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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, 2020

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2020, 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 $26,682,897. This figure excludes an aggregate of 11,358,436 shares of common stock held by affiliates, including officers and directors, as of June 30, 2020. 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 23, 2021, there were 41,782,584 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the 2021 Annual Meeting of Stockholders (Part III) to be filed within 120 days after the end of the Registrant's year ended December 31, 2020.

NOVABAY PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2020

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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.

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, competitors, 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 forward-looking statements represent our management's beliefs and assumptions only as of the date of this report and our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, even if new information becomes available in the future.

PART I

ITEM 1. BUSINESS

NovaBay Pharmaceuticals, Inc. is a medical device company predominantly focused on eye care. A majority of our revenue comes from Avenova®, an FDA cleared product sold in the United States that has proven in laboratory testing to have broad antimicrobial properties as it removes 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 is available directly to consumers through our on-line sales channel and is also often prescribed and dispensed by eyecare professionals for blepharitis and dry-eye disease.

We continue to promote Avenova through all four of our primary distribution channels: (1) our direct-to-consumer model, allowing customers to order online and 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 physician dispensed channel, allowing patients to buy Avenova during office visits to their preferred eye care specialist. We achieved record overall Avenova unit sales in 2020 despite the global COVID-19 pandemic and general economic conditions that challenged many businesses throughout 2020.

Late in 2020, we also launched a rebranded CelleRx® into the beauty industry as CelleRx® Clinical Reset™. Prior to this rebranding, our marketing of CelleRx focused on medical professionals only.

Beyond Avenova and CelleRx, we have developed additional products containing our proprietary, stable and pure form of hypochlorous acid, including NeutroPhase® and PhaseOne® for the wound care market.

In addition to our proprietary products, we responded to the national need for protective personal equipment (PPE) in the first half of 2020 by tapping into our international supply network and launching the sale of KN95 Masks and other PPE. Although sales from the KN95 Masks were significant in the second quarter of 2020, we experienced a significant decrease in PPE sales in the third and fourth quarters as supply shortages narrowed, prices declined and distribution competition increased. As we have returned our focus to our core business in eyecare, we do not currently anticipate dedicating significant future Company resources toward the sale of PPE and we do not expect significant future revenue from PPE sales.

Avenova

Avenova is a proprietary solution of 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, it is well suited for daily use. Avenova offers distinct advantages when compared to alternative lid and lash regimens that contain soaps, bleach, and other impurities, as Avenova removes unwanted microorganisms from the skin without the use of those harmful ingredients. Avenova's target market is the millions of Americans who suffer from minor irritation of the skin around the eye (commonly referred to as blepharitis) as well as anyone who suffers from dry eye (commonly described as a gritty sandy sensation while blinking). We began selling prescription Avenova in the United States in 2014.

In the second quarter of 2019, we began selling Avenova online as an over-the-counter product. By creating a product that does not require a doctor's prescription, we made Avenova available to many more potential customers and broadened our addressable market. This direct-to-consumer version of Avenova also 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.

The launch of over-the-counter Avenova proved to be especially fortuitous during the COVID-19 pandemic as it allowed consumers to order Avenova on-line without a prescription and without leaving their homes.

Over-the-counter Avenova is now our leading product by unit sales and net revenue despite having a lower average net selling price than prescription Avenova. This sales performance reflects our ongoing focus and increasing spend on digital marketing and public relations initiatives. Avenova is now available on Amazon.com, Walmart.com, and Avenova.com. Late in 2020, we also began working with CVS, one of the nation's largest retail chains to make Avenova available at CVS store locations throughout the U.S. and on CVS.com beginning in the first quarter of 2021.

Despite the shift to a direct-to-consumer model, support from ophthalmologists and optometrists remains strong. The continual endorsement of medical professionals has created a "doctor recommended" halo effect around our brand. This is a key differentiating factor in a crowded consumer space and is a result of our high quality and reliable efficacy. Our physician dispensed channel is particularly important in this regard as patients are able to purchase Avenova conveniently and immediately upon recommendation in the doctor's office. We believe this also creates repeat Avenova customers who subsequently purchase Avenova through other channels.

We also make prescription Avenova accessible nationwide in nearly all retail pharmacies across the United States through agreements with McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation. We also have agreements directly with some preferred pharmacy networks through our Partner Pharmacy Program. These agreements provide greater control over the patient experience at consistent contract pricing.

We continue to build 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.

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 these detergent based products, Avenova consists solely of saline and 0.01% pure hypochlorous acid, without the toxic impurities included in competitive offerings. While there are some hypochlorous acid based products on the market, they all include bleach or other dangerous impurities. Because Avenova lacks these impurities, we believe that physicians and their patients will continue to choose Avenova over other competitive products. While cheaper antibacterial soaps are commonly used to reduce or prevent bacterial contamination on the skin, we do not view them as true competitors of Avenova.

CelleRx Clinical Reset (Dermatology)

CelleRx Clinical Reset is a gentle and soothing facial spray that disrupts the layer of bacteria that settles and grows on the face. When this barrier is out of balance, acne, rosacea and infection can set in. As the brand name suggests, Clinical Reset gets the skin back to a healthy baseline to heal itself while also enabling absorption of other skincare products. It is formulated with our patented, pure, prescription-grade hypochlorous acid and can replace or augment a morning cleanse for dry sensitive skin, reduce bacteria after exercising, calm skin following microdermabrasion and other aesthetic facial procedures and combat environmental aggressors. Unlike many harsh products used for the same purpose, it is gentle and is not an antibiotic.

We are leveraging new consumer focused messaging and the product's pharmaceutical pedigree in robust social media and print advertising campaigns marketing CelleRx Clinical Reset in the beauty industry.

NeutroPhase and PhaseOne (Wound Care)

Consisting of higher concentrations of hypochlorous acid, NeutroPhase and PhaseOne are used for the cleansing and irrigation of intraoperative pocket lavage, before subcutaneous closure, stage I to IV pressure injuries, stasis ulcers, leg ulcers, diabetic foot ulcers, first-degree and second-degree burns, post-surgical wounds, grafted and donor sites, minor burns, superficial abrasions, wounds, and moistening absorbent wound dressings.

Both NeutroPhase and PhaseOne compete 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 our solution has distinct competitive advantages because it is made without the toxic bleach and other preservative chemicals found in other products, making it gentle, non-irritating, and non-sensitizing to skin and new tissue. PhaseOne is distributed through commercial partners in the United States and NeutroPhase is distributed in China by Pioneer Pharma.

Customers, Manufacturing and Suppliers

Avenova is available on Amazon.com, Walmart.com, and Avenova.com. Online sales accounted for 56% of all Avenova revenue and 57% of all Avenova units sold across all channels in 2020.

Historically, we have called on ophthalmologists, optometrists, and other eye care professionals who can prescribe Avenova. With thousands of doctors prescribing and selling the product, no individual doctor represented in excess of 10% of our revenues for the year ended December 31, 2020.

CelleRx is distributed to customers primarily through online channels, while NeutroPhase and PhaseOne rely on distribution partners.

We currently outsource manufacturing of all our products 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.

Research and Development

For the years ended December 31, 2020 and 2019, we incurred total research and development expenses of approximately $0.3 million and $0.2 million, respectively. Pursuant to our business strategy of focusing our resources on growing the commercial sales of Avenova, and increasingly on our recently rebranded CelleRx Clinical Reset, 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 in the near-term.

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 in the United 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. We believe 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 medical 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 medical device.

None of our products are Class II or Class III medical devices.

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. 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 anti-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 (“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. Notably, in 2019, we received notices from several national third-party payors that they would not cover Avenova. 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, 2020, we had a total of 25 employees, 22 of whom were full-time employees and 3 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 the provisions 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 intends to renew the lease upon expiration.

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"). Our website is not part of this annual report on Form 10-K. 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

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

We have historically incurred net losses, and we may never achieve or maintain sustained profitability. In addition, at this time, we expect to incur substantial marketing and sales expenses as we continue efforts to increase sales of our Avenova and CelleRx products, and our results of operations may fluctuate significantly.

We will need to generate significant revenues to achieve and maintain profitability. Even with current Avenova sales, if we cannot successfully market and sell our Avenova or CelleRx products, we may not be able to generate sufficient revenues to achieve or maintain profitability. 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

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;
- changes in our earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earnings estimates;
- developments in our industry;
- the sale of a substantial number of shares of common stock by our largest stockholder, Pioneer Pharma (Hong Kong) Company Ltd. ("Pioneer Hong Kong"), within a short period of time; 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.

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

We have never paid cash dividends on, or repurchased shares of, our common stock and do not anticipate paying cash dividends or repurchasing shares of our common stock in the foreseeable future. The payment of dividends on, or the repurchase of shares of, 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 or repurchase stock, 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 sell your shares or that you will not lose the entire amount of your investment.

China Pioneer Pharma Holdings Limited ("China Pioneer") and/or China Kington Asset Management ("China Kington") have influence over our corporate matters.

Pioneer Hong Kong, a subsidiary of China Pioneer, beneficially owns approximately 12.4% of our outstanding common stock. Our director Mr. Xinzhou "Paul" Li is the chairman of China Pioneer and our director Mr. Mijia "Bob" Wu is a Non-Executive Director of China Pioneer as well as the Managing Director of China Kington (an affiliated party of the Company due to various historical transactions as disclosed in reports filed with the SEC).

As a result, subject to the fiduciary duties Messrs. Li and Wu owe to the Company in their role as directors, 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.

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

Historically, the Company's stockholders' equity as been below the minimum requirements of Section 1003(a) of the NYSE American Company Guide (the "Company Guide") though the Company has met all such minimum requirements since October 13, 2020. In accordance with Section 1009(h) of the Company Guide, if the Company is again determined to be below any of the continued listing standards prior to October 13, 2021, the NYSE American will examine the relationship between the two incidents of non-compliance and re-evaluate the Company's method of financial recovery from the first incident. The NYSE American will take the appropriate action which, depending on the circumstances, may include initiating its compliance procedures or initiating 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.

Risks Relating to Our Business

Our business may be adversely affected by the coronavirus outbreak.

In December 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China. In January 2020, COVID-19 spread to other countries, including the United States, and efforts to contain the spread of this coronavirus intensified. In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 outbreak, "shelter in place" orders and other public health measures were implemented across much of the United States, including the San Francisco Bay area counties where the Company's headquarters is located. Due to "shelter in place" orders and other public health guidance measures, the Company implemented a work-from-home policy for all staff members. As the shelter-in-place restrictions are lifted, the Company has opened its business in phases by staggering the timeline for returning employees to work. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business, financial condition and results of operation, particularly in relation to our field sales representatives. In particular, in the second quarter of 2020, we experienced a slowdown in Avenova sales in our prescription and in-office direct channels, as patient visits to eyecare specialists decreased substantially due to the nationwide shelter-in-place mandates. Overall, the impact of COVID-19 has been minimal on the sales of Avenova as an increase in online sales has made up for the decrease in prescription revenue.

The COVID-19 global pandemic continues to evolve. The extent to which the outbreak may continue to affect our business, financial condition and results of operations will depend on future developments, which are uncertain and cannot be predicted at this time, such as the duration of the outbreak, evolution of COVID-19 into novel strands of the disease, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing, quarantines or lock-downs in the United States and elsewhere, business closures or business disruptions and the effectiveness of actions taken in the United States and elsewhere to contain and treat the disease through vaccination. Future developments in these and other areas present material uncertainty and risk with respect to our business, financial condition and results of operations.

Our future success is largely dependent on the successful commercialization of our products, particularly Avenova.

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 judge correctly 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 and/or CelleRx, which could cause our commercialization efforts to be unprofitable or less profitable than expected.

Acceptance and use of Avenova and/or CelleRx by physicians and customers may depend on a number of factors including: (i) perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products; (ii) published studies demonstrating the cost-effectiveness of our products relative to competing products; (iii) availability of reimbursement for our products from government or commercial payers as relates to Avenova; and (iv) 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.

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, and against products such as Restasis, Xiidra, eye wipes, baby shampoo and soap. 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, particularly as the market has a heightened focus on antimicrobial products in the wake of the COVID-19 pandemic. Many of our competitors have substantially more resources and a greater marketing scale than we do. We may not be able to sustain 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.

Revenue generated from the KN95 Masks represents a temporary source of revenue for the Company.

During the COVID-19 pandemic, we tapped into our global healthcare supply network to secure KN95 Masks. While receiving a modest profit margin on the KN95 Masks in 2020, the Company does not believe that the revenue generated from the KN95 Masks will be a long-term source of revenue for the Company. Due to increased supply, the demand for the KN95 Masks has already declined, and the Company expects such demand to continue to decline. The Company does not expect this revenue source to extend past the current COVID-19 pandemic.

Our business may be adversely affected if there is a default on the Payment Protection Program ("PPP") loan (the "PPP Loan").

We entered into a PPP Loan with Wells Fargo Bank, N.A. in an aggregate principal amount of $900,505, which was established under the CARES Act. Under the terms of the CARES Act, recipients can apply for and receive forgiveness for all or a portion of loans granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for certain permissible purposes as set forth in the PPP, including, but not limited to, payroll costs (as defined under the PPP) and mortgage interest, rent or utility costs and the maintenance of employee and compensation levels. While we believe that we meet the qualifications for loan forgiveness, there is no assurance that the Company will obtain forgiveness of the PPP Loan, in whole or in part, and therefore, the Company may be liable for paying the PPP Loan back.

The PPP Loan contains customary events of default relating to, among other things, payment defaults or breach of representations and warranties. If the PPP Loan is not forgiven, the Company may default on the PPP Loan and trigger the immediate repayment of all amounts outstanding and/or the Lender filing suit and obtaining judgment against the Company. The Company submitted the PPP loan forgiveness application in March 2021.

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

We rely 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 aspects of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing 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, 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 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.

Risk Related to Government Regulation

We expect continuous 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.

Although we had short-term revenue generation from the sale of KN95 Masks in 2020 and hope to receive revenue from CelleRx Clinical Reset as a lifestyle hygiene product, our ability to generate product sales will depend primarily 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 cleared medical device;
- acceptance in the medical community;
- the safety of Avenova's predicate devices;

- the number of patients who use Avenova;
- coverage or reimbursement by third-party payors;
- our ability to successfully market Avenova;
- reopening and resurgence of patient visits to eyecare specialists after the nationwide shelter-in-place mandates cease; and
- the amount and nature of competition from competing companies with similar products.

The sale of Avenova will be subject to, among other things, regulatory and commercial and market uncertainties that may be outside of our control. The clearance that we have received from the FDA for our Avenova, NeutroPhase, PhaseOne and CelleRx 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.

In addition, there can be no assurance that government regulations applicable to our products 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 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 industry standards, practices or regulations applicable 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, 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 products such as Avenova and CelleRx, like our other cleared products, are not approved by the FDA as a drug, and we rely solely on the 510(k) clearance of our products as a medical device.

