NovaBay Pharmaceuticals, Inc.
Form 424B5
October 16, 2014

**Filed Pursuant to Rule 424(b)(5)**

**Registration No. 333-180460**

**PROSPECTUS SUPPLEMENT**

**(To the Prospectus Dated May 1, 2012)**

**Common Stock**

We have entered into an At The Market Offering Agreement, or sales agreement, with Ascendiant Capital Markets, LLC, or Ascendiant, relating to shares of our common stock offered by this prospectus supplement and the accompanying prospectus. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $10 million from time to time through Ascendiant as our sales agent.

We have terminated our previous sales agreement with Ascendiant entered into in November 2013 and, accordingly, as a result of the filing of this prospectus supplement, we will no longer offer shares of our common stock under the prospectus supplement we filed on November 14, 2013 in connection with our previous sales agreement with Ascendiant.

Our common stock is listed on the NYSE MKT under the symbol “NBY.” The last reported sale price of our common stock on October 15, 2014 was $0.71 per share.

Sales of our common stock, if any, under this prospectus supplement and the accompanying prospectus may be made in sales deemed to be “at-the-market” equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through the NYSE MKT, the existing trading market for our common stock, sales made to or through a market maker other than on the NYSE MKT or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law. Under the terms of the sales agreement, we may also sell shares to Ascendiant as principal for its own account. Ascendiant is not required to sell any specific number or dollar amount of securities, but will act as a sales agent using commercially reasonable efforts consistent with its

normal trading and sales practices, on mutually agreed terms between Ascendiant and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

The compensation to Ascendiant for sales of common stock sold pursuant to the sales agreement will be 3% of the gross proceeds of any shares of common stock sold under the sales agreement. Other compensation may apply when Ascendiant purchases shares as principal at a price agreed by us and Ascendiant. We have also agreed to reimburse certain expenses of Ascendiant in connection with the sales agreement as further described in the Plan of Distribution section. In connection with the sale of the common stock on our behalf, Ascendiant will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Ascendiant will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Ascendiant with respect to certain liabilities, including liabilities under the Securities Act or the Exchange Act of 1934, as amended, or the Exchange Act.

The market value of our outstanding common equity held by non-affiliates as of August 19, 2014, was approximately $58.7 million, based on 50,779,057 shares of outstanding common stock, of which 47,028,685 shares were held by non-affiliates, and a per share price of $1.25, the closing price on August 19, 2014. As of the date of this prospectus, we have offered and sold securities for aggregate gross proceeds of $9,647,505 pursuant to General Instruction I.B.6. of Form S-3 during the 12 calendar month period that ends on, and includes, the date of this prospectus.

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**Our business and an investment in our common stock include significant risks. Before purchasing our common stock, please review the information under the heading "Risk Factors" beginning on page S-4 of this prospectus supplement, page 6 of the accompanying prospectus, in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, and under similar headings in the other documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus or are filed after the date hereof.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or accompanying prospectus. Any representation to the contrary is a criminal offense.**

Prospectus Supplement dated October 16, 2014.

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**Prospectus Supplement**



**Prospectus**

**ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement is part of a registration statement (No. 333-180460) that we filed with the Securities and Exchange Commission (the "SEC") using a "shelf" registration process. Under the registration statement, we registered the offering by us of common stock, preferred stock, debt securities and warrants for sale from time to time in one or more offerings. This prospectus supplement provides specific information about the offering by us of our common stock under the shelf registration statement. This document is in two parts. The first part is the prospectus supplement, which adds to and updates information contained in the accompanying prospectus. The second part, the accompanying prospectus dated May 1, 2012, including the documents incorporated by reference therein, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference that was filed with the SEC before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in the accompanying prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

Before buying any of the common stock that we are offering, we urge you to carefully read this prospectus supplement and the accompanying prospectus, together with the information incorporated by reference as described under the headings "Where You Can Find More Information" and "Incorporation of Certain Information by Reference" in this prospectus supplement, as well as any free writing prospectus prepared by or on behalf of us or to which we have referred you. These documents contain important information that you should consider when making your investment decision.

