

NovaBay Pharmaceuticals, Inc.
Form 10-K
March 23, 2017
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, 2016

OR

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

For the transition period from _____ to _____

Commission file number 001-33678

NOVABAY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware **68-0454536**
(State or other jurisdiction of incorporation or organization) **(I.R.S. Employer Identification No.)**

2000 Powell Street, Suite 1150, Emeryville, California 94608

(Address of principal executive offices) (Zip Code)

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

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

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

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

None

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

Yes No

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

Yes No

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). Yes No

As of June 30, 2016, 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 Mkt, was approximately \$7,530,005. This figure excludes an aggregate of 6,144,900 shares of common stock held by officers and directors as of June 30, 2016. 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 22, 2017, there were 15,288,175 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the Proxy Statement for the 2017 Annual Meeting of Stockholders expected to be held in June 2, 2017.

NOVABAY PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

PART I

ITEM 1. BUSINESS

Overview

We are a pharmaceutical company that develops, manufactures, and markets innovative anti-infective products for a multitude of uses. However, we are predominantly focused on commercializing prescription Avenova[®] for the domestic eye care market in the United States.

Avenova is the only eye care product formulated with our proprietary, stable and pure form of hypochlorous acid (marketed as Neutrox[®]). By replicating the antimicrobial chemicals used by white blood cells to fight infection, Avenova has proven in laboratory testing to have broad antimicrobial properties. It removes microorganisms and debris from the skin on the eyelids and lashes without burning or stinging. It is also the only commercial product clinically validated to reduce bacterial load on the ocular skin surface, the buildup of which can cause the chronic eye condition blepharitis.

In November 2015, we introduced a new business strategy to restructure our business and focus on growing sales of Avenova in the United States. This new strategy allowed us to achieve our goal of reaching adjusted positive cash flow from operations (excluding working capital changes) by the end of 2016. Our current three-part business strategy is comprised of: (1) focusing our resources on growing the commercial sales of Avenova in the U.S. eye care market, including the implementation of an innovative sales and marketing strategy to increase product margin and profitability; (2) significantly reducing expenses through the restructuring of our operations and other cost reduction measures; and (3) seeking additional sources of revenue through partnering, divesting and/or other means of monetizing non-core assets in urology, dermatology, and wound care.

In addition to Avenova, we have also developed other commercial products containing Neutrox, including NeutroPhase® for the wound care market and CelleRx for the dermatology market. We have partnerships for NeutroPhase in the U.S., as well as select overseas markets, most notably China.

Avenova

Based on positive sales performance in 2015, we incrementally grew our salesforce to 49 medical sales representatives in 2016 and to 55 in January 2017. Having previously been managed through a professional employer organization, we transitioned our contract salesforce to direct employees of the Company in January 2017. This marked an important milestone in establishing ourselves as a truly consolidated company under the direction of one management team. We believe we are poised for success with all our sales representatives having extensive experience with eye care products and medical devices, a skill set critical for rapid adoption of Avenova in the marketplace.

We currently believe our target market to be the estimated 30 million Americans who suffer from blepharitis and chronic dry-eye. To access our target market, our salesforce is calling on a base of prescribers that includes the approximately 17,000 ophthalmologists and approximately 37,000 optometrists in the U.S. Our sales and marketing campaign targets major urban areas such as New York, Los Angeles, Boston, Atlanta, and San Francisco.

Avenova offers distinct advantages, when compared to alternative regimens that contain soaps, bleach, and other impurities, as it removes unwanted microorganisms from the skin without the use of harmful ingredients such as detergents and bleach. The removal of these harmful items helps control eyelid inflammation, itching and other painful symptoms. Many key opinion leaders in the field of ophthalmology and optometry have embraced Avenova as a tool in the management of lid and lash hygiene and have joined our Ophthalmic and Optometry Advisory Boards (the “Advisory Boards”) to promote its use among their peers. Our Advisory Board members are essential in our goal of educating other physicians that Avenova, used twice daily, is well suited for treating a variety of chronic eye conditions.

