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, 2019

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	**Trading Symbol(s)**	**Name of Each Exchange On Which Registered**
Common Stock, par value $0.01 per share	NBY	NYSE American

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 15(d) of the Exchange 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 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, 2019, 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 $15,627,956. This figure excludes an aggregate of 11,485,433 shares of common stock held by affiliates, including officers and directors, as of June 30, 2019. 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, 2020, there were 28,010,564 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, 2019

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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. 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

NovaBay Pharmaceuticals, Inc. is a medical device company predominately focused on eye care. For the past four years, we have been focused primarily on commercializing Avenova®, an FDA cleared 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 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 around the eye, including the eyelid.

In the first quarter of 2019, our gross and net revenue and profit margins were adversely affected when many national insurance payors stopped reimbursing customers for their purchase of Avenova. Despite consistent demand for Avenova, we were challenged by the costs of maintaining an expanded commercial organization with our new lower net selling price. In the first quarter of 2019, we made a strategic shift by significantly reducing the number of field sales representatives by about three-quarters and redeploying our remaining representatives in territories that account for about 95% of retail pharmacy sales. This shift allowed us to effectively utilize our streamlined commercial resources to reach higher-prescribing physicians while significantly reducing our operating expenses.

Going forward, our core business strategy is centered around increasing sales of Avenova in all distribution channels: (1) Avenova Direct, our direct-to-consumer model, allowing customers to forego time-consuming doctor visits and trips to the pharmacy; (2) Retail Pharmacies, selling to consumers through local pharmacies across 50 states; (3) our Partner Pharmacy Program, providing a consistent patient experience at contracted pricing; and (4) our Buy-and-Sell channel, allowing patients to buy Avenova during their office visits to their preferred eye care specialist.

Beyond Avenova, 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. For NeutroPhase, we have established a U.S. distribution partner and an international distribution partner in China. For CelleRx, we began selling directly to the consumer on November 1, 2019 through CelleRx.com, a low-cost online distribution channel leveraging much of the same infrastructure already in place for Avenova Direct. Avenova, NeutroPhase, and CelleRx are medical devices cleared by the FDA under the Food and Drug Administration Act Section 510(k).

Avenova

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 use. We believe that Avenova offers distinct advantages when compared to alternative regimens that contain soaps, bleach, and other impurities, as Avenova removes unwanted microorganisms from the skin without the use of harmful ingredients such as detergents and bleach.

We currently believe our target market is the millions of Americans who suffer from minor irritation of the skin around the eye (commonly referred to as blepharitis). We began selling Avenova in the United States in 2014. 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 provide greater control over the patient experience at consistent contract pricing. 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.

Avenova Direct was launched on June 1, 2019 to U.S. customers exclusively on Amazon.com. Avenova Direct is the same strength hypochlorous formulation as Avenova Rx, but comes in a smaller 20mL size and is sold without a prescription. This channel offers the Company stable gross-to-net pricing and provides customers with easy access to our product. This model capitalizes on a trend to sell pharmaceutical products directly to consumers in response to increased cost shifting to consumers through high-deductible health plans, and adds convenience by allowing customers to forego a time-consuming doctor visit and trip to the pharmacy. We are promoting this program through complimentary social media marketing to target consumers in specific demographics, as well as to ophthalmologists, optometrists, and current and former Avenova patients.

We expect that our prescription business will continue to be an important part of total Avenova sales because the support for Avenova from the medical community is important to maintaining its reputation as a preferred product. Although we are seeking and have pursued new distribution channels such as Avenova Direct, we continue to focus the efforts of our sales staff 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, directly through the practitioners' office or Avenova Direct.

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 Avenova lacks these impurities, we believe that physicians and their patients will choose Avenova over other competitive prescription products or over-the-counter hypochlorous acid products. While cheaper antibacterial soaps are commonly used to reduce or prevent bacterial contamination on the skin, we do not view them as effective competitors of Avenova.

CelleRx (Dermatology)

Created for cosmetic procedures, CelleRx (0.01% hypochlorous acid as a preservative in solution), an FDA-cleared medical device, 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. Beginning November 1, 2019, we now sell CelleRx directly to the consumer through CelleRx.com, our online distribution channel.

NeutroPhase (Wound Care)

Consisting of 0.03% hypochlorous acid, NeutroPhase, an FDA-cleared medical device, 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.

Aganocide® Compounds

This second product category includes auriclosene®, (NVC-422), 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" or 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.

Customers, Manufacturing and Suppliers

Historically, our salesforce primarily called on ophthalmologists, optometrists, and other eye care professionals who can prescribe Avenova. There are currently over 7,000 doctors prescribing Avenova in the United States. These doctors have written approximately 135,000 prescriptions in the United States for Avenova in 2019. 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, 2019.

Now, in addition to prescriptions, U.S. customers have direct access to Avenova through Avenova Direct. Since the consumer launch of Avenova Direct on Amazon.com and Avenova.com on June 1, 2019, this distribution channel has generated $1.0 million in revenue. During the second half of the year Avenova Direct accounted for 28% of all Avenova revenue and 43% of all Avenova units sold across all channels. Similarly, CelleRx is distributed to customers through an online channel, CelleRx.com, while NeutroPhase relies on distribution partners.

We currently outsource manufacturing of Avenova, CelleRx and NeutroPhase to two contract manufacturers with facilities located in the United States. We believe our contract manufacturers have adequate manufacturing capacity to satisfy our demands and 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 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, 2019, we maintain many worldwide patents. 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, as well as CelleRx and NeutroPhase. 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 as we are instead focused almost exclusively on Avenova. Within our Aganocide compound patent family, we own eight issued U.S. patents.

Research and Development

For the years ended December 31, 2019 and 2018, we incurred total research and development expenses of approximately $0.2 million and $0.3 million, respectively. Pursuant to our business strategy focusing our resources on growing the commercial sales of Avenova and maintaining expense, we are currently not conducting any substantive research and development. Any substantial research and development costs incurred in the future would likely be related to our urology program, which we do not expect to move forward at this time.

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 FDA 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 12 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 that 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 who 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, in 2019, we received notices from several national payors that Avenova would not be covered. Currently, none of our products are reimbursed by federal healthcare programs, such as Medicare and Medicaid, and we do not anticipate 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, 2019, we had a total of 28 employees, 26 of whom were full-time employees and 2 were part-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our principal executive office and administrative operations are located in Emeryville, California. On August 24, 2016, we entered into an Office Lease (the "Lease"), pursuant to which we leased approximately 7,799 rentable square feet of real property located on the eleventh floor (Suite 1150) at 2000 Powell Street, Emeryville, California 94608 from KBSIII Towers at Emeryville, LLC (the "Landlord"), for our 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

On February 27, 2019, the Company issued a $1.0 million promissory note payable to Pioneer Pharma (Hong Kong) Company Ltd. (“Pioneer Hong Kong”), which was amended on June 25, 2019 (the “Promissory Note”). The Promissory Note currently bears an interest payment of $300 thousand (initially $150 thousand) and is payable in full upon the Company's next financing with Pioneer Hong Kong and in no event after July 1, 2020 (an extension per the June amendment from the initial maturity date of July 27, 2019). The transaction 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 Promissory Note, the Company paid China Kington a 2% fee for brokering the transaction and has entered into a consulting agreement with China Kington for a term of one year. 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 thousand pursuant to such consulting agreement.

On March 26, 2019 (the “Closing Date”), the Company entered into a Securities 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 net proceeds of $2.0 million after deducting an original issue discount of $200 thousand and debt issuance cost of Lender’s transaction fees of $15 thousand. The Company recognized an additional $182 thousand of debt issuance costs associated with the issuance of the Convertible Note.

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.

On August 8, 2019, the Company entered into a securities purchase agreement (the "August SPA") with certain domestic investors for the sale and issuance of 4,198,566 shares of common stock in a registered direct offering and 4,198,566 warrants exercisable for 4,198,566 shares of common stock in a simultaneous private placement at an offering price of $1.00 per share. The August SPA prohibits the Company from redeeming in common stock or common stock equivalents in satisfaction of the Promissory Note with Iliad Research & Trading, L.P. and may only issue common stock in satisfaction of the Promissory Note if the stock price equals or exceeds $2.00. The Lender started redeeming $200 thousand of the Convertible Note every month since September 27, 2019. As of December 31, 2019, the Company had repaid a total of $800 thousand, $652 thousand of which was applied against the outstanding balance of the convertible note. See Note 10, "Convertible Note" of the Notes to Consolidated Financial Statements for detailed information related to the convertible note.

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 2020 expenses will exceed our 2020 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. Any additional financing that we are able to secure in the near-term may be limited and may only provide working capital sufficient into the second quarter of 2020. As such, additional funding will be needed in both the short- and long-term in order to pursue our business plan, which includes a direct-to-consumer marketing campaign for Avenova Direct, 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 have recently suffered and will continue to suffer, from a decline in product revenue due to the decrease in insurance coverage of Avenova by national payors;
- we expect to incur substantial marketing and sales expenses as we continue to attempt to increase sales of our Avenova product;
- our results of operations may fluctuate significantly;
- we may be unable to develop and commercialize our product candidates; and
- it may be difficult to forecast accurately our key operating and performance metrics because of our limited operating history.

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

Risks Relating to Owning Our Common Stock

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

On April 12, 2019, we received a letter from the NYSE American notifying us that our stockholders' equity as of December 31, 2018 was below the minimum requirements of Section 1003(a)(iii) of the NYSE American Company Guide (the "Company Guide") (requiring stockholders' equity of $6.0 million or more if a company has reported losses from continuing operations and/or net losses in its five most recent fiscal years) and requiring the Company to submit a plan to regain compliance by October 12, 2020. On May 16, 2019, the Company was further notified by NYSE American that the Company was not in compliance with the minimum stockholders' equity requirements of Sections 1003(a)(i) and 1003(a)(ii) of the Company Guide requiring stockholders' equity of $2.0 million or more and $4.0 million or more, respectively, if the Company has reported losses from continuing operations and/or net losses in three of the four most recent fiscal years. Therefore, the Company is subject to the procedures and requirements of Section 1009 of the Company Guide, and, in compliance with such requirements, the Company submitted a plan to regain compliance on May 11, 2019. The Company was notified on June 27, 2019 that the Company's plan to regain compliance had been accepted. If the Company does not regain compliance with those standards, or does not make progress consistent with the plan, the NYSE American staff may commence delisting proceedings.

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.

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

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

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

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

The number of shares of our common stock being actively traded may be very low and any stockholder wishing to sell his, her, or its stock may cause a significant fluctuation in the price of our stock. We have a number of large stockholders, including our two largest stockholders, Mr. Jian Ping Fu and China Pioneer Pharma Holdings Limited ("China Pioneer"). As of March 24, 2020, each of Mr. Fu and China Pioneer owned approximately 18.9% and 18.5% of our common stock, respectively. The sale of a substantial number of shares of common stock by such large stockholders within a short period of time could cause our stock price to decrease substantially. In addition, low trading volume of a stock increases the possibility that, despite rules against such activity, the price of the stock may be manipulated by persons acting in their own self-interest. We may not have adequate market makers and market making activity to prevent manipulation.

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

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

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

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

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

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

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

China Pioneer beneficially owns approximately 18.6% of our outstanding common stock. Our director Mr. Xinzhou "Paul" Li is the chairman of China Pioneer. Pursuant to the arrangement of a certain bridge loan, facilitated by China Kington in January 2016, two (2) 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 (as defined below). Effective March 21, 2019, Mr. Jian Ping Fu purchased all of the 1,700,000 shares previously held by OP Financial Investments Limited, and Mr. Fu now beneficially owns approximately 19.0% of our common stock. Subsequent to such purchase by Mr. Fu, effective May 1, 2019, Mr. Lawrence Liu resigned from the Company's Board. On July 20, 2019, Mr. Xiaopei (Ray) Wang, a nominee of Mr. Fu, was appointed to the Board of Directors. China Kington and its affiliates have served as placement agent for three purchases of Company securities by Mr. Fu during 2016, one purchase of Company securities by OP Financial Investments Limited in 2018 and two private placements in 2019. Additionally, China Kington facilitated the Promissory Note from Pioneer Hong Kong in February 2019.

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, and/or Mr. Fu 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, and Mr. Fu could ensure that four (4) of our seven (7) directors are either nominees of China Pioneer, Pioneer Hong Kong, or China Kington after our 2021 annual meeting of stockholders. In the interim, China Pioneer, Pioneer Hong Kong, China Kington, and/or Mr. Fu could exert significant indirect influence on us and our management.

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 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 150,526 shares of our common stock, of which the warrants exercisable for 112,526 shares expired on March 6, 2020 (with the warrants exercisable for 394,169 shares previously exercised), and the warrants exercisable for 38,000 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 agreed to reduce the exercise price of all Warrants to such lower price (with such provision only applicable to the October 2015 Warrants due to the expiration of the July 2011 Warrants and March 2015 Warrants). The exercise price of the October 2015 Warrants is currently set at $0.2061 as a result of the Company's transaction with Triton Funds LP. Any further reduction of the exercise price for the October 2015 Warrants could 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 October 2015 Warrants are currently exercisable and will remain so after any exercise price adjustment. In the past, we 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 to the October 2015. 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.

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 96% of our revenue for 2019. We are dedicating a substantial amount of our resources to advance Avenova aggressively. 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:

- the 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 we 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, is 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. This risk may grow with the increased visibility of Avenova Direct online. 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 two 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 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. We rely solely on Amazon.com for sales of Avenova Direct. If something were to impair the relationship between NovaBay and Amazon.com it would have a negative impact on our business.

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 our 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 the 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 as well as our products under development, if and when 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 our 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 distributors will sell Avenova or NeutroPhase or products that we currently do not sell but may sell in the future such as 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.

Our business may be adversely affected by the recent coronavirus outbreak.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. In January 2020, this coronavirus spread to other countries, including the United States, and efforts to contain the spread of this coronavirus intensified including certain San Francisco Bay area counties (including Alameda county where the Company is located) ordering a shelter-in-place mandate.