Our business and future growth depend on the development, use and sale of products that are subject to FDA regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA. As a medical device, we may only 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. If and to the extent that the relaunch of CelleRx as a lifestyle hygiene product is successful, we would have similar restrictions due to the status of CelleRx as a 510(k) cleared product.

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 online, as well as the FDA's increased focus on antimicrobial products in the wake of the COVID-19 pandemic. 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 and promotion activities.

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 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 (in particular, direct to consumer advertising), promotion and pricing of pharmaceutical products. Certain regulatory changes or decisions could make it more difficult for us to sell our products. 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, criminal prosecution and other enforcement actions. Any of these events could prevent us from marketing our products and our business may not be able to continue past such concerns. 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, 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. 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 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. 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.

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, such as Avenova, NeutroPhase, PhaseOne and CelleRx, 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 regulated 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, it 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 our 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 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 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.

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 (or inability) 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. 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.

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. 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 applicable 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) HIPAA, which, among other things, created 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.

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.

Risks Related to Potential Litigation

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. We 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.

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 may be subject to product liability claims, and 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 our products or products that we currently do not sell but may sell in the future, which are defective, to which patients/customers react in an unexpected manner, or which are alleged to have side effects or otherwise not work for the product’s intended purpose. The manufacture and sale of such products may expose us to potential liability, including regulatory enforcement actions, 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 reputation, financial condition, business and results of operations. 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.

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.

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.

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 as well as additional damages in connection with his separation from service with the Company. The arbitration was settled on December 23, 2020. Mr. McGovern released the Company from all outstanding obligations upon settlement.

As of December 31, 2020, there were 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, 2021, there were approximately 127 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.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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. A majority of our revenue comes from Avenova®, an FDA cleared product sold in the United States that has proven in laboratory testing to have broad antimicrobial properties as it removes 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 is available directly to consumers through our online sales channel and is also often prescribed and dispensed by eyecare professionals for blepharitis and dry-eye disease.

We continue to promote Avenova through all four of our primary distribution channels: (1) our direct-to-consumer model, allowing customers to order online and 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 physician dispensed channel, allowing patients to buy Avenova during office visits to their preferred eye care specialist. We achieved record overall Avenova unit sales in 2020 despite the global COVID-19 pandemic and general economic conditions that challenged many businesses throughout 2020.

Avenova was launched as an over-the-counter product during the second quarter of 2019. By creating a product that does not require a doctor’s prescription, we made Avenova available to many more potential customers and broadened our addressable market. Over-the-counter Avenova also 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.

The launch of over-the-counter Avenova online proved to be especially fortuitous during the COVID-19 pandemic as it allowed consumers to order Avenova on-line without a prescription and without leaving their homes.

Over-the-counter Avenova is now our leading product by unit sales and net revenue despite having a lower average net selling price than prescription Avenova. This sales performance reflects our ongoing focus and increasing spend on digital marketing and public relations initiatives to promote Avenova directly to the end consumer. Avenova is available on Amazon.com, Walmart.com, and Avenova.com. Late in 2020, we also began working with CVS, one of the nation’s largest retail chains to make Avenova available at CVS store locations throughout the U.S. and on CVS.com beginning in late February 2021.

Although we expect the online sales channel to continue to be our fastest-growing channel, support for Avenova from the medical community is important to maintaining its reputation as a preferred product. The "doctor recommended" halo effect around our brand remains strong due in part to our continued promotion of prescription Avenova.

Late in 2020, we also launched a rebranded CelleRx® into the beauty industry as CelleRx® Clinical Reset™. Prior to this rebranding, our marketing of CelleRx focused on medical professionals only. Clinical Reset is formulated with NovaBay's patented, pure, prescription-grade hypochlorous acid (HOCl), the same molecule produced by the human body's immune system to fight infection and heal wounds. It keeps the skin's natural barrier intact, which when out of balance can allow acne, rosacea and infection to set in. Clinical Reset is complementary to a daily beauty regime for use on clean skin or over makeup. Prior to this relaunch, our marketing of CelleRx focused on medical professionals only. With the rebranding, we intend to leverage new consumer focused messaging and the product's pharmaceutical pedigree in robust social media and print advertising campaigns marketing CelleRx Clinical Reset in the beauty industry.

Beyond Avenova and CelleRx, we have developed additional products containing our proprietary, stable and pure form of hypochlorous acid, including NeutroPhase® and PhaseOne® for the wound care market.

In addition to our proprietary products, we responded to the national need for protective personal equipment (PPE) in the first half of 2020 by tapping into our international supply network and launching the sale of KN95 Masks and other PPE. Although sales from the KN95 Masks were significant in the second quarter of 2020, we experienced a significant decrease in PPE sales in the third and fourth quarters as supply shortages narrowed, prices declined and distribution competition increased. As we have returned our focus to our core business in eyecare, we do not currently anticipate dedicating significant future Company resources toward the sale of PPE and we do not expect significant future revenue from PPE sales.

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 to 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

The Company charges bad debt expense and records an allowance for doubtful accounts when management believes it to be unlikely that specific invoices will be collected. Management identifies amounts due that are in dispute and it believes are unlikely to be collected. Management recorded a nominal reserve for accounts receivable at December 31, 2020. At December 31, 2019, management reserved $51 thousand based on specific amounts that were in dispute or were over 120 days past due as of that date.

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 filled but unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the price paid to these manufacturers is included in inventory. Inventory is stated at the lower of cost or estimated net realizable value determined by the first-in, first-out method. At December 31, 2020 and 2019, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $236 thousand and $247 thousand, respectively.

Leases

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 consolidated balance sheets.

Revenue Recognition

Revenue generated through the Company's webstore for Avenova and KN95 Masks is recognized upon receipt by the customer through multiple third-party carriers. Shipping and handling costs are expensed as fulfillment costs are incurred and included in cost of goods sold in the consolidated statements of operations and comprehensive loss. We present revenue net of sales taxes and refunds.

Revenue generated through Amazon.com and Walmart.com for Avenova and other products is recognized upon fulfillment, which generally occurs upon delivery of the related products to a third-party carrier or, in the case of an Amazon/Walmart delivery, to the customer. We present revenue net of commissions and any related fulfillment and shipping fees charged by these partners. Fees paid to partners for promoting our product are expensed as incurred and are included in sales and marketing expenses within the operating expenses in the consolidated statements of operations and comprehensive loss.

The Company also generates Avenova product revenue through product sales to its major distribution partners. Product supply of Avenova 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. Upon recognition of product sales, 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, and product returns. Because the Company did 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 was based on an average of peer and competitor company historical return rates through the end of the third quarter of 2020. The Company updated the return rate assumption quarterly. Beginning in the fourth quarter of 2020, the Company determined that it had adequate historical data to estimate future returns based on its own experience. The Company increased its return rate assumption based on historical data and recorded a $0.4 million increase in its accrual for future returns. The Company will continue to monitor and update its return rate assumption quarterly. Payment for product supply is typically due 30 days after control transfers to the distributor.

Revenue generated through the Company's partner pharmacies is recognized when control of the product transfers to the end customer.

Bulk orders of KN95 Masks were shipped directly to the customer from a manufacturer in China. Revenue was recognized when control of the product passed to the customer, which was upon delivery of the KN95 Masks to the customer.

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, 2019	$ (142)	$ (13)	$ 153	$ (432)	$ (434)
Current provision related to sales made during current period	(422)	(66)	(1,392)	(62)	(1,942)
Increase in provision related to sales made during prior periods	—	—	—	(396)	(396)
Payments	473	69	1,294	363	2,199
Balance at December 31, 2020	$ (91)	$ (10)	$ 55	$ (527)	$ (573)

Cost of Goods Sold

Cost of goods sold includes third-party manufacturing costs, shipping and handling costs, and other costs associated with products 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 all costs associated with research, development and regulatory activities, including submissions to the Food and Drug Administration ("FDA").

Advertising Costs

Advertising costs are expensed in the period in which the costs are incurred. Advertising expenses were $1.7 million, $0.5 million, and $0, respectively, for the years ended December 31, 2020, 2019, and 2018.

Stock-Based Compensation

The Company's stock-based compensation includes grants of stock options and restricted stock units ("RSUs") to employees, consultants and non-employee directors. The expense associated with these grants 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. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes 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 RSUs 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 common stock purchase warrants issued in connection with its equity offerings in accordance with the provisions of ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*.

The Company accounts for common stock purchase warrants issued in connection with share-based compensation arrangements in accordance with the provisions of ASC 718, *Stock Compensation,* which encompasses the provisions of ASC 480, *Distinguishing Liabilities from Equity*.

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). Additionally, for common stock purchase warrants accounted for in accordance with ASC 718, *Stock Compensation,* the Company classifies as liabilities any contracts where it believes the warrants are deemed to be probable of issuance.

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 are determined using the Black-Scholes option pricing model, the Binomial Lattice ("Lattice") valuation model, or the Monte Carlo simulation model where deemed appropriate. These values are subject to a significant degree of management's judgment.

Recent Accounting Pronouncements

See Note 2, "Summary of Significant Accounting Policies", to 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, 2020 and 2019

	Year Ended December 31,		Dollar Change	Percent Change
	2020	2019		
	(in thousands)		(in thousands)	
Statement of Operations				
Sales:				
Product revenue, net	$ 9,916	$ 6,556	$ 3,360	51%
Other revenue, net	18	43	(25)	(58%)
Total sales, net	9,934	6,599	3,335	51%
Cost of goods sold	3,970	1,738	2,232	128%
Gross profit	5,964	4,861	1,103	23%
Research and development	285	184	101	55%
Sales and marketing	6,173	8,767	(2,594)	(30%)
General and administrative	5,932	5,310	622	12%
Total operating expenses	12,390	14,261	(1,871)	(13%)
Operating loss	(6,426)	(9,400)	2,974	(32%)
Non-cash (loss) gain on changes in fair value of warrant liability	(5,216)	749	(5,965)	(796%)
Non-cash gain on changes in fair value of embedded derivative liability	3	424	(421)	(99%)
Other income (expense), net	605	(1,425)	2,030	(142%)
Loss before provision for income taxes	(11,034)	(9,652)	(1,382)	14%
Provision for income taxes	(5)	(6)	1	(17%)
Net loss and comprehensive loss	$ (11,039)	$ (9,658)	$ (1,381)	14%

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

Product revenue, net, increased by $3.4 million, or 51%, to $9.9 million for the year ended December 31, 2020, from $6.6 million for the year ended December 31, 2019. The change in product revenue, net, is primarily the result of $3.1 million in product revenue, net, generated from the sale of KN95 Masks during the year ended December 31, 2020 with no comparable revenue during the year ended December 31, 2019. Further, Avenova revenue decreased $0.3 million in 2020 from $6.3 million in 2019 to $6.0 million for the year ended December 31, 2020. The decrease was the net result of an overall decrease in the average net selling price of Avenova products which was partially offset by an overall increase in Avenova units sold. The increase in units sold reflects a higher number of non-prescription Avenova and buy-and-sell units sold, partially offset by a decrease in the number of prescription units sold. The decrease in the overall net selling price was largely due to a lower net selling price associated with over-the-counter Avenova, which was launched in June 2019.

Other revenue, net, decreased by $25 thousand, or 58%, to $18 thousand for the year ended December 31, 2020, from $43 thousand for the year ended December 31, 2019. The decrease 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 with no comparable revenue during the year ended December 31, 2020.

Cost of goods sold increased by $2.2 million, or 128%, to $4.0 million for the year ended December 31, 2020, from $1.7 million for the year ended December 31, 2019. The increase was the result of the cost of KN95 Masks sold during the year ended December 31, 2020 with no comparable sales during the year ended December 31, 2019, as well as an increase in the number of Avenova units sold during the year ended December 31, 2020 as compared to the year ended December 31, 2019.

Gross profit increased by $1.1 million, or 23%, to $6.0 million for the year ended December 31, 2020, from $4.9 million for the year ended December 31, 2019. The increase in gross profit was primarily due to the KN95 Mask sales.

Research and Development

Research and development expenses increased by $0.1 million, or 55%, to $0.3 million for the year ended December 31, 2020, from $0.2 million for the year ended December 31, 2019. The increase is primarily the result of regulatory expenses incurred under the Microprofit Agreement as further described in Note 8, “Commitments and Contingencies”, to the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report.

Sales and marketing

Sales and marketing expenses decreased by $2.6 million, or 30%, to $6.2 million for the year ended December 31, 2020, from $8.8 million for the year ended December 31, 2019. The decrease was primarily due to a decrease in sales representative headcount, and lower travel and related expenses due to the impact of COVID-19. This decrease was partly off-set by an increase in Avenova digital advertising and costs associated with the Company's relaunch of CelleRx Clinical Reset.

General and administrative

General and administrative expenses increased by $0.6 million, or 12%, to $5.9 million for the year ended December 31, 2020, from $5.3 million for the year ended December 31, 2019. The increase is primarily a result of increased legal expenses incurred and the settlement amount paid in conjunction with a dispute with the Company's former Interim President & Chief Executive Officer and Chief Financial Officer as further described in Note 8, "Commitments and Contingencies", to the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report.

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

The adjustments to the fair value of warrant liability resulted in a loss of $5.2 million for the year ended December 31, 2020 compared to a gain of $0.7 million for the year ended December 31, 2019. For additional information regarding the warrants and their valuation, please see Note 11, "Warrant Liability", to the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report.

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 $3 thousand for the year ended December 31, 2020 compared to a gain of $0.4 million for the year ended December 31, 2019. For additional information, please see Note 10, "Convertible Note", to the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report.

Other income (expense), net

Other income (expense), net, was a net income of $0.6 million for the year ended December 31, 2020 compared to an expense of $1.4 million for the year ended December 31, 2019. During the year ended December 31, 2020, the Company recorded income of $0.9 million as the result of income recognized as qualifying expenses incurred under the PPP Loan. Please see Note 18, "Paycheck Protection Program", to the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report. This income was partially offset by the interest due on the Promissory Note issued in February 2019 and the amortization of discount and issuance cost related to the Convertible Note issued in March 2019.

The expense of $1.4 million for the year ended December 31, 2019 was due to interest of $0.2 million due on the Promissory Note issued in February 2019, the amortization of discount and issuance cost of $0.8 million related to the Convertible Note issued in March 2019, and the issuance cost of $0.4 million related to the issuance of warrants in August 2019. For additional information regarding the Promissory Note, please see Note 9, "Related Party Note Payable" to the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report. For additional information regarding the Convertible Note, please see Note 10, "Convertible Note" to the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report. For additional information regarding the issuance of common stock, Series A Preferred Stock and warrants in August 2019, please see Note 12, "Stockholders' Equity", to the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report.

Comparison of Years Ended December 31, 2019 and 2018

For this discussion, see the "Comparison of Years Ended December 31, 2019 and 2018 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, 2019.