Because prescription Avenova has been shown to neutralize bacterial toxins *in vitro*, it was specifically designed for daily eyelid hygiene. It is the only commercially available product to be clinically validated in a multicenter study to significantly reduce the bacteria that can cause blepharitis. Data from the clinical study showed that Avenova reduced the bacterial load on ocular skin surface by more than 90% (*S. epidermidis* by 99.5%) within 20 minutes of use without affecting the diversity of the remaining bacteria. Results of this clinical study were presented at the Association for Research in Vision and Ophthalmology (“ARVO”) annual meeting in May 2016. We expect to present data from additional clinical studies to further validate the use of Avenova in managing blepharitis and other eye conditions. Avenova may also be useful in pre- and post-surgical settings for LASIK and cataract patients, as well as managing contact lens intolerance. We believe the total potential market for this product is approximately 41 million patients.

We expect continued benefit from the support of the key opinion leaders on the Advisory Board, our active schedule of educational and marketing programs and strong presence at major eye care conferences in the coming months, including the American Academy of Ophthalmology, the American Optometric Association, the American Society of Cataract and Refractive Surgery Conferences and the South-Eastern Congress of Optometry, as well as numerous Vision Expo meetings held around the U.S. We also plan to continue advertising in leading ophthalmic and optometric trade journals. At these meetings, in professional publications, and in surveys, nationally prominent ophthalmologists and optometrists are reporting on patient improvements in eye care from the use of Avenova.

We have distribution agreements with McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation that make Avenova accessible in 90% of the approximate 67,000 retail pharmacies across the U.S. Avenova also is marketed through the top ophthalmology and optometry networks. These include the Vision Source Independent Optometry Network, the largest independent optometry network in the U.S. representing 2,800 independent optometrist offices, and ALLDocs Optometry Group (also known as The Association of LensCrafters Leaseholding Doctors), the second largest independent optometry group in the U.S., which works closely with its LensCrafters partners.

Throughout 2016 we reported increases in key metrics, including the total number of prescribers, as well as growth in prescription volume as reported by distributors and the number of retail pharmacies ordering Avenova, both of which have been confirmed by third-party prescription data providers. Increases in Avenova volume include growth of Avenova product reorders and new prescriptions.

We expect that our prescription business will be the main driver of long-term Avenova sales growth and gross margin expansion. We are focusing our primary sales efforts on building our prescription business under a value pricing model. Our strategy is supported by the high percentage rate of insurance reimbursement, with over 90% of Avenova prescriptions filled at pharmacies covered by insurance at the end of 2016. As a result of this focus, we have significantly increased the percentage of total Avenova prescriptions. We are working to improve insurance reimbursement coverage for Avenova and we are aligning our product pricing accordingly.

We also expect to invest in systems that support prescribing physicians' efforts to educate their patients. We have made it easy for doctors to get Avenova into the hands of patients by providing availability through well-known national pharmacy chains, specialty pharmacies, or directly through the practitioners' office. Furthermore, in order to ensure consistent pricing, we have instituted rebate cards to ensure the best price for the patient at the pharmacy. This method, combined with reimbursement under insurance plans, could provide us with potential additional revenue upside.

Competition

There are many companies that sell lid and lash scrubs, most of these are surfactant (soap) based, such as lid scrubs or baby shampoos. Unlike its competitors, Avenova consists of saline and 0.01% pure hypochlorous acid, without the bleach impurities included in competitive offerings. While newer prescription products have recently been commercially launched, they all include bleach or other impurities. Because it lacks these impurities, we believe that physicians and their patients will choose Avenova over other competitive prescription products or over-the-counter (“OTC”) soap products.

Strategic Alternatives and Other Assets

The third key aspect of our business strategy is to seek additional sources of revenue through partnering, divesting and/or other means of monetizing non-core assets. We therefore are in the process of seeking additional sources of revenue by licensing or selling select non-core assets in urology, dermatology, and wound care, as described in more detail below.

Aganocide Compounds

In addition to our Neutrox family of products, we have synthesized and developed a second category of novel compounds also aimed at harnessing the power of white blood cell chemistry to address the global, topical anti-infective market. This second product category includes auriclosene, our lead clinical-stage Aganocide compound, which is a patented, synthetic molecule with a broad spectrum of uses against bacteria, viruses and fungi. Mimicking the anti-infective chemistry and mechanism of action that human white blood cells use against infections, Aganocides possess a significantly reduced likelihood of bacteria or viruses developing resistance, which is critical for advanced anti-infectives. Auriclosene has been designated as a new chemical entity and granted broad composition of matter patent protection to 2028 by the U.S. Patent Office.