The outbreak and any preventative or protective actions that we or our customers may take in respect of this coronavirus may result in a period of disruption to work in progress. Our businesses could be disrupted, and our ongoing and future revenues could be negatively affected. Any resulting financial impact cannot be reasonably estimated at this time but may materially affect our business and financial condition. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

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

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. On July 29, 2019, Mr. John McGovern, the Company’s former Interim President & Chief Executive Officer and Chief Financial Officer, submitted a demand for arbitration seeking severance in the amount of $370,000 as well as additional damages in connection with his separation from service with the Company. The Company does not believe the claims asserted by Mr. McGovern have any merit, and the Company intends to defend against all such claims. As of December 31, 2019, there are no other matters that, in the opinion of management, would ultimately result in liability that would have a material adverse effect on the Company’s financial position, results of operations or cash flows.

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 24, 2020, there were approximately 95 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

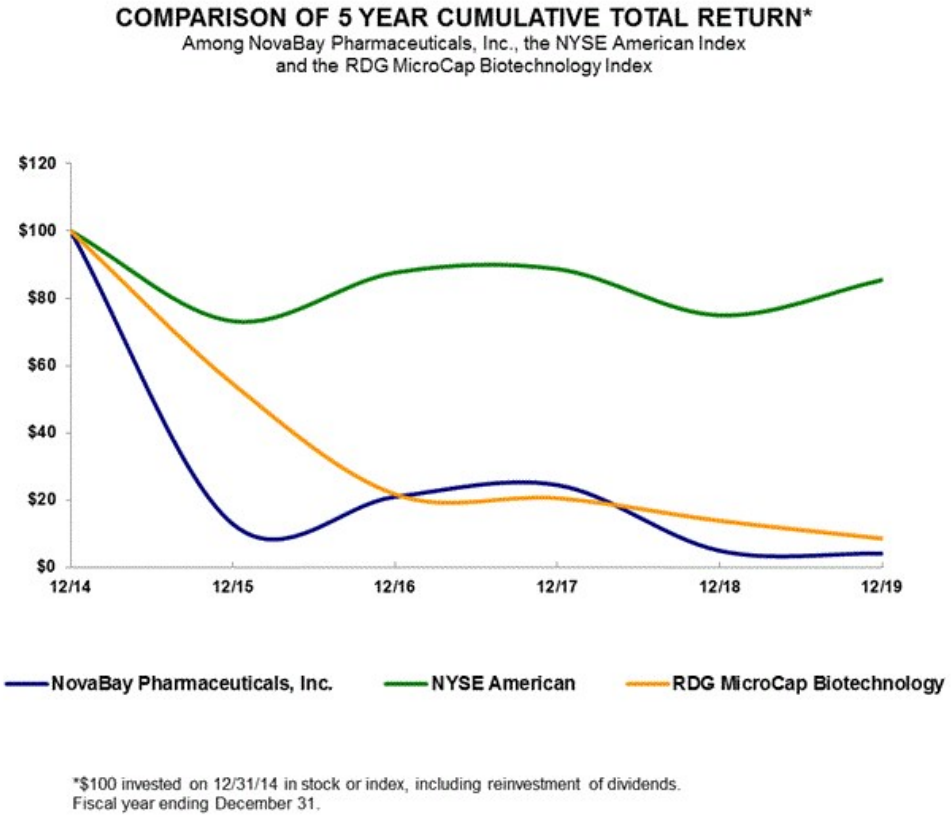
We have not paid cash dividends on our common stock since our inception. We currently expect to retain earnings primarily for use in the operation and expansion of our business; therefore, we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends 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.



	12/14	12/15	12/16	12/17	12/18	12/19
NovaBay Pharmaceuticals, Inc.	**100.00**	**12.83**	**20.95**	**24.44**	**4.91**	**4.06**
NYSE American	**100.00**	**73.17**	**87.62**	**88.68**	**74.91**	**85.42**
RDG MicroCap Biotechnology	**100.00**	**54.53**	**21.69**	**20.57**	**13.81**	**8.53**

(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,				
	2019	2018	2017	2016	2015
	(in thousands, except per share data)				
Statements of Operations Data:					
Sales:					
Product revenue, net	$ 6,556	$ 12,474	$ 18,127	$ 11,617	$ 4,146
Other revenue, net	43	34	103	280	235
Total sales, net	6,599	12,508	18,230	11,897	4,381
Product cost of goods sold	1,738	1,503	2,784	2,464	1,261
Gross profit	4,861	11,005	15,446	9,433	3,120
Operating expenses:					
Research and development	184	259	410	1,371	5,728
Sales and marketing	8,767	12,789	13,711	11,809	10,523
General and administrative	5,310	5,828	8,636	7,235	8,006
Total operating expenses	14,261	18,876	22,757	20,415	24,257
Operating loss	(9,400)	(7,871)	(7,311)	(10,982)	(21,137)
Non-cash gain (loss) on changes in fair value of warrant liability	749	1,311	(101)	(2,099)	2,149
Non-cash gain on changes in fair value of embedded derivative liability	424	—	—	—	—
Other (expense) income, net	(1,425)	19	12	(68)	17
Loss before provision for income taxes	(9,652)	(6,541)	(7,400)	(13,149)	(18,971)
Provision for income taxes	(6)	(4)	(3)	(2)	(2)
Net loss	$ (9,658)	$ (6,545)	$ (7,403)	$ (13,151)	$ (18,973)
Less: Preferred deemed dividend	800	—	—	—	—
Less: Retained earnings reduction related to warrants down round feature triggered	29	—	—	—	—
Net loss attributable to common stockholders	$ (10,487)	$ (6,545)	$ (7,403)	$ (13,151)	$ (18,973)
Net loss per share attributable to common stockholders:					
Basic	$ (0.48)	$ (0.39)	$ (0.48)	$ (1.40)	$ (6.82)
Diluted	$ (0.48)	$ (0.46)	$ (0.48)	$ (1.40)	$ (6.82)
Shares used in computing net loss per share:					
Basic (after 1 for 25 reverse stock split)	21,641	16,921	15,324	9,408	2,784
Diluted (after 1 for 25 reverse stock split)	21,641	17,058	15,324	9,408	2,784

	As of December 31,				
	2019	2018	2017	2016	2015
			(in thousands)		
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 6,937	$ 3,183	$ 3,199	$ 9,512	$ 2,385
Working capital	3,694	4,761	4,016	10,148	(106)
Total assets	11,220	9,361	10,079	15,381	5,077
Deferred revenue—current and non-current	—	41	3,375	4,053	2,418
Common stock and additional paid-in capital	125,997	119,935	113,668	110,772	85,422
Total stockholders' equity (deficit)	973	4,954	2,594	7,101	(5,098)

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®, an FDA cleared 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 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 around the eye, including the eyelid.

In the first quarter of 2019, many national insurance payors stopped reimbursing Avenova. Despite consistent demand for Avenova, we were challenged by the costs of maintaining an expanded commercial organization with our new lower net selling price. In the second quarter of 2019, we made a strategic shift by significantly reducing the number of field sales representatives by about three-quarters and redeploying our remaining representatives in territories that account for about 95% of retail pharmacy sales. This shift allowed us to effectively utilize our streamlined commercial resources to reach higher-prescribing physicians while significantly reducing our operating expenses.

Going forward, our core business strategy is centered around increasing sales of Avenova in all distribution channels: (1) Avenova Direct, our direct-to-consumer model, allowing customers to forego time-consuming doctor visits and trips to the pharmacy; (2) Retail Pharmacies, selling to consumers through local pharmacies across 50 states; (3) our Partner Pharmacy Program, providing a consistent patient experience at contracted pricing; and (4) our Buy-and-Sell channel, allowing patients to buy Avenova during their office visits to their preferred eye care specialist.

Beyond Avenova, 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. For NeutroPhase, we have established a U.S. distribution partner and an international distribution partner in China. For CelleRx, we began selling directly to the consumer on November 1, 2019 through CelleRx.com, a low-cost online distribution channel leveraging much of the same infrastructure already in place for Avenova Direct. Avenova, NeutroPhase, and CelleRx are medical devices cleared by the FDA under the Food and Drug Administration Act Section 510(k).

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, 2019 and 2018, management had reserved $51 thousand and $10 thousand, respectively, primarily based on specific amounts that were in dispute or were over 120 days past due as of those dates.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. At December 31, 2019 and 2018, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $247 thousand and $104 thousand, respectively.

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

Leases

In February 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases (Topic 842)*, to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019. Using the optional transition method, prior period financial statements have not been recast to reflect the new lease standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use assets may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component for all leases in which it is a lessee or a lessor. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities current and operating lease liabilities non-current. As a result, as of the effective date, the Company no longer recognizes deferred rent on the balance sheet.

Revenue Recognition

The Company generates product revenue through product sales to its major distribution partners, a limited number of distributors and via its webstore and Amazon.com. 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 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 ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 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, 2018	$ (600)	$ (61)	$ (329)	$ (442)	$ (1,432)
Current provision related to sales made during current period	(1,085)	(183)	(4,193)	(247)	(5,708)
Payments	1,543	231	4,675	257	6,706
Balance at December 31, 2019	$ (142)	$ (13)	$ 153	$ (432)	$ (434)

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 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 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 lower of cost or estimated net realizable value.

Research and Development Costs

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

Stock-Based Compensation

The Company's stock-based compensation includes grants of stock options and restricted stock units, or restricted stock units ("RSUs"), to employees, consultants and non-employee directors. The expense associated with these programs is recognized in the Company's consolidated statements of stockholders' equity based on their fair values as they are earned under the applicable vesting terms or the length of an offering period. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model. See Note 13, "Equity-Based Compensation" of the Notes to Consolidated Financial Statements 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

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

The Company accounts for the issuance of common stock purchase warrants issued in connection with the equity offerings in accordance with the provisions of Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging*. The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). For warrants that are classified as liabilities, the Company records the fair value of the warrants 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 Black-Scholes valuation method or the Binomial Lattice ("Lattice") valuation model where deemed appropriate. These values are subject to a significant degree of the Company's judgment.

On January 1, 2019, the Company adopted ASU 2017-11 and changed its method of accounting for certain warrants that were initially recorded as liabilities due to their down round features on a modified retrospective basis. ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as liabilities. We will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For warrants classified as equity, we will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share.

Recent Accounting Pronouncements

See Note 2, "Summary of Significant Accounting Policies" of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this report for information on recent accounting pronouncements.

Results of Operations

Comparison of Years Ended December 31, 2019 and 2018

(in thousands, except percentages)	Year Ended December 31, 2019	2018	Dollar Change	Percent Change
	(in thousands)		(in thousands)	
Statement of Operations				
Sales:				
Product revenue, net	$ 6,556	$ 12,474	$ (5,918)	(47%)
Other revenue, net	43	34	9	26%
Total sales, net	6,599	12,508	(5,909)	(47%)
Product cost of goods sold	1,738	1,503	235	16%
Gross profit	4,861	11,005	(6,144)	(56%)
Research and development	184	259	(75)	(29%)
Sales and marketing	8,767	12,789	(4,022)	(31%)
General and administrative	5,310	5,828	(518)	(9%)
Total operating expenses	14,261	18,876	(4,615)	(24%)
Operating loss	(9,400)	(7,871)	(1,529)	19%
Non-cash gain on changes in fair value of warrant liability	749	1,311	(562)	(43%)
Non-cash gain on changes in fair value of embedded derivative liability	424	—	424	100%
Other (expense) income, net	(1,425)	19	(1,444)	(7600%)
Loss before provision for income taxes	(9,652)	(6,541)	(3,111)	48%
Provision for income taxes	(6)	(4)	(2)	50%
Net loss and comprehensive loss	$ (9,658)	$ (6,545)	$ (3,113)	48%

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

Product revenue, net, decreased by $5.9 million, or 47%, to $6.6 million for the year ended December 31, 2019, from $12.5 million for the year ended December 31, 2018. The decrease in product revenue, net, is primarily the result of a decrease in the net selling price of Avenova products, along with a decrease in the number of Avenova units sold. The decrease in the net selling price as well as the decrease in the number of units sold of Avenova was largely due to a decrease in insurance coverage of the product by national payors. In response to this pricing pressure, NovaBay launched Avenova Direct, which although assisted in increasing Avenova sales, has a lower net selling price.

Other revenue, net, increased by $9 thousand, or 26%, to $43 thousand for the year ended December 31, 2019, from $34 thousand for the year ended December 31, 2018. The increase in Other revenue was due to the Company being relieved of contract liability as a result of changes in contract terms associated with the distribution agreement with China Pioneer in the first quarter of 2019.

Product cost of goods sold increased by $0.2 million, or 16%, to $1.7 million for the year ended December 31, 2019, from $1.5 million for the year ended December 31, 2018. The increase in product cost of goods sold was primarily the result of a higher production cost as a result of non-continuous production.

Gross profit decreased by $6.1 million, or 56%, to $4.9 million for the year ended December 31, 2019, from $11.0 million for the year ended December 31, 2018. The decrease in gross profit was primarily the result of decreased product revenue, net.

Research and Development

Research and development expenses decreased by $75 thousand, or 29%, to $184 thousand for the year ended December 31, 2019, from $259 thousand for the year ended December 31, 2018. 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 $4.0 million, or 31%, to $8.8 million for the year ended December 31, 2019, from $12.8 million for the year ended December 31, 2018. The decrease was primarily due to a decrease in sales representative headcount, along with a decrease in complimentary samples of Avenova provided to doctors and contractual samples of NeutroPhase provided to China Pioneer. This decrease was partly off-set by an increase in Avenova Direct advertising.

General and administrative

General and administrative expenses decreased by $0.5 million, or 9%, to $5.3 million for the year ended December 31, 2019, from $5.8 million for the year ended December 31, 2018. The decrease is primarily a result of a reduction in force. This includes the resignations of both the then CEO/CFO in the first quarter of 2019 and the then CEO in the third quarter of 2018, resulting in lower executive officer salary and stock-based compensation. Also contributing to the decrease was lower depreciation. This decrease was partly off-set by severance payment and a consulting agreement with the CEO who resigned in the third quarter of 2018 and later resigned from the board of directors in the third quarter of 2019.

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

The adjustments to the fair value of warrants was a gain of $0.7 million for the year ended December 31, 2019, compared to a gain of $1.3 million for the year ended December 31, 2018.