Liquidity and Capital Resources

As of December 31, 2020, our cash and cash equivalents were $12.0 million, compared to $6.9 million as of December 31, 2019. Based primarily on the funds available at December 31, 2020, management believes that the Company's existing cash and cash equivalents and cash flows generated from product sales will be sufficient to enable the Company to meet its planned operating expenses at least through March 25, 2022. However, changing circumstances may cause the Company to expend cash significantly faster than currently anticipated, and the Company may need to spend more cash than currently expected because of circumstances beyond its control. Additionally, our future results, cash expenditures and ability to obtain additional external financing could be adversely affected by the COVID-19 pandemic and general adverse economic conditions.

Cash Used in Operating Activities

Net cash used in operating activities was $4.7 million for the year ended December 31, 2020, which consisted primarily of a net loss of $11.0 million, adjusted by non-cash loss of $5.2 million on the change in fair value of warrant liability, stock-based compensation expenses of $0.5 million, issuance of RSUs for services of $0.2 million, non-cash interest expense related to amortization of debt issuance cost and debt discount of $0.2 million, and a net increase of $0.2 million in our net operating assets and liabilities.

Net cash used in operating activities was $7.9 million for the year ended December 31, 2019, which consisted primarily of a net loss of $9.7 million, adjusted by non-cash gain of $0.7 million on the change in fair value of warrant liability, non-cash interest expense related to amortization of debt issuance cost and debt discount of $0.7 million, non-cash gain of $0.4 million on the change in fair value of embedded derivative liability, stock compensation expenses of $0.5 million, issuance of RSUs related to employee separation agreement of $0.2 million, non-cash impairment of operating lease right-of-use assets of $0.1 million, depreciation and amortization expenses of $0.1 million and issuance of warrants for service of $0.1 million, and a net increase of $1.2 million in our net operating assets and liabilities.

Cash Used in Investing Activities

For the years ended December 31, 2020 and 2019, cash used in investing activities was $26 thousand and $19 thousand, respectively, for the purchase of property and equipment.

Cash Provided by Financing Activities

Net cash provided by financing activities was $9.8 million for the year ended December 31, 2020. The Company received net proceeds of $5.2 million from the at-the-market offering and equity program (“ATM Program”), and an additional $7.1 million from the exercise of warrants. These amounts were offset by repayments of $1.5 million on the Convertible Note issued to Iliad Research and Trading L.P. and repayment of $1.0 million on the Promissory Note, both paid using proceeds raised through the ATM program pursuant to the ATM Agreement, dated April 27, 2020, with Ladenburg.

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 2019. The Company received an additional $0.3 million from the exercise of warrants and stock options during 2019.

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, 2020. 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, 2020	September 30, 2020	June 30, 2020	March 31, 2020	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
	(in thousands, except per share data)							
Statements of Operations Data:								
Sales:								
Product revenue, net	$ 1,878	$ 2,167	$ 3,979	$ 1,892	$ 1,702	$ 1,615	$ 1,789	$ 1,450
Other revenue, net	10	3	5	—	2	—	—	41
Total sales, net	1,888	2,170	3,984	1,892	1,704	1,615	1,789	1,491
Cost of goods sold	813	536	2,040	581	593	401	403	341
Gross profit	1,075	1,634	1,944	1,311	1,111	1,214	1,386	1,150
Operating expenses:								
Research and development	36	125	115	9	18	49	32	85
Sales and marketing	1,498	1,692	1,423	1,560	2,157	1,544	1,535	3,531
General and administrative	1,299	1,879	1,477	1,277	1,174	1,333	1,198	1,605
Total operating expenses	2,833	3,696	3,015	2,846	3,349	2,926	2,765	5,221
Operating loss	(1,758)	(2,062)	(1,071)	(1,535)	(2,238)	(1,712)	(1,379)	(4,071)
Non-cash gain (loss) on changes in fair value of warrant liability	8	(1,589)	(3,772)	137	(187)	1,480	(487)	(57)
Non-cash gain (loss) on changes in fair value of embedded derivative liability	—	1	—	2	1	669	(246)	—
Other income (expense), net	—	429	362	(186)	(259)	(719)	(387)	(60)
Loss before provision for income taxes	(1,750)	(3,221)	(4,481)	(1,582)	(2,683)	(282)	(2,499)	(4,188)
Provision for income taxes	(4)	—	(1)	—	(3)	—	(2)	(1)
Net loss	$ (1,754)	$ (3,221)	$ (4,482)	$ (1,582)	$ (2,686)	$ (282)	$ (2,501)	$ (4,189)
Less: Preferred deemed dividend	—	—	—	—	800	—	—	—
Less: Retained earnings reduction related to warrants down round feature triggered	—	—	—	—	—	—	29	—
Net loss attributable to common stockholders	$ (1,754)	$ (3,221)	$ (4,482)	$ (1,582)	$ (3,486)	$ (282)	$ (2,530)	$ (4,189)
Net loss per share attributable to common stockholders:								
Basic	$ (0.04)	$ (0.08)	$ (0.15)	$ (0.06)	$ (0.13)	$ (0.01)	$ (0.14)	$ (0.25)
Diluted	$ (0.04)	$ (0.08)	$ (0.15)	$ (0.06)	$ (0.13)	$ (0.02)	$ (0.14)	$ (0.25)
Shares used in computing net loss per share:								
Basic	41,776	40,037	30,384	27,978	27,630	23,096	18,613	17,093
Diluted	41,776	40,067	30,384	27,978	27,630	23,213	18,613	17,093

As of December 31, 2020, we had net operating loss carryforwards for federal and state income tax purposes of $117.3 million and $96.2 million, respectively. The federal net operating loss carryforwards consist of $100.1 million generated before January 1, 2018, which will begin to expire in 2024 and $17.2 million that will carryforward indefinitely but are subject to an 80% limitation for years following December 31, 2020. The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") changed net loss carryforward provisions, allowing a full utilization of NOL carryforwards through December 31, 2020. The state net operating loss carryforwards will begin to expire in 2028. The state net operating loss carryforwards will begin to expire in 2028. As of December 31, 2020, 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, 2020 and December 31, 2019 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. In 2020, the Company experienced unusually high revenue in the quarter ended June 30, 2020 due to sales of the KN95 Masks.

Contractual Obligations

Our contractual cash commitments as of December 31, 2020 were as follows (in thousands):

Contractual Obligations	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Facility leases	$ 438	$ 75	$ —	$ —	$ 513
Equipment leases	16	13	—	—	29
Total	$ 454	$ 88	$ —	$ —	$ 542

Our commitments as of December 31, 2020 consisted primarily of a facility operating lease and an operating lease for two copiers.

The total commitment for the facility lease as of December 31, 2020 was $0.5 million due over the lease term, compared to $0.9 million as of December 31, 2019.

We had an operating lease for 2 copiers as of December 31, 2020. The total commitment for the lease as of December 31, 2020 was $29 thousand due over the lease terms, compared to $45 thousand as of December 31, 2019.

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, 2020 were 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, 2020 and 2019, 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, 2020 and 2019 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Product Revenue Allowances for Rebates and Product Returns

Description of the Matter

As described in Note 2 to the consolidated financial statements, when recognizing revenue from product sales of Avenova to the Company's major distribution partners, the Company makes an estimate of the amount of consideration the Company expects to be entitled to. Upon recognition of these product sales, the Company records estimates for variable consideration consisting of service fees, discounts, rebates, and product returns, resulting in a reduction in product revenue. The variable consideration provisions are recorded within accrued liabilities. Liabilities related to rebate programs involve the use of significant assumptions and judgments in their calculation. These significant assumptions and judgments include historical claims experience, the payer channel mix, claims submission time lags, and inventory levels in the distribution channel. Product return allowances are estimated utilizing existing return policies with customers, historical sales and return rates, and inventory levels in the distribution channel.

Management’s estimated allowance for rebates and product returns requires a high degree of judgment and is subject to change based on various quantitative and qualitative factors. Accordingly, extensive audit effort and a high degree of auditor judgment were needed to evaluate management’s estimates and assumptions used in the determination of rebates and product returns.

How We Addressed the Matter in Our Audit

We obtained an understanding of and evaluated the design of controls relating to the Company’s processes for estimating rebates and product returns.

We evaluated the significant accounting policies relating to rebates and product returns, as well as management’s application of the policies, for appropriateness and reasonableness.

To test management’s estimates of rebates and returns, we obtained management’s calculations for the respective estimates and performed one or more of the following procedures: clerically tested the calculation, agreed relevant inputs to the terms of relevant contracts, assessed subsequent events related to these estimates, evaluated the methodologies and assumptions used and the underlying data used by the Company, evaluated the assumptions used by management against historical trends, evaluated the change in estimated accruals from the prior periods, and assessed the historical accuracy of the Company’s estimates against actual results.

/s/ OUM & CO. LLP
San Francisco, California
March 25, 2021
We have served as the Company's auditor since 2010.

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,952	$ 6,937
Accounts receivable, net of allowance for doubtful accounts ($0 and $51 at December 31, 2020 and December 31, 2019, respectively)	1,106	1,066
Inventory, net of allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments ($236 and $247 at December 31, 2020 and December 31, 2019, respectively)	608	492
Prepaid expenses and other current assets	576	886
Total current assets	14,242	9,381
Operating lease right-of-use assets	436	1,252
Property and equipment, net	84	110
Other assets	476	477
TOTAL ASSETS	$ 15,238	$ 11,220
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$ 302	$ 331
Accrued liabilities	2,115	1,778
Operating lease liabilities	416	930
Note payable, related party	—	1,202
Convertible note	—	1,409
Embedded derivative liability	—	3
Warrant liability	—	34
Total current liabilities	2,833	5,687
Operating lease liabilities-non-current	87	505
Warrant liability	—	4,055
Total liabilities	2,920	10,247
Stockholders' equity:		
Preferred stock: 5,000 shares authorized; none outstanding at December 31, 2020 and December 31, 2019	—	—
Common stock, $0.01 par value; 75,000 and 50,000 shares authorized, 41,782 and 27,938 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	418	279
Additional paid-in capital	147,963	125,718
Accumulated deficit	(136,063)	(125,024)
Total stockholders' equity	12,318	973
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 15,238	$ 11,220

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,		
	2020	2019	2018
Sales:			
Product revenue, net	$ 9,916	$ 6,556	$ 12,474
Other revenue, net	18	43	34
Total sales, net	9,934	6,599	12,508
Cost of goods sold	3,970	1,738	1,503
Gross profit	5,964	4,861	11,005
Research and development	285	184	259
Sales and marketing	6,173	8,767	12,789
General and administrative	5,932	5,310	5,828
Total operating expenses	12,390	14,261	18,876
Operating loss	(6,426)	(9,400)	(7,871)
Non-cash (loss) gain on changes in fair value of warrant liability	(5,216)	749	1,311
Non-cash gain on changes in fair value of embedded derivative liability	3	424	—
Other income (expense), net	605	(1,425)	19
Loss before provision for income taxes	(11,034)	(9,652)	(6,541)
Provision for income taxes	(5)	(6)	(4)
Net loss and comprehensive loss	$ (11,039)	$ (9,658)	$ (6,545)
Less: Preferred deemed dividend	—	800	—
Less: Retained earnings reduction related to warrants down round feature triggered	—	29	—
Net loss attributable to common stockholders	$ (11,039)	$ (10,487)	$ (6,545)
Net loss per share attributable to common stockholders (basic)	$ (0.31)	$ (0.48)	$ (0.39)
Net loss per share attributable to common stockholders (diluted)	$ (0.31)	$ (0.48)	$ (0.46)
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (basic)	35,076	21,641	16,921
Weighted-average shares of common stock outstanding used in computing net loss per share of common stock (diluted)	35,076	21,641	17,058

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
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 related to adoption of ASU 2017-11	—	—	—	—	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 stock options	—	—	—	—	37	—	37
Stock option modification	—	—	—	—	105	—	105
Balance at December 31, 2019	—	$ —	27,938	279	125,718	(125,024)	973
Net loss	—	—	—	—	—	(11,039)	(11,039)
Reclassification of warrant liability to equity related to warrant modification	—	—	—	—	197	—	197
Issuance of common stock, net of offering costs	—	—	5,838	58	5,162	—	5,220
Issuance of common stock in connection with exercise of warrants, net	—	—	7,791	78	16,128	—	16,206
Issuance of RSUs to non-employees for services	—	—	193	2	218	—	220
Issuance of stock for option exercises	—	—	20	1	6	—	7
Vesting of employee restricted stock awards	—	—	2	—	2	—	2
Stock-based compensation expense related to employee and director stock options	—	—	—	—	415	—	415
Stock-based compensation expense related to non-employee stock options	—	—	—	—	64	—	64
Stock option modification	—	—	—	—	53	—	53
Balance at December 31, 2020	—	$ —	41,782	$ 418	$ 147,963	$ (136,063)	$ 12,318

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

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

	Year ended December 31,		
	2020	**2019**	**2018**
Operating activities:			
Net loss	$ (11,039)	$ (9,658)	$ (6,545)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	51	65	266
Gain from early operating lease termination	(54)	—	—
Impairment of property and equipment	—	32	—
Loss on disposal of property and equipment	1	3	1
Impairment of operating lease right-of-use assets	—	125	—
Stock-based compensation expense for options and stock issued to employees and directors	415	334	594
Stock-based compensation expense for options and stock issued to non-employees	64	37	—
Stock option modification expense	53	105	77
Issuance of RSUs to employees	2	10	—
Issuance of RSUs related to employee separation agreement	—	220	—
Issuance of RSUs to non-employees for services	220	20	—
Non-cash loss (gain) on changes in fair value of warrant liability	5,216	(749)	(1,311)
Non-cash gain on changes in fair value of embedded derivative liability	(3)	(424)	—
Interest expense related to amortization of debt issuance and debt discount	141	670	—
Interest expense related to amortization of debt issuance related to related party note payable	2	18	—
Issuance of warrants for services	—	59	—
Changes in operating assets and liabilities:			
Accounts receivable	(317)	2,319	774
Inventory	(116)	(212)	198
Prepaid expenses and other current assets	310	888	(97)
Operating lease right-of-use assets	816	861	—
Other assets	1	9	62
Accounts payable and accrued liabilities	321	(1,841)	482
Operating lease liabilities	(878)	(1,066)	—
Deferred rent	—	—	(69)
Related party note payable	73	204	—
Long-term obligations	—	42	—
Net cash used in operating activities	(4,721)	(7,929)	(5,568)
Investing activities:			
Purchases of property and equipment	(26)	(19)	(44)
Net cash used in investing activities	(26)	(19)	(44)
Financing activities:			
Proceeds from common stock issuances, net	5,220	6,698	5,585
Proceeds from exercise of warrants	7,098	67	—
Proceeds from exercise of options, net	7	189	11
Proceeds from preferred stock issuances, net	—	2,598	—
Proceeds from issuance of related party note payable	—	1,000	—
Proceeds from stock options & RSUs sold to cover taxes	—	4	1
Proceeds from convertible notes, net of discount	—	2,000	—
Payment on the convertible note	(1,563)	(652)	—
Payment on the related party loan	(1,000)	—	—
Debt issuance cost	—	(202)	—
Net cash provided by financing activities	9,762	11,702	5,597
Net increase (decrease) in cash, cash equivalents, and restricted cash	5,015	3,754	(15)
Cash, cash equivalents and restricted cash, beginning of year	7,412	3,658	3,673
Cash, cash equivalents and restricted cash, end of year	$ 12,427	$ 7,412	$ 3,658

	Year ended December 31,		
	2020	2019	2018
Supplemental disclosure of cash flow information:			
Interest paid	$ 49	$ 148	$ —
Income taxes paid	$ 14	$ 14	$ 14

	Year ended December 31,		
	2020	2019	2018
Supplemental disclosure of non-cash information:			
Warrant liability transferred to equity in connection with exercise of warrants	$ 9,108	$ 553	$ —
Warrant liability transferred to equity related to warrant modification	$ 197	$ —	$ —
Non-cash payment of related party loan accrued interest by offsetting related party accounts receivables - see Note 9	$ 277	$ —	$ —
Cumulative effect of adoption of ASC 606	$ —	$ —	$ 2,638
Cumulative effect of adoption of ASU 2017-11	$ —	$ 56	$ —
Addition of operating lease, right-of-use asset	$ —	$ 2,473	$ —
Fixed asset purchases, included in accounts payable and accrued liabilities	$ —	$ 10	$ (49)
Fair value of warrants issued in connection with financings	$ —	$ 5,269	$ —
Conversion of preferred stock to common stock	$ —	$ 584	$ —
Reclass of EmeryStation lease security deposit from long term to short term	$ —	$ 65	$ —
Reclass of EmeryStation sublease security deposit from long term to short term	$ —	$ 198	$ —

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

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. (the "Company") is a medical device company predominantly focused on eye care. Our main product is Avenova®, an FDA cleared product sold in the United States that has proven in laboratory testing to have broad antimicrobial properties as it removes 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 and is available direct to consumers through on-line distribution channels and is also often prescribed and dispensed by eyecare professionals for blepharitis and dry-eye disease. During the second quarter of 2020, our primary source of revenue was from third-party manufactured disposable KN95 facial coverings ("KN95 Masks") which we offered in response to the consumer demand created by the COVID-19 pandemic. Sales of our KN95 Masks continued in the second half of 2020 but were not our primary source of revenue and declined substantially over time. We do not anticipate that KN95 Masks will provide a significant future source of revenue.