AIS (Urology)

Our urology program utilizes the technology of our Aganocide compounds and is in an advanced stage of clinical development. Statistically significant and clinically meaningful results have been reported from two Phase 2 clinical studies with our Auriclosene Irrigation Solution (“AIS”) in urinary catheter blockage and encrustation (“UCBE”). We announced the results of a Phase 2b clinical study in September 2016 which demonstrated that AIS, when compared

with the product that represents the current standard of care, proved more effective in reducing urinary blockage in patients with chronic indwelling urinary catheters who have repeat history of blockage. In this study, AIS exhibited the potential for rapid decolonization of a range of urologic pathogens. Approximately 100,000 patients in the U.S. currently chronically suffer from UCBE. We estimate that the healthcare costs to manage these patients is in the billion-dollar range.

CelleRx (Dermatology).

Created for cosmetic procedures, CelleRx (0.015% Neutrox) is a gentle cleansing solution that is effective for post-laser resurfacing, chemical peels and other cosmetic surgery procedures. Cosmetic surgeons and aesthetic dermatologists have found that CelleRx results in less pain, erythema, and exudate compared to Dakin solution, which contains bleach impurities. CelleRx is a non-alcohol formulation that doesn't dry or stain the skin, and most importantly, has been shown to reduce the patient's downtime post procedure.

CelleRx is well positioned in the cosmetic surgery and aesthetic dermatology space as an adjunct therapy for the pre/post procedural phase of chemical and laser facial skin peels. Currently many generic creams and salves, as well as home-mixed acetic acid potions, are used for this purpose. We believe that CelleRx is clearly differentiated in this field. CelleRx is unique prescription product with 510(k) clearance as a skin and wound cleanser. CelleRx has proven to be safe, soothing and have an unusually broad spectrum antimicrobial action in solution. Many clinicians have used the product clinically and have reported excellent results.

intelli-Case

In addition to improving the eyecare of many Americans through promoting Avenova for lid and lash hygiene, we have developed a contact lens case that improves the safety of those contact lens wearers who use hydrogen peroxide solution to disinfect their lenses. In June 2015, we received FDA-clearance for the intelli-Case, a highly innovative, easy-to-use device for use with hydrogen peroxide disinfection solutions for soft and rigid gas permeable contact lenses. More than 24 million Americans disinfect their contact lenses with a multipurpose disinfection system to prevent potentially serious infections. Approximately two million use hydrogen peroxide as a disinfection solution. Many ophthalmologists and optometrists favor the disinfection and lens material compatibility peroxide systems provide, yet side effects associated with misuse and non-compliance minimize peroxide system use. Hydrogen peroxide in too low of a concentration does not fully disinfect lenses and in too high of a concentration can severely irritate the eye.

The intelli-Case monitors the neutralization of hydrogen peroxide during the disinfection cycle with sophisticated microprocessor electronics embedded in the cap of what otherwise looks like a standard peroxide lens case. The LED indicators on the lid inform the user if the lenses are safe to insert into the eyes, resulting in a disinfection system that is safe yet simple to use. We are seeking potential partners with the resources to make this breakthrough device available to the largest number of contact lens wearers as soon as possible.

NeutroPhase (Wound Care).

We believe that NeutroPhase is a well-suited product to treat the six million patients in the U.S. who suffer from chronic non-healing wounds, such as pressure, venous stasis and diabetic ulcers. Consisting of 0.03% Neutrox, NeutroPhase is used to cleanse and remove microorganisms from any type of acute or chronic wound, and can be used with any type of wound care modality. Recently, NeutroPhase has been found to be an effective irrigation solution as part of the adjunct treatment for Necrotizing Fasciitis (“NF”). Also known as flesh-eating disease, NF typically has a high mortality and amputation rate (30% and 70%, respectively) even with aggressive debridement and antibiotic treatment. *In vitro* studies have shown that, in solution, NeutroPhase both kills the microorganisms implicated in NF and neutralizes the toxins secreted by the microorganisms. Success using NeutroPhase as an irrigation solution has established it as an effective part of the adjunct treatment for this deadly disease.

In March 2015, the National Necrotizing Fasciitis Foundation (“NNFF”) named NeutroPhase its official “Flesh Eating Disease” wound cleanser. The NNFF is a non-profit organization established in 1997 by two survivors of the disease. NNFF has evolved to become the world’s leading resource for information regarding necrotizing fasciitis, as well as a repository of cases reported worldwide.