For additional information regarding the warrants and their valuation, please see Note 11, “Warrant Liability” in the Notes to Consolidated Financial Statements included in Part II, Item 8 of this report. For the years ended December 31, 2019 and 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.

Non-cash gain on changes in fair value of embedded derivative liability

The adjustments to the fair value of embedded derivative liability resulted in a gain of $0.4 million for the year ended December 31, 2019. The gain resulted from the Company’s intent to settle the Convertible Note in cash in lieu of stock pursuant to the August SPA. For additional information regarding the terms of the August SPA, please see Note 12, “Stockholders’ Equity” in the Notes to Consolidated Financial Statements. The Company did not record a comparable loss or gain for the year ended December 31, 2018.

Other (expense) income, net

Other (expense) income, net, was an expense of $1.4 million compared to income of $19 thousand for the years ended December 31, 2019 and December 31, 2018, respectively. The expense of $1.4 million for the year ended December 31, 2019 was due to the interest of $204 thousand due on the Promissory Note issued in February 2019, the amortization of the issuance cost of $18 thousand related to the Promissory Note issued in February 2019, the amortization of discount and issuance cost of $831 thousand related to the Convertible Note issued in March 2019, and the issuance cost of $384 thousand related to the issuance of warrants in August 2019. For additional information regarding the Promissory Note, please see Note 9, “Related Party Notes Payable” of the Notes to Consolidated Financial Statements. For additional information regarding the Convertible Note, please see Note 10, “Convertible Note” of the Notes to Consolidated Financial Statements. For additional information regarding the issuance of common stock, Series A Preferred Stock and warrants in August 2019, please see Note 12, “Stockholders’ Equity” in the Notes to Consolidated Financial Statements.

Comparison of Years Ended December 31, 2018 and 2017

For this discussion, see the "Comparison of Years Ended December 31, 2018 and 2017 in Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Liquidity and Capital Resources

As of December 31, 2019 and December 31, 2018, our cash and cash equivalents were $6.9 million, compared to $3.2 million as of December 31, 2018. 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, 2019, cash used in operating activities was $7.9 million compared to $5.6 million for the year ended December 31, 2018. The increase was primarily due to the increase in net loss by $3.1 million due to decreased product sales combined with reduction in insurance coverage of the product by national payors, a decrease in depreciation and amortization expense of $0.2 million, unfavorable changes in working capital of $0.2 million and gain on change of the derivative liability fair value by $0.4 million, offset by the impairment of right-of-use assets and property and equipment of $0.2 million, increase in stock compensation of $0.1 million, favorable change of the warrant liability fair value by $0.6 million, and interest expense related to amortization of debt issuance cost and debt discount of $0.7 million.

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.

Cash Used in Investing Activities

For the years ended December 31, 2019, 2018 and 2017, cash used in investing activities was for the purchase of property and equipment of $19 thousand, $44 thousand and $244 thousand, respectively.

Cash Provided by Financing Activities

Net cash provided by financing activities was $11.7 million for the year ended December 31, 2019, which was attributable to net proceeds of $12.1 million from several financing activities during 2019, including the private placement with three accredited investors in June 2019, issuance of common stock to Triton Funds LP in the second quarter of 2019, issuance of the Promissory Note to Pioneer Hong Kong in February 2019, issuance of the Convertible Note to Iliad Research and Trading L.P. in March 2019, issuance of common stock in a direct registered offering and warrant in a simultaneous private placement in August 2019 and issuance of the Series A Preferred Stock and warrants in a private placement in August 2019. The aggregate proceeds of $12.1 million was offset by repayments of $0.7 million on the convertible note issued to Iliad Research and Trading L.P. during the year of 2019. The Company received an additional $0.3 million from exercise of warrants and stock options during the year of 2019.

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 Company's private placement of 1,700,000 shares of the Company's common stock for an aggregate price of $5.984 million, net of $0.4 million of issuance costs (the "OP Private Placement"). See Note 12, "Stockholders' Equity" in the Notes to Consolidated Financial Statements 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.

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, 2019. 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, 2019	September 30, 2019	June 30, 2019	March 31, 2019	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
	(in thousands, except per share data)							
Statements of Operations Data:								
Sales:								
Product revenue, net	$ 1,702	$ 1,615	$ 1,789	$ 1,450	$ 3,604	$ 3,142	$ 2,794	$ 2,934
Other revenue, net	2	—	—	41	21	—	—	13
Total sales, net	1,704	1,615	1,789	1,491	3,625	3,142	2,794	2,947
Product cost of goods sold	593	401	403	341	441	332	479	251
Gross profit	1,111	1,214	1,386	1,150	3,184	2,810	2,315	2,696
Operating expenses:								
Research and development	18	49	32	85	107	45	61	46
Sales and marketing	2,157	1,544	1,535	3,531	3,186	3,230	2,977	3,396
General and administrative	1,174	1,333	1,198	1,605	1,502	1,344	1,360	1,622
Total operating expenses	3,349	2,926	2,765	5,221	4,795	4,619	4,398	5,064
Operating loss	(2,238)	(1,712)	(1,379)	(4,071)	(1,611)	(1,809)	(2,083)	(2,368)
Non-cash (loss) gain on changes in fair value of warrant liability	(187)	1,480	(487)	(57)	340	267	490	214
Non-cash gain (loss) on changes in fair value of embedded derivative liability	1	669	(246)	—	—	—	—	—
Other (expense) income, net	(259)	(719)	(387)	(60)	6	4	5	4
Loss before provision for income taxes	(2,683)	(282)	(2,499)	(4,188)	(1,265)	(1,538)	(1,588)	(2,150)
Provision for income taxes	(3)	—	(2)	(1)	(3)	—	(1)	—
Net loss	$ (2,686)	$ (282)	$ (2,501)	$ (4,189)	$ (1,268)	$ (1,538)	$ (1,589)	$ (2,150)
Less: Preferred deemed dividend	800	—	—	—	—	—	—	—
Less: Retained earnings reduction related to warrants down round feature triggered	—	—	29	—	—	—	—	—
Net loss attributable to common stockholders	$ (3,486)	$ (282)	$ (2,530)	$ (4,189)	$ (1,268)	$ (1,538)	$ (1,589)	$ (2,150)
Net loss per share attributable to common stockholders:								
Basic	$ (0.13)	$ (0.01)	$ (0.14)	$ (0.25)	$ (0.07)	$ (0.09)	$ (0.09)	$ (0.13)
Diluted	$ (0.13)	$ (0.02)	$ (0.14)	$ (0.25)	$ (0.07)	$ (0.11)	$ (0.12)	$ (0.14)
Shares used in computing net loss per share:								
Basic	27,630	23,096	18,613	17,093	17,089	17,089	17,089	16,406
Diluted	27,630	23,213	18,613	17,093	17,089	17,148	17,292	16,670

As of December 31, 2019, we had net operating loss carryforwards for federal and state income tax purposes of $111.0 million and $90.5 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 $16.2 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, 2019, 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, 2019 and December 31, 2018 as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Seasonality

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

Contractual Obligations

Our contractual cash commitments as of December 31, 2019 were as follows (in thousands):

Contractual Obligations	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Facility leases	$ 1,025	$ 513	$ —	$ —	$ 1,538
Vehicle leases	6	—	—	—	6
Equipment leases	16	29	—	—	45
Total	$ 1,047	$ 542	$ —	$ —	$ 1,589

Our commitments as of December 31, 2019 consist of two operating facility leases, the Lease and the lease for EmeryStation, 15 operating vehicle leases, and 2 copiers.

The total commitment for the Lease as of December 31, 2019 was $0.9 million due over the lease term, compared to $1.4 million as of December 31, 2018.

The total commitment of the EmeryStation lease as of December 31, 2019 was $0.6 million due over such lease term, compared to $1.3 million as of December 31, 2018. 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 $0.6 million in the year ending December 31, 2020, under the Sublease Agreement for the lease of EmeryStation.

We have operating leases for a fleet of 15 vehicles as of December 31, 2019. The total commitment for these leases as of December 31, 2019 was $6 thousand due over the lease terms, compared to $176 thousand as of December 31, 2018.

We have an operating lease for 2 copiers as of December 31, 2019. The total commitment for the lease as of December 31, 2019 was $45 thousand due over the lease terms, compared to an immaterial amount as of December 31, 2018.

See Note 8, “Commitments and Contingencies” in the Notes to Consolidated Financial Statements 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, 2019 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, 2019 and 2018, 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, 2019 and 2018 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2019**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has experienced operating losses for most of its history and expects expenses to exceed revenues in 2020. 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 consolidated 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 26, 2020
We have served as the Company's auditor since 2010.

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,937	$ 3,183
Accounts receivable, net of allowance for doubtful accounts ($51 and $10 at December 31, 2019 and December 31, 2018, respectively)	1,066	3,385
Inventory, net of allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments ($247 and $104 at December 31, 2019 and December 31, 2018, respectively)	492	280
Prepaid expenses and other current assets	886	1,760
Total current assets	9,381	8,608
Operating lease right-of-use assets	1,252	—
Property and equipment, net	110	201
Other assets	477	552
TOTAL ASSETS	$ 11,220	$ 9,361
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$ 331	$ 551
Accrued liabilities	1,778	3,255
Deferred revenue	—	41
Operating lease liabilities	930	—
Notes payable, related party	1,202	—
Convertible note	1,409	—
Embedded derivative liability	3	—
Warrant liability	34	—
Total current liabilities	5,687	3,847
Operating lease liabilities-non-current	505	—
Deferred rent	—	184
Warrant liability	4,055	178
Other liabilities	—	198
Total liabilities	10,247	4,407
Stockholders' equity:		
Preferred stock: 5,000 shares authorized; none outstanding at December 31, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value; 50,000 shares authorized; 27,938 and 17,089 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	279	171
Additional paid-in capital	125,718	119,764
Accumulated deficit	(125,024)	(114,981)
Total stockholders' equity	973	4,954
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 11,220	$ 9,361

As the Company adopted the requirements of ASU 2016-02, *Leases (Topic 842)*, as of January 1, 2019, using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 2.

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,		
	2019	2018	2017
Sales:			
Product revenue, net	$ 6,556	$ 12,474	$ 18,127
Other revenue, net	43	34	103
Total sales, net	6,599	12,508	18,230
Product cost of goods sold	1,738	1,503	2,784
Gross profit	4,861	11,005	15,446
Research and development	184	259	410
Sales and marketing	8,767	12,789	13,711
General and administrative	5,310	5,828	8,636
Total operating expenses	14,261	18,876	22,757
Operating loss	(9,400)	(7,871)	(7,311)
Non-cash gain (loss) on changes in fair value of warrant liability	749	1,311	(101)
Non-cash gain on changes in fair value of embedded derivative liability	424	—	—
Other (expense) income, net	(1,425)	19	12
Loss before provision for income taxes	(9,652)	(6,541)	(7,400)
Provision for income taxes	(6)	(4)	(3)
Net loss and comprehensive loss	$ (9,658)	$ (6,545)	$ (7,403)
Less: Preferred deemed dividend	800	—	—
Less: Retained earnings reduction related to warrants down round feature triggered	29	—	—
Net loss attributable to common stockholders	$ (10,487)	$ (6,545)	$ (7,403)
Net loss per share attributable to common stockholders (basic)	$ (0.48)	$ (0.39)	$ (0.48)
Net loss per share attributable to common stockholders (diluted)	$ (0.48)	$ (0.46)	$ (0.48)
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (basic)	21,641	16,921	15,324
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (diluted)	21,641	17,058	15,324

As the Company adopted the requirements of ASU 2016-02, *Leases (Topic 842)*, as of January 1, 2019, using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 2.

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

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

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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
Net loss	—	—	—	—	—	—	(9,658)	(9,658)
Reclassification of Warrant Liability to Equity – see Note 2	—	—	—	—	412	—	(356)	56
Down round feature adjustment related to warrants	—	—	—	—	29	—	(29)	—
Issuance of Series A Preferred Stock and common stock warrants, net of offering costs	2,700	584	—	—	—	—	—	—
Conversion of Series A Preferred Stock to common stock	(2,700)	(584)	2,700	27	557	—	—	584
Beneficial conversion feature upon issuance of Series A Preferred Stock	—	—	—	—	800	—	—	800
Deemed dividend from beneficial conversion feature of Series A Preferred Stock	—	—	—	—	(800)	—	—	(800)
Issuance of common stock in connection with offering, net of offering costs	—	—	7,467	75	3,427	—	—	3,502
Issuance of common stock in connection with exercise of warrants	—	—	389	4	616	—	—	620
Issuance of RSUs related to employee separation agreement	—	—	168	2	218	—	—	220
Issuance of common stock for option exercises	—	—	83	—	189	—	—	189
Issuance of RSUs to non-employees for services	—	—	36	—	20	—	—	20
Vesting of employee restricted stock awards	—	—	6	—	10	—	—	10
Stock-based compensation expense related to employee and director stock options	—	—	—	—	334	—	—	334
Stock-based compensation expense related to non-employee and director stock options	—	—	—	—	37	—	—	37
Stock option modification	—	—	—	—	105	—	—	105
Balance at December 31, 2019	—	$ —	27,938	$ 279	$ 125,718	$ —	$ (125,024)	$ 973

As the Company adopted the requirements of ASU 2016-02, *Leases (Topic 842)*, as of January 1, 2019, using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 2.