We are offering to sell, and are seeking offers to buy, the shares only in jurisdictions where such offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the shares in certain jurisdictions or to certain persons within such jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about and observe any restrictions relating to the offering of the shares and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless the context requires otherwise, all references in this report to "we," "our," "us," the "Company," "NovaBay" and "NovaBay Pharmaceuticals" refer to NovaBay Pharmaceuticals, Inc. and its subsidiaries, and with respect to NovaBay Pharmaceuticals, Inc. 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.

This prospectus supplement and the accompanying prospectus, including the information incorporated by reference into this prospectus supplement and the accompanying prospectus, include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement and the accompanying prospectus, or any related free writing prospectus, are the property of their respective owners.

**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights selected information about our company, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus, in the documents we incorporate by reference and in any free writing prospectus that we have authorized for use in connection with this offering. This summary is not complete and does not contain all the information that you should consider before investing in our common stock. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the "Risk Factors" contained in this prospectus supplement, the accompanying prospectus and the financial statements and notes incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering, before making an investment decision. This prospectus supplement may add to, update, or change information in the accompanying prospectus.*

**Overview**

We are a biopharmaceutical company focused on addressing the unmet therapeutic needs of the global, topical anti-infective market with its two distinct product categories: (1) its advance clinical stage Aganocide® compounds and (2) its three commercial products containing a pure hypochlorous solution, NeutroPhase® for wound care, Advanced i-Lid™ Cleanser for the eye care market, and CelleRx™ for the dermatology market.

***Aganocide Compounds***

Our first-in-class Aganocide compounds, led by auriclosene (NVC-422), are patented, synthetic molecules with a broad spectrum of activity against bacteria, viruses and fungi. Mimicking the mechanism of action that human white blood cells use against infections, Aganocides possess a reduced likelihood that bacteria or viruses will be able to develop resistance, which is critical for advanced anti-infectives. In recognition of NVC-422's first-in-class chemical structure and therapeutic characteristics, The World Health Organization (WHO) approved a new generic nomenclature by which NVC-422 would be universally identified. In February 2013, we announced that the WHO had approved *auriclosene* as the new International Non-Proprietary Name (INN) for NVC-422.

Having demonstrated therapeutic proof-of-concept, these compounds are well suited to treat and prevent a wide range of local, non-systemic infections. We are currently developing our Aganocide compound for two large therapeutic markets:

**Urology** – Statistically-significant and clinically-meaningful results from a Phase 2 clinical study of Auriclosene Irrigation Solution to reduce urinary catheter blockage and encrustation (UCBE) were announced in September 2013. Study CL1001 achieved the study's primary endpoints and showed clear benefits for patients with long-term indwelling catheters. We plan to initiate the next study in fourth quarter of 2014.

**Dermatology** - Partnered with Galderma, a leading dermatology company, we are developing a topical formulation of auriclosene (NVC-422) for treating impetigo, a highly contagious skin infection. In November 2013, NovaBay announced that a Phase 2b clinical study in impetigo, which was managed by Galderma, had been completed. While the study showed that the auriclosene formulation was safe and well tolerated, it did not meet its primary clinical endpoint. Knowledge gained from the two previous impetigo studies is expected to lead to both improvements in the clinical study protocol and an optimized auriclosene formulation in the next Phase 2 study that is currently being planned. NovaBay will be responsible the execution and the cost of the upcoming study, which is expected to be approximately $2 million. Based on the results of this study, we intend to work with Galderma to determine the next steps in the development of topical auriclosene for skin infections.

***Hypochlorous Solution Products***

We have developed a pure form of hypochlorous acid which serves as the active ingredient for its three commercialized products: NeutroPhase® for wound care; Advanced i-Lid™ Cleanser for the eye care market; and CelleRx™ for the dermatology market.