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. The Company is managed as a single segment focused on commercializing Avenova in the United States.

Liquidity

Based primarily on the funds available at December 31, 2020, management believes that the Company's existing cash and cash equivalents and cash flows generated from product sales will be sufficient to enable the Company to meet its planned operating expenses at least through March 25, 2022. However, changing circumstances may cause the Company to expend cash significantly faster than currently anticipated, and the Company may need to spend more cash than currently expected because of circumstances beyond its control. Additionally, our future results, cash expenditures and ability to obtain additional external financing could be adversely affected by the COVID-19 pandemic and general adverse economic conditions.

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 contract liabilities related to product sales, useful lives for property and equipment and related depreciation calculations, assumptions for valuing options and warrants, income taxes and other contingencies. Actual results could differ from those estimates.

Cash, Cash Equivalents, and Restricted Cash

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, 2020 and 2019, the Company's cash and cash equivalents were held in a highly-rated, major financial institution 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 (in thousands):

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 11,952	$ 6,937
Restricted cash included in other assets	475	475
Total cash, cash equivalents, and restricted cash in the consolidated statements of cash flows	$ 12,427	$ 7,412

The restricted cash amount included in other assets on the consolidated balance sheets represents 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 and Major Partners

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. The Company maintains deposits of cash, cash equivalents and restricted cash 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, 2020, revenues were derived primarily from sales of Avenova. Avenova is sold directly to consumers through Amazon.com, Avenova.com and Walmart.com. Avenova is also sold with a prescription through local pharmacies via three major distribution partners, at eye care specialist offices and through a limited number of partner pharmacies. The Company also generated revenue from the sale of KN95 Masks through the Company's webstore and offline bulk orders, primarily during the second quarter of 2020. The Company does not expect KN95 Masks to provide a significant future source of revenue.

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 year ended December 31, 2018, revenues were derived primarily from sales of Avenova directly to three major distribution partners and to doctors through the Company's internal sales team.

During the years ended December 31, 2020, 2019 and 2018, revenues from each product were as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Avenova	$ 5,974	$ 6,347	$ 12,305
KN95 Masks	3,124	—	—
NeutroPhase	524	209	169
Other products	294	—	—
Total product revenue, net	9,916	6,556	12,474
Other revenue, net	18	43	34
Total sales, net	$ 9,934	$ 6,599	$ 12,508

During the years ended December 31, 2020, 2019 and 2018, Avenova revenues from our major distribution partners greater than 10% were as follows:

Major distribution partner	2020	2019	2018
Over-the-counter Avenova via Amazon	50%	15%	—%
Prescription Avenova distributor A	*%	16%	23%
Prescription Avenova distributor B	*%	15%	25%
Prescription Avenova distributor C	*%	17%	26%

***Not greater than 10%**

As of December 31, 2020 and 2019, accounts receivable from our major distribution partners greater than 10% were as follows:

	Year Ended December 31,	
Major distribution partner	**2020**	**2019**
Distributor A	18%	28%
Chongqing Pioneer Pharma Holdings Limited	16%	—%
Distributor B	14%	19%
Distributor C	14%	13%
Amazon	11%	20%

The Company relies on two contract manufacturers to produce its products. The Company does not own any manufacturing facilities and intends to continue to rely on third parties for the supply of finished goods. Contract manufacturers may or may not be able to meet the Company's needs with respect to timing, quantity or quality. In particular, it is possible that we may suffer from unexpected supply chain delays in light of the worldwide COVID-19 pandemic.

Fair Value of Financial Assets and Liabilities

The Company's financial instruments include cash and cash equivalents, restricted cash, accounts receivable, accounts payable, and accrued liabilities. The Company's cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments.

The Company follows Accounting Standards Codification ("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 to be unlikely that specific invoices will be collected. Management identifies amounts due that are in dispute and it believes are unlikely to be collected. Management recorded a nominal reserve for accounts receivable at December 31, 2020. At December 31, 2019, management reserved $51 thousand based on specific amounts that were in dispute or were over 120 days past due as of that date.

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 filled but unlabeled bottles; and (3) finished goods. We utilize contract manufacturers to produce our products and the price paid to these manufacturers is included in inventory. Inventory is stated at the lower of cost or estimated net realizable value determined by the first-in, first-out method. At December 31, 2020 and 2019, management had recorded an allowance for excess and obsolete inventory and lower of cost or estimated net realizable value adjustments of $236 thousand and $247 thousand, respectively.

Property and Equipment

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

The costs of normal maintenance, repairs, and minor replacements are expensed as 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. The Company reviews long-lived assets and right-of-use assets for impairment at least annually or whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. 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. During the third quarter of 2019, the Company recorded an impairment charge of $32 thousand related to previously capitalized software. There were no such impairment charges during the year ended December 31, 2020.

Leases

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 consolidated balance sheets.

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.

Revenue Recognition

Revenue generated through the Company’s webstore for Avenova and KN95 Masks is recognized upon receipt by the customer through multiple third-party carriers. Shipping and handling costs are expensed as fulfillment costs are incurred and included in cost of goods sold in the consolidated statements of operations and comprehensive loss. We present revenue net of sales taxes and refunds.

Revenue generated through Amazon.com and Walmart.com for Avenova and other products is recognized upon fulfillment, which generally occurs upon delivery of the related products to a third-party carrier or, in the case of an Amazon/Walmart delivery, to the customer. We present revenue net of commissions and any related fulfillment and shipping fees charged by these partners. Fees paid to partners for promoting our product are expensed as incurred and are included in sales and marketing expenses within the operating expenses in the consolidated statements of operations and comprehensive loss.

The Company also generates Avenova product revenue through product sales to its major distribution partners. Product supply of Avenova 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. Upon recognition of product sales, 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, and product returns. Because the Company did 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 was based on an average of peer and competitor company historical return rates through the end of the third quarter of 2020. The Company updated the return rate assumption quarterly. Beginning in the fourth quarter of 2020, the Company determined that it had adequate historical data to estimate future returns based on its own experience. The Company increased its return rate assumption based on historical data and recorded a $0.4 million increase in its accrual for future returns. The Company will continue to monitor and update its return rate assumption quarterly. Payment for product supply is typically due 30 days after control transfers to the distributor.

Revenue generated through the Company's partner pharmacies is recognized when control of the product transfers to the end customer.

Bulk orders of KN95 Masks were shipped directly to the customer from a manufacturer in China. Revenue was recognized when control of the product passed to the customer, which was upon delivery of the KN95 Masks to the customer.

Cost of Goods Sold

Cost of goods sold includes third-party manufacturing costs, shipping and handling costs, and other costs associated with products 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 all costs associated with research, development and regulatory activities, including submissions to the Food and Drug Administration ("FDA").

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.

Advertising Costs

Advertising costs are expensed in the period in which the costs are incurred. Advertising expenses were $1.7 million, $0.5 million, and $0, respectively, for the years ended December 31, 2020, 2019, and 2018.

Stock-Based Compensation

The Company's stock-based compensation includes grants of stock options and restricted stock units ("RSUs") to employees, consultants and non-employee directors. The expense associated with these grants 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. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes 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 RSUs 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 common stock purchase warrants issued in connection with its equity offerings in accordance with the provisions of ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*.

The Company accounts for common stock purchase warrants issued in connection with share-based compensation arrangements in accordance with the provisions of ASC 718, *Stock Compensation,* which encompasses the provisions of ASC 480, *Distinguishing Liabilities from Equity*.

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). Additionally, for common stock purchase warrants accounted for in accordance with ASC 718, *Stock Compensation,* the Company classifies as liabilities any contracts where it believes the warrants are deemed to be probable of issuance.

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 are determined using the Black-Scholes option pricing model, the Binomial Lattice ("Lattice") valuation model, or the Monte Carlo simulation model where deemed appropriate. These values are subject to a significant degree of management's judgment.

On January 1, 2019, the Company adopted Accounting Standards Update ("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* ("ASU 2017-11") on a modified retrospective basis. 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.

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.

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

	Year Ended December 31,		
Numerator	**2020**	**2019**	**2018**
Net loss	$ (11,039)	$ (9,658)	$ (6,545)
Less: Preferred deemed dividend	—	800	—
Less: Retained earnings reduction related to warrants down round feature triggered	—	29	—
Net loss attributable to common stockholders, basic	(11,039)	(10,487)	(6,545)
Less: Gain on changes in fair value of warrant liability	—	—	1,311
Net loss attributable to common stockholders, diluted	$ (11,039)	$ (10,487)	$ (7,856)
Denominator			
Weighted average shares outstanding, basic	35,076	21,641	16,921
Net loss per share, basic	$ (0.31)	$ (0.48)	$ (0.39)
Weighted average shares outstanding, basic	35,076	21,641	16,921
Effect of dilutive warrants	—	—	137
Weighted average shares outstanding, diluted	35,076	21,641	17,058
Net loss per share, diluted	$ (0.31)	$ (0.48)	$ (0.46)

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

	Year Ended December 31,		
	2020	**2019**	**2018**
Stock options	3,165	2,183	3,374
Stock warrants	7,067	8,588	—
	10,232	10,771	3,374

Recent Accounting Pronouncements

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"). 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 adopted the new standard effective January 1, 2020, and the adoption of this guidance did not 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* ("ASU 2016-13"). 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, 2023. 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*, which simplifies the accounting for income taxes. The Company adopted the new standard effective January 1, 2021, and the adoption of this guidance did not have a material impact on our consolidated financial statements.

In August 2020, FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for convertible instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature. As a result, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost. ASU 2020-06 also requires the application of the if-converted method for calculating diluted earnings per share and the treasury stock method will be no longer available. The new guidance is effective for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. ASU 2020-06 is effective for the Company in our first quarter of fiscal 2023. We are currently evaluating the impact of ASU 2020-06 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 are classified within Level 1 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.

As of December 31, 2020, there were no warrants outstanding that were classified as liabilities. The Company's outstanding warrants consist of the 2019 Domestic Warrants, 2019 Foreign Warrants and the 2019 Ladenburg Warrants, all of which were classified as equity as of December 31, 2020. The 2019 Domestic Warrants and the 2019 Foreign Warrants were amended and exercised in July 2020 (see Note 12, "Stockholders' Equity"), resulting in a decrease of $9.1 million in warrant liability. The 2019 Ladenburg Warrants were also amended in July 2020 (see Note 12, "Stockholders' Equity"), resulting in a decrease of $0.2 million in warrant liability.

The embedded derivative liability related to the Convertible Note (as defined below) was fully settled in September 2020. See Note 10, "Convertible Note" for further discussion of the settlement of the Convertible Note and embedded derivative liability during the third quarter of 2020.

The following table presents the Company's assets measured at fair value on a recurring basis as of December 31, 2020 (in thousands):

		Fair Value Measurements Using		
	Balance at December 31, 2020	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	$ —	$ —

There were no liabilities measured at fair value on a recurring basis as of December 31, 2020.

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

		Fair Value Measurements Using		
	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 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, 2020 (in thousands):

	2020
Fair value of warrant liability and embedded derivative liability at December 31, 2019	$ 4,092
Increase in fair value of warrant liability	5,238
Decrease in fair value of embedded derivative liability	(2)
Decrease in fair value related to warrants expired	(22)
Fair value of warrant liability transferred to equity upon exercise	(9,108)
Fair value of 2019 Ladenburg Warrant liability transferred to equity upon warrant modification	(197)
Elimination of embedded derivative liability upon settlement of convertible note	(1)
Fair value of warrant liability and embedded derivative liability at December 31, 2020	$ —

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 2019 Domestic, Foreign and Ladenburg Warrants	5,269
Decrease in fair value of 2019 Domestic, Foreign and Ladenburg Warrant liability	(1,214)
Increase in fair value of July 2011 and October 2015 Warrant liability	465
Derivative liability embedded in convertible note issued in March 2019	427
Decrease in fair value of embedded derivative liability	(424)
Fair value of warrant liability and embedded derivative liability at December 31, 2019	$ 4,092

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Prepaid insurance	$ 165	$ 94
Prepaid sales rebates	144	401
Prepaid security deposit for lease	65	65
Prepaid dues and subscription	53	82
Prepaid patents	47	85
Other	102	159
Total prepaid expenses and other current assets	$ 576	$ 886

NOTE 5. INVENTORY

Inventory consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Raw materials and supplies	$ 159	$ 185
Finished goods	685	554
Less: Reserve for excess and obsolete inventory	(236)	(247)
Total inventory, net	$ 608	$ 492

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Office and laboratory equipment	$ 20	$ 20
Furniture and fixtures	157	157
Computer equipment and software	365	349
Production equipment	65	65
Leasehold improvements	79	79
Total property and equipment, at cost	686	670
Less: accumulated depreciation and amortization	(602)	(560)
Total property and equipment, net	$ 84	$ 110

Depreciation and amortization expense was $51 thousand, $65 thousand, and $266 thousand for the years ended December 31, 2020, 2019 and 2018, respectively.