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

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

	2019	2018	2017
Operating activities:			
Net loss	$ (9,658)	$ (6,545)	$ (7,403)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	65	266	95
Impairment of property and equipment	32	—	—
Loss on disposal of property and equipment	3	1	—
Impairment of operating lease right-of-use assets	125	—	—
Stock-based compensation expense for options and stock issued to employees and directors	334	594	1,867
Stock-based compensation expense for options and stock issued to non-employees	37	—	137
Stock option modification expense	105	77	504
Issuance of RSUs to employees	10	—	—
Issuance of RSUs related to employee separation agreement	220	—	—
Issuance of RSUs to non-employees for services	20	—	34
Non-cash (gain) loss on changes in fair value of warrant liability	(749)	(1,311)	101
Non-cash gain on changes in fair value of embedded derivative liability	(424)	—	—
Interest expense related to amortization of debt issuance and debt discount	670	—	—
Interest expense related to amortization of debt issuance related to related party notes payable	18	—	—
Issuance of warrants for services	59	—	—
Changes in operating assets and liabilities:			
Accounts receivable	2,319	774	(1,509)
Inventory	(212)	198	369
Prepaid expenses and other current assets	888	(97)	313
Operating lease right-of-use assets	861	—	—
Other assets	9	62	(73)
Accounts payable and accrued liabilities	(1,800)	516	(260)
Operating lease liabilities	(1,066)	—	—
Deferred rent	—	(69)	27
Deferred revenue	(41)	(34)	(472)
Related party notes payable	204	—	—
Long-term obligations	42	—	—
Net cash used in operating activities	(7,929)	(5,568)	(6,270)
Investing activities:			
Purchases of property and equipment	(19)	(44)	(244)
Net cash used in investing activities	(19)	(44)	(244)
Financing activities:			
Proceeds from preferred stock issuances, net	2,598	—	—
Proceeds from common stock issuances, net	6,698	5,585	—
Proceeds from issuance of related party notes payable	1,000	—	—
Proceeds from exercise of options, net	189	11	185
Proceeds from stock options & RSUs sold to cover taxes	4	1	26
Proceeds from exercise of warrants	67	—	38
Settlement of restricted stock for tax withholding	—	—	(48)
Proceeds from convertible notes, net of discount	2,000	—	—
Payment on the convertible note	(652)	—	—
Debt issuance cost	(202)	—	—
Net cash provided by financing activities	11,702	5,597	201
Net increase (decrease) in cash, cash equivalents, and restricted cash	3,754	(15)	(6,313)
Cash, cash equivalents and restricted cash, beginning of year	3,658	3,673	9,986
Cash, cash equivalents and restricted cash, end of year	$ 7,412	$ 3,658	$ 3,673

	Year ended December 31,		
	2019	2018	2017
Supplemental disclosure of cash flow information:			
Interest paid	$ 148	$ —	$ —
Income taxes paid	$ 14	$ 14	$ —

	Year ended December 31,		
	2019	2018	2017
Supplemental disclosure of non-cash information:			
Cumulative effect of adoption of ASU 606	$ —	$ 2,638	$ —
Cumulative effect of adoption of ASU 2017-11	$ 56	$ —	$ —
Addition of operating lease, right-of-use asset	$ 2,473	$ —	$ —
Stock issued to consultants for services, included in accounts payable and accrued liabilities	$ —	$ —	$ 1
Fixed asset purchases, included in accounts payable and accrued liabilities	$ 10	$ (49)	$ (49)
Warrant liability transferred to equity	$ 553	$ —	$ 58
Fair value of warrants issued in connection with financings	$ 5,269	$ —	$ —
Severance paid in RSU to non-employee	$ —	$ —	$ 69
Conversion of preferred stock to common stock	$ 584	$ —	$ —
Reclassification of EmeryStation lease security deposit from long term to short term	$ 65	$ —	$ —
Reclassification of EmeryStation sublease security deposit from long term to short term	$ 198	$ —	$ —

As the Company adopted the requirements of ASU 2016-02, *Leases (Topic 842)*, as of January 1, 2019, using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 2.

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

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. (the "Company") 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 the wound care market, and CELLERX® for the aesthetic dermatology market. The Aganocide compounds have target applications in the dermatology and urology markets but are still in a clinical phase and not yet commercially available.

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 was 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 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"). 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, 2019, the Company believes these resources will be sufficient to fund its operations into the second quarter of 2020. The Company has sustained operating losses for the majority of its corporate history and expects that its 2020 expenses will exceed its 2020 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.

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, 2019, the Company's cash and cash equivalents were held in a highly-rated, major financial institution in the United States. As of December 31, 2018, the Company's cash and cash equivalents were held in two highly-rated, major financial institutions in the United States.

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 6,937	$ 3,183
Restricted cash included in Other assets	475	475
Total cash, cash equivalents, and restricted cash in the statements of cash flows	$ 7,412	$ 3,658

The restricted cash amount included in Other assets on the consolidated balance sheets represent amounts held as certificates 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 a highly-rated, major financial institution in the United States.

Deposits in this bank 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 institution in which the deposits are held.

During the year ended December 31, 2019, revenues were derived primarily from sales of Avenova directly to doctors through the Company's webstore, directly to consumers through Amazon.com, and to pharmacies via three major distribution partners and specialty pharmacies. During the years ended December 31, 2018 and 2017, 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, 2019, December 31, 2018 and December 31, 2017, revenues from our major distribution or collaboration partners greater than 10% were as follows:

	Year Ended December 31,		
Major distribution or collaboration partner	**2019**	**2018**	**2017**
Distributer A	16%	23%	22%
Distributer B	17%	26%	23%
Distributer C	15%	25%	21%
Collaborator D	*%	*%	10%
Avenova Direct via Amazon	15%	—%	—%

***Not greater than 10%**

As of December 31, 2019 and December 31, 2018, accounts receivable from our major distribution or collaboration partners greater than 10% were as follows:

	Year Ended December 31,	
Major distribution or collaboration partner	**2019**	**2018**
Distributer A	28%	32%
Distributer B	13%	31%
Distributer C	19%	23%
Avenova Direct via Amazon	20%	—%

The Company relies on two contract sole source manufacturers to produce its finished goods. The Company does not have any manufacturing facilities and intends to continue to rely on third parties for the supply of finished goods. There is a risk however that 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

The Company's financial instruments include cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, related party notes payable, a convertible note, and warrants. The fair value of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, and related party notes payable is carried at cost, which management believes approximates fair value due to the short-term nature of these instruments.

The Secured Convertible Promissory Note issued on March 26, 2019 (the "Convertible Note") is carried at cost, which management believes approximates fair value. Additionally, the derivative liability related to certain embedded features contained within the Convertible Note is carried at fair value. The warrant liability is also carried at fair value.

The Company follows ASC 820, *Fair Value Measurements and Disclosures*, with respect to assets and liabilities that are measured at fair value on a recurring basis and nonrecurring basis. Under this standard, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The standard also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available in the circumstances. There are three levels of inputs that may be used to measure fair value:

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

Categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

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, 2019 and December 31, 2018, management had reserved $51 thousand and $10 thousand, respectively, primarily based on specific amounts that are in dispute or were over 120 days past due.

Inventory

Inventory is comprised of (1) raw materials and supplies, such as bottles, packaging materials, labels, boxes and pumps; (2) goods in progress, which are normally unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the cost associated with manufacturing is included in inventory. At December 31, 2019 and 2018, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $247 thousand and $104 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 and operating lease right-of-use assets in accordance with ASC 360, *Property, Plant and Equipment*, 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 or right-of-use assets are present. Management periodically evaluates the carrying value of long-lived assets and right-of-use assets. 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. During the first quarter of 2019, in connection with the restructuring of its U.S. sales force, the Company reviewed its fleet leases for impairment and recorded an impairment charge of $125 thousand, which is reflected in the results for the year ended December 31, 2019. See Note 8, “Commitments and Contingencies” for further information regarding the impairment. During the third quarter of 2019, the Company recorded an impairment charge of $32 thousand related to previously capitalized software, which is reflected in the results for the year ended December 31, 2019.

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019. Using the optional transition method, prior period financial statements have not been recast to reflect the new lease standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term, at an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use assets may be required for items such as initial direct costs paid or incentives received.

The Company has elected to combine lease and non-lease components as a single component for all leases in which it is a lessee or a lessor. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities current and operating lease liabilities non-current. As a result, as of the effective date, the Company no longer recognizes deferred rent on the balance sheet.

Comprehensive Income (Loss)

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

Revenue Recognition

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

Patent Costs

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

Stock-Based Compensation

The Company's stock-based compensation includes grants of stock options and RSUs to employees, consultants and non-employee directors. The expense associated with these programs is recognized in the Company's consolidated statements of stockholders' equity based on their fair values as they are earned under the applicable vesting terms or the length of an offering period. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model. See Note 13, "Equity-Based Compensation" 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

The Company accounts for the issuance of common stock purchase warrants issued in connection with its equity offerings in accordance with the provisions of ASC 815, *Derivatives and Hedging*. The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). For warrants that are classified as liabilities, the Company records the fair value of the warrants 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 Black-Scholes valuation method or the Binomial Lattice ("Lattice") valuation model where deemed appropriate. These values are subject to a significant degree of the Company's judgment.

On January 1, 2019, the Company adopted ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; 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* on a modified retrospective basis. ASU 2017-11 changes the classification analysis of certain equity-linked financial instruments with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, securities with anti-dilution features no longer preclude equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, freestanding equity-linked financial instruments (or embedded conversion features) would no longer be accounted for as liabilities at fair value because of the existence of an anti-dilution feature. Upon adoption of ASU 2017-11, the Company changed its method of accounting for warrants by reclassifying warrant liabilities related to outstanding warrants that have a down round feature to additional paid in capital, which increased additional paid-in capital by $56 thousand and decreased warrant liability by $56 thousand for the year ended December 31, 2019. In addition, because of the modified retrospective adoption, the Company recorded a cumulative-effect adjustment of $356 thousand to the Company's beginning accumulated deficit as of January 1, 2019, with an offset that increased additional paid-in capital by $356 thousand (see Note 11, "Warrant Liability").

Net Loss per Share

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

Basic EPS is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period, including stock options and warrants, using the treasury stock method. 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, 2019, both basic and diluted EPS was a net loss of $0.48 per share.

The following table sets forth the calculation of basic EPS and diluted EPS (in thousands, except per share amounts):

	Year Ended December 31,		
Numerator	**2019**	**2018**	**2017**
Net loss	$ (9,658)	$ (6,545)	$ (7,403)
Less: Preferred deemed dividend	800	—	—
Less: Retained earnings reduction related to warrants down round feature triggered	29	—	—
Net loss attributable to common stockholders, basic	(10,487)	(6,545)	(7,403)
Less gain on changes in fair value of warrant liability	—	1,311	—
Net loss attributable to common stockholders, diluted	$ (10,487)	$ (7,856)	$ (7,403)
Denominator			
Weighted average shares outstanding, basic	21,641	16,921	15,324
Net loss per share, basic	$ (0.48)	$ (0.39)	$ (0.48)
Weighted average shares outstanding, basic	21,641	16,921	15,324
Effect of dilutive warrants	—	137	—
Weighted average shares outstanding, diluted	21,641	17,058	15,324
Net loss per share, diluted	$ (0.48)	$ (0.46)	$ (0.48)

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

	Year Ended December 31,		
	2019	**2018**	**2017**
		(in thousands)	
Stock options	2,183	3,374	2,960
Stock warrants	8,588	—	544
	10,771	3,374	3,504

Recent Accounting Pronouncements

SEC Disclosure Regulation Simplifications

During the fourth quarter of 2018 and first quarter of 2019, the SEC published Final Rule Release No. 33-10532, "Disclosure Update and Simplification" and Final Rule Release No. 33-10618, "Fast Act Modernization and Simplification of Regulation S-K." These standards, effective for quarterly and annual reports, streamline disclosure requirements by removing certain redundant topics. For the Company, the most notable standard implemented herein is the removal of comparative information for fiscal years December 31, 2018 and 2017 in the Management's Discussion and Analysis of Financial Condition and Results of Operations of this Form 10-K.

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which replaced the prior guidance for leases. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Disclosure requirements have been enhanced with the objective of enabling financial statement users to assess the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 became effective for the Company beginning in the first quarter of 2019. The Company has implemented the standard using an optional transition method that allows the Company to initially apply the new leases standard as of the adoption date and recognize a cumulative-effect adjustment to the opening balance of accumulated deficit, if applicable, in the period of adoption. In connection with the adoption, the Company has elected to utilize the package of practical expedients, including not reassessing: (1) the lease classification for any expired or existing leases, (2) the treatment of initial direct costs as they relate to existing leases, and (3) whether expired or existing contracts are or contain leases. The Company also elected the practical expedient not to separate lease and non-lease components of its operating leases in which it is the lessee.

The adoption of the new leases standard resulted in the following adjustments to the consolidated balance sheet as of January 1, 2019 (in thousands):

Prepaid expenses and other current assets (a)	$	(49)
Operating lease right-of-use assets		2,239
Other assets (b)		(2)
Other accrued liabilities (c)		(101)
Operating lease liability		1,063
Deferred rent		(184)
Operating lease liability - non-current		1,410

(a) Represents current portion of prepaid fleet leasing costs reclassified to operating lease right-of-use assets.

(b) Represents noncurrent portion of prepaid fleet leasing costs reclassified to operating lease right-of-use assets.

(c) Represents current portion of deferred rent and lease incentive liability reclassified to operating lease liability.

The adoption of the new leases standard did not impact previously reported financial results because the Company applied the optional transition method and therefore all adjustments were reflected as of January 1, 2019, the date of adoption.

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 480, *Distinguishing Liabilities from Equity* ("ASC 480"), with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. ASU 2017-11 is effective for public companies for the annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods. The Company adopted ASU 2017-11 on a modified retrospective basis effective January 1, 2019. Upon adoption of ASU 2017-11, the Company changed its method of accounting for warrants by reclassifying warrant liabilities related to outstanding warrants that have a down round feature to additional paid-in capital on its March 31, 2019 consolidated balance sheets, and recorded a cumulative-effect adjustment to the Company's beginning accumulated deficit as of January 1, 2019 (see Note 11, "Warrant Liability").

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.* ASU 2018-07 aligns the measurement and classification guidance for share-based payments to nonemployees with the guidance for share-based payments to employees, with certain exceptions. Under the new standard, equity-classified share-based payment awards issued to nonemployees will be measured on the grant date, instead of the current requirement to remeasure the awards through the performance completion date. The Company adopted ASU 2018-07 effective January 1, 2019, and this guidance had an approximately $2 thousand impact on the Company's financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 improved the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements. The Company will adopt the new standard effective January 1, 2020 and does not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. ASU 2016-13 is effective for the Company for annual and interim reporting periods beginning January 1, 2020. The Company will adopt the new standard effective January 1, 2023. We are currently evaluating the impact of the new guidance on our consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12)*, which simplifies the accounting for income taxes. This guidance will be effective for us in the first quarter of 2021 on a prospective basis. We are currently evaluating the impact of the new guidance on our consolidated financial statements.