NeutroPhase is an FDA 510(k)-cleared skin and wound cleanser. NeutroPhase contains a patented pure hypochlorous solution which has the potential to be the best suited product on the market 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. Internationally, NeutroPhase is distributed through commercial partners. In January 2012, we entered into an exclusive distribution agreement with Pioneer Pharma Holdings Limited (HK:1345), or Pioneer, a Shanghai-based company, for the distribution of NeutroPhase throughout Asia and mainland China. We recently expanded the agreement with Pioneer so that it includes the licensing rights to CelleRx™ and i-Lid™ Cleanser. We are in the process of securing other partnerships for distribution around the world.

i-Lid Cleanser is an advanced eye lid and lash cleanser. In August 2014, we launched a dedicated i-Lid Cleanser sales force in the United States. Our salespeople are targeting both optometrists and ophthalmologists, explaining why i-Lid Cleanser is a significant advance in the management of “dry eye” and blepharitis. We believe the U.S. market size to be approximately $500 million, and we believe that no other products offering what we believe to be are the unique advantages of i-Lid Cleanser. Importantly, we believe our i-Lid Cleanser is the first non-detergent, non-irritating product to be prescribed for these conditions.

CelleRx is a topical solution specially designed to gently clean and ease discomfort following aesthetic dermatology and plastic surgery procedures. Recently introduced at The Aesthetics Meeting in April 2014, we believe that our CelleRx product will be a popular post-procedure product for the aesthetic surgery and dermatology markets.

**Recent Developments**

On August 20, 2014, we announced in a press release that our NVC-422 ophthalmic formulation did not meet the primary or secondary endpoints in a Phase 2 clinical study in patients with adenoviral conjunctivitis. We do not intend to initiate any new studies of NVC-422 for this indication.

On September 3, 2014, we announced in a press release that China’s Food and Drug Administration has cleared NeutroPhase for sale throughout mainland China. We intend to begin shipping NeutroPhase to China in the fourth quarter of 2014 to support Pioneer’s launch of the product in early 2015.

In September 2014, we established an Optometry Advisory Board to help oversee the development, marketing and medical use of i-Lid Cleanser. The five members of the new board are nationally known optometrists who we expect will bring valuable insights regarding our eye care products.

On September 30, 2014, our cash and cash equivalents and short-term investments were $9.1 million.

**Company Information**

We were incorporated under the laws of the State of California on January 19, 2000 as NovaCal Pharmaceuticals, Inc., and subsequently changed our name to NovaBay Pharmaceuticals, Inc. In June 2010, we changed the state in which we are incorporated, which we refer to as the Reincorporation, and are now incorporated under the laws of the State of Delaware.

Our corporate address is 5980 Horton Street, Suite 550, Emeryville, CA 94608, and our telephone number is (510) 899-8800. Our website address is *www.novabaypharma.com*. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this prospectus supplement or the accompanying prospectus, and you should not consider it part of this prospectus supplement or the accompanying prospectus. Our website address is included in this document as an inactive textual reference only.

**The Offering**

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| Common stock offered by us pursuant to this prospectus supplement | Shares of our common stock having an aggregate offering price of up to $10 million. |
| Common stock to be outstanding immediately after the offering | Assuming all $10 million of our common stock are sold at an assumed offering price of $0.71 per share, the last reported sale price of our common stock on the NYSE MKT on October 15, 2014, we would have 64,863,564 shares of common stock outstanding. (1) |
| Manner of Offering | "At-the-market" offering that may be made from time to time through our sales agent, Ascendiant. See "Plan of Distribution" on page S-26. |
| Use of proceeds | We currently intend to use the net proceeds from this offering for working capital and general corporate purposes, including research and development, clinical trials, selling, and general and administrative expenses. See "Use of Proceeds" on page S-24 of this prospectus supplement. |
| NYSE MKT Symbol for our common stock | NBY |
| Risk factors | Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page S-4 of this prospectus supplement and page 6 of the accompanying prospectus. |

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(1) The number of shares of our common stock that will be issued and outstanding immediately after this offering as shown above is based on 50,779,057 shares of common stock issued and outstanding as of June 30, 2014, and excludes the following:

- shares of common stock issuable upon the exercise of stock options outstanding, of which there were 7,473,476 outstanding as of June 30, 2014, with a weighted average exercise price of $1.64 per share;

- shares of common stock issuable upon the vesting of outstanding restricted stock units, of which there were 74,950 outstanding as of June 30, 2014;

shares of common stock issuable upon the exercise of our outstanding warrants, of which there were warrants outstanding as of June 30, 2014, to purchase 1,225,000 shares of common stock at an exercise price of $2.75 per share, 3,465,505 shares of common stock at an exercise price of $1.33 per share, 30,000 shares of common stock at an exercise price of $2.50 per share, 30,000 shares of common stock at an exercise price of $3.75 per share, and 1,400,000 shares of common stock at an exercise price of $1.56 per share, and 15,000 shares of common stock at an exercise price of $2.50 per share; and

1,313,995 common stock not subject to stock awards and reserved for issuance under our equity incentive plans.

