's named executive officers ("NEOs") during the fiscal year. The aggregate grant date fair value is computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. See Note 12 to the Company's consolidated financial statements in this Annual Report, regarding assumptions underlying the valuation of the Company's equity awards. These amounts do not correspond to the actual value that may be recognized by the Company's NEOs.

(2) These amounts include individual life insurance premiums paid for by the Company. In the case of Mr. Sieczkarek, the amount includes a $13,500 annual car allowance.

(3) In connection with his appointment as Interim President and CEO, Mr. McGovern's base salary was increased to $370,000 per annum, effective October 1, 2018.

(6) Mr. McGovern entered into an employment agreement with the Company, effective July 16, 2017, pursuant to which he will receive an annual base salary of $298,000. Mr. McGovern's compensation is from July 16, 2017 (his date of hire) through December 31, 2017.

(7) Effective September 28, 2018, Mr. Sieczkarek was replaced in the roles of President and CEO upon the appointment of Mr. McGovern as the Interim President and CEO. Accordingly, Mr. Sieczkarek's 2018 compensation is from January 1, 2018 through September 28, 2018.

(8) Mr. Stuart resigned as Chief Commercial Officer of the Company effective July 23, 2018. Accordingly, Mr. Stuart's 2018 compensation is from January 1, 2018 through July 23, 2018.

(9) Mr. Stuart entered into an employment agreement with the Company, effective December 1, 2017, pursuant to which he would receive an annual base salary of $300,000. Accordingly, Mr. Stuart's 2018 compensation is from December 1, 2017 (his date of hire) through December 31, 2017.

2018 Stock Option Awards

On May 31, 2018, Mr. Hall was awarded 190,000 stock options to vest over four years.

Mr. McGovern was awarded 90,000 stock options on May 31, 2018 to vest over four years; and, in connection with being appointed Interim President and CEO, Mr. McGovern received an additional stock option award of 250,000 shares of the Company's common stock on October 9, 2018.

On January 31, 2019, the Board determined 0% achievement of the Company's stated 2018 goals for its executive team. Further, Mr. Sieczkarek's outstanding performance shares for 2018 and 2019 were forfeited.

2017 Stock Option Awards

In January 2017, Mr. Hall was awarded 143,000 stock options, under the Company's 2007 Omnibus Incentive Plan (the "2007 Plan") at an exercise price per share equal to the closing sales price of the Company's common stock on the

NYSE American on the date of grant. Only 15% of Mr. Hall's options (or 21,450 shares) vested on January 31, 2018, in direct proportion to the 15% achievement of the stated 2017 corporate goals, as approved and determined by the Board.

Mr. McGovern received an initial stock option award of 100,000 shares of the Company's common stock upon joining the Company on July 16, 2017.

In connection with Mr. Sieczkarek entering into a new employment agreement with the Company, effective June 1, 2017 which subsequently expired June 1, 2018, he received a stock option award of 250,000 shares of the Company's common stock. One-fourth (1/4) of such 250,000 shares subject to this option vested on January 31, 2018, in direct proportion to the percentage achievement of the Company's 2017 corporate goals. As the Board determined that only 15% achievement of the stated 2017 corporate goals was accomplished, only 9,375 shares of the available 62,500 shares vested.

Under Mr. Sieczkarek's prior employment agreement, effective June l, 2016, he received an initial stock option award of 675,000 shares of the Company's common stock, one-third (1/3) of which vested on January 31, 2017 in proportion to the percentage achievement of the Company's stated 2016 corporate goals, with the remaining two-thirds (2/3) of such shares vesting in equal parts on January 31, 2018 and 2019, also subject to the successful completion of certain performance criteria of the prior year. Such outstanding two-thirds (2/3) of Mr. Sieczkarek's option award was forfeited on January 31, 2019, due to his earlier resignation from the positions of President and CEO. Mr. Sieczkarek also received a stock option award of 238,609 shares of the Company's common stock granted in January 2017, equal to six percent (6%) of the aggregate number of shares issued pursuant to the Company's warrants exercised during the 2016 calendar year. The first tranche of the June 1, 2016 stock option award vested on January 31, 2017 in direct proportion to the percentage achievement of the Company's stated 2016 corporate goals, which the Board determined to be 100%. The second tranche of the June 1, 2016 stock option award vested on January 31, 2018 in direct proportion to the percentage achievement of the Company's stated 2017 corporate goals, which the Board determined to be 15%.

Mr. Stuart received an initial stock option award of 100,000 shares of the Company's common stock and 10,000 restricted stock units upon joining the Company in December 2017. The restricted stock units were to vest in proportion to certain performance criteria being met before August 1, 2018. Due to Mr. Stuart's resignation in April 2018, none of Mr. Stuart's stock options or restricted stock units vested.

2018 Performance Incentives

The Board, upon the recommendation of the Compensation Committee, established there would be no bonus payments for the 2018 fiscal year for any of its executive officers.