NeutroPhase is competing in a crowded wound cleanser market with many older and lower-priced products with similar uses. However, we believe NeutroPhase has distinct competitive advantages in a market where there is currently no dominant product. In the U.S. and internationally, NeutroPhase is distributed through commercial partners, such as Pioneer Pharma Company Limited, or “Pioneer,” a Shanghai-based company, for the distribution of NeutroPhase throughout Southeast Asia and mainland China and in the U.S., by Principle Business Enterprise (“PBE”).

U.S. FDA Regulatory Clearance of Neutrox-based Products. We are marketing Avenova, NeutroPhase, and CelleRx as medical devices regulated under the FDA 510(k) process. Avenova and CelleRx fall under the general intended use of skin and wound cleansers. NeutroPhase was cleared by the U.S. FDA “*for use under the supervision of healthcare professionals for cleansing and removal of foreign material, including microorganisms and debris from wounds, and for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions, and minor irritations of the skin. It is also intended for moistening and debriding acute and chronic dermal lesions, such as Stage I to IV pressure ulcers, stasis ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, and grafted and donor sites.*”

Recent Events

On October 28, 2016, the Company received a letter from the NYSE MKT informing it that the Company is back in compliance with the NYSE MKT continued listing standards set forth in Part 10 of the NYSE MKT Company Guide (the “Company Guide”). Specifically, the Company had resolved the continued listing deficiencies with respect to Sections 1003(a)(i), 1003(a)(ii) and 1003(a)(iii) of the Company Guide referenced in the NYSE MKT’s letters dated April 28, 2015, July 10, 2015 and March 17, 2016. The Company is subject to ongoing review for compliance with NYSE MKT requirements as part of the NYSE MKT’s routine monitoring.

Equity

In February 2016, we closed a financing with accredited investors in which we raised a total of \$2.8 million, or approximately \$2.6 million in net cash proceeds after deducting a placement agent commission due to China Kington Asset Management (“China Kington”) and other offering costs of \$0.2 million.

In May 2016, we closed the first tranche of an April 2016 financing (the “April 2016 Financing”) in which we raised a total of \$7.8 million, or approximately \$7.3 million in net cash proceeds after deducting China Kington’s placement agent commission and other offering costs of \$0.5 million.

In August 2016, we closed the second tranche of this financing, raising a total of \$4.0 million, or approximately \$3.8 million in net cash proceeds after deducting China Kington’s placement agent commission and other offering costs of \$0.2 million.

During the third quarter of 2016, certain warrant holders exercised warrants in the amount of \$6.9 million, or approximately \$6.6 million in net cash proceeds after deducting placement agent commissions and other offering costs of \$0.3 million.

During the fourth quarter of 2016, certain warrant holders exercised warrants in the amount of \$0.9 million, or approximately \$0.9 million in net cash proceeds after deducting placement agent commissions and other offering costs of approximately \$32 thousand.

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

Borrowings

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

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

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

Office Lease

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

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

Employees

As of December 31, 2016, we had 21 direct full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. In January 2017, we internalized our contract salesforce of 58 medical sales representatives. As of February 28, 2017, we have a total of 78 direct full time employees.

Available Information

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

ITEM 1A. RISK FACTORS

Our business is subject to a number of risks, the most important of which are discussed below. You should consider carefully the following risks in addition to the other information contained in this report and our other filings with the SEC before deciding to buy, sell or hold our common stock. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline and you may lose all or part of your investment. The risks and uncertainties described below are not the only ones facing our Company. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations.

Risks Relating to Our Liquidity

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

We have historically incurred net losses and we may never achieve or maintain sustained profitability. In addition, at this time:

- we expect to incur substantial marketing and sales expenses as we continue to attempt to increase sales of our Avenova product
- our results of operations may fluctuate significantly
- we may be unable to develop and commercialize our product candidates and
- it may be difficult to forecast accurately our key operating and performance metrics because of our limited operating history.

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

material adverse impact on the market price of our common stock.

Risks Relating to Owning Our Common Stock

If we conduct offerings in the future, the price at which we offer our securities may trigger a price protection provision included in warrants originally issued in July 2011, March 2015 and October 2015, reducing the probability and magnitude of any future share price appreciation.