**RISK FACTORS**

*Any investment in our securities involves a high degree of risk, including the risks described below and in the section titled "Risk Factors" contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 6, 2014, as amended, and our Quarterly Report on Form 10-Q filed with the SEC on July 31, 2014, which are incorporated by reference herein (collectively, our "Reports"). Before purchasing our common stock, you should carefully consider the risk factors set forth below and in our Reports as well as all other information contained in this prospectus supplement and the accompanying prospectus and incorporated by reference, including our consolidated financial statements in our Reports and any free writing prospectus that we have authorized for use in connection with this offering. The risks and uncertainties described below and in our Reports are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the risks described below or in our Reports actually occur, our business, financial condition and results of operations could suffer. As a result, the trading price of our stock could decline, perhaps significantly, and you could lose all or part of your investment. The risks discussed below and in our Reports also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See the section entitled "Special Note Regarding Forward-Looking Statements."*

**Risks Relating to this Offering**

***Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any return for us. Our failure to apply these funds effectively could have a material adverse effect on our business, the commercialization of our product candidates and cause the price of our common stock to decline.

***You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.***

The offering price per share in this offering may exceed the net tangible book value per share of our common stock outstanding prior to this offering. Assuming that an aggregate of 14,084,507 shares of our common stock are sold at a

price of $0.71 per share, the last reported sale price of our common stock on the NYSE MKT on October 15, 2014, for aggregate gross proceeds of $10 million, and after deducting commissions and estimated offering expenses payable by us, you will experience immediate dilution of $0.39 per share, representing the difference between our as adjusted net tangible book value per share as of June 30, 2014, after giving effect to this offering and the assumed offering price. The exercise of outstanding stock options and warrants will result in further dilution of your investment. See the section entitled "Dilution" below for a more detailed discussion of the dilution you will incur if you participate in this offering.

***A substantial number of shares of our common stock may be sold in this offering, which could cause the price of our common stock to decline.***

In this offering we may sell a substantial number of shares of our common stock (up to 14,084,507 shares, or approximately 28% of our outstanding common stock as of June 30, 2014, assuming an offering price of $0.71 per share, the last reported sale price of our common stock on the NYSE MKT on October 15, 2014). This sale and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

***You may experience future dilution as a result of future equity offerings.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering. Additionally, you may incur dilution as a result of grants of equity awards under our equity incentive plans, or upon exercise of options or warrants currently outstanding with exercise prices at or below the public offering price of our common stock in this offering. See the section entitled “Dilution” below for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

***Our share price may be volatile and there may not be an active trading market for our common stock.***

There can be no assurance that the market price of our common stock will not decline below its present market price or that there will be an active trading market for our common stock. The market prices of biotechnology companies have been and are likely to continue to be highly volatile. Fluctuations in our operating results and general market conditions for biotechnology stocks could have a significant impact on the volatility of our common stock price. We have experienced significant volatility in the price of our common stock. From January 1, 2012, through October 15, 2014, the share price of our common stock has ranged from a high of $2.03 to a low of $0.69 Factors contributing to such volatility include, but are not limited to:

results of preclinical studies and clinical trials;

information relating to the safety or efficacy of products or product candidates;

developments regarding
regulatory filings;

announcements of new collaborations;

failure to enter into collaborations;

developments in existing collaborations;

our funding requirements and the terms of our financing arrangements;

technological innovations or new indications for our therapeutic products and product candidates;

introduction of new products or technologies by us or our competitors;

sales and estimated or forecasted sales of products for which we receive royalties, if any;

government regulations;

developments in patent or other proprietary rights;

the number of shares issued and outstanding;

the number of shares trading on an average trading day;

announcements regarding other participants in the biotechnology and pharmaceutical industries; and

market speculation regarding any of the foregoing.