2017 Performance Incentives

The Board, upon the recommendation of the Compensation Committee, established the bonus payments for the 2017 fiscal year to be paid to the NEOs. The final amount and timing of award payments were at the discretion of the Compensation Committee, and the Compensation Committee could modify the amount of the bonus pool at its discretion, or defer or cancel awards at its discretion. The pre-established target bonuses were 50% of base salary for Mr. Sieczkarek and 30% of base salary for each of Messrs. McGovern (prorated for his joining the Company mid-year) and Hall. Mr. Stuart did not participate in the 2017 performance incentive program as he was hired in December 2017. To establish the bonus payments for 2017 performance, the Compensation Committee applied the criteria previously established by it for the Company's bonus structure, and determined that a corporate goal achievement of 15% should be applied to the pre-established target bonuses for the executive officers.

Such corporate goal achievement is utilized by the Company both to determine vesting of performance awards (as outlined under "Stock Option Awards" above), as well as bonus calculations. As CEO, Mr. Sieczkarek's bonus opportunity was weighted 100% based upon the Company's corporate goal achievement. Accordingly, Mr. Sieczkarek's 2017 bonus was 15% of the available target bonus. For Messrs. McGovern and Hall, their bonus opportunity was weighted 50% based upon the Company's corporate goal achievement and 50% based upon their individual goal achievement. The Board determined that both Messrs. McGovern and Hall accomplished 100% of their individual goal achievement for 2017. Accordingly, Messrs. McGovern and Hall's 2017 bonus was 57.5% of their available target bonuses, with Mr. McGovern's pro rated to reflect his joining the Company on July 16, 2017.

Outstanding Equity Awards at December 31, 2018

The following table presents the outstanding equity awards held by each of the NEOs as of December 31, 2018. Stock options were granted pursuant to the Company's 2002 Stock Option Plan ("2002 Plan") and 2005 Stock Option Plan ("2005 Plan") prior to the Company's initial public offering in October 2007, pursuant to the 2007 Plan thereafter until its expiration in March 2017, and all awards since then have been pursuant to the Company's 2017 Omnibus Incentive Plan ("2017 Plan"). All options granted under the 2002 Plan and 2005 Plan were immediately exercisable and subject to a right of repurchase for any shares exercised prior to vesting. The options granted under the 2007 Plan and 2017 Plan are not exercisable until they have vested.

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable[1]	Number of Securities Underlying Unexercised Options (#) Unexercisable[1]	Option Exercise Price ($)	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares or units that have not vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares or units that have not vested
Justin M. Hall, Esq.	–	190,000	$ 2.20	05/31/2028		
	21,450 [2]	–	$ 2.78	01/25/2027	–	–
	110,000[3]	–	$ 2.78	06/06/2026		
	1,500	500	$ 6.75	10/05/2025		
	1,200	–	$ 18.75	09/26/2024		
	760	–	$ 42.75	09/26/2023		
	1,200	–	$ 30.50	02/01/2023		
John J. McGovern, CPA[4]	–	250,000[5]	$ 1.45	10/09/2028		
	–	90,000	$ 2.20	05/31/2028		
	31,250	68,750	$ 3.80	07/17/2027	–	–
Mark M. Sieczkarek, M.B.A. [6]	9,375 [7]	–	$ 2.35	06/02/2027	–	–
	238,609[8]	–	$ 3.60	01/25/2027		
	33,750 [9]	–	$ 2.78	06/06/2026		
	16,032	–	$ 2.02	01/04/2026		
	966	–	$ 19.75	06/12/2025		
	3,707	–	$ 16.00	01/02/2025		
	1,343	–	$ 28.50	01/30/2024		
	1,200	–	$ 31.25	01/09/2024		
Lewis Stuart[10]	–	–	$ –	–	–	–

(1) Unless otherwise noted, each option vests as to 25% of the shares underlying the option on the first anniversary of the grant date, with the remainder vesting in 12 equal installments thereafter at the end of each calendar quarter. Options have a term of ten (10) years from the date of grant.

(2) Mr. Hall was granted 143,000 stock options to vest on January 31, 2018, in direct proportion to the percentage achievement of the stated 2017 corporate goals, as approved and determined by the Board. Such determination resulted in a 15% payout or 21,450 shares vesting.

(3) The options vested and became exercisable on January 31, 2017, in direct proportion to the percentage achievement of the stated 2016 corporate goals, as approved and determined by the Board, which was 100%.

(4) Mr. McGovern subsequently resigned on March 7, 2019, after the date of the above table. As a result, Mr. McGovern forfeited his unvested awards as of his resignation date, as outlined further in "Item 11. Executive Compensation—Summary Compensation Table—2018 Stock Option Awards."

(5) The options were to vest in 12 equal installments every three months over four years.

(6) Mr. Sieczkarek ceased being an employee on September 18, 2018.

(7) Mr. Sieczkarek was initially awarded 250,000 stock option of which one-fourth (1/4) of the shares subject to this option vested on January 31, 2018, in direct proportion to the percentage achievement of the stated 2017 corporate goals, as approved and determined by the Board. Such determination resulted in a 15% payout, or 9,375 shares vesting. The remaining three-fourths (3/4) of the shares subject to this option were to vest in equal parts on January 31, 2019, 2020 and 2021, in direct proportion to the percentage achievement of the stated corporate goals for the previous fiscal year of such date. Such outstanding 187,500 options were forfeited on January 31, 2019, due to Mr. Sieczkarek's earlier resignation from the positions of President and CEO.