During the year ended December 31, 2020, the Company disposed of damaged, unusable and fully depreciated property and equipment with cost of approximately $10 thousand. As a result, the Company recognized an immaterial loss on the disposal of these assets in the consolidated statements of operation and comprehensive loss for the year ended December 31, 2020.

During the year ended December 31, 2019, the Company discontinued development of a software package for internal use. This resulted in a $32 thousand impairment charge recorded to general and administrative expense in the consolidated statements of operation and comprehensive loss for the year ended December 31, 2019.

During the year 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 statements 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, 2020	December 31, 2019
Avenova contract liabilities	$ 730	$ 822
Employee payroll and benefits	632	463
Sublease security deposit	198	198
Inventory purchases	181	—
Consulting service	98	109
Related party consulting service	—	33
Other	276	153
Total accrued liabilities	$ 2,115	$ 1,778

NOTE 8. COMMITMENTS AND CONTINGENCIES

Indemnification Agreements

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, 2020.

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, 2020.

Legal Matters

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 in connection with his separation from service with the Company. The arbitration was settled in December 2020. Mr. McGovern released the Company from all outstanding obligations upon settlement.

As of December 31, 2020, there were 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 had a lease commitment for laboratory facilities and office space at EmeryStation North in Emeryville, California ("EmeryStation") under an operating lease. In July 2016, the Company subleased the EmeryStation space (the "Sublease Agreement"). The Sublease Agreement commenced September 8, 2016. The EmeryStation lease and Sublease Agreement were terminated as of August 31, 2020 pursuant to a sublease termination agreement executed on July 31, 2020. In conjunction with the termination, the Company recognized a gain of $54 thousand which is recorded within the operating expenses in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2020.

In addition to the facility leases, the Company previously leased 54 vehicles under a master fleet lease agreement. Each lease was for a period of 36 months, which commenced upon the delivery of the vehicles 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 sales and marketing expenses 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 terminated the lease agreement related to the idled vehicles early and had 15 leased vehicles as of December 31, 2019. The lease agreement expired in the first quarter of 2020.

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 (e.g. common area maintenance) 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 net lease costs for the years ended December 31, 2020 and 2019 are as follows (in thousands):

Lease Costs	**Year Ended December 31,**	
	2020	**2019**
Operating lease cost	$ 826	$ 1,130
Sublease income	(421)	(632)
Net lease cost	$ 405	$ 498
Other information		
Operational cash flow used for operating leases	$ 927	$ 1,285

The Company has measured its operating lease liabilities at its incremental borrowing rate over the remaining term for each operating lease. The weighted average remaining lease term and the weighted average discount rate are summarized as follows:

	December 31,	
	2020	**2019**
Weighted-average remaining lease term (in years)	1.2	1.7
Weighted-average discount rate	12%	12%

Operating lease expense was $0.5 million for the year ended December 31, 2018, under Topic 840.

Future lease payments under non-cancelable leases as of December 31, 2020 were as follows (in thousands):

2021	$ 454
2022	88
Thereafter	—
Total future minimum lease payments	542
Less imputed interest	(39)
Total	$ 503
Reported as:	
Operating lease liability	$ 416
Operating lease liability- non-current	87
Total	$ 503

Contracts

On May 13, 2020, the Company entered into an agreement with TLF Bio Innovation Lab LLC ("TLF Bio Innovation") to manage the relaunch of the Company's CelleRx product (the "TLF Agreement") which was further amended on September 4, 2020 and subsequently terminated on February 4, 2021. Under the agreement, the Company paid TLF Bio Innovation a monthly cash fee. Additionally, upon the successful completion of certain milestones, TLF Bio Innovation was eligible to receive warrants exercisable for up to 2 million shares of the Company's common stock with an exercise price equal to the average closing price of the Company's common stock for the last calendar month immediately prior to the date on which an individual milestone was achieved. No warrants were issued to TLF Bio Innovation under the agreement in 2020.

On April 16, 2020, the Company entered into an international distribution agreement with Shenzhen Microprofit Biotech Co., LTD ("Microprofit") (the "Microprofit Agreement"). In accordance with the Microprofit Agreement, the Company is assisting Microprofit to apply for approval of Microprofit's SARS-CoV-2 IgG and IgM Antibody Combined Test Kit ("Test Kits") by the FDA. Under the terms of the Microprofit Agreement, if such approvals are granted, the Company will issue warrants to certain Microprofit officers exercisable for an aggregate number of shares of the Company's common stock equivalent to 12% of the Company's outstanding common stock on the date of approval. If FDA approval is received, the Microprofit Agreement grants the Company exclusive rights to distribute the Test Kits in the United States through December 31, 2021. As of December 31, 2020, the Company has determined that the issuance of warrants under this agreement is not probable.

In connection with the Microprofit Agreement, on April 16, 2020, the Company entered into an intermediary distribution agreement with Chongqing Pioneer Pharma Holdings Limited ("Chongqing Pioneer"), a related party, which was subsequently amended on June 29, 2020. The amended agreement provides that the Company will purchase all Test Kits from Chongqing Pioneer as an intermediary.

NOTE 9. RELATED PARTY NOTE PAYABLE

On February 27, 2019, the Company issued a $1.0 million promissory note payable to Pioneer Pharma (Hong Kong) Company Ltd. ("Pioneer Pharma"), which was amended on June 25, 2019 and May 14, 2020 (the "Promissory Note"). The Promissory Note provided for an interest payment of $0.2 million which was initially amended to a payment of $0.3 million and subsequently amended to the delivery of 65,178 units of NeutroPhase (40ml) to Pioneer Pharma. The second amendment to the Promissory Note also provided the Company with the right to repay the note at any time. On May 14, 2020, the Company repaid the $1.0 million principal balance of the Promissory Note using proceeds raised through the at-the-market offering and equity program ("ATM Program") (see Note 12, "Stockholders' Equity"). The Company settled the accrued interest through two separate shipments of NeutroPhase in 2020. Upon full repayment of principal and interest during the year ended December 31, 2020, the Company was released from the Promissory Note with Pioneer Pharma.

In connection with the Promissory Note, the Company paid China Kington a 2% fee for brokering the transaction and entered into a consulting agreement with China Kington for a term of one year, which expired on March 1, 2020. Bob Wu, acting in a dual role as a member of the Company's Board of Directors and as principal of China Kington, was paid $0.1 million pursuant to such consulting agreement. Upon the expiration of the original consulting agreement, the parties entered into a new consulting agreement, in which no cash compensation will be paid. Debt issuance costs associated with the issuance of the Promissory Note of $20 thousand was recognized and recorded as an offset to the related party note payable in the consolidated balance sheets.

The interest expense recognized, including amortization of the issuance costs, was $75 thousand and $0.2 million during the years ended December 31, 2020 and 2019, respectively.

NOTE 10. CONVERTIBLE NOTE

On March 26, 2019, 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 March 26, 2019. The Convertible Note had an original principal amount of $2.2 million, beared interest at a rate of 10% per annum and matured 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 $0.2 million and debt issuance cost of Lender's transaction fees of $15 thousand. The Company recognized an additional $0.2 million of debt issuance costs associated with the issuance of the Convertible Note. The Convertible Note was repaid in full during the third quarter of 2020. Upon full repayment, the Company was released from the Iliad Securities Purchase Agreement with Lender.

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:

Assumptions	As of March 26, 2019
Stock price (latest bid price)	$ 1.28
Equity volatility	94%
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:

Assumptions	As of December 31, 2019
Stock price	$ 0.65
Equity volatility	193%
Risk-free interest rate	1.60%
Remaining term	0.74

During the years ended December 31, 2020 and 2019, the Company recorded a gain of $3 thousand and $0.4 million, respectively, in the consolidated statements of operations and comprehensive loss.

The aggregate $0.6 million discount, including the original issue discount, and the aggregate $0.2 million 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 discount and debt issuance costs were amortized to interest expense using the effective interest rate method over the term of the Convertible Note, assuming that the Convertible Note would be redeemed at the maximum $0.2 million per month beginning in September 2019. During the years ended December 31, 2020 and 2019, the effective interest rate on the Convertible Note was 20% and 53%, respectively. Interest expense recognized, including amortization of the issuance costs and debt discount, was $0.2 million and $0.8 million, respectively, during the years ended December 31, 2020 and 2019.

NOTE 11. WARRANT LIABILITY

July 2011 Warrants

As further described in Note 12, "Stockholders' Equity", the Company issued the July 2011 Warrants in the third quarter of 2011. The terms of the July 2011 Warrants required registered shares to be delivered upon warrant exercise and potential cash-settlement in the event of a specified fundamental transaction. Under ASC 480, *Distinguishing Liabilities from Equity*, the warrants were classified as liabilities because the Company's potential obligation to deliver registered shares and cash-settle the warrants were deemed to be beyond the Company's control. The fair value of outstanding July 2011 Warrants was determined at each reporting date using a Lattice model with changes in fair value recorded in the consolidated statements of operations and comprehensive loss.

During the second quarter of 2019, a total of 14,400 July 2011 Warrants were exercised, resulting in gross proceeds of $3 thousand. The liability associated with these warrants was adjusted to fair value of $27 thousand as of the date of exercise with the change in fair value recorded in the consolidated statements of operations and comprehensive loss. The fair value was then transferred to equity.

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

Expected price volatility	115%
Expected term (in years)	0.18
Risk-free interest rate	1.52%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.44

On March 6, 2020, 35,107 July 2011 Warrants expired unexercised. There were no July 2011 Warrants outstanding as of December 31, 2020.

October 2015 Warrants

As further described in Note 12, "Stockholders' Equity", the Company issued the October 2015 Warrants in the third quarter of 2015. The terms of the October 2015 Warrants required potential cash-settlement in the event of a specified fundamental transaction. Under ASC 480, *Distinguishing Liabilities from Equity*, the warrants were classified as liabilities because the Company's potential obligation to cash-settle the warrants was deemed to be beyond the Company's control. The fair value of outstanding October 2015 Warrants was determined at each reporting date using a Lattice model with changes in fair value recorded in the consolidated statements of operations and comprehensive loss.

During the second quarter of 2019, a total of 144,000 October 2015 Warrants were exercised, resulting in gross proceeds of $30 thousand. The liability associated with these warrants was adjusted to fair value of $0.4 million as of the date of exercise, with the change in fair value recorded in the consolidated statements of operations and comprehensive loss. The fair value was then transferred to equity.

During the third quarter of 2019, a total of 102,602 October 2015 Warrants were exercised, resulting in gross proceeds of $21 thousand. The liability associated with these warrants was adjusted to fair value of $0.2 million as of the date of exercise, with the change in fair value recorded in the consolidated statements of operations and comprehensive loss. The fair value was then transferred to equity.

The key assumptions used to value outstanding October 2015 Warrants as of December 31, 2019 were as follows:

Expected price volatility	184%
Expected term (in years)	0.83
Risk-free interest rate	1.59%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 0.49

During the fourth quarter of 2020, a total of 22,680 October 2015 Warrants were exercised, resulting in gross proceeds of $5 thousand. The liability associated with these warrants was adjusted to fair value of $12 thousand as of the date of exercise, with the change in fair value recorded in the consolidated statements of operations and comprehensive loss. The fair value was then transferred to equity.

On October 27, 2020, 15,320 October 2015 expired unexercised. There were no October 2015 Warrants outstanding as of December 31, 2020.

2019 Domestic, Foreign & Ladenburg Warrants

As further described in Note 12, “Stockholders’ Equity”, the Company issued the 2019 Domestic Warrants, the 2019 Foreign Warrants and the 2019 Ladenburg Warrants in the third quarter of 2019. The terms of the 2019 Domestic Warrants, 2019 Foreign Warrants and 2019 Ladenburg Warrants all required potential cash-settlement in the event of a specified fundamental transaction. Under ASC 480, *Distinguishing Liabilities from Equity*, the warrants were classified as liabilities because the Company’s potential obligation to cash-settle the warrants was deemed to be beyond the Company’s control. The fair value of outstanding warrants was determined at each reporting date using a Black-Scholes option pricing model with the changes in fair value recorded in the consolidated statements of operations and comprehensive loss.

Upon issuance, the fair value of the 2019 Domestic Warrants, 2019 Foreign Warrants and 2019 Ladenburg Warrants was determined to be $3.1 million, $2.0 million and $0.1 million, respectively, in accordance with the following key assumptions as of August 13, 2019:

Assumptions	2019 Domestic Warrants	2019 Foreign Warrants	2019 Ladenburg Warrants
Expected price volatility	149%	149%	155%
Expected term (in years)	5.50	5.50	5.00
Risk-free interest rate	1.58%	1.58%	1.57%
Dividend yield	0.00%	0.00%	0.00%
Weighted-average fair value of warrant	$ 0.75	$ 0.75	$ 0.74

As of December 31, 2019, the fair value of the 2019 Domestic Warrants, 2019 Foreign Warrants and 2019 Ladenburg Warrants was determined to be $2.4 million, $1.6 million and $95 thousand, respectively, in accordance with the following key assumptions:

Assumptions	2019 Domestic Warrants	2019 Foreign Warrants	2019 Ladenburg Warrants
Expected price volatility	154%	154%	160%
Expected term (in years)	5.13	5.13	4.61
Risk-free interest rate	1.70%	1.70%	1.69%
Dividend yield	0.00%	0.00%	0.00%
Weighted-average fair value of warrant	$ 0.57	$ 0.57	$ 0.57

In the third quarter of 2020, as further described in Note 12, “Stockholders’ Equity”, the 2019 Domestic Warrants and 2019 Foreign Warrants were exercised at reduced exercise prices. The warrant liabilities associated with these warrants was adjusted to their fair values as of the date of exercise, with the change in fair values recorded in the consolidated statements of operations and comprehensive loss. The fair values were then transferred to equity. As of the date of exercise, the fair value of the 2019 Domestic Warrants and 2019 Foreign Warrants was determined to be $4.9 million and $4.2 million, respectively, in accordance with the following key assumptions:

Assumptions	2019 Domestic Warrants	2019 Foreign Warrants
Expected price volatility	178%	178%
Expected term (in years)	4.57	4.57
Risk-free interest rate	0.25%	0.27%
Dividend yield	0.00%	0.00%
Weighted-average fair value of warrant	$ 1.18	$ 1.54

There were no 2019 Domestic Warrants or 2019 Foreign Warrants outstanding as of December 31, 2020.

In the third quarter of 2020, as further described in Note 12, “Stockholders’ Equity”, the Company amended the 2019 Ladenburg Warrants. The Company’s potential obligation to cash-settle the warrants if a specified fundamental transaction occurred was amended to apply only in situations within the Company’s control. Pursuant to this change, the 2019 Ladenburg Warrants were no longer classified as liabilities. The warrant liability associated with these warrants was adjusted to fair value as of the date of the amendment, with the change in fair value recorded in the consolidated statements of operations and comprehensive loss. The fair value was then transferred to equity. The fair value of the 2019 Ladenburg Warrants was determined to be $0.2 million on the date of amendment in accordance with the following key assumptions:

Expected price volatility	186%
Expected term (in years)	4.05
Risk-free interest rate	0.22%
Dividend yield	0.00%
Weighted-average fair value of warrants	$ 1.17

The 2019 Ladenburg Warrants will no longer be adjusted to fair value in reporting periods after the amendment. All 2019 Ladenburg Warrants remained outstanding as of December 31, 2020.

