NovaBay Pharmaceuticals, Inc.
Form 10-K
March 14, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
xANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012

OR

o 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.)

5980 Horton Street, Suite 550, Emeryville CA 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 o No x

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 o No x

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 x No o

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 x No o

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. o

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	o	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	x

(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 o No x

As of June 30, 2012, 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 $31,214,233. This figure excludes an aggregate of 4,184,161 shares of common stock held by officers and directors as of June 30, 2012. 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 11 2013, there were 36,994,053 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2013 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

NOVABAY PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012

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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.

NovaBay®, NovaBay Pharma®, AgaNase®, Aganocide®, NeutroPhase®, AgaDerm®, and Going Beyond AntibioticsTM are trademarks of NovaBay Pharmaceuticals, Inc. All other trademarks and trade names are the property of their respective owners.

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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, competition, 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 inte 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 this report 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 in this report and have filed as exhibits to the report completely 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 look at notation for Pioneer – should not be collaboration

NovaBay Pharmaceuticals is a clinical-stage biotechnology company focused on addressing the large unmet therapeutic needs of the global anti-infective market with its two distinct categories of products, Aganocides® and NeutroPhase®.

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 (the Reincorporation), and are now incorporated under the laws of the State of Delaware. All references to "we," "us," "our," or "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.

Aganocide® Compounds
NovaBay's 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 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, NovaBay announced that WHO had approved auriclosene as the new International Non-Proprietary Name (INN) for NVC-422.

Having demonstrated therapeutic proof-of-concept in three Phase 2 clinical studies, these compounds are well suited to treat and prevent a wide range of local, non-systemic infections. NovaBay is currently focused in three large therapeutic markets:

- Dermatology - Partnered with Galderma, a leading dermatology company, the companies are developing a gel formulation of auriclosene (NVC-422) for treating the highly contagious skin infection, impetigo. A global Phase 2b