(8) This option award grant was issued to Mr. Sieczkarek pursuant to his 2016 employment agreement. The options vested and became exercisable on January 31, 2017, in direct proportion to the percentage achievement of the stated 2016 corporate goals, as approved and determined by the Board, which was 100%.

(9) This option award grant was issued to Mr. Sieczkarek pursuant to his 2016 employment agreement. One-third (1/3) of the shares subject to this option vested on January 31, 2017, in direct proportion to the percentage achievement of the stated 2016 corporate goals, as approved and determined by the Board. Only 33,750 shares of the second tranche vested on January 31, 2018 because the Board determined that only 15% of the stated 2017 corporate goals had been met. The third tranche would have vested on January 31, 2019, subject to the successful completion of the 2018 corporate goals, as determined by the Board. Such outstanding 450,000 options were forfeited on January 31, 2019, due to Mr. Sieczkarek's earlier resignation from the positions of President and CEO.

(10) On April 23, 2018, Mr. Lewis resigned effective July 23, 2018. Mr. Lewis was granted restricted stock units on December 14, 2017 that would have vested if certain performance criteria was met and certified by the Compensation Committee before August 1, 2018 as well as certain stock options. The awards were subject to Mr. Stuart's continued employment and therefore the restricted stock units and unvested options were forfeited upon his resignation.

Employment Agreements

The Company executed an employment agreement with Mr. Hall on December 19, 2017. The principal terms of his employment agreement are summarized below. The Company is not currently anticipating entering into a new employment agreement with Mr. Hall as a result of his appointment to Interim President and Chief Executive Officer. At the present time, Mr. Raleigh has no employment agreement or other material plan or arrangement with the Company, and the Company is not currently anticipating entering into any such arrangement with Mr. Raleigh as a result of his appointment to the positions of Interim Chief Financial Officer and Treasurer. However, in recognition of Mr. Raleigh’s recent appointment to the positions of Interim Chief Financial Officer and Treasurer and the Company’s desire to retain Mr. Raleigh, the Board of Directors of the Company approved a $100,000 one-time cash bonus payment to Mr. Raleigh on March 29, 2019.

Mr. McGovern was party to an employment agreement, dated July 16, 2017, prior to his resignation from the Company. Mr. Sieczkarek's employment agreement with the Company expired on June 1, 2018 while he was still President and CEO of the Company.

Justin Hall

On December 19, 2017, the Company and Mr. Hall executed an employment agreement in connection with the expiration of Mr. Hall's employment agreement dated as of December 29, 2015, which expired on December 31, 2017.

Mr. Hall's new employment agreement provides for at-will employment and a term commencing on January 1, 2018 and ending on December 31, 2019 unless earlier terminated. Mr. Hall's employment agreement provides for an annual base salary of two hundred sixty thousand dollars ($260,000), subject to at least annual review. Mr. Hall's salary may be adjusted by action of the Board, based on Mr. Hall's performance, the financial performance of the Company and the compensation paid to a general counsel in comparable positions. Such adjustments shall not reduce Mr. Hall's then-current annual base salary unless he provides written consent.

In addition, Mr. Hall shall be eligible for any bonus plan that is deemed appropriate by the Board. The bonus amount shall be determined by the Board, in its sole discretion, based upon, among others, the following factors: (i) the fulfillment, during the relevant year, of specific milestones and tasks delegated, for such year, to Mr. Hall as set by Mr. Hall and the Company's President and/or the Board, before the end of the first calendar quarter; (ii) the evaluation of Mr. Hall by the Company's President and/or the Board; (iii) the Company's financial, product and expected progress and (iv) other pertinent matters relating to the Company's business and valuation. Any bonus will be payable within two and a half (2½) months following the end of the year for which the bonus was earned. The Compensation Committee shall have the sole discretion to pay any or all of the annual bonus in the form of equity compensation. Any such equity compensation shall be issued from the 2017 Plan, and shall be fully vested upon payment.

In the event the Company terminates Mr. Hall for cause (as defined in the employment agreement), he shall be entitled to any earned but unpaid wages or other compensation (including reimbursements of his outstanding expenses and unused vacation) earned through the termination date.

In the event the Company terminates Mr. Hall without cause (including death, disability or for constructive termination; each as defined in the employment agreement) which is not in connection with a change of control, provided such termination constitutes a "separation from service" as such term is defined in Section 409A of the Code and, subject to his execution of a release of claims in favor of the Company, he shall be entitled to an amount equal to Mr. Hall's annualized base salary in effect on the date of separation from service plus the full target annual bonus percentage for the current fiscal year (the "Severance Amount"). The Severance Amount will be paid in twelve (12) equal consecutive monthly installments at the monthly base salary rate in effect at the time of Mr. Hall's termination, with such installments commencing within sixty (60) days following Mr. Hall's separation from service. The Severance Amount shall be in addition to Mr. Hall's earned wages and other compensation (including reimbursements of his outstanding expenses and unused vacation) through the date his employment is terminated from the Company.