NOTE 3. FAIR VALUE MEASUREMENTS

The Company follows ASC 820, *Fair Value Measurements and Disclosures*, with respect to assets and liabilities that are measured at fair value on a recurring basis and nonrecurring basis. Under this standard, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of 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.

As of December 31, 2019, the Company's warrants consist of warrants to purchase the Company's common stock issued in July 2011, March 2015, October 2015, June 2019 and August 2019, out of which the warrants issued in July 2011, October 2015 and August 2019 are classified as liabilities. March 2015 and June 2019 warrants are considered to be indexed to the Company's stock and are therefore classified in equity. The Company's warrant liability is classified within Level 3 of the fair value hierarchy because the value is calculated using significant judgment based on the Company's own assumptions in the valuation of this liability. The Company determined the fair value of the warrant liability using the Black-Scholes valuation method or the Lattice valuation model where deemed appropriate. See Note 11, "Warrant Liability" for further discussion of the calculation of the fair value of the warrant liability.

As a result of the call option and the put feature within the Convertible Note, the Company recorded a derivative liability on its consolidated balance sheet with a corresponding debt discount which is netted against the face value of the Convertible Note. The fair value of embedded derivative liability is classified within Level 3 of the fair value hierarchy because the value is calculated using significant judgment based on the Company's own assumptions in the valuation of this liability. The Company determined the fair value of the embedded derivative liability using the Monte Carlo simulation model. See Note 10, "Convertible Note" for further discussion of the calculation of the fair value of the embedded derivative liability.

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of December 31, 2019:

		Fair Value Measurements Using		
(in thousands)	**Balance at December 31, 2019**	**Quoted Prices in Active Markets for Identical Items (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Assets				
Restricted cash held as a certificate of deposit	$ 324	$ 324	$ —	$ —
Deposit held as a certificate of deposit	151	151	—	—
Total assets	$ 475	$ 475	$ —	$ —
Liabilities				
Warrant liability	$ 4,089	$ —	$ —	$ 4,089
Embedded derivative liability	3	—	—	3
Total liabilities	$ 4,092	$ —	$ —	$ 4,092

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

Upon adoption of ASU 2017-11, effective January 1, 2019, the Company reclassified 210,586 warrants from warrant liabilities to equity, and the Company is no longer required to record the change in fair values for these instruments, resulting in $56 thousand of the fair value of the warrant liabilities being reclassified to stockholders' equity. 334,109 July 2011 and October 2015 warrants continued to be classified as a liability as of January 1, 2019, out of which 158,400 warrants were exercised in the second quarter of 2019 and 102,602 warrants were exercised in the third quarter of 2019, with 73,107 July 2011 and October 2015 warrants remaining outstanding as of December 31, 2019.

For the year ended December 31, 2019, the net change in fair value associated with the July 2011 and October 2015 warrants was a decrease of $88 thousand, of which $465 thousand is reported in the Company's consolidated statement of operations as a loss from the change in fair value of warrant liabilities and approximately $553 thousand as a reclassification of the fair value of the warrant liabilities to stockholders' equity in connection with the exercise of the warrants. In August 2019, the Company issued a total of 7,066,508 warrants to purchase 7,066,508 shares of the Company's common stock in two security offerings. The Company recorded $5.3 million of warranty liabilities upon issuance of these warrants. For the year ended December 31, 2019, the net change in fair value associated with these warrants resulted in a gain of $1.2 million. See Note 11, "Warranty Liability" for further discussion of the calculation of the fair value of the warrant liability.

The following is a reconciliation of the beginning and ending balances for the liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the year ended December 31, 2019:

(in thousands)	**2019**
Fair value of warrant liability at January 1, 2019	$ 178
Fair value of warrant liability reclassified to equity-Adoption of ASU 2017-11	(56)
Fair value of July 2011 and October 2015 warrants transferred to equity upon exercise	(553)
Issuance of Domestic, Foreign and Ladenburg warrants	5,269
Decrease in fair value of Domestic, Foreign and Ladenburg warrant liability during the year ended December 31, 2019	(1,214)
Increase in fair value of July 2011 and October 2015 warrant liability during the year ended December 31, 2019	465
Derivative liability embedded in Convertible Note issued in March 2019	427
Decrease in fair value of embedded derivative liability during the year ended December 31, 2019	(424)
Fair value of warrant liability and embedded derivative liability at December 31, 2019	$ 4,092

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. The following is a reconciliation of the beginning and ending balances for the liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the year ended December 31, 2018:

(in thousands)	**2018**
Fair value of warrant liability at January 1, 2018	$ 1,489
Decrease in fair value during the year ended December 31, 2018	(1,311)
Fair value of warrant liability at December 31, 2018	$ 178

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

(in thousands)	December 31, 2019	December 31, 2018
Prepaid sales rebates	$ 401	$ 925
Rent receivable	—	108
Prepaid rent	—	130
Prepaid employees' benefits	8	113
Prepaid dues and subscription	82	130
Prepaid insurance	94	57
Prepaid patents	85	79
Prepaid security deposit for lease	65	—
Retainer	46	—
Other	105	218
Total prepaid expenses and other current assets	$ 886	$ 1,760

NOTE 5. INVENTORY

Inventory consisted of the following:

(in thousands)	December 31, 2019	December 31, 2018
Raw materials and supplies	$ 185	$ 217
Finished goods	554	167
Less: Reserve for excess and obsolete inventory	(247)	(104)
Total inventory, net	$ 492	$ 280

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

(in thousands)	December 31, 2019	December 31, 2018
Office and laboratory equipment	$ 20	$ 24
Furniture and fixtures	157	157
Computer equipment and software	349	385
Production equipment	65	65
Leasehold improvements	79	79
Total property and equipment, at cost	670	710
Less: accumulated depreciation and amortization	(560)	(509)
Total property and equipment, net	$ 110	$ 201

Depreciation and amortization expense was $65 thousand, $266 thousand and $95 thousand for the years ended December 31, 2019, 2018 and 2017, respectively.

In the quarter ended September 30, 2019, the Company determined to discontinue development of a software for internal use. This resulted in a $32 thousand impairment charge recorded to general and administrative expense in the consolidated statement of operation and comprehensive loss for the year ended December 31, 2019.

In the quarter ended December 31, 2019, the Company disposed of damaged, unusable and fully depreciated property and equipment. As a result, the Company recognized a $3 thousand loss on the disposal of these assets, which was recorded to general and administrative expense in the consolidated statement of operation and comprehensive loss for the year ended December 31, 2019.

NOTE 7. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(in thousands)	December 31, 2019	December 31, 2018
Employee payroll and benefits	$ 463	$ 708
Avenova contract liabilities	822	2,282
Deferred rent	—	101
Sublease security deposit	198	—
Accrued interest on Convertible Note	13	—
Consulting service	109	—
Related party consulting service	33	—
Other	140	164
Total accrued liabilities	$ 1,778	$ 3,255

NOTE 8. COMMITMENTS AND CONTINGENCIES

Directors and Officers Indemnification

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 and 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, 2019.

In the normal course of business, the Company provides indemnification of varying scope under its agreements with other companies, typically its clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, it generally indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with the 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, 2019.

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. On July 29, 2019, Mr. John McGovern, the Company's former Interim President & Chief Executive Officer and Chief Financial Officer, submitted a demand for arbitration seeking severance in the amount of $370,000 as well as additional damages in connection with his separation from service with the Company. The Company does not believe the claims asserted by Mr. McGovern have any merit, and the Company intends to defend against all such claims. As of December 31, 2019, there are no other matters that, in the opinion of management, would ultimately result in liability that would have a material adverse effect on the Company's financial position, results of operations or cash flows.

Leases

The Company leases office space for its corporate headquarters, located in Emeryville, California. The initial lease term is through February 28, 2022. The Company has the option to extend the term of the lease for one five (5)-year period upon written notice to the landlord. The Company intends to exercise the renewal option for this lease. The Company also has a lease commitment for laboratory facilities and office space at EmeryStation North in Emeryville, California ("EmeryStation") under an operating lease that will expire on October 31, 2020. There are no stated renewal terms. Per the terms of the agreements, the Company does not have any residual value guarantees.

In July 2016, the Company subleased all rentable square feet of real property at EmeryStation ("Sublease Agreement"). The Sublease Agreement commenced September 8, 2016. The Sublease Agreement will terminate on October 21, 2020 and there are no stated renewal terms. Per the terms of the agreement, the sublessee does not have any residual value guarantees.

In addition to the facility leases, the Company has 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 during the first quarter of 2017. During the first quarter of 2019, in connection with the restructuring of its U.S. sales force, the Company reviewed its fleet leases for impairment. The Company estimated fair value based on the lowest level of identifiable estimated future cash flows and recorded an impairment charge of $125 thousand, which is included in the Sales and Marketing expenses line item within the Operating Expenses in the Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2019. During the fourth quarter of 2019, the Company early terminated the lease agreement related to the idled vehicles, and has 15 leased vehicles as of December 31, 2019.

Additionally, the Company had an operating lease for 2 copiers which expired in August 2019. The Company renewed the lease in October 2019. The new lease will expire in October 2022. The monthly lease payment for the copiers is not material.

In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the original lease term and not the remaining lease term. The Company has elected to account for each lease component and its associated non-lease components as a single lease component, and has allocated all of the contract consideration across lease components only. This will potentially result in the initial and subsequent measurement of the balances of the right-of-use assets and lease liability for leases being greater than if the policy election was not applied. The leases include variable components (i.e. common area maintenance, excess mileage charges, etc.) that are paid separately from the monthly base payment based on actual costs incurred and therefore were not included in the right-of-use assets and lease liability, but are reflected as an expense in the period incurred.

The components of lease costs, lease term and discount rate for the year ended December 31, 2019 are as follows (in thousands except lease term and discount rate):

Lease Costs

Operating lease cost	$	1,130
Sublease income		(632)
Net lease cost	$	498
Other information		
Operational cash flow used for operating leases	$	1,285
Weighted-average remaining lease term (in years)		1.7
Weighted-average discount rate		12%

Operating lease expense was $505 thousand and $483 thousand for the years ended December 31, 2018 and 2017, respectively, under Topic 840.

Future lease payments under non-cancelable leases as of December 31, 2019 were as follows (in thousands):

2020	$	1,047
2021		454
2022		88
Thereafter		—
Total future minimum lease payments		1,589
Less imputed interest		(154)
Total	$	1,435
Reported as:		
Operating lease liability	$	930
Operating lease liability- non-current		505
Total	$	1,435

Future lease payments to be received under non-cancelable leases as of December 31, 2019 were as follows (in thousands):

2020	$	577
2021		—
2022		—
Thereafter		—
Total future minimum lease payments	$	577

NOTE 9. RELATED PARTY NOTES PAYABLE

On February 27, 2019, the Company issued a $1.0 million promissory note payable to Pioneer Pharma (Hong Kong) Company Ltd. (“Pioneer Hong Kong”), which was amended on June 25, 2019 (the “Promissory Note”). The Promissory Note currently bears an interest payment of $300 thousand (initially $150 thousand) and is payable in full upon the Company's next financing with Pioneer Hong Kong and in no event after July 1, 2020 (an extension per the June amendment from the initial maturity date of July 27, 2019). The transaction 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 Promissory Note, the Company paid China Kington a 2% fee for brokering the transaction and has entered into a consulting agreement with China Kington for a term of one year. 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 thousand pursuant to such consulting agreement. Debt issuance costs associated with the issuance of the Promissory Note of $20 thousand is recognized and recorded as an offset to the related party notes payable in the consolidated balance sheet. The debt issuance cost is being amortized to interest expense using the effective interest rate method over the term of the Promissory Note, assuming that the Promissory Note will be fully paid on July 1, 2020. The Company determined that the changes in the terms of Promissory Note per the June amendment are accounted for as troubled debt restructurings in accordance with ASC 470, *Debt*. However, as future undiscounted cash flow is greater than the net carrying value of the original Promissory Note, no gain was recognized. The Company established a new effective interest rate based on the carrying value of the original debt and the revised cash flows.

The interest expense recognized, including amortization of the issuance costs, was $222 thousand during the year ended December 31, 2019.

The Promissory Note is presented as follows as of December 31, 2019:

(in thousands)		
Principal amount	$	1,000
Unamortized debt issuance costs		(2)
Accrued interest		204
Total debt		1,202
Less: short-term		1,202
Long-term	$	—

NOTE 10. CONVERTIBLE NOTE

On March 26, 2019 (the "Closing Date"), the Company entered into a Securities 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 $2.2 million, 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 net proceeds of $2.0 million after deducting an original issue discount of $200 thousand and debt issuance cost of Lender's transaction fees of $15 thousand. The Company recognized an additional $182 thousand of debt issuance costs associated with the issuance of the Convertible Note.

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 unregistered shares of the Company's common stock at a conversion price of $1.65 per share. Beginning on September 26, 2019, the Convertible Note also provides the Lender with the right to redeem all or any portion of the Convertible Note ("Redemption Amount") up to $200 thousand per calendar month. The payments of each Redemption Amount may be made, at the option of the Company, in cash, by converting such Redemption Amount into unregistered shares of Common Stock ("Redemption Conversion Shares"), or a combination thereof. The number of Redemption Conversion Shares equals the portion of the applicable Redemption Amount being converted divided by the lesser of $1.65 or the Market Price. The Market Price is defined as 85% of the lowest closing bid price during the 20 trading days immediately preceding the applicable measurement date. In addition, the Company may redeem the Convertible Note at its option at any time at a redemption price equal to 115% of the aggregate outstanding balance of principal and interest.

The Company has reserved 3,200,000 shares of its authorized and unissued common stock to provide for all issuances of common stock under the Convertible Note.

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 first encumbered by that certain lien of up to $1.0 million, plus accrued and unpaid interest and fees, in favor of Pioneer Hong Kong described above.