**Risks Relating to our Business**

***Our future success is largely dependent on the successful commercialization of i-Lid Cleanser, CelleRx, and NeutroPhase.***

The future success of our business is largely dependent upon the successful development and commercialization of i-Lid Cleanser, CelleRx, and NeutroPhase. We are dedicating a substantial amount of our resources to advance i-Lid Cleanser, CelleRx, and NeutroPhase as aggressively as possible over the next twelve months. If we encounter difficulties in the commercialization of i-Lid Cleanser, CelleRx, and NeutroPhase, we will not have the resources necessary to continue our business in its current form. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to successfully commercialize our products. We believe we have created an efficient commercial organization, taking advantage of outsourcing options where prudent to maximize the effectiveness of our commercial expenditures. However, we may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution necessary to be successful. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Such expenses may be disproportionate compared to the revenues we may be able to generate on sales of i-Lid Cleanser, CelleRx, and NeutroPhase. If this occurs, it will have an adverse impact on operations and ability to fund any ongoing clinical trials.

***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.***

As of September 30, 2014, we had cash and cash equivalents and short-term investments of $9.1 million, which we believe is sufficient to fund our operations through at least the next twelve months at our current level of spending. While we have reduced our staff levels and reduced both our research and general expenditures, we expect our capital outlays and operating expenditures to increase over at least the next several years as we expand our clinical and regulatory activities as well as expand our sales activities with respect to i-Lid Cleanser. Conducting clinical trials is very expensive, and we expect that we will need to raise additional capital, through future private or public equity offerings, strategic alliances or debt financing, before we achieve commercialization of auriclosene, our primary Aganocide compound, or any of any of our other Aganocide compounds. In addition, we may require even more significant capital outlays and operating expenditures if we do not continue to partner with third parties to develop and commercialize our products.

Our future capital requirements will depend on many factors, including:

- the extent to which we receive milestone payments or other funding from corporate partners, if any;

the scope, rate of progress and cost of our pre-clinical studies and clinical trials and other research and development activities;

future clinical trial results;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the cost and timing of regulatory approvals;

the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

the effect of competing technological and market developments;

the costs associated with marketing and selling i-Lid Cleanser, CelleRx, and NeutroPhase;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Additional financing may not be available on favorable terms, or at all. Our ability to obtain additional financing may be negatively affected by the recent volatility in the financial markets, as well as the general downturn in the economy and decreased consumer confidence. Even if we succeed in selling additional securities to raise funds, our existing stockholders' ownership percentage would be diluted and new investors may demand rights, preferences or privileges senior to those of existing stockholders. If we raise additional capital through strategic alliance and licensing arrangements, we may have to trade our rights to our technology, intellectual property or products to others on terms that may not be favorable to us. If we raise additional capital through debt financing, the financing may involve covenants that restrict our business activities.

In addition, it is often the case that the cost of pharmaceutical development can be significantly greater than initially anticipated. This may be due to any of a large number of possible reasons, some of which could have been anticipated, while others may be caused by unpredictable circumstances. A significant increase in our costs would cause the amount of financing that would be required to enable us to achieve our goals to be likewise increased.

If we determine that we need to raise additional funds and we are not successful in doing so, we may be unable to complete the clinical development of some or all of our product candidates or to seek or obtain FDA approval of our product candidates. Such events could force us to discontinue product development, enter into a relationship with a strategic partner earlier than currently intended, reduce sales and marketing efforts or forego attractive business opportunities.

***We are an early stage company with a history of losses and expect that we will incur net losses in the future, and that we may never achieve or maintain sustained profitability.***