In the event the Company terminates Mr. Hall without cause in connection with a change of control (as defined in the employment agreement), he shall be entitled to a Change of Control Severance (the "CoC Severance Amount") in place of the Severance Amount described above. The CoC Severance Amount shall be: (i) an amount equal to twice Mr. Hall's base salary and (ii) an amount equal to the cash portion of Mr. Hall's target Annual Bonus for the fiscal year in which the termination occurs (with it deemed that all performance goals have been met at one hundred percent (100%) of budget or plan) multiplied by one hundred fifty percent (150%). For a period of eighteen (18) months, Mr. Hall may elect coverage for, and the Company shall reimburse Mr. Hall for, the amount of his premium payments for group health coverage, if any, elected by Mr. Hall pursuant to the Consolidated Omnibus Budget Reconciliation Act

of 1985, as amended ("COBRA"); provided, however, that Mr. Hall shall be solely responsible for all matters relating to his continuation of coverage pursuant to COBRA, including (without limitation) his election of such coverage and his timely payment of premiums.

Moreover, all options held by Mr. Hall will be subject to full accelerated vesting on the date of termination without cause, in connection with payment of either the Severance Amount or the CoC Severance Amount, and the exercise period shall be extended to three (3) years from the date of termination. In order to terminate Mr. Hall for cause (or for Mr. Hall to resign for constructive termination), the acting party shall give notice to the other party specifying the reason for termination and providing a period of thirty (30) days to cure the reason specified. If there is no cure within thirty (30) days or the notified party earlier refuses to effect the cure, the termination shall then be deemed effective.

Director Compensation

The compensation and benefits for services as a member of the Company's Board is determined by the Board. Directors employed by us are not compensated for service on the Board or any committee of the Board; however, we reimburse all directors for any out-of-pocket expenses incurred in connection with attending meetings of the Board and committees of the Board.

The Board, upon recommendation of the Compensation Committee, revised the Company's Non-Employee Director Compensation Plan, effective January 1, 2018 (the "2018 Non-Employee Director Compensation Plan"), to limit the directors' annual retainer compensation to cash only though the compensation amounts remained unchanged from the prior year. The Board also added the position of a lead independent director with annual compensation of $20,000. Under the 2018 Non-Employee Director Compensation Plan, each non-employee director received an annual stock option grant of 20,000 shares, granted at the Company's 2018 annual meeting of stockholders. On October 9, 2018, the Board approved further amending the 2018 Non-Employee Director Compensation Plan, effective October 1, 2018, to include cash compensation for a non-employee Chairman of the Board in the amount of $52,000 per annum, in addition to the base cash compensation for a non-employee director in the amount of $30,000 per annum.

Effective January 1, 2019, the Board approved the 2019 Non-Employee Director Compensation Plan, which terms remain unchanged from the terms of the amended 2018 Non-Employee Director Compensation Plan. However, upon the change in the Board Chairman effective March 8, 2019 to Paul Freiman, Mr. Freiman will only receive the non-employee Chairman of the Board fee ($52,000 annually) and will no longer receive the lead independent director fee ($20,000 annually).

The approved director compensation for 2018 was a combination of options and cash. All cash compensation was payable quarterly on the first (1st) business day of the beginning of the quarter. Approved director compensation for 2018 was as follows:

Board Meetings	**Chairman of Committee for Committee Meetings**	**All Other Members for Committee Meetings**
	Chairman of the Audit Committee: Annual cash compensation of $12,000 per year.	
Chairman of the Board: Annual cash compensation of $52,000 per year.	*Chairman of the Compensation Committee*: Annual cash compensation of $10,000 per year.	*Member of the Audit Committee*: Annual cash compensation of $6,000 per year.
Member of the Board: The annual fee consists of: (i) $30,000 in cash and (ii) 20,000 options granted. The options are granted on the first day of the year on which the NYSE American is open for trading, and vest in equal monthly installments at the beginning of each month, over the course of one year.	*Chairman of the N&CG Committee*: Annual cash compensation of $8,000 per year.	*Member of the N&CG and Compensation Committees*: Annual cash compensation of $5,000 per year.
	Lead Independent Director (if different from Chairman of the Board): Annual cash compensation of $20,000 per year.	

Non-employee directors also may be granted additional awards under the Company's equity incentive plans at the discretion of the Board.

The compensation received during 2018 by each non-employee director is set forth below.