The Convertible Note contains events of default upon the occurrence and during the continuance of which all obligations may be declared immediately due and payable. Under certain events of default, the outstanding balance of principal and interest shall be automatically due and payable in cash. Upon other events of default, the Lender, at its option, can elect to increase the outstanding balance by up to 15%, depending on the magnitude of the default, without accelerating the outstanding balance.

The Company's prepayment terms represent an embedded call option, the Lender's share redemption terms represent an embedded put option and certain events of default represent embedded derivatives, each of which require bifurcation. A single derivative comprising all bifurcatable features was measured at fair value using a Monte Carlo simulation model. The key assumptions used to value the combined embedded derivative upon issuance at March 26, 2019 were as follows:

Assumption	As of March 26, 2019
Stock price (latest bid price)	$ 1.28
Equity volatility	93.8%
Risk-free interest rate	2.34%
Remaining term	1.5

The key assumptions used to value the combined embedded derivative as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Stock price	$ 0.65
Equity volatility	192.6%
Risk-free interest rate	1.60%
Remaining term	0.74

The fair value of the combined embedded derivative was $3 thousand as of December 31, 2019. During the year ended December 31, 2019, the Company recorded a gain of $424 thousand, in the consolidated statements of operations and comprehensive loss.

The aggregate $627 thousand discount, including the original issue discount, and the aggregate $197 thousand of debt issuance costs, including the Company's issuance costs and payment for the Lender's transaction fees, were recorded at issuance, and were classified as an offset to the Convertible Note on the consolidated balance sheet. The Convertible Note is presented as follows as of December 31, 2019:

(in thousands)	
Principal amount	$ 1,563
Unamortized discount	(117)
Unamortized debt issuance costs	(37)
Total debt	1,409
Less: short-term	1,409
Long-term	$ —

The discount and debt issuance costs are being amortized to interest expense using the effective interest rate method over the term of the Convertible Note, assuming that the Convertible Note will be redeemed at the maximum $200 thousand per month beginning in September 2019. During the year ended December 31, 2019, the effective interest rate on the Convertible Note was 52.67%. Interest expense recognized, including amortization of the issuance costs and debt discount, was $831 thousand during the year ended December 31, 2019.

On August 8, 2019, the Company entered into a securities purchase agreement (the "August SPA") with certain domestic investors for the sale and issuance of 4,198,566 shares of common stock in a registered direct offering and 4,198,566 warrants exercisable for 4,198,566 shares of common stock in a simultaneous private placement at an offering price of $1.00 per share. The August SPA prohibits the Company from redeeming in common stock or common stock equivalents in satisfaction of the Promissory Note with Iliad Research & Trading, L.P. and may only issue common stock in satisfaction of the Promissory Note if the stock price equals or exceeds $2.00. See Note 12, "Stockholders' Equity" for further discussion of the terms of the August SPA.

The Lender started redeeming $200 thousand of the Convertible Note every month since September 27, 2019. As of December 31, 2019, the Company had repaid a total of $800 thousand in cash, $652 thousand of which was applied against the outstanding balance of the convertible note. As of December 31, 2019, the Company's contractual maturity of the principal balance of the Convertible Note was as follows:

(in thousands)	
2020	$ 1,563
2021 and thereafter	—
Total	$ 1,563

NOTE 11. 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.

In May 2019, the strike price of the July 2011 Warrants, March 2015 Warrants and October 2015 Warrants was further reduced to $0.2061 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Triton Funds LP at that price.

The key assumptions used to value the July 2011 Warrants as of December 31, 2019 and December 31, 2018 were as follows:

	As of	
Assumption	**December 31, 2019**	**December 31, 2018**
Expected price volatility	115%	77%
Expected term (in years)	0.18	1.18
Risk-free interest rate	1.52%	2.60%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$ 0.44	$ 0.29

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.

As described in Note 2, “Summary of Significant Account Policies,” upon adoption of ASU 2017-11, the Company determined that excluding the consideration of the down round provision, the Long-Term and Short-Term Warrants are considered to be indexed to the Company’s stock and should be classified in equity. The Company reclassified warrant liabilities related to the Long-Term and Short-Term Warrants to additional paid-in capital on its March 31, 2019 consolidated balance sheets, which increased additional paid-in capital by $56 thousand and decreased warrant liability by $56 thousand. In addition, because of the modified retrospective adoption, the Company recorded a cumulative-effect adjustment of $356 thousand to the Company's beginning accumulated deficit as of January 1, 2019, with an offset that increased additional paid-in capital by $356 thousand.

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

Assumption	As of December 31, 2018
Expected price volatility	77%
Expected term (in years)	1.18
Risk-free interest rate	2.60%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.24

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

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

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, 2019 and December 31, 2018 were as follows:

	As of	
Assumption	December 31, 2019	December 31, 2018
Expected price volatility	184%	73%
Expected term (in years)	0.83	1.83
Risk-free interest rate	1.59%	2.51%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrants	$ 0.49	$ 0.38

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.

During the second quarter of 2019, a total of 158,400 warrants to purchase 158,400 shares of common stock were exercised related to the July 2011 Warrants and the October 2015 Warrants resulting in gross proceeds of $33 thousand. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $0.4 million, with any change in fair value recorded in the consolidated statement of operations and comprehensive loss. The $0.4 million fair value was subsequently transferred to equity as of the date of exercise.

During the third quarter of 2019, a total of 102,602 warrants to purchase 102,602 shares of common stock were exercised related to the October 2015 Warrants resulting in gross proceeds of $21 thousand. Upon exercise, the warrant liability associated with these warrants was adjusted to its fair value as of the date of exercise of $0.2 million, with any change in fair value recorded in the consolidated statement of operations and comprehensive loss. The $0.2 million fair value was subsequently transferred to equity as of the date of exercise.

In August 2019, the Company issued: (1) warrants to purchase up to 4,198,566 shares of Company common stock to certain domestic investors in connection with its registered direct offering of 4,198,566 shares of common stock (the "2019 Domestic Warrants"); (2) warrants to purchase up to 2,700,000 shares of Company common stock to certain foreign investors in connection with a private placement of the Series A Preferred Stock (the "2019 Foreign Warrants"); and (3) warrants to purchase up to 167,942 shares of Company common stock to Ladenburg Thalmann & Co., Inc. for its services as placement agent in the registered direct offering (the "2019 Ladenburg Warrants"). See Note 12, "Stockholders' Equity" for further discussion of the terms of the financing transactions in August 2019.

The 2019 Domestic Warrants are exercisable six months after the date of issuance and will expire on February 13, 2025, with an exercise price of $1.15. The terms of the 2019 Domestic 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 an acquisition of the Company. The 2019 Domestic 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 the 2019 Domestic Warrants be classified as liabilities. The fair values of these warrants have been determined using the Black-Scholes 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 2019 Domestic Warrants at issuance on August 13, 2019 was $3.1 million.

The key assumptions used to value the 2019 Domestic Warrants as of August 13, 2019 were as follows:

Assumption	As of August 13, 2019
Expected price volatility	149.29%
Expected term (in years)	5.50
Risk-free interest rate	1.58%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.75

The key assumptions used to value the 2019 Domestic Warrants as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Expected price volatility	154.10%
Expected term (in years)	5.13
Risk-free interest rate	1.70%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.57

The 2019 Ladenburg Warrants were exercisable immediately upon issuance and will expire on August 8, 2024, with an exercise price of $1.25. The terms of the 2019 Ladenburg Warrants are consistent with the 2019 Domestic Warrants, and therefore were classified as liabilities in accordance with ASC 480. The fair values of these warrants have been determined using the Black-Scholes 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 2019 Ladenburg Warrants at issuance on August 13, 2019 was $124 thousand.

The key assumptions used to value the 2019 Ladenburg Warrants as of August 13, 2019 were as follows:

Assumption	As of August 13, 2019
Expected price volatility	155.19%
Expected term (in years)	5.00
Risk-free interest rate	1.57%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.74

The key assumptions used to value the 2019 Ladenburg Warrants as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Expected price volatility	159.94%
Expected term (in years)	4.61
Risk-free interest rate	1.69%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.57

The 2019 Foreign Warrants were exercisable upon shareholders' approval, which was received on October 9, 2019, and will expire on February 13, 2025, with an exercise price of $1.15. The terms of the warrants are consistent with the 2019 Domestic Warrants, and therefore were classified as liabilities in accordance with ASC 480. The fair values of these warrants have been determined using the Black-Scholes 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 2019 Foreign Warrants at issuance on August 13, 2019 was $2.0 million.

The key assumptions used to value the 2019 Foreign Warrants as of August 13, 2019 were as follows:

Assumption	As of August 13, 2019
Expected price volatility	149.29%
Expected term (in years)	5.50
Risk-free interest rate	1.58%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.75

The key assumptions used to value the 2019 Foreign Warrants as of December 31, 2019 were as follows:

Assumption	As of December 31, 2019
Expected price volatility	154.10%
Expected term (in years)	5.13
Risk-free interest rate	1.70%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.57

The details of all outstanding warrant liability as of December 31, 2019 were as follows:

(shares and dollars in thousands)	Shares	Warrant Liability
Warrant liability - current		
July 2011 Warrants	35	$ 15
October 2015 Warrants	38	19
	73	$ 34
Warrant liability – non-current		
2019 Domestic Warrants	4,199	$ 2,410
2019 Foreign Warrants	2,700	1,550
2019 Ladenburg Warrants	168	95
	7,067	$ 4,055

NOTE 12. STOCKHOLDERS' EQUITY

Preferred Stock

Under the Company's amended articles of incorporation, the Company is authorized to issue up to 5,000,000 shares of preferred stock in such series and with such rights and preferences as may be approved by the Board of Directors. As of December 31, 2019 and December 31, 2018, there were no shares of preferred stock outstanding.

On August 8, 2019, the Company entered into a securities purchase agreement for the sale of (i) 2,700,000 shares of the Series A Preferred Stock that automatically converted into 2,700,000 shares of common stock, at a ratio of 1:1, upon the approval of the Company's stockholders, which occurred on October 9, 2019, and (ii) 2,700,000 common stock purchase warrants exercisable for 2,700,000 shares of Common Stock.

The rights of the Series A Preferred Stock included the following:

Conversion. As described above, the Series A Preferred Stock automatically converted into 2,700,000 shares of Common Stock, at a ratio of 1:1, upon the approval of the Company's stockholders, which occurred on October 9, 2019. Prior to stockholder approval, the Preferred Stock was not convertible.

Anti-dilution Protection. The Series A Preferred Stock did not contain any price-based anti-dilution protection.

Liquidation Preference. In the event of the Company's liquidation, dissolution or winding up (voluntary or involuntary), the holders of Preferred Stock were entitled to receive the same amount as a holder of common stock.

Voting Rights. Shares of Series A Preferred Stock generally had no voting rights except as required by law and certain enumerated voting rights such as increasing the authorized shares of preferred stock.

Dividend Rights. The holders of Series A Preferred Stock were entitled to receive dividends on shares of the Series A Preferred Stock equal (on an as if converted to common stock basis) to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. The Series A Preferred Stock were not entitled to any other dividends.

Redemption. The Series A Preferred Stock had no redemption rights. The Company was not obligated to redeem or repurchase any shares of Preferred Stock.

As the conversion trigger was dependent upon shareholder approval which is considered to be outside the control of the Company, the Series A Preferred Stock was considered to be contingently redeemable and as a result, was classified as mezzanine equity in the Company's interim balance sheet as of September 30, 2019. Upon conversion of the Series A Preferred Stock into shares of the Company's common stock in October 2019, it is classified as equity in the Company's balance sheet as of December 31, 2019.

The Company applied the fair value allocation methodology for allocating the proceeds of $2.7 million received from the Series A financing. The Company first allocated $2.0 million based on the fair value of the warrants as of the issuance date, with residual amount being allocated to the Series A Preferred Stock. See Note 11, "Warrant Liability" for further discussion of the key assumptions used to value the warrants.

China Kington served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $162 thousand**.** The Company incurred additional issuance costs of $33 thousand. The Company allocated $93 thousand to the warrant liability, which was expensed during the period and $102 thousand was recorded as a reduction to the Series A Preferred Stock.

On October 9, 2019, the Company held a special meeting of stockholders (the "Special Meeting"), at which the Company's stockholders approved (i) the conversion of 2,700,000 shares of the Series A Preferred Stock into 2,700,000 shares of the Company's common stock, and (ii) the 2,700,000 shares of Company common stock that may be issued upon the exercise of the 2,700,000 2019 Foreign Warrants, in accordance with the stockholder approval requirements of NYSE American LLC Company Guide Section 713(a). A beneficial conversion feature of $800 thousand was recorded as a discount to the preferred stock and an increase to additional paid in capital. Because the Series A Preferred Stock was perpetual, in October 2019, the Company fully amortized the discount related to the beneficial conversion feature on the deemed dividend in the consolidated statement of operations and comprehensive loss, which is reflected in the results for the year ended December 31, 2019.

Common Stock

During the first quarter of 2018, the Company 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. 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.

On March 29, 2019, the Company entered into a Common Stock Purchase Agreement with Triton Funds LP, a Delaware limited partnership ("Triton"), pursuant to which the Company had the right to sell up to $3.0 million of shares of common stock of the Company at a purchase price equal to 90% of the lowest trading price of the common stock of the Company for the five business days prior to the applicable closing date. The Company also entered into a Registration Rights Agreement on March 29, 2019 with Triton, pursuant to which the Company registered such shares for resale by Triton on a registration statement on Form S-3 filed with the SEC on April 1, 2019 and declared effective on April 12, 2019. In connection with the transaction with Triton Funds LP, the Company entered into a Letter Agreement with Triton Funds LLC, an affiliate of Triton, pursuant to which the Company issued 150,000 shares of common stock to Triton Funds LLC. During the second quarter of 2019, the Company issued to Triton Funds LP an aggregate of 1,747,312 shares of the Company's common stock, par value $0.01 per share, for an aggregate purchase price of $360 thousand. The Company also incurred and paid other offering costs of $122 thousand. On September 5, 2019, the Company received an additional $288 thousand in connection with the financing and recorded the amount in additional paid-in capital from issuance of common stock. No additional shares were issued related to the receipt of $288 thousand. The Common Stock Purchase Agreement with Triton Funds LP expired as of December 31, 2019 and the remaining registered but unsold shares were deregistered on February 1, 2020.