NOTE 12. STOCKHOLDERS' EQUITY

Preferred Stock

The Company is authorized to issue up to 5,000,000 shares of preferred stock with rights and preferences as may be approved by its Board of Directors under its Amended and Restated Certificate of Incorporation.

In the third quarter of 2019, the Company entered into a securities purchase agreement for the sale of (i) 2,700,000 shares of Series A Preferred Stock and (ii) 2,700,000 common stock purchase warrants exercisable for 2,700,000 shares of common stock (the “2019 Foreign Warrants) for gross proceeds of $2.7 million. The 2019 Foreign Warrants were issued with an exercise price of $1.15 and an expiration date of February 13, 2025. See section entitled “August 2019 Common Stock Purchase Agreement, 2019 Domestic Warrants, 2019 Ladenburg Warrants and 2019 Foreign Warrants” below for additional information about the 2019 Foreign Warrants and their subsequent renegotiation and exercise in the third quarter of 2020.

The Company allocated the proceeds between the Series A Preferred Stock and 2019 Foreign Warrants by applying the fair value allocation methodology. The Company first allocated $2.0 million to the 2019 Foreign Warrants, with the residual amount allocated to the Series A Preferred Stock. See Note 11, “Warrant Liability” for further discussion of the key assumptions used to value the 2019 Foreign Warrants.

The Company incurred total issuance costs of $0.2 million in conjunction with the securities purchase agreement. China Kington served as placement agent in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $0.2 million, which is included in the issuance costs. The Company allocated $93 thousand of the issuance costs to the warrant liability which was expensed in the Company’s consolidated statements of operations and comprehensive loss during the period. The remaining $0.1 million was recorded as a reduction of Series A Preferred Stock in the Company’s consolidated balance sheets.

In October 2019, the Company’s stockholders approved the conversion of all 2,700,000 outstanding shares of Series A Preferred Stock into 2,700,000 shares of the Company’s common stock. In connection with the conversion, the Company recorded a beneficial conversion feature of $0.8 million as a discount to Series A Preferred Stock and an increase to additional paid in capital. Because the Series A Preferred Stock was perpetual, the Company fully amortized the discount related to the beneficial conversion feature on the deemed dividend in the consolidated statements of operations and comprehensive loss in the fourth quarter of 2019.

There were no shares of preferred stock outstanding as of December 31, 2020 and 2019.

Common Stock

In the second quarter of 2020, the Company filed an amendment to its Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 50,000,000 to 75,000,000 upon approval by the Company's stockholders.

July 2011 Warrants

In the third quarter of 2011, the Company issued 139,520 common stock purchase warrants exercisable for 139,520 shares of common stock in connection with a registered direct financing (the "July 2011 Warrants"). The July 2011 Warrants were issued with an exercise price of $33.25 and an expiration date of July 5, 2016. In October 2015, in connection with a separate financing event, the exercise price of outstanding July 2011 Warrants was reduced to $5.00 per share and the expiration date extended to March 6, 2020. In February 2016 and May 2019, the exercise price of outstanding July 2011 Warrants was reduced to $1.81 and $0.2061 per share, respectively, pursuant to price protection provisions of the warrants.

In March 2020, a total of 35,107 July 2011 Warrants expired unexercised. As of December 31, 2020, there were no July 2011 Warrants outstanding.

March 2015 Warrants

In the first quarter of 2015, the Company issued 649,133 common stock purchase warrants exercisable for 649,133 shares of common stock in connection with private placement offering (the "March 2015 Warrants"). The exercise price of individual March 2015 Warrants varied between $15.00 and $16.25 per share at the time of issuance. The Company issued 278,200 of the March 2015 Warrants with an expiration date of March 6, 2020 and the remaining 370,933 March 2015 Warrants with an expiration date of June 6, 2015. In October 2015, in connection with a separate financing event, the exercise price of all outstanding March 2015 Warrants was reduced to $5.00 per share and the expiration date of all outstanding warrants expiring on June 6, 2015 was extended to March 6, 2020. In February 2016 and May 2019, the exercise price of all outstanding July 2011 Warrants was reduced to $1.81 and $0.2061 per share, respectively, pursuant to price protection provisions of the warrants.

On January 1, 2019, the Company adopted ASU 2017-11 on a modified retrospective basis and changed its method of accounting for the March 2015 Warrants which were initially recorded as liabilities due to their price protection provisions (down round features). After implementation, the Company only recognized the value of down round features on the March 2015 Warrants when triggered. In accordance with ASC 820, the Company calculated the value of the down round feature triggered in May 2019 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. The Company recorded the resulting $29 thousand value as a dividend, which reduced income available to common shareholders in the basic EPS calculation.

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

During the first quarter of 2020, a total of 70,000 March 2015 Warrants were exercised, resulting in gross proceeds of $14 thousand.

In the first quarter of 2020, all remaining 7,419 March 2015 Warrants expired unexercised. As of December 31, 2020, there were no March 2015 Warrants outstanding.

October 2015 Warrants

In the fourth quarter of 2015, the Company issued 442,802 common stock purchase warrants exercisable for 442,802 shares of common stock in connection with a public offering (the "October 2015 Warrants"). The warrants were issued with an exercise price of $5.00 and an expiration date of October 27, 2020. In February 2016 and May 2019, the exercise price of outstanding October 2015 Warrants was reduced to $1.81 and $0.2061 per share, respectively, pursuant to price protection provisions of the warrants.

During the second quarter of 2019, a total of 158,400 October 2015 Warrants were exercised, resulting in gross proceeds of $33 thousand.

During the third quarter of 2019, a total of 102,602 October 2015 Warrants were exercised, resulting in gross proceeds of $21 thousand.

During the fourth quarter of 2020, a total of 22,680 October 2015 Warrants were exercised, resulting in gross proceeds of $5 thousand.

During the fourth quarter of 2020, all remaining 15,320 October 2015 Warrants expired unexercised. As of December 31, 2020, there were no October 2015 Warrants outstanding.

February 2018 Common Stock Purchase Agreement

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 for gross proceeds of $6.0 million. China Kington served as the placement agent for the purchase in exchange for a commission equal to six percent (6%) of the gross proceeds, totaling $0.4 million. The Company also paid other issuance costs of $34 thousand.

March 2019 Common Stock Purchase Agreement

During the first quarter of 2019, the Company entered into a common stock purchase agreement for the sale of up to 3 million shares of common stock to Triton Funds LP ("Triton"). During the second quarter of 2019, the Company sold 1,747,312 shares of common stock to Triton for gross proceeds of $0.4 million under the agreement. In connection with the transaction, the Company issued 150,000 shares of common stock to Triton Funds LLC, an affiliate of Triton. The Company incurred and paid other offering costs of $0.1 million in connection with the sale. During the third quarter of 2019, the Company received an additional $0.3 million in connection with the agreement and recorded the amount in additional paid-in capital from issuance of common stock as no additional shares were issued for the payment. The agreement with Triton expired on December 31, 2019 with the remaining registered but unsold shares deregistered in the first quarter of 2020.

June 2019 Private Placement and June 2019 Warrants

During the second quarter of 2019, the Company entered into a private placement agreement to sell 1,371,427 shares of common stock and 1,371,427 common stock purchase warrants exercisable for 1,371,427 shares of common stock (the "June 2019 Warrants") for an aggregate subscription price of $2.4 million. Three accredited investors, Messrs. Xiao Rui Liu, Hai Dong Pang and Ping Huang, subscribed to the private placement 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 $0.1 million. The Company also paid other offering costs of $27 thousand.

The June 2019 Warrants were issued with an exercise price of $0.87 and an expiration date of June 17, 2020. The June 2019 Warrants were callable by the Company if the closing price of the Company's common stock, as reported on the NYSE American, was $1.00 or greater.

During the first quarter of 2020, a total of 228,571 June 2019 Warrants were exercised, resulting in gross proceeds of $199 thousand. The Company paid China Kington a fee of $12 thousand, or six percent (6%) of the gross proceeds, for brokering the exercise transaction.

During the second quarter of 2020, a total of 571,428 June 2019 Warrants were exercised, resulting in gross proceeds of $497 thousand. The Company paid China Kington a fee of $29 thousand, or six percent (6%) of the gross proceeds, for brokering the exercise transaction.

In the second quarter of 2020, all remaining 571,428 June 2019 Warrants expired unexercised. As of December 31, 2020, there were no June 2019 Warrants outstanding.

August 2019 Common Stock Purchase Agreement, 2019 Domestic Warrants, 2019 Ladenburg Warrants and 2019 Foreign Warrants

In the third quarter of 2019, the Company entered into a purchase agreement for the sale of (i) 4,198,566 shares of common stock and (ii) 4,198,566 common stock purchase warrants exercisable for 4,198,566 shares of common stock (the "2019 Domestic Warrants") for gross proceeds of $4.2 million. The 2019 Domestic Warrants were issued with an exercise price of $1.15 and an expiration date of February 13, 2025.

The Company allocated the proceeds between the common stock and 2019 Domestic Warrants by applying the fair value allocation methodology. The Company first allocated $3.1 million to the 2019 Domestic Warrants, with the residual amount allocated to the common stock. See Note 11, "Warrant Liability" for further discussion of the key assumptions used to value the 2019 Domestic Warrants.

Ladenburg Thalmann & Co. Inc. ("Ladenburg") served as the placement agent for the transaction in exchange for a commission representing six percent (6%) of the gross proceeds, totaling $0.3 million, and 167,942 common stock purchase warrants exercisable for 167,942 shares of common stock with an exercise price of $1.25 per share and an expiration date of August 8, 2024 (the "2019 Ladenburg Warrants"). In addition, the Company reimbursed the Placement Agent $60 thousand for certain expenses. The Company also incurred and paid other offering costs of $0.3 million.

The Company incurred total issuance costs of $0.5 million in conjunction with the securities purchase agreement. The Company allocated $0.2 million of the issuance costs to the warrant liability which was expensed in the Company's consolidated statements of operations and comprehensive loss during the period. The remaining $0.3 million was recorded as a reduction of additional paid-in capital in the Company's consolidated balance sheets. 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 in the Company's consolidated balance sheets. See Note 11, "Warrant Liability" for a discussion of the key assumptions used to value the 2019 Ladenburg Warrants.

During the third quarter of 2019, the Company also issued the 2019 Foreign Warrants in conjunction with a preferred stock securities agreement as described in the section entitled "Preferred Stock" above.

During the third quarter of 2020, the Company and the holders of the 2019 Domestic Warrants and the 2019 Foreign Warrants entered into exercise agreements which resulted in the cash exercise of the warrants at a reduced exercise price of $0.99. The Company received aggregate gross proceeds of approximately $6.8 million from the exercises. The Company incurred and paid other offering costs of $0.2 million. The Company also incurred and paid a $0.2 million fee to China Kington for brokering the transaction, which equaled six percent (6%) of the gross proceeds from the 2019 Foreign Warrants.

During the third quarter of 2020, the Company and all holders of the 2019 Domestic Warrants and 2019 Foreign Warrants entered into warrant repricing letter agreements. Pursuant to the agreement, in consideration for the exercise in full of the 2019 Domestic Warrants and 2019 Foreign Warrant, the Company agreed to: (1) reduce the exercise price of the 2019 Domestic Warrants and the 2019 Foreign Warrants to $0.99 per share prior to exercise, and (2) in a private placement, issue new common stock purchase warrants (the "New Warrants") to purchase up to a number of shares of common stock, equal to 100% of the number of 2019 Domestic Warrants and 2019 Foreign Warrants currently held by such holders upon the holders exercising their warrants.

The New Warrants became exercisable six months after their issuance, for an aggregate of 6,898,566 shares of common stock. The New Warrants have an exercise price of $1.65 per share and will expire five and a half years after their issuance. The Company determined that the common stock issued from exercise of the 2019 Domestic and 2019 Foreign Warrants, and the New Warrants to be one unit of account, and therefore did not allocate the proceeds between the common stock and the New Warrants as, the proceeds, even if allocated, would be both recognized in additional paid-in capital.

During the third quarter of 2020, the Company also entered into a reprice agreement with Ladenburg which reduced the exercise price to $0.99 per share and amended certain terms of the 2019 Ladenburg Warrants. The Company's potential obligation to cash-settle the warrants if a specified fundamental transaction occurred was amended to apply only in situations within the Company's control. As further described in Note 11, "Warrant Liability", the 2019 Ladenburg Warrants were no longer classified as a liability as a result of this amendment.

April 2020 At the Market Offering

In the second quarter of 2020, the Company established the ATM Program with Ladenburg. For additional information regarding the offering and equity program, see the Company's Current Reports on Form 8-K filed with the SEC on April 27, 2020 and June 15, 2020. During the second quarter of 2020, 5,836,792 shares of common stock were issued under the ATM Program for total net proceeds of $5.6 million, net of offering costs of $0.4 million.

TLF Bio Innovation Stock Purchase

On May 13, 2020, TLF Bio Innovation purchased 1,000 shares of the Company's common stock for total proceeds of $1 thousand in conjunction with the services agreement described in Note 8, "Commitments and Contingencies".

Outstanding Warrants

The following table summarizes information about the Company's warrants outstanding at December 31, 2020, 2019 and 2018, and activity during the three years then ended.

	Warrants (in thousands)	Weighted-Average Exercise Price
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
Warrants granted	6,899	$ 1.65
Warrants exercised	(7,791)	$ 0.97
Warrants expired	(629)	$ 0.81
Outstanding at December 31, 2020	7,067	$ 1.63

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”). The 2007 Plan expired on March 15, 2017. Upon expiration, new awards cannot be issued pursuant to the 2007 Plan, but outstanding awards continue to be governed by its terms. Stock options granted under the 2007 Plan expire no later than ten years from the date of grant. All stock options outstanding under the 2007 Plan were fully vested as of December 31, 2020.

In March 2017, the Company adopted the 2017 Omnibus Incentive Plan (the “2017 Plan”), which was approved by stockholders 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”), RSUs and other share-based awards to employees, directors, and consultants, as determined by the Board. The 2017 Plan does not affect awards previously granted under the 2007 Plan. Upon adoption, the 2017 Plan allowed 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, 2020, there were 1,969,624 shares available for future awards under the 2017 Plan. Subsequent to December 31, 2020, on January 15, 2021, the number of shares available for future awards under the 2017 Plan was increased by 1,671,303 shares.