Name	Fees Earned or Paid in Cash	Option Awards($)[1]	Total ($)
Paul E. Freiman,	$71,000	$ 32,525	$103,525
Mark M. Sieczkarek[2]	$20,500	$ -	$20,500
Xinzhou (Paul) Li	$30,000	$ 32,525	$62,525
Xiaoyan (Henry) Liu[3]	$7,500	$ -	$7,500
Yanbin (Lawrence) Liu[3]	$22,500	$ 32,525	$55,025
Yonghao (Carl) Ma, Ph.D.	$40,000	$ 32,525	$72,525
Gail Maderis, M.B.A.	$47,000	$ 32,525	$79,525
Mijia (Bob) Wu, M.B.A.	$30,000	$ 32,525	$62,525
Todd Zavodnick, M.B.A.	$44,000	$ 32,525	$76,525

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(1) These amounts represent the aggregate grant date fair value of $1.63 per share for the stock option awards granted in fiscal year 2018. The assumptions used to determine the value of stock options are described in Note 12 to the Company's consolidated financial statements in this Annual Report. At December 31, 2018, the aggregate number of vested and unvested stock options for each of the non-employee directors that held stock options was as follows: Mr. Freiman, 74,364 vested and 8,333 unvested; Mr. Sieczkarek, 529,981 vested and 0 unvested; Mr. Li, 16,915 vested and 8,333 unvested; Mr. Henry Liu, 15,245 vested and 0 unvested; Mr. Lawrence Liu, 11,667 vested and 8,333 unvested; Dr. Ma, 35,296 vested and 8,333 unvested; Ms. Maderis, 75,878 vested and 8,333 unvested; Mr. Wu, 26,912 vested and 8,333 unvested; and Mr. Zavodnick, 45,366 vested and 8,333 unvested.

(2) In connection with Mr. Sieczkarek no longer serving as our President and Chief Executive Officer as of October 1, 2018, Mr. Sieczkarek received compensation for his role as a director and Chairman of the Board from October 1, 2018 to December 31, 2018.

(3) Mr. Henry Liu resigned effective March 21, 2018 with Mr. Lawrence Liu replacing him on the Board effective March 21, 2018.

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

Equity Compensation Plan Information

The following table provides information as of December 31, 2018, with respect to shares of the Company's common stock that may be issued under existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available For Future Issuance under Equity Compensation Plans (excluding some securities reflected in first column)
Equity compensation plans approved by security holders[1]	***3,374,220***	$ 4.13	1,188,485
Equity compensation plans not approved by security holders	**—**	$ **—**	**—**
Total	***3,374,220***	$ 4.13	1,188,485

(1) Consists of the 2002 Plan, 2005 Plan, 2007 Plan and 2017 Plan. No additional option grants are being made under the 2002 Plan, 2005 Plan or 2007 Plan. The 2017 Plan became effective on June 2, 2017, and 1,188,485 shares were reserved for issuance under that plan at December 31, 2018.

Security Ownership of Certain Beneficial Owners and Management

The following table indicates information as of March 29, 2019, regarding the ownership of the Company's common stock by:

- each person who is known by us to own more than five percent (5%) of the Company's shares of common stock;
- each of the senior executive officers who are NEOs under SEC proxy rules;
- each of the directors; and
- all of the directors and executive officers as a group.

The percentage of shares beneficially owned is based on 17,094,804 shares of common stock outstanding as of March 29, 2019. Except as indicated in the footnotes to this table, and as affected by applicable community property laws, all persons listed have sole voting and investment power for all shares shown as beneficially owned by them and no shares are pledged.

Name and Address of Beneficial Owner[1]	**Number of Shares Beneficially Owned**	**Percent of Class**
Beneficial Owners Holding More Than 5% (other than Executive Officers and Directors)		
China Pioneer Pharma Holdings Limited[2] 190 Elgin Avenue, George Town, Grand Cayman, Cayman Islands KY1-9005	5,212,748	30.5%
Jian Ping Fu ("***Mr. Fu***")[3] 11 Williams Road Mt. Eliza, Melbourne VIC 3930 Australia	3,983,304	23.3%
OP Financial Investments Limited ("***OP Financial***")[4] 27/F, Two Exchange Square 8 Connaught Place Hong Kong	1,700,000	9.9%
Executive Officers and Directors		
Justin M. Hall, Esq.[5]	139,765	*
Jason Raleigh [6]	20,949	*
Mark M. Sieczkarek, M.B.A.[7]	1,518,927	8.6%
Paul E. Freiman[8]	83,341	*

Gail Maderis, M.B.A.[9]	82,544	*
Mijia (Bob) Wu, M.B.A. [10]	81,197	*
Xinzhou (Paul) Li[2],[11]	23,581	*
Yonghao (Carl) Ma, Ph.D.[12]	41,962	*
Todd Zavodnick, M.B.A.[13]	52,032	*
Yanbin (Lawrence) Liu[4],[14]	18,333	*
All directors and executive officers as a group (10 persons)	2,062,631	11.34%

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* Less than one percent (1%).

(1) The address for each director and officer of NovaBay listed is c/o NovaBay Pharmaceuticals, Inc., 2000 Powell Street, Suite 1150, Emeryville, CA 94608. Number of shares beneficially owned and percent of class is calculated in accordance with SEC rules. A beneficial owner is deemed to beneficially own shares the beneficial owner has the right to acquire within 60 days of March 29, 2019. For purposes of calculating the percent of class held by a single beneficial owner, the shares that such beneficial owner has the right to acquire within 60 days of March 29, 2019 are also deemed to be outstanding; however, such shares are not deemed to be outstanding for purposes of calculating the percentage ownership of any other beneficial owner.