On June 26, 2019, the Company entered into a private placement to sell 1,371,427 shares of Company common stock and warrants to purchase an additional 1,371,427 shares of Company common stock for an aggregate subscription price of $2.4 million to three accredited investors including Messrs. Xiao Rui Liu, Hai Dong Pang and Ping Huang, each of whom subscribed for $1.0 million, $0.4 million and $1.0 million, respectively. China Kington served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $144,000. The Company also incurred and paid other offering costs of $27 thousand.

On August 8, 2019, the Company entered into the August SPA for the sale and issuance of 4,198,566 shares of common stock at an offering price of $1.00 per share. In connection with the August SPA, the Company issued 4,198,566 warrants to purchase 4,198,566 shares of Company common stock with an exercise price of $1.15. Ladenburg Thalmann & Co. Inc. ("Placement Agent") served as placement agent for the transaction in exchange for a commission representing six percent (6%) of the gross proceeds, totaling $252 thousand, and the issuance of the 2019 Ladenburg Warrants to purchase up to 167,942 shares of the common stock with an exercise price of $1.25. In addition, the Company reimbursed the Placement Agent $60 thousand for certain expenses. The Company also incurred and paid other offering costs of $312 thousand. The August SPA limits the Company's ability to issue new common stock or common stock equivalents for a period of one year (six months if it is an "at the market" offering with the Placement Agent) until the daily volume weighted average price of the Company's common stock equals or exceeds $2.00 for a period of 10 consecutive days. The Company is prohibited from redeeming in common stock or common stock equivalents in satisfaction of the Promissory Note with Iliad Research & Trading, L.P. and may only issue common stock in satisfaction of the Promissory Note if the stock price equals or exceeds $2.00. See Note 10, "Convertible Note", for detailed information related to the convertible note.

The Company applied the fair value allocation methodology for allocating the proceeds of $4.2 million received from the financing. The Company first allocated $3.1 million based on the fair value of the 2019 Domestic Warrants as of the issuance date, with the residual amount being allocated to the common stock. See Note 11, "Warrant Liability" for further discussion of the key assumptions used to value the warrants.

In connection with the financing, the Company incurred issuance cost of $488 thousand of which $233 thousand was allocated to the warrant liability and expensed during the period and $255 thousand was recorded as a reduction to additional paid-in capital from the issuance of common stock. As the 2019 Ladenburg Warrants were accounted for as a stock issuance cost, $59 thousand was allocated to the warrant liability and expensed during the period and $65 thousand was recorded as a reduction to additional paid-in capital from the issuance of common stock.

Stock Warrants

In February 2016, the strike prices of the July 2011, March 2015, 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 2019, the strike price of the July 2011, March 2015, and October 2015 Warrants was reduced to $0.2061 per share, pursuant to the price protection provisions in such warrants, because the Company sold common stock to Triton Funds LP at that price.

As more fully described in Note 3, "Fair Value Measurements," the March 2015 Warrants were reclassified from warrant liabilities to equity upon adoption of ASU 2017-11. Upon the down round feature being triggered in May 2019 and the strike price being reduced to $0.2061 per share resulting from the sale of common stock to Triton Funds LP at a price of $0.2061 per share, the Company measured the value of the effect of the down round feature as the difference between (1) the March 2015 Warrants' fair value (without the down round feature) using the pre-trigger exercise price and (2) the March 2015 Warrants' fair value (without the down round feature) using the reduced exercise price in accordance with ASC 820, *Fair Value Measurements and Disclosures*, and as a result, recorded a $29 thousand dividend, which is treated as a reduction to income available to common shareholders in the basic EPS calculation. The July 2011 Warrants and October 2015 Warrants were excluded from this exercise as they were classified as liabilities.

During the second quarter of 2019, a total of 158,400 warrants to purchase 158,400 shares of common stock were exercised related to the October 2015 Warrants resulting in gross proceeds of $33 thousand. Please see Note 11, "Warrant Liability", for further details.

During the second quarter of 2019, a total of 133,167 warrants to purchase 133,167 shares of common stock were exercised related to the March 2015 Warrants. Out of the 133,167 warrants exercised, 70,000 warrants were exercised in a cashless transaction, resulting in 64,979 shares issued. The remaining warrants were exercised for gross proceeds of $13 thousand.

In June 2019, the Company issued 1,371,427 warrants to purchase 1,371,427 shares of Company common stock in a private placement. Please see the preceding subsection, "Common Stock," for further details regarding such private placement. Such warrants have a one (1)-year term and an exercise price of $0.87, callable by the Company if the closing price of the Company's common stock, as reported on the NYSE American, is $1.00 or greater.

In July 2019, a total of 102,602 warrants to purchase 102,602 shares of common stock were exercised related to the October 2015 Warrants resulting in gross proceeds of $21 thousand. Please see Note 11, "Warrant Liability", for further details.

In August 2019, the Company issued 4,198,566 warrants to purchase 4,198,566 shares of Company common stock in connection with a registered direct offering of common stock. Such warrants will be exercisable six months after date of issuance and will expire on February 13, 2025, with an exercise price of $1.15. The Company issued 167,942 warrants to purchase 167,942 shares of Company common stock to the Placement Agent in connection with such offering. Such warrants were exercisable immediately upon issuance and will expire on August 8, 2024, with an exercise price of $1.25. Please see the preceding subsection, "Common Stock," for further details regarding such offering.

In August 2019, the Company also issued 2,700,000 warrants to purchase 2,700,000 shares of Company common stock in connection with its private placement of Series A Preferred Stock. Such warrants were exercisable upon shareholders' approval and will expire on February 13, 2025, with an exercise price of $1.15. Please see the preceding subsection, "Preferred Stock," for further details regarding such private placement.

The following table summarizes information about the Company's warrants outstanding at December 31, 2019, 2018 and 2017, and activity during the three years then ended.

	Warrants (in thousands)		Weighted-Average Exercise Price
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
Warrants granted	8,438	$	1.11
Warrants exercised	(394)	$	0.21
Warrants expired	-	$	-
Outstanding at December 31, 2019	8,588	$	1.09

NOTE 13. 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 (the "Board"). At the inception of the 2007 Plan, 80,000 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. The 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) 4% 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, 2019, there were 1,789,174 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 Plan and the 2017 Plan.

Stock Option Summary

The following table summarizes information about the Company's stock options and restricted stock outstanding at December 31, 2019, 2018 and 2017, 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, 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
Options granted	145	$ 0.37		
Restricted stock units granted	204	$ —		
Options exercised	(83)	$ 2.30		
Restricted stock units vested	(209)	$ —		
Options forfeited/cancelled	(1,247)	$ 4.01		
Restricted stock units cancelled	(1)	$ —		
Outstanding at December 31, 2019	2,183	$ 4.03	6.6	$ 43
Vested and expected to vest at December 31, 2019	2,165	$ 4.05	6.5	$ 43
Vested at December 31, 2019	1,818	$ 4.44	6.2	$ —
Exercisable at December 31, 2019	1,818	$ 4.44	6.2	$ —

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, 2019 for options that have a quoted market price in excess of the exercise price. There were 83 thousand stock option awards exercised during the year ended December 31, 2019 for which the Company received cash payments of $189 thousand. There was no intrinsic value for stock option awards exercised for the year ended December 31, 2019. 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.

As of December 31, 2019, total unrecognized compensation cost related to unvested stock options and restricted stock was approximately $491 thousand. This amount is expected to be recognized as stock-based compensation expense in the Company's consolidated statements of operations and comprehensive loss over the remaining weighted average vesting period of 2.20 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, "Summary of Significant Account Policies," for a description of the accounting policies that the Company applied to value its stock-based awards.

During the years ended December 31, 2019, 2018 and 2017, the Company granted options to employees and directors to purchase an aggregate of 145,000, 1,085,000, and 1,529,000 shares of common stock, respectively.

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

	Year Ended December 31,		
Assumption	**2019**	**2018**	**2017**
Expected price volatility	112.41%	89.30%	87.78%
Expected term (in years)	6.14	5.98	6.90
Risk-free interest rate	1.99%	2.80%	2.12%
Dividend yield	0.00%	0.00%	0.00%
Weighted-average fair value of options granted during the period	$ 0.31	$ 1.51	$ 2.34

Expected Price Volatility—This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. The computation of expected volatility was based on the historical volatility of our own stock.

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

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

Dividend Yield—We have not made any dividend payments nor do we have plans to pay dividends in the foreseeable future.

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

As part of Mr. Mark Sieczarek's separation agreement, in July 2019, the Company paid him the amount due under the agreement via 168 thousand shares of fully vested registered stock. The expense related to this separation agreement was accrued for and expensed during July 2019, and the shares were issued to him via fully vested registered stock in July 2019. See further details on Mr. Mark Sieczarek's resignation below.

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

For the years ended December 31, 2019, 2018 and 2017, the Company recognized stock-based compensation expense of $449 thousand, $671 thousand, and $2,371 thousand, respectively, for option awards to employees and directors.

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.

In April 2019, the Company modified stock options held by Mr. Yonghao (Carl) Ma, who resigned as a director of the Company, effective April 29, 2019. The option exercise period for Mr. Liu was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $14 thousand, which is included in the $449 thousand of stock-based compensation recognized in 2019 noted above.

In May 2019, the Company modified stock options held by Mr. Yanbin (Lawrence) Liu, who resigned as a director of the Company, effective May 1, 2019. The option exercise period for Mr. Yanbin Liu was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $7 thousand, which is included in the figure above.

In July 2019, the Company modified stock options held by Mr. Mark Sieczarek, who resigned as a director of the Company, effective July 20, 2019. The option exercise period for Mr. Mark Sieczarek was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $60 thousand, which is included in the figure above.

In September 2019, the Company modified stock options held by Mr. Todd Zavodnick, who resigned as a director of the Company, effective September 11, 2019. The option exercise period for Mr. Todd Zavodnick was extended from three months to three years, calculated from his date of resignation. Also, his stock option awards became fully vested at the date of his resignation. In connection with the stock option modification, the Company recognized stock-based compensation expense of $24 thousand, which is included in the figure above.

Stock-Based Awards to Non-Employee Consultants

During the year ended December 31, 2019, the Company did not grant options to purchase shares of common stock to non-employees. During the years ended December 31, 2018 and 2017 the Company granted options to purchase an aggregate of 33,000 and 86,000 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**
Expected price volatility	85.03%	87.41%
Expected term (in years)	10.0	10.0
Risk-free interest rate	2.94%	2.27%
Dividend yield	0.00%	0.00%
Weighted-average fair value of options granted during the period	$ 1.99	$ 2.40

During the fourth quarter of the year ended December 31, 2019, the Company paid two consultants, Ms. Moon and Ms. Xiao, via a combination of 36 thousand registered shares and cash for services rendered, based on the terms of their consulting agreement.

The Company did not grant restricted stock to non-employees during the 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.

For the years ended December 31, 2019, 2018 and 2017, the Company recognized stock-based compensation expense of $37 thousand, $0, and $243 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.

Summary of Stock-Based Compensation Expense

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

	Year Ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Research and development	$ 42	$ 32	$ 113
Sales and marketing	93	141	152
General and administrative	351	498	2,277
Total stock-based compensation expense	$ 486	$ 671	$ 2,542

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 14. LICENSE, COLLABORATION AND DISTRIBUTION AGREEMENTS

Transactions under the Company's major distribution agreements are recognized upon transfer of control to its major distribution partners at the amount of consideration that the Company expects to be entitled to. The Company 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.

Milestone payments are included in the estimated transaction price when they are considered probable of being achieved. For license and collaboration revenue, the transaction price under license and collaboration 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 presents changes in the Company's contract assets and liabilities for the year ended December 31, 2019:

	Balance at Beginning of the Period	**Additions**	**Deductions**	**Balance at the end of the Period**
		(in thousands)		
Contract liabilities: deferred revenue	$ 41	$ -	$ (41)	$ -
Contract liabilities: accrued liabilities	1,432	5,708	(6,706)	434
Total	$ 1,473	$ 5,708	$ (6,747)	$ 434

For the years ended December 31, 2019 and 2018, the Company recognized the following revenue (in thousands):

	Year Ended December 31,	
	2019	2018
Revenue recognized in the period from:		
Amounts included in contract liabilities at the beginning of the year:		
Performance obligations satisfied	$ 1,473	$ 1,453
New activities during the year:		
Performance obligations satisfied	5,126	11,055
	$ 6,599	$ 12,508

License, Collaboration and Distribution Agreements

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

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

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

Pursuant to the Purchase Agreement, the Company also received $2.5 million from China Pioneer for the purchase of restricted units (comprising one share of common stock and a warrant for the purchase of one share of common stock). The unit purchase was completed in two tranches: (1) 800,000 units in September 2012; and (2) 1,200,000 units in October 2012, with both tranches at a purchase price of $1.25 per unit. The fair value of the total units sold was $3.5 million, based upon the trading price of the Company's 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 $1.0 million, the Company 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)	**2019**	**2018**	**2017**
Amortization of upfront technology and access fees	$ 41	$ 34	$ 103
Product revenue	209	169	1,956
Total revenue recognized	$ 250	$ 203	$ 2,059

At December 31, 2018, the Company had deferred revenue of $41 thousand that relates to unsatisfied performance obligations of sample supply due to China Pioneer and an incremental discount on future product sales due to Pioneer China. During the year ended December 31, 2019, the Company earned $41 thousand in revenue due to the Company being relieved of contract liability as a result of changes in contract terms associated with the distribution agreement with China Pioneer. The Company did not have any deferred revenue at December 31, 2019.

Avenova Distribution Agreements and Specialty Pharmacies

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.

Since the start of 2019 the number of pharmacies in our Partner Pharmacy Program has increased from 4 to 14, placing us on track to increase Avenova sales through retail pharmacies from one-quarter to one-half of all sales. Our partner pharmacies provide patients with a quality experience that includes a relatively short time between receiving the initial prescription and filling it, fast refills and home delivery. The combination of a pre-negotiated price along with a reduction in coupon and rebate usage improves our gross-to-net and per-script profitability. During the years ended December 31, 2019, 2018 and 2017, the revenue generated from these pharmacies comprised 21%, 1% and 0% of our total product revenue, respectively.