We have incurred net losses each year since our inception through June 30, 2014, with the exception of 2009. For the years ended December 31, 2013, 2012 and 2011, we had net losses of approximately $16.0 million, $7.0 million and $5.1 million, respectively. For the six months ended June 30, 2014 we have net losses of approximately $6.5 million. We were able to record a profit in 2009 due to our receipt of a $3.75 million milestone payment under our agreement with Galderma; however, there is no assurance that we will receive any additional large milestone payments under this or any other agreement and, as a result, may not be able to achieve or maintain profitability in the future. Through June 30, 2014, we had an accumulated deficit of approximately $62.9 million. We have been, and expect to remain for the foreseeable future, engaged in research and development. We have incurred substantial research and development expenses, which were approximately $12.5 million, $9.3 million and $9.9 million for the years ended December 31, 2013, 2012 and 2011, respectively and $4.8 million for the six months ended June 30, 2014. We expect to continue to make, for at least the next several years, significant expenditures for the development of products that incorporate our Aganocide compounds, as well as continued research into the biological activities of our Aganocide compounds, which expenditures are accounted for as research and development expenses. We also expect to incur substantial marketing and sales expenses as we have just recently launched i-Lid Cleanser. We expect to incur substantial losses for the foreseeable future, and we may never achieve or maintain sustained profitability. We anticipate that our expenses related to our clinical trials and regulatory activities will increase substantially in the foreseeable future as we:

conduct pre-clinical studies and clinical trials for our product candidates in different indications;

develop, formulate, manufacture and commercialize our product candidates either independently or with partners;

pursue, acquire or in-license additional compounds, products or technologies, or expand the use of our technology;

maintain, defend and expand the scope of our intellectual property; and

hire additional qualified personnel.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully market and sell our products, or develop, obtain regulatory approval for and commercialize auriclosene, 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.

***We have limited data on the use of some of our products in humans and will need to perform costly and time consuming clinical trials to bring our products to market.***

Much of the data that we have on our auriclosene compound is from in-vitro (laboratory) studies, in-vivo animal studies, Phase 1 human safety studies, or some small-scale Phase 2a or other exploratory clinical studies. We will need to conduct additional Phase 2 and Phase 3 human clinical trials to confirm such results in larger patient populations to obtain approval from the FDA of our Aganocide drug product candidates. Often, positive in-vitro, in-vivo animal studies, or early human clinical trials are not followed by positive results in later clinical trials, and we may not be able to demonstrate that our Aganocide product candidates are safe and effective for indicated uses in humans or that they are active against antibiotic resistant microbes, do not allow pathogens to develop resistance or are active against bacteria in biofilm. In addition, for each indication, we estimate that it will take between three and five years to conduct the necessary clinical trials. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved Aganocide product for commercialization or achieve sales or profits.

***If we are unable to develop and obtain regulatory approval for our Aganocide compounds, we may never generate product revenues from our Aganocide compounds.***

To date, our revenues have been derived mainly from research and development collaboration and license agreements. We have not yet generated any substantial revenue from i-Lid Cleanser and CelleRx. We have generated only limited revenues from sales of NeutroPhase, and we cannot guarantee that we will ever be able to generate substantial revenue from i-Lid Cleanser, CelleRx or NeutroPhase. Our Aganocide compounds are still in development and we will not be able to generate commercial revenue from the sale of these product candidates until we have received regulatory approval for them. Satisfaction of all regulatory requirements applicable to our product candidates typically takes many years, is dependent upon the type, complexity, novelty and classification of the product candidates, and requires the expenditure of substantial resources for research and development and testing. We must demonstrate that our product candidates satisfy rigorous standards of safety and efficacy before we can submit for and gain approval from the FDA and regulatory authorities in other countries. In addition, to compete effectively, our products will need to be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. We cannot be certain that the clinical development of any of our current product candidates or any other product that we may develop in the future will be successful, that they will receive the regulatory approvals required to commercialize them, or that any of our other in-licensing efforts or pre-clinical testing will yield a product suitable for entry into clinical trials. For example, in August 2014 we announced that our ophthalmic formulation of auriclosene did not meet the primary or secondary endpoints in a Phase 2 clinical study in patients with adenoviral

conjunctivitis, and that we do not intend to initiate any new studies of auriclosene for this indication. Our commercial revenues from sales of Aganocide products will be derived from sales of products that may not be commercially available for at least the next several years. If we are unable to successfully advance or develop our Aganocide compounds, it will have a material adverse effect on our business.

***We have three commercialized products, i-Lid Cleanser, CelleRx and NeutroPhase, and if these products do not gain market acceptance, our business will suffer.***

A number of factors may affect the market acceptance of i-Lid Cleanser, CelleRx and NeutroPhase, or any other products we develop or acquire, including, among others:

- the price of our products relative to other products for the same or similar treatments;
- the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our products for their indicated applications and treatments;