(2) Director Xinzhou (Paul) Li is Chairman and Executive Director of China Pioneer Pharma and Director of Pioneer Hong Kong. Mr. Li disclaims beneficial ownership of the shares of the Company common stock held by China Pioneer Pharma and Pioneer Hong Kong. China Pioneer Pharma has sole voting and sole investment power with respect to 24,327 of these shares. In addition, China Pioneer Pharma and Pioneer Hong Kong (by virtue of its indirect ownership by China Pioneer Pharma (discussed below)), share voting power and share investment power over the remaining 5,188,421 shares. Pioneer Hong Kong is a wholly-owned subsidiary of China Pioneer Pharma. The address for Pioneer Hong Kong is: Flat 2605, 26/F Trendy Centre, 682 Castle Peak Road, Lai Chi Kok, Kowloon, Hong Kong.

(3) Mr. Fu holds sole voting power and sole investment power over all 3,983,304 shares.

(4) Director Yanbin (Lawrence) Liu is Joint Chief Operating Officer & Head of Direct Investment of OP Financial. Mr. Liu disclaims beneficial ownership of the shares of the Company common stock held by OP Financial. OP Financial has sole voting and sole investment power over all 1,700,000 shares.

(5) Includes (i) 3,405 shares of common stock held directly by Mr. Hall (with sole voting power over 3,405 shares, shared voting power over no shares, sole investment power over 3,405 shares and shared investment power over no shares), and (ii) 136,360 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019 or within 60 days after such date.

(6) Reflects 20,949 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date.

(7) Includes (i) 988,945 shares held directly by Mr. Sieczkarek (with sole voting power over 988,945 shares, shared voting power over no shares, sole investment power over 988,945 shares and shared investment power over no shares), and (ii) 529,982 shares of common stock issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date.

(8)

Includes (i) 2,311 shares held by the Paul Freiman and Anna Mazzuchi Freiman Trust, of which Mr. Freiman and his spouse are trustees (with sole voting power over 625 shares, shared voting power over 1,061 shares, sole investment power over no shares and shared investment power over 1,686 shares), and (ii) 81,030 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date.

(9) Reflects 82,544 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date. The right to exercise these stock options is held by the Gail J. Maderis Revocable Trust dated April 7, 2013.

(10) Includes (i) 47,619 shares of common stock held jointly by Mr. Wu and his spouse, Qian Xia (with sole voting power over no shares, shared voting power over 47,619 shares, sole investment power over no shares and shared investment power over 47,619 shares), and (ii) 33,578 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date. As Non-Executive Director of China Pioneer Pharma, Mr. Wu disclaims beneficial ownership of the shares of the Company common stock held by China Pioneer Pharma and Pioneer Hong Kong. See Note (2) above for shares of the Company owned by China Pioneer Pharma and Pioneer Hong Kong.

(11) Reflects 23,581 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date.

(12) Reflects 41,962 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date.

(13) Reflects 52,032 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date.

(14) Reflects 18,333 shares issuable upon exercise of outstanding options which are exercisable as of March 29, 2019, or within 60 days after such date.

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

Certain Relationships and Related Transactions

The Company's Audit Committee has the responsibility of reviewing any possible related party transactions. In conducting its review, the Audit Committee applies the principles of the Code of Ethics and its Conflict of Interest Policy to: (a) the relationship of the related persons to the transaction; (b) the relationship between the Company and the related persons; (c) the importance of the interest to the related persons; and (d) the amount involved in the transaction. Since December 31, 2017, there has not been any transaction, nor is there any proposed transaction, in which the Company was a participant, and in which a "related party" of the Company had or is expected to have a direct or indirect material interest, in which the amount involved exceeded or will exceed the lesser of $120,000 or one percent (1%) of the average of the Company's total assets at the end of the last two (2) completed fiscal years, that would require disclosure, except for the following:

Pioneer Pharma (Hong Kong) Company Limited Loan

On February 27, 2019, the Company issued a promissory note payable to Pioneer Pharma (Hong Kong) Company Limited ("Pioneer"), loaning the Company $1,000,000. The loan includes an interest payment of $150,000 and is payable in full upon the Company's next financing with Pioneer and in no event after July 27, 2019. The loan was facilitated by China Kington Asset Management Co. Ltd. ("China Kington") in which it has a perfected security interest in all tangible and intangible assets of the Company. In connection with the February 2019 Loan, the Company must pay China Kington a 2% fee for brokering the transaction and enter into a consulting agreement with China Kington for the term of one year to facilitate closer oversight of the Company's expenses and strategic direction by the Board of Directors. Bob Wu, acting in a dual role as a member of the Company’s Board of Directors and as principal of China Kington, will be paid $100,000 pursuant to this consulting agreement. The Company's Board approved the loan and related documents on February 24, 2019.

February 2018 Share Purchase Agreement

On February 5, 2018, we entered into a share purchase agreement (the "Share Purchase Agreement") with OP Financial, an investment firm based in Hong Kong focused on cross-border investment opportunities and listed on the Hong Kong Stock Exchange. Under the Share Purchase Agreement, we issued and sold to OP Financial a total 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 Financial Private Placement"). China Kington agreed to serve as placement agent in exchange for a commission equal to six percent (6%) of the total purchase price of the shares sold to OP Financial upon the closing of the OP Financial Private Placement. The Audit Committee recommended to the Board and the Board approved the Share Purchase Agreement on February 5, 2018. The OP Financial Private Placement closed on February 8, 2018. Given OP Financial's significant investment in NovaBay, one of the board members is a representative of OP Financial, Yanbin (Lawrence) Liu.