During the years ended December 31, 2019, 2018 and 2017, the Company earned $4.6 million, $11.0 million and $13.6 million, respectively, in sales revenue for its Avenova product from its distribution agreements and specialty pharmacies.

Under the Avenova product distribution arrangements, the Company had a contract liability balance of $0.4 million and $1.4 million at December 31, 2019 and December 31, 2018, respectively. The contract liability is included in accrued liabilities in the consolidated balance sheet. The contract liability as of December 31, 2019 and December 31, 2018 included a prepayment of $0.4 million and $0.9 million rebate, respectively, that is recorded in the prepaid expenses and other current assets in the consolidated balance sheet (see Note 4, "Prepaid Expenses and Other Current Assets").

Avenova Direct

In an effort to improve patient access, Avenova Direct was launched on June 1, 2019 to U.S. customers exclusively on Amazon.com. Avenova Direct is the same strength hypochlorous formulation as Avenova Rx, but comes in a 20mL size. This channel offers the Company with stable gross-to-net pricing and provides customers with easy access to our product. This model capitalizes on a trend to sell pharmaceutical products directly to consumers in response to high-deductible health plans, allowing customers to forego a time-consuming doctor visit and trip to the pharmacy. We are promoting this program through complementary social media marketing to target consumers in specific demographics, as well as to ophthalmologists, optometrists, and current and former Avenova patients. During the year ended December 31, 2019, the revenue generated from Avenova Direct was $1.0 million.

NOTE 15. 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, 2019 and 2018, we made $9 thousand and $14 thousand contributions to the plan, respectively.

NOTE 16. INCOME TAXES

Loss before provision for income taxes consisted of the following:

	Year Ending December 31,		
(in thousands)	**2019**	**2018**	**2017**
United States	$ (9,652)	$ (6,541)	$ (7,400)
International	—	—	—
	$ (9,652)	$ (6,541)	$ (7,400)

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

	Year Ending December		
(in thousands)	**2019**	**2018**	**2017**
Current			
Federal	$ —	$ —	$ —
State	6	4	3
Other	—	—	—
Total current tax expense	6	4	3
Deferred			
Federal	—	—	—
State	—	—	—
Other	—	—	—
Total deferred tax expense	—	—	—
Income tax provision	$ 6	$ 4	$ 3

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, 2019 and 2018 are as follows:

(in thousands)	December 31 2019	2018
Deferred tax assets:		
Net operating losses	$ 29,427	$ 26,790
Accruals	222	446
Deferred revenue	—	10
Stock options	1,191	1,425
Other deferred tax assets	765	716
Property and equipment	6	9
Lease liability	301	—
Total deferred tax assets	31,912	29,396
Deferred tax liabilities:		
Lease asset	(301)	—
Total deferred tax liabilities	(301)	—
Valuation allowance	(31,611)	(29,396)
Net deferred taxes	$ —	$ —

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded 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 arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance. The valuation allowance increased by $2.2 million during 2019, $0.9 million during 2018, and decreased by $10.1 million during 2017.

Net operating loss and tax credit carryforwards as of December 31, 2019, are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal (Post December 31, 2017)	$ 16,151	Do Not Expire
Net operating losses, federal (Pre January 1, 2018)	$ 94,886	Beginning in 2024
Net operating losses, state	$ 90,455	Beginning in 2028
Tax credits, federal	$ 1,316	Beginning in 2026
Tax credits, state	$ 325	Indefinite

Under Section 382 of the Internal Revenue Code of 1986, as amended, 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 carryforwards and other pre-change tax attributes, such as research credits may be limited.

A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the below years are as follows (in thousands):

(in thousands)	Year ended December 31, 2019	2018
Unrecognized benefit - beginning of period	$ 974	$ 931
Gross decreases - prior period tax positions	—	43
Unrecognized benefit - end of period	$ 974	$ 974

The entire amount of the unrecognized tax benefits would not impact our effective tax rate if recognized. Accrued interest and penalties related to unrecognized tax benefits are classified as income tax expense and were immaterial. We do not anticipate that total unrecognized tax benefits will significantly change in the next 12 months. The Company files income tax returns in the United States and in California. Other jurisdictions are not significant. The tax years 2004 - 2019 remain open in the federal jurisdiction and 2006 - 2019 for California. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions.

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,		
	2019	2018	2017
Statutory Rate	21.0%	21.0%	34.0%
State Tax	3.1%	(0.3%)	0.2%
Stock Based Compensation Expense	(3.7%)	(4.3%)	(2.1%)
Change in Valuation Allowance	(23.0%)	(13.0%)	141.7%
Other	(0.3%)	(0.5%)	0.7%
Warrant/equity expenses	1.7%	4.2%	(0.5%)
Impact of 162m	1.1%	1.3%	(4.6%)
Tax Reform - Tax Rate Change	0.0%	0.0%	(169.5%)
Impact of ASC 606	0.0%	(8.5%)	0.0%
Total	(0.1%)	(0.1%)	(0.1%)

NOTE 17. RELATED PARTY TRANSACTIONS

Related Party Financing

See Note 9, “Related Party Notes Payable” for a description of the Promissory Note issued on February 27, 2019, as amended on June 25, 2019 and Note 12, “Stockholders’ Equity” for a description of the Company’s financing transactions in June 2019 and August 2019.

Related Party Revenue

The Company recognized related party revenues from product sales and license and collaboration fees of $250 thousand, $77 thousand, and $27 thousand for the years ended December 31, 2019, 2018 and 2017, respectively. In fulfillment of the performance obligations under the Purchase Agreement with China Pioneer, the Company supplied product samples with a cost of $176 thousand, $426 thousand, and $102 thousand for the years ended December 31, 2019, 2018 and 2017, respectively. These costs were recorded as a sales and marketing expense. Related party accounts receivable was $0 and $39 thousand as of December 31, 2019 and December 31, 2018, respectively. See Note 14, “License, Collaboration and Distribution Agreements” for additional information regarding the Company's distribution agreements with China Pioneer, the Company's second largest stockholder.

Related Party Expenses

The Company recognized related party commission expense of $326 thousand, $359 thousand, and $0 for the years ended December 31, 2019, 2018 and 2017, respectively. The Company paid China Kington a fee of $20 thousand, $144 thousand and $162 thousand in the first, second and third quarter of 2019, respectively. The first quarter fee represented the broker fee for the issuance of the Promissory Note to Pioneer Hong Kong. The second quarter fee represented the commission for the private placement with three accredited investors which closed on June 26, 2019. The third quarter fee represented the commission for the private placement with three accredited investors which closed on August 8, 2019. All of the fees were recorded as an offset to the additional paid-in capital in the consolidated balance sheet. For the year ended December 31, 2019, $18 thousand was recorded to interest expense using the effective interest rate method over the term of the Promissory Note. See Note 12, “Stockholders’ Equity” for additional information regarding such commissions.

A fee of $50 thousand was paid to Director Bob Wu in the first quarter of 2019 and represented the consulting fees pursuant to that certain Consulting Agreement, between the Company and China Kington, dated March 11, 2019. The Company recorded an $83 thousand expense related to Mr. Wu’s consulting service for the year ended December 31, 2019. The Company paid an additional fee of $50 thousand to Mr. Wu in March 2020 pursuant to the Consulting Agreement. See Note 9, “Related Party Notes Payable” for additional information regarding such fees.

The fees paid to China Kington during the year ended December 31, 2018 represented the commission on its sale of the Company’s common stock. See Note 12, “Stockholders’ Equity” for additional information regarding such commissions.

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, 2019, 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, 2019. 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, 2019. Our management has concluded that, as of December 31, 2019, our internal control over financial reporting was effective based on these criteria.

Changes in Internal Control Over Financial Reporting

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be included in our Proxy Statement for the 2020 Annual Meeting of Stockholders (the “2020 Proxy Statement”) and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in the 2020 Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included in the 2020 Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included in the 2020 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be included in the 2020 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

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

		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 October 2015 offering, as amended	10-K	001-33678	4.5	3/23/2017	
4.5	Form of 2019 Domestic Warrant issued in August 2019	8-K	001-33678	4.1	8/9/2019	
4.6	Form of 2019 Foreign Warrant issued in August 2019	8-K	001-33678	4.2	8/9/2019	
4.7	Form of Warrant in June 2019 offering	8-K	001-33678	4.2	6/19/2019	
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 Justin M. Hall)	8-K	001-33678	10.1	2/6/2020	
10.8+	Executive Employment Agreement (Employment Agreement of Jason Raleigh)	8-K	001-33678	10.2	2/6/2020	
10.9	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	
10.10	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	
10.11	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	
10.12	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	
10.13	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	
10.14	Office Lease (between the Company and KBSIII Towers at Emeryville, LLC)	8-K	001-33678	10.1	8/26/2016	
10.15	Sublease Agreement by and between NovaBay Pharmaceuticals, Inc. and Zymergen, Inc., dated July 11, 2016	8-K	001-33678	10.1	7/15/2016	
10.16†	Collaboration and License Agreement by and between NovaBay Pharmaceuticals, Inc. and Galderma S.A.	10-Q, as amended	001-33678	10.2	8/04/2009	
10.17†	Amendment No. 1 to the Collaboration and License Agreement	10-K	001-33678	10.18	3/30/2010	
10.18†	Amendment No. 2 to the Collaboration and License Agreement	10-K	001-33678	10.24	3/10/2011	
10.19†	International Distribution Agreement (by and between the Company and Pioneer Pharma Co. Ltd.)	10-K	001-33678	10.18	3/27/2012	
10.20	Commission structure for warrant exercise	8-K	001-33678	Item 1.01	9/30/2016	
10.21	Promissory Note Payable to Pioneer Pharma (Hong Kong) Company Limited, dated February 27, 2019	8-K	001-33678	10.1	3/01/2019	
10.22	First Amendment to the Promissory Note (payable to Pioneer Pharma (Hong Kong) Company Limited), dated June 25, 2019	8-K	001-33678	10.1	6/26/2019	
10.23	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	
10.24	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	

10.25	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	
10.26	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	
10.27	Consulting Agreement between the Company and China Kington, dated March 1, 2019	10-K, as amended	001-33678	10.31	3/29/2019	
10.28	Common Stock Purchase Agreement between the Company and Triton Funds LP, dated March 29, 2019	8-K	001-33678	10.1	4/01/2019	
10.29	Registration Rights Agreement between the Company and Triton Funds, LP, dated March 29, 2019	8-K	001-33678	10.2	4/01/2019	
10.30	Letter Agreement between the Company and Triton Funds LLC, dated March 29, 2019	8-K	001-33678	10.3	4/01/2019	
10.31	Securities Purchase Agreement between the Company and certain named purchasers, dated June 17, 2019	8-K	001-33678	10.1	6/19/2019	
10.32	Placement Agency Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated August 8, 2019	8-K	001-33678	1.1	8/9/2019	
10.33	Form of Securities Purchase Agreement between the Company and certain named domestic purchasers, dated August 8, 2019	8-K	001-33678	10.1	8/9/2019	
10.34	Securities Purchase Agreement between the Company and certain named foreign purchasers, dated August 8, 2019	8-K	001-33678	10.2	8/9/2019	
23	Consent of Independent Registered Public Accounting Firm					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 26, 2020

By: /s/ Justin Hall
Justin Hall
President and Chief Executive Officer
(principal executive officer)

Date: March 26, 2020

By: /s/ Jason Raleigh
Jason Raleigh
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**	President and Chief Executive Officer (*principal executive officer*)	March 26, 2020
/s/ JASON RALEIGH **Jason Raleigh**	Chief Financial Officer (*principal financial officer*)	March 26, 2020
/s/ PAUL E. FREIMAN **Paul E. Freiman**	Chairman of the Board	March 26, 2020
/s/ XINZHOU LI **Xinzhou Li (Paul LI)**	Director	March 26, 2020
/s/ XIAOYAN LIU **Xiaoyan Liu (Henry LIU)**	Director	March 26, 2020
/s/ GAIL MADERIS **Gail Maderis, M.B.A.**	Director	March 26, 2020
/s/ SWAN SIT **Swan Sit**	Director	March 26, 2020
/s/ XIAOPEI WANG **Xiaopei (Ray) Wang**	Director	March 26, 2020
/s/ MIJIA WU **Mijia Wu, M.B.A. (Bob WU)**	Director	March 26, 2020
/s/ YENYOU ZHENG **Yenyou (Jeff) Zheng**	Director	March 26, 2020

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statements on Form S-8 (File Nos. 333-236328, 333-222625, 333-218469, 333-215680, 333-211754, 333-208985, 333-203109, 333-196764, 333-194383, 333-185998, 333-180461, 333-171981, 333-147334, 333-157041, and 333-164469), Form S-3 (File Nos. 333-233623, 333-232860, 333-230672, 333-211944 and 333-211943) and Form S-1 (File No. 333-234330) of NovaBay Pharmaceuticals, Inc. of our report dated March 26, 2020 (which report expresses an unqualified opinion and includes an explanatory paragraph related to substantial doubt about the Company's ability to continue as a going concern), relating to the consolidated financial statements of NovaBay Pharmaceuticals, Inc., which appears in this Annual Report on Form 10-K.

/s/ OUM & CO. LLP

San Francisco, California
March 26, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Justin Hall, certify that:

1. I have reviewed this Form 10-K of NovaBay Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2020

/s/ Justin Hall
Justin Hall
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason Raleigh, certify that:

1. I have reviewed this Form 10-K of NovaBay Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2020

/s/ Jason Raleigh
Jason Raleigh
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of NovaBay Pharmaceuticals, Inc. (the Company) on Form 10-K for the fiscal year ended December 31, 2019 (the Report), I, Justin Hall, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2020

/s/ Justin Hall
Justin Hall
President and Chief Executive Officer

This Certification is made solely for the purpose of 18 USC Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of NovaBay Pharmaceuticals, Inc. (the Company) on Form 10-K for the fiscal year ended December 31, 2019 (the Report), I, Jason Raleigh, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2020

/s/ Jason Raleigh
Jason Raleigh
Chief Financial Officer

This Certification is made solely for the purpose of 18 USC Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.