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 10% 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, 2020, 2019, and activity during the year ended December 31, 2020:

(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, 2019	2,183	$ 4.03	6.6	$ 43
Options granted	1,556	$ 0.92		
Restricted stock units granted	353	$ —		
Options exercised	(20)	$ 0.30		
Restricted stock units vested	(196)	$ —		
Options forfeited/cancelled	(709)	$ 5.29		
Restricted stock units cancelled	(1)	$ —		
Outstanding at December 31, 2020	3,165	$ 2.05	7.6	$ 189
Vested and expected to vest at December 31, 2020	2,825	$ 2.19	7.4	$ 157
Vested at December 31, 2020	1,465	$ 3.35	5.5	$ 40
Exercisable at December 31, 2020	1,465	$ 3.35	5.5	$ 40

The aggregate intrinsic value in the table above 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, 2020 for options that have a quoted market price in excess of the exercise price. There were 20 thousand stock option awards exercised during the year ended December 31, 2020 for which the Company received cash payments of $7 thousand. There was an intrinsic value of approximately $8 thousand for stock option awards exercised for the year ended December 31, 2020. There were 83 thousand stock option awards exercised during the year ended December 31, 2019 for which the Company received cash payments of $0.2 million. 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.

As of December 31, 2020, total unrecognized compensation cost related to unvested stock options and restricted stock was approximately $1.1 million. This amount is expected to be recognized as stock-based compensation expense in the Company's consolidated statements of operations and comprehensive loss over the remaining weighted average vesting period of 2.54 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 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, 2020, 2019, and 2018, the Company granted options to employees and directors to purchase an aggregate of 1,156,000, 145,000, and 1,085,000 shares of common stock, respectively.

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

	Year Ended December 31,		
Assumptions	**2020**	**2019**	**2018**
Expected price volatility	161%	112%	89%
Expected term (in years)	6.45	6.14	5.98
Risk-free interest rate	0.45%	1.99%	2.80%
Dividend yield	0.00%	0.00%	0.00%
Weighted-average fair value of options granted during the period	$0.94	$0.31	$1.51

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.

During the year ended December 31, 2020, the Company granted 160,000 RSUs to one employee. No employees were granted RSUs during the year ended December 31, 2019. In addition, the Company granted restricted stock to employees totaling 12,000 shares of common stock in the year ended December 31, 2018.

For the years ended December 31, 2020, 2019, and 2018, the Company recognized stock-based compensation expense of $0.5 million, $0.4 million, and $0.7 million, respectively, for option awards to employees and directors.

The Company modified stock options held by Mr. Yonghao (Carl) Ma in April 2019, Mr. Yanbin (Lawrence) Liu in May 2019, Mr. Mark Sieczkarek in July 2019, Mr. Todd Zavodnick in September 2019, Ms. Gail Maderis in April 2020 and Mr. Xiaopei Wang in August 2020, who each resigned as a director of the Company. The option exercise period for each of the former directors listed was extended from three months to three years, calculated from each director's date of resignation. Each director's stock option awards became fully vested at the date of his or her resignation. In connection with the stock option modification for each of Messrs. Ma, Liu, Sieczkarek, Zavodnick, Ms. Maderis and Mr. Wang, the Company recognized stock-based compensation expense of $14 thousand, $7 thousand, $60 thousand, $24 thousand, $36 thousand and $17 thousand, respectively, which are included in the figure above.

Stock-Based Awards to Non-Employees

During the year ended December 31, 2020, the Company granted options to purchase an aggregate of 400,000 shares of common stock to non-employees in exchange for advisory and consulting services. Out of the 400,000 shares, 300,000 shares were granted to a related party, Eric Wu, Partner and Senior Vice President of China Kington and the brother of Bob Wu, who serves on the Company's Board of Directors, in connection with the Company's re-launch of CelleRx Clinical Reset. Please refer to Note 17, "Related Party Transactions", for more details related to the consulting service agreement. During the year ended December 31, 2019, the Company did not grant options to purchase shares of common stock to non-employees. During the year ended December 31, 2018, the Company granted options to purchase an aggregate of 33,000 shares of common stock to non-employees in exchange for advisory and consulting services.

Stock options granted to non-employees 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,		
Assumptions	**2020**	**2019**	**2018**
Expected price volatility	162%	—	85%
Expected term (in years)	6.34	—	10.0
Risk-free interest rate	0.50%	—	2.94%
Dividend yield	0.00%	—	0.00%
Weighted-average fair value of options granted during the period	$ 0.73	—	$ 1.99

In connection with Mr. Sieczkarek's resignation, the Company granted 168 thousand shares of fully vested registered stock to Mr. Sieczkarek during the year ended December 31, 2019. The expense related to these shares was recorded in the Company's consolidated statements of operations and comprehensive loss. At the time of his resignation, the Company also entered into a two-year consulting agreement with Mr. Sieczkarek under which he is entitled to receive additional shares of fully vested registered stock in exchange for consulting services. According to the terms of the agreement, the stock units are to be issued in two tranches of $0.2 million each for a total aggregate fair market value equal to $0.4 million. The number of shares issued for each tranche is calculated using the closing price on each respective grant date. In July 2020, the Company issued 192,983 shares to Mr. Sieczkarek to fulfill the first tranche. The second tranche will be issued in July 2021. The expense related to the shares to be issued under the consulting agreement is being recorded over the term of the Consulting Agreement.

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 agreements.

The Company did not grant restricted stock to non-employees during the year ended December 31, 2018.

For the years ended December 31, 2020, 2019, and 2018, the Company recognized stock-based compensation expense of $64 thousand, $37 thousand, and $0, respectively, related to non-employee options and restricted stock grants.

Summary of Stock-Based Compensation Expense

A summary of the stock-based compensation expense included in results of operations for the options and restricted stock awards discussed above is as follows (in thousands):

	Year Ended December 31,		
	2020	**2019**	**2018**
Research and development	$ 23	$ 42	$ 32
Sales and Marketing	85	93	141
General and administrative	424	351	498
Total stock-based compensation expense	$ 532	$ 486	$ 671

NOTE 14. LICENSE, COLLABORATION AND DISTRIBUTION AGREEMENTS

Transactions under the Company's major distribution agreements are recognized upon transfer of control of product sold 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 amounts that are estimated to be subject to significant reversal, including allowances for services, discounts, rebate programs, and product returns.

The following table presents changes in the Company's contract assets and liabilities for the year ended December 31, 2020 (in thousands):

	Balance at Beginning of the Period	**Additions**	**Deductions**	**Balance at the end of the Period**
Contract Liabilities: Deferred Revenue	$ —	$ 2	$ —	$ 2
Contract Liabilities: Accrued Liabilities	434	2,338	(2,199)	573
Total	$ 434	$ 2,340	$ (2,199)	$ 575

The following table presents changes in the Company's contract assets and liabilities for the year ended December 31, 2019 (in thousands):

	Balance at Beginning of the Period	**Additions**	**Deductions**	**Balance at the end of the Period**
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, 2020, 2019 and 2018, the Company recognized the following revenue (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Revenue recognized in the period from:			
Amounts included in contract liabilities at the beginning of the period:			
Performance obligations satisfied	$ 434	$ 1,473	$ 1,453
New activities in the period:			
Performance obligations satisfied	9,500	5,126	11,055
	$ 9,934	$ 6,599	$ 12,508

Avenova Distribution Agreements and Specialty Pharmacies

Prescription Avenova is made available in local pharmacies and major pharmacy retail chains under nationwide distribution agreements with McKesson Corporation, Cardinal Health and AmerisourceBergen. We have also entered into direct agreements with preferred pharmacy networks as part of our Partner Pharmacy Program. During the years ended December 31, 2020, 2019 and 2018, the Company earned $1.7 million, $4.6 million and $11.0 million, respectively, in sales revenue for its Avenova product from these distribution and partner pharmacy agreements.

Under the prescription Avenova product distribution arrangements, the Company had a contract liability balance of $0.7 million as of December 31, 2020 and $0.8 million as of December 31, 2019. The contract liability is included in accrued liabilities in the consolidated balance sheets. The Company also recorded a prepayment of $0.1 million and $0.4 million for rebates related to these distribution agreements as of December 31, 2020 and December 31, 2019, respectively, that is recorded in the prepaid expenses and other current assets in the consolidated balance sheets (see Note 4, “Prepaid Expenses and Other Current Assets”).

Over-the-counter Avenova

Non-prescription Avenova was launched online on June 1, 2019 direct to U.S. customers. Over-the-counter Avenova is offered primarily for sale on Amazon.com, the Company’s website (Avenova.com) and Walmart.com. Over-the-counter Avenova is the same strength hypochlorous formulation as our prescription Avenova product, but comes in a smaller size. This channel provides the Company with more stable pricing and provides customers with easy access to our product. During the years ended December 31, 2020 and 2019, the revenue generated from over-the-counter Avenova was $3.3 million and $1.0 million, respectively. There was no comparable revenue during the year ended December 31, 2018.

KN95 Masks

During 2020, predominantly in the second quarter, the Company engaged in reselling KN95 Masks. Revenue generated from the sale of KN95 Masks was $3.1 million during the year ended December 31, 2020. There was no comparable revenue during the years ended December 31, 2019 and 2018.

License, Collaboration and Other Distribution Agreements

In January 2012, the Company entered into a distribution agreement with China Pioneer Pharma Holdings Limited (“China Pioneer”), a Shanghai-based company that markets high-end pharmaceutical products in China and the Company’s largest stockholder, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, NovaBay received an upfront payment of $0.3 million. NovaBay also received $0.3 million 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 $0.6 million 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 $0.5 million upon the purchase of NeutroPhase product, payable in NovaBay unregistered restricted common stock.

Pursuant to the Purchase Agreement, we also received $2.5 million from China Pioneer for the purchase of units (comprising one share of common stock and a warrant for the purchase of one share of common stock). The unit purchase was completed in two tranches: (1) 800,000 units in September 2012; and (2) 1,200,000 units in October 2012, with both tranches at a purchase price of $1.25 per unit. The fair value of the total units sold was $3.5 million, based upon the trading price of our common stock on the dates the units were purchased and the fair value of the warrants based on the Black-Scholes 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, we reallocated $0.6 million 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 included 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.

The Distribution Agreement and the Purchase Agreement expired on December 31, 2019 and were not renewed.

Revenue that has been recognized under these agreements during the years ended December 31, 2019 and 2018 is as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Product revenue	$ 209	$ 47
Amortization of upfront technology and access fees	41	34
Total revenue recognized	$ 250	$ 77

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.

As further described in Note 8, "Commitments and Contingencies", on April 16, 2020, the Company entered into an international distribution agreement with Microprofit and the related intermediary distribution agreement with Chongqing Pioneer, a related party, which was subsequently amended on June 29, 2020. As of December 31, 2020, the Company is still awaiting approval from the FDA to import and sell the COVID-19 antibody test kits.

On February 26, 2019, the Company entered into a private label agreement with PhaseOne Health, LLC., ("PhaseOne") to distribute a private label product with hypochlorous acid concentration of 0.025%. During the years ended December 31, 2020 and 2019, the Company recognized revenue of $0.2 million and $0, respectively, related to this contract.

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, 2020, 2019 and 2018, we contributed $13 thousand, $9 thousand, and $14 thousand to the plan, respectively.

NOTE 16. INCOME TAXES

For the years ended December 31, 2020, 2019 and 2018, loss before provision for income taxes consisted of the following (in thousands):

	Year Ending December 31,		
	2020	**2019**	**2018**
United States	$ (11,034)	$ (9,652)	$ (6,541)
International	—	—	—
	$ (11,034)	$ (9,652)	$ (6,541)

For the years ended December 31, 2020, 2019 and 2018, the federal and state income tax provision is summarized as follows (in thousands):

	Year Ending December		
	2020	**2019**	**2018**
Current			
Federal	$ —	$ —	$ —
State	5	6	4
Other	—	—	—
Total current tax expense	5	6	4
Deferred			
Federal	—	—	—
State	—	—	—
Other	—	—	—
Total deferred tax expense	—	—	—
Income tax provision	$ 5	$ 6	$ 4

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, 2020 and 2019 are as follows (in thousands):

	December 31	
	2020	2019
Deferred tax assets:		
Net operating losses	$ 31,115	$ 29,427
Stock options	790	1,191
Research and development credits	641	641
Accruals	267	222
Operating lease liabilities	109	301
Property and equipment	2	6
Other deferred tax assets	81	124
Total deferred tax assets	33,005	31,912
Deferred tax liabilities:		
Operating lease right-of-use assets	(108)	(301)
Total deferred tax liabilities	(108)	(301)
Valuation allowance	(32,897)	(31,611)
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.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act was enacted. The CARES Act changed net loss carryforward and back provisions and the business interest expenses limitation. The Company has evaluated the impact of the CARES Act and determined that none of the changes would result in a material cash benefit to the Company.

The valuation allowance increased by $1.3 million, $2.2 million and $0.9 million during the years ended December 31, 2020, 2019 and 2018, respectively.

Net operating loss and tax credit carryforwards as of December 31, 2020, are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal (Post December 31, 2017)	$ 17,223	Do Not Expire
Net operating losses, federal (Pre January 1, 2018)	$ 100,104	Beginning in 2024
Net operating losses, state	$ 96,250	Beginning in 2028
Tax credits, federal	$ 1,316	Beginning in 2026
Tax credits, state	$ 325	Indefinite

A reconciliation of the beginning and ending balance of unrecognized income tax benefits follows (in thousands):

	Year ended December 31,	
	2020	2019
Unrecognized benefit - beginning of period	$ 974	$ 974
Change during the period	—	—
Unrecognized benefit - end of period	$ 974	$ 974

The entire amount of the unrecognized tax benefits would not impact our effective tax rate if recognized. The balance of unrecognized tax benefits increased as a result of a comprehensive analysis to substantiate the company's research credits. 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 - 2020 remain open in the federal jurisdiction and 2006 - 2020 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,		
	2020	2019	2018
Statutory rate	21.0%	21.0%	21.0%
State tax	3.2%	3.1%	(0.3%)
Change in valuation allowance	(11.7%)	(23.0%)	(13.0%)
Warrant/equity expenses	(10.3%)	1.7%	4.2%
Stock-based compensation expense	(4.0%)	(3.7%)	(4.3%)
Other	1.7%	(0.3%)	(0.5%)
Impact of 162m	—	1.1%	1.3%
Impact of ASC 606	—	—	(8.5%)
Total	(0.1%)	(0.1%)	(0.1%)

NOTE 17. RELATED PARTY TRANSACTIONS

Related Party Financing

See Note 9, “Related Party Note Payable” for a description of the Promissory Note issued on February 27, 2019, as amended on June 25, 2019 and May 14, 2020 and Note 12, “Stockholders’ Equity” for a description of the Company’s financing transactions in June 2019 and August 2019. During the second quarter of 2020, the Company repaid the $1.0 million principal balance of the Promissory Note using proceeds raised through the ATM Program.

Related Party Revenue

The following table summarizes information about the Company’s related party revenue and cost of goods sold during the years ended December 31, 2020, 2019 and 2018, respectively (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Related party revenue:			
NeutroPhase	$ 524	$ 209	$ 47
Licensing	—	41	34
Total related party revenue	$ 524	$ 250	$ 77
Cost of goods sold			
NeutroPhase	$ 384	$ 176	$ 426
Licensing	—	—	—
Total related party expenses	$ 384	$ 176	$ 426

Related party accounts receivable was $0.2 million and $0 as of December 31, 2020 and December 31, 2019, respectively. See Note 14, “License, Collaboration and Distribution Agreements” for additional information regarding the Company's distribution agreements with China Pioneer, the Company's largest stockholder.