Director Independence

The Company's Board has determined that each of Mr. Freiman, Ms. Maderis, Dr. Ma, and Mr. Zavodnick satisfies the requirements for "independence" as defined in the NYSE American Company Guide. The remaining non-independent directors will not serve on any committees of the Board.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth the fees billed to us for the fiscal years ended December 31, 2018 and 2017, by OUM, the Company's independent registered public accounting firm, for such years:

	2018	**2017**
Audit Fees	$220,370	$222,721
Audit-Related Fees	875	—
Tax Fees	—	—
All Other Fees	$6,895	$38,322
Total Fees	$228,140	$261,043

Audit Fees. Audit fees consisted of fees billed by OUM for professional services rendered in connection with the audit and quarterly reviews of the Company's consolidated financial statements and other engagements, such as review of documents filed with the SEC.

Audit-Related Fees. Audit-related fees comprise fees for professional services rendered by OUM that are reasonably related to the performance of the audit or review of the Company's consolidated financial statements and internal controls over financial reporting that are not reported in "Audit Fees." There were no such services rendered by OUM in 2018 and 2017 that meet the above category description.

Tax Fees. These are fees for professional services rendered by OUM with respect to tax compliance, tax advice and tax planning. There were no such services rendered by OUM in 2018 and 2017 that meet the above category description.

All Other Fees. All other fees consisted of fees associated with the review of registration statements on Form S-3 and Form S-8, comfort letters and consents performed by OUM.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services

All engagements for services by OUM or other independent registered public accounting firms are subject to prior approval by the Audit Committee; however, *de minimis* non-audit services instead may be approved in accordance with applicable SEC rules. The Audit Committee approved all services provided by OUM for the fiscal years ended December 31, 2017 and December 31, 2018.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

(1) *Financial Statements*. The financial statements listed in the Index for Item 8 hereof are filed as part of this report.

(2) *Financial Statement Schedules*. All schedules have been omitted because they are not required or the required information is included in our consolidated financial statements and notes thereto.

(3) *Exhibits*. The following exhibits are filed as part of this Report:

		Incorporation by Reference				Filed Herewith
Exhibit Number	Exhibit Description	Form	File Number	Exhibit/ Form 8-K Item Reference	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of NovaBay Pharmaceuticals, Inc.	10-K	001-33678	3.1	3/21/2018	
3.2	Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-33678	3.1	6/04/2018	
3.3	Bylaws	8-K	001-33678	3.2	6/29/2010	
4.1	Form of 2011 Warrant, as amended (issued pursuant to the placement agent agreement dated June 29, 2011, as amended)	10-K	001-33678	4.1	3/23/2017	
4.2	Form of Warrant issued in March 2015 Offering, as amended (issued with 15-month term)	10-K	001-33678	4.2	3/23/2017	
4.3	Form of Warrant issued in March 2015 Offering, as amended (issued with 5-year term)	10-K	001-33678	4.3	3/23/2017	
4.4	Form of Warrant issued in May 2015 offering	10-Q	001-33678	4.7	8/13/2015	
4.5	Form of Warrant issued in October 2015 offering, as amended	10-K	001-33678	4.5	3/23/2017	
4.6	Registration Rights Agreement (between the Company, Pioneer Pharma (Singapore) Pte. Ltd., and Anson Investments Master Fund LP, et al.)	8-K	001-33678	10.2	3/09/2015	

4.7	Registration Rights Agreement (between the Company, China Kington Investment Co. Ltd. and Dr. Dean Rider)	10-Q	001-33678	4.9	8/13/2015
4.8	Registration Rights Agreement (among the Company and each of the purchasers named therein).	8-K	001-33678	4.2	4/05/2016
10.1+	Indemnity Agreement (Form of Indemnity Agreement between the Company and its Directors and Officers)	10-Q	001-33678	10.1	8/12/2010
10.2+	NovaCal Pharmaceuticals, Inc. 2005 Stock Option Plan	S-1 as amended	333-140714	10.2	3/30/2007
10.3+	NovaBay Pharmaceuticals, Inc. 2007 Omnibus Incentive Plan (as amended and restated)	S-8	333-215680	99.1	1/24/2017
10.4+	NovaBay Pharmaceuticals, Inc. 2017 Omnibus Incentive Plan	S-8	333-218469	99.1	6/02/2017
10.5+	NovaBay Pharmaceuticals, Inc. 2017 Omnibus Incentive Plan (Form Agreements to the 2017 Omnibus Incentive Plan)	S-8	333-218469	99.2	6/02/2017
10.6+	Non-Employee Director Compensation Plan	8-K	001-33678	10.1	10/11/2018
10.7+	Executive Employment Agreement (Employment Agreement of Mark M. Sieczkarek expired June 1, 2018)	8-K	001-33678	10.1	6/06/2017
10.8+	Executive Employment Agreement (Employment Agreement of John J. McGovern)	8-K	001-33678	10.1	7/10/2017
10.9+	Executive Employment Agreement (Employment Agreement of Lewis Stuart)	8-K	001-33678	10.1	11/28/2017
10.10+	Executive Employment Agreement (Employment Agreement of Justin M. Hall)	8-K	001-33678	10.1	12/20/2017
10.11	Office Lease between EmeryStation Associates II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North	S-1, as amended	333-140714	10.10	3/30/2007
10.12	Fifth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-K	001-33678	10.20	3/14/2008
10.13	Sixth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-Q, as amended	001-33678	10.1	11/14/2008
10.14	Seventh Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-Q	001-33678	10.2	8/09/2012
10.15	Eighth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-K	001-33678	10.19	3/04/2016
10.16	Office Lease (between the Company and KBSIII Towers at Emeryville, LLC)	8-K	001-33678	10.1	8/26/2016
10.17	Sublease Agreement by and between NovaBay Pharmaceuticals, Inc. and Zymergen, Inc., dated July 11, 2016	8-K	001-33678	10.1	7/15/2016
10.18†		10-Q,	001-33678	10.2	8/04/2009