As part of our October 2015 offering, we agreed to provide certain price protections affecting currently outstanding warrants exercisable for an aggregate of 565,695 shares of our common stock, of which 281,093 shares must be issued, if at all, by March 6, 2020, and 284,602 shares must be issued, if at all, by October 27, 2020 (the “Warrants”). Specifically, in the event that we undertake a third-party equity financing of either: (1) common stock at a sale price of less than \$5.00 per share or (2) convertible securities with an exercise price of less than \$5.00 per share, we have agreed to reduce the exercise price of all Warrants to such lower price. The exercise price of the Warrants is currently set at \$1.81 as a result of our February 2016 private placement offering. The further reduction of the exercise price for the Warrants would limit the probability and magnitude of future share price appreciation, if any, by placing downward pressure on our stock price if it exceeds such offering sale price. All of the Warrants are currently exercisable and will remain so after any exercise price adjustment. In the past, we have extended the expiration dates or adjusted other terms of the Warrants as consideration for certain offering conditions, and we cannot assure you that we will not do so in the future. Any such modifications would reduce the probability and magnitude of any share price appreciation during the period of the extension. We cannot guarantee that you will receive a return on your investment when you do sell your shares or that you will not lose the entire amount of your investment. If you do receive a return on your investment, it may be lower than the return you would have realized in the absence of the price protection provisions discussed hereof.

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

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

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

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

The number of shares of our common stock being actively traded may be very low and any stockholder wishing to sell his, her, or its stock may cause a significant fluctuation in the price of our stock. We have a number of large stockholders, including our principal stockholders China Pioneer Pharma Holdings Limited ("China Pioneer"), Pioneer Pharma (Hong Kong) Company Limited as a wholly-owned subsidiary of China Pioneer and the recipient of all of the holdings of Pioneer Pharma (Singapore) Pte. Ltd. pursuant to an internal corporate reorganization of China Pioneer ("Pioneer Hong Kong") and Mr. Jian Ping Fu. Each of China Pioneer and Mr. Fu own 34% and 26% of our common stock, respectively. The sale of a substantial number of shares of common stock by such large stockholders within a short period of time could cause our stock price to decrease substantially. In addition, low trading volume of a stock increases the possibility that, despite rules against such activity, the price of the stock may be manipulated by persons acting in their own self-interest. We may not have adequate market makers and market making activity to prevent manipulation.

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

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

include:

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

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

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

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

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

As of March 1, 2017, China Pioneer beneficially owns approximately 34% of our common stock. Our director Mr. Xinzhou “Paul” Li is the chairman of China Pioneer. Pursuant to the arrangement of our Bridge Loan, two (2) of our directors were nominated by China Kington, including Mr. Mijia “Bob” Wu, who is the Managing Director of China Kington and Non-Executive Director of Pioneer Hong Kong, and Mr. Xiaoyan “Henry” Liu, who has worked closely with China Kington on other financial transactions in the past. Mr. Jian Ping Fu beneficially owns approximately 26% of our common stock. China Kington and its affiliates have served as placement agent for three purchases of Company securities by Mr. Fu during the last year.

As a result, China Pioneer, Pioneer Hong Kong as a wholly-owned subsidiary of China Pioneer and China Kington have input on all matters before our Board of Directors and may be able to exercise significant influence over all matters requiring board and stockholder approval. Please see the risk factor entitled “*We may be unable to raise additional capital on acceptable terms in the future, which may in turn limit our ability to develop and commercialize products and technologies.*” China Pioneer, Pioneer Hong Kong and China Kington may choose to exercise their influence in a manner that is not in the best interest of our general stockholders.

In addition, were China Pioneer, Pioneer Hong Kong and Mr. Fu to cooperate, they could unilaterally elect all of their preferred director nominees at our 2017 Annual Meeting of Stockholders. Even with our classified board, China Pioneer, Pioneer Hong Kong and Mr. Fu could ensure that five (5) of our eight (8) directors are either nominees of China Pioneer, Pioneer Hong Kong or China Kington. In the interim, China Pioneer, Pioneer Hong Kong, China Kington and/or Mr. Fu could exert significant indirect influence on us and our management.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss (“NOL”) carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. Since our formation, we have raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders’ subsequent disposition of those shares, may have resulted in one or more changes of control, as defined by Section 382 of the Code. We have not currently completed a study to assess whether any change of control has occurred, or whether there have been multiple changes of control since our formation, due to the significant complexity and cost associated with such study. If we have experienced a change of control at any time since its formation, its NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. In addition, since we may need to raise additional funding to finance our operations, we may undergo further ownership changes in the future. If we earn net taxable income, our ability to use

our pre-change NOL carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Risks Relating to Our Business

Our future success is largely dependent on the successful commercialization of A