Other Related Party Expenses

During the year ended December 31, 2020, the Company purchased KN95 Masks through an affiliate of China Pioneer. As of December 31, 2020 and 2019, related party accounts payable was $8 thousand and $0, respectively.

The following table summarizes information about the Company's other related party expenses excluding stock-based compensation during the years ended December 31, 2020, 2019 and 2018, respectively (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Commissions to China Kington related to:			
OP Private Placement	$ —	$ —	$ 359
June 2019 Private Placement	—	144	—
August 2019 Private Placement	—	162	—
Exercise of June 2019 Warrants	41	—	—
Exercise of 2019 Foreign Warrants	160	—	—
Promissory Note to Pioneer Pharma (Hong Kong) Company Ltd.	—	20	—
Total commissions to China Kington	201	326	359
Board Director Bob Wu consulting fee	17	83	—
Total related party expenses	$ 218	$ 409	$ 359

In connection with the Company's re-launch of CelleRx Clinical Reset, on November 17, 2020, the Company entered into a consulting agreement with Eric Wu. Eric Wu is Partner and Senior Vice President of China Kington and the brother of Bob Wu, who serves on the Company's Board of Directors. Pursuant to the Agreement, Eric Wu will act as a consultant to the Company in support of the CelleRx product re-launch as well as in potential financings and other transaction opportunities. The term of the Agreement is for twelve months. As consideration for his services, the Company granted Eric Wu options exercisable for 300,000 shares of the Company's common stock under the Company's 2017 Omnibus Incentive Plan with an exercise price equal to the Company's closing stock price on the date of the grant and vesting on the one year anniversary of the grant date. Stock-based compensation expense of $15 thousand was recorded for the year ended December 31, 2020 related to Eric Wu's options.

NOTE 18. PAYCHECK PROTECTION PROGRAM

On May 6, 2020, the Company received loan proceeds in the amount of $0.9 million from Wells Fargo Bank, N.A. (the "PPP Loan") pursuant to the Paycheck Protection Program ("PPP") under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), which was enacted on March 27, 2020.The terms of the PPP Loan were subsequently revised in accordance with the provisions of the Paycheck Protection Flexibility Act of 2020, or the PPP Flexibility Act, which was enacted on June 5, 2020. The PPP loan provides for an interest rate of 1.00% per year and matures two years after the date of initial disbursement, with initial principal and interest payments coming due late in fiscal 2021. The Note may be prepaid by the Company at any time prior to the maturity with no prepayment penalties. Funds from the PPP Loan may only be used for payroll costs, costs used to continue group health care benefits, rent and utilities incurred during the 24-week period after receiving the PPP Loan (collectively, "Qualifying Expenses") in order for the PPP Loan to be forgiven in whole or in part. The Company used the entire PPP Loan amount for the Qualifying Expenses and expects the PPP Loan to be forgiven in whole prior to repayment.

Since the Company determined that there is reasonable assurance that it will meet the conditions for forgiveness of the full loan amount, we accounted for the forgivable PPP Loan as a government grant that we earned through the Company's compliance with the loan forgiveness criteria. PPP proceeds received was accounted for as an income grant. A deferred income liability was recognized upon receipt of the forgivable loan proceeds. The deferred income liability was recognized as other income as Qualifying Expenses were incurred. For the year ended December 31, 2020, $0.9 million was recognized as other income and recorded in the consolidated statements of operations and comprehensive loss, respectively.

NOTE 19. SUBSEQUENT EVENTS

The number of shares of Common Stock available for issuance under the stockholder-approved 2017 Plan is subject to an automatic annual increase on the first day of each of the Company's fiscal years beginning on January 1, 2018 and ending on January 1, 2027 by an amount equal to (i) four percent (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 as determined by the Board. For 2021, the Board authorized an increase of 1,671,303 shares of the Company's common stock under the 2017 Plan, consisting of the full four percent (4%) increase allowed pursuant to the 2017 Plan's evergreen provision.

On February 4, 2021, as described in the Company's Current Report on Form 8-K filed with the SEC on February 8, 2021, the Company terminated the TLF Agreement. With the CelleRx Clinical Reset relaunch complete, the Company determined it would transition to other advisors who specialize in the further commercialization of the product.

On March 17, 2021, the Company's insurance company notified the Company that it would reimburse $0.3 million related to the arbitration between John McGovern and the Company upon completion of its audit.

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, 2020, 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, 2020. 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, 2020. Our management has concluded that, as of December 31, 2020, 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 2021 Annual Meeting of Stockholders (the “2021 Proxy Statement”) and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in the 2021 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 2021 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 2021 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 2021 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	Amendment to the Amended and Restated Certificate of Incorporation, as amended	8-K	001-33678	3.1	5/28/2020	
3.4	Bylaws	8-K	001-33678	3.2	6/29/2010	
4.1	Description of Securities					X
4.2	Form of Warrant pursuant to the International Distribution Agreement with Shenzhen Microprofit Biotech Co., Ltd., dated April 16, 2020	8-K	001-33678	4.1	4/20/2020	
4.3	Form of Warrant pursuant to the Services Agreement with TLF Bio Innovation Lab, LLC, dated May 13, 2020	8-K	001-33678	4.1	5/18/2020	
4.4	Form of July 2020 Warrant	8-K	001-33678	4.1	7/21/2020	
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+	Executive Employment Agreement (Employment Agreement of Justin M. Hall)	8-K	001-33678	10.1	2/6/2020	
10.7+	Executive Employment Agreement (Employment Agreement of Andrew D. Jones)	8-K	001-33678	10.8	5/5/2020	
10.8	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	
10.9	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	
10.10	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	
10.11	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	
10.12	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	
10.13	Ninth Amendment to Lease between EmeryStation Office II, LLC (Landlord) and NovaCal Pharmaceuticals, Inc. (Tenant), EmeryStation North Project	10-Q	001-33678	10.14	08/06/2020	
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	Sublease Termination Agreement by and between the Company and Zymergen, Inc.	10-Q	001-33678	10.17	8/06/2020	
10.17†	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	
10.18†	Amendment No. 1 to the Collaboration and License Agreement	10-K	001-33678	10.18	3/30/2010	
10.19†	Amendment No. 2 to the Collaboration and License Agreement	10-K	001-33678	10.24	3/10/2011	
10.20†	International Distribution Agreement (by and between the Company and Pioneer Pharma Co. Ltd.)	10-K	001-33678	10.18	3/27/2012	
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	Second Amendment to the Promissory Note (payable to Pioneer Pharma (Hong Kong) Company Limited), dated May 14, 2020	8-K	001-33678	10.1	5/15/2020	
10.24	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	
10.25*	International Distribution Agreement between the Company and Shenzhen Microprofit Biotech Co., Ltd., dated April 16, 2020	8-K	001-33678	10.1	4/20/2020	
10.26*	Intermediary Distribution Agreement between the Company and Chongqing Pioneer Pharma Holdings Limited, dated April 16, 2020	8-K	001-33678	10.2	4/20/2020	
10.27*	First Amendment to Intermediary Distribution Agreement between the Company and Chongqing Pioneer Pharma Holdings Limited, dated June 29, 2020	10-Q	001-33678	10.31	08/06/2020	
10.28	At the Market Offering Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated April 27, 2020	8-K	001-33678	1.1	4/27/2020	

10.29	Paycheck Protection Program Promissory Note and Agreement, dated May 3, 2020, between the Company and Wells Fargo Bank, N.A.	10-Q	001-33678	10.28	5/7/2020	
10.30	Services Agreement between the Company and TLF Bio Innovation Lab, LLC, dated May 13, 2020	8-K	001-33678	10.1	5/18/2020	
10.31*	First Amendment to Services Agreement between the Company and TLF Bio Innovation Lab, LLC, dated September 4, 2020	8-K	001-33678	10.1	09/10/2020	
10.32	Securities Purchase Agreement between the Company and TLF Bio Innovation Lab, LLC, dated May 13, 2020	8-K	001-33678	10.2	5/18/2020	
10.33	Form of Exercise Agreement with Holders of 2019 Domestic Warrants	8-K	001-33678	10.1	7/21/2020	
10.34	Form of Exercise Agreement with Holders of 2019 Foreign Warrants	8-K	001-33678	10.2	7/21/2020	
10.35	Form of Reprice Agreement with Ladenburg	8-K	001-33678	10.3	7/21/2020	
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.

* Certain confidential portions of this exhibit were omitted by means of marking such portions with brackets because the confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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 25, 2021

By: /s/ Justin Hall
Justin Hall
Chief Executive Officer, General Counsel and Director
(principal executive officer)

Date: March 25, 2021

By: /s/ Andrew Jones
Andrew Jones
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 Andrew Jones, 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**	Chief Executive Officer, General Counsel and Director (*principal executive officer*)	March 25, 2021
/s/ ANDREW JONES **Andrew Jones**	Chief Financial Officer (*principal financial officer*)	March 25, 2021
/s/ PAUL E. FREIMAN **Paul E. Freiman**	Chairman of the Board	March 25, 2021
/s/ XINZHOU LI **Xinzhou Li (Paul Li)**	Director	March 25, 2021
/s/ SWAN SIT **Swan Sit**	Director	March 25, 2021
/s/ MIJIA WU **Mijia Wu, M.B.A. (Bob Wu)**	Director	March 25, 2021
/s/ YENYOU ZHENG **Yenyou (Jeff) Zheng**	Director	March 25, 2021

Exhibit 4.1

DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 75,000,000 shares of common stock, $0.01 par value per share ("Common Stock"), and 5,000,000 shares of preferred stock, $0.01 par value per share. A description of material terms and provisions of our amended and restated certificate of incorporation and bylaws affecting the rights of holders of our capital stock is set forth below. The description is intended as a summary, and is qualified in its entirety by reference to our amended and restated certificate of incorporation and the bylaws.

On December 18, 2015, we effected a 1-for-25 reverse stock split and 25 shares of our outstanding Common Stock decreased to one share of Common Stock. Similarly, the number of shares of Common Stock issuable upon the exercise of outstanding stock options or warrants, or upon the vesting of outstanding restricted stock units, decreased on a 1-for-25 basis and the exercise price of each outstanding option and warrant increased proportionately.

Common Stock

Dividend rights. Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our Common Stock are entitled to receive dividends out of funds legally available if our Board of Directors (the "Board"), in its discretion, determines to issue dividends and then only at the times and in the amounts that our Board may determine.

Voting rights. Each holder of Common Stock is entitled to one vote for each share of Common Stock held on all matters submitted to a vote of stockholders. Our amended and restated certificate of incorporation does not provide for the right of stockholders to cumulate votes for the election of directors. Our amended and restated certificate of incorporation establishes a classified Board, divided into three classes with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No preemptive or similar rights. Our Common Stock is not entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions. The rights, preferences and privileges of the holders of our Common Stock are subject to, and may be adversely affected by, the rights of the holders of any series of our preferred stock that we may designate and issue in the future.

Right to receive liquidation distributions. Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to holders of our Common Stock are distributable ratably among the holders of our Common Stock, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of our preferred stock.

The rights of the holders of our Common Stock are subject to, and may be adversely affected by, the rights of holders of shares of any preferred stock that we may designate and issue in the future.

Anti-takeover effects of provisions of our certificate of incorporation and bylaws and Delaware law

Amended and restated certificate of incorporation and bylaws. Our amended and restated certificate of incorporation provides that our Board is divided into three classes with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because holders of our Common Stock do not have cumulative voting rights in the election of directors, stockholders holding a majority of the shares of Common Stock outstanding are able to elect all of our directors. Our Board is able to elect a director to fill a vacancy created by the expansion of the Board or due to the resignation or departure of an existing board member. Our amended and restated certificate of incorporation and bylaws also provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by written consent, and that only the Board pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders. In addition, our bylaws include a requirement for the advance notice of nominations for election to the Board or for proposing matters that can be acted upon at a stockholders' meeting. Our amended and restated certificate of incorporation provides for the ability of the Board to issue, without stockholder approval, up to 5,000,000 shares of preferred stock with terms set by the Board, which rights could be senior to those of our Common Stock. Our amended and restated certificate of incorporation and bylaws also provide that approval of at least 66-2/3% of the shares entitled to vote at an election of directors will be required to adopt, amend or repeal our bylaws, or repeal the provisions of our amended and restated certificate of incorporation regarding the election of directors and the inability of stockholders to take action by written consent in lieu of a meeting.

The foregoing provisions make it difficult for holders of our Common Stock to replace our Board. In addition, the authorization of undesignated preferred stock makes it possible for our Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our Company.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. This section prevents some Delaware corporations from engaging, under some circumstances, in a business combination, which includes a merger or sale of at least 10% of the corporation's assets with any interested stockholder, meaning a stockholder who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of the corporation's outstanding voting stock, unless:

- the transaction is approved by the Board prior to the time that the interested stockholder became an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder's becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or
- at or subsequent to such time that the stockholder became an interested stockholder, the business combination is approved by the Board and authorized at an annual or special meeting of stockholders by at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We do not plan to "opt out" of these provisions. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

Transfer Agent and Registrar

Computershare Shareholder Services, Inc., located in Providence, Rhode Island, Providence County, is the transfer agent and registrar for our Common Stock in the United States and Computershare Investor Services, Inc., located in Toronto, Ontario, Canada, is the co-transfer agent and registrar for our Common Stock in Canada. The transfer agent for any series of preferred stock that we may offer under this prospectus will be named and described in the prospectus supplement related to that series.

Listing on the NYSE American

Our Common Stock is listed on the NYSE American under the symbol "NBY." The applicable prospectus supplement will contain information, where applicable, as to any other listing, if any, on the NYSE American or any securities market or other exchange of the preferred stock covered by such prospectus supplement.

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. 333-252155, 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. 333-248238, 333-233623, 333-232860, 333-230672, 333-211944 and 333-211943) and Form S-1 (File Nos. 333-238317 and 333-234330) of NovaBay Pharmaceuticals, Inc. of our report dated March 25, 2021, 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 25, 2021

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 25, 2021

/s/ Justin Hall
Justin Hall
Chief Executive Officer, General Counsel and Director *(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, Andrew Jones, 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 25, 2021

/s/ Andrew Jones
Andrew Jones
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 annual report of NovaBay Pharmaceuticals, Inc. (the Company) on Form 10-K for the fiscal year ended December 31, 2020 (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 25, 2021

/s/ Justin Hall
Justin Hall
Chief Executive Officer, General Counsel and Director

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 annual report of NovaBay Pharmaceuticals, Inc. (the Company) on Form 10-K for the fiscal year ended December 31, 2020 (the Report), I, Andrew Jones, 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 25, 2021

/s/ Andrew Jones
Andrew Jones
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.