Collaboration and License Agreement by and between NovaBay Pharmaceuticals, Inc. and Galderma S.A.	as amended

10.19†	Amendment No. 1 to the Collaboration and License Agreement	10-K	001-33678	10.18	3/30/2010	
10.20†	Amendment No. 2 to the Collaboration and License Agreement	10-K	001-33678	10.24	3/10/2011	
10.21†	International Distribution Agreement (by and between the Company and Pioneer Pharma Co. Ltd.)	10-K	001-33678	10.18	3/27/2012	
10.22	Commission structure for warrant exercise	8-K	001-33678	Item 1.01	9/30/2016	
10.23	Share Purchase Agreement (by and between the Company and Ch-gemstone Capital (Beijing) Co., Ltd.) (terminated January 31, 2018)	10-Q	001-33678	10.1	11/14/2017	
10.24	Amended and Restated Share Purchase Agreement (by and between the Company and Ch-gemstone Capital (Beijing) Co., Ltd.) (terminated January 31, 2018)	8-K	001-33678	10.1	11/21/2017	
10.25	Share Purchase Agreement (by and between the Company and OP Financial Investments Limited)	8-K	001-33678	10.1	2/06/2018	
10.26	Promissory Note Payable to Pioneer Pharma (Hong Kong) Company Limited, dated February 27, 2019	8-K	001-33678	10.1	3/01/2019	
10.27	Security Agreement with China Kington Asset Management Co. Ltd., dated February 27, 2019 (in connection with the Promissory Note of the same date)	8-K	001-33678	10.2	3/01/2019	
10.28	Securities Purchase Agreement between the Company and Iliad Research and Trading, L.P., dated March 26, 2019	8-K	001-33678	10.2	3/28/2019	
10.29	Secured Convertible Promissory Note from the Company to Iliad Research and Trading, L.P., dated March 26, 2019	8-K	001-33678	10.3	3/28/2019	
10.30	Security Agreement between the Company and Iliad Research and Trading, L.P., dated March 26, 2019	8-K	001-33678	10.4	3/28/2019	
10.31	Consulting Agreement between the Company and China Kington, dated March 1, 2019					X
31.1	Certification of the Principal Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a)					X
31.2	Certification of the Principal Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a)					X
32.1	Certification by the Chief Executive Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)					X
32.2	Certification by the Chief Financial Officer of NovaBay Pharmaceuticals, Inc., as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X

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

+ Indicates a management contract or compensatory plan or arrangement

† NovaBay Pharmaceuticals, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been separately filed with the Securities and Exchange Commission.

SIGNATURES

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

Date: March 29, 2019

By: /s/ Justin Hall
Justin Hall

Interim President and Chief Executive Officer

(principal executive officer)

Date: March 29, 2019

By: /s/ Jason Raleigh
Jason Raleigh

Interim Chief Financial Officer

(principal financial officer)

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ JUSTIN HALL **Justin Hall**	Interim President and Chief Executive Officer (*principal executive officer*)	March 29, 2019
/s/ JASON RALEIGH **Jason Raleigh**	Interim Chief Financial Officer (*principal financial officer*)	March 29, 2019
/s/ PAUL E. FREIMAN **Paul E. Freiman**	Chairman of the Board	March 29, 2019
/s/ MARK M. SIECZKAREK **Mark M. Sieczkarek, M.B.A.**	Director	March 29, 2019
/s/ YONGHAO MA **Yonghao Ma, Ph.D. (Carl MA)**	Director	March 29, 2019
/s/ GAIL MADERIS **Gail Maderis, M.B.A.**	Director	March 29, 2019
/s/ TODD ZAVODNICK **Todd Zavodnick**	Director	March 29, 2019
/s/ XINZHOU LI **Xinzhou Li (Paul LI)**	Director	March 29, 2019
/s/ MIJIA WU **Mijia Wu, M.B.A. (Bob WU)**	Director	March 29, 2019
/s/ XIAOYAN LIU **Xiaoyan Liu (Henry LIU)**	Director	March 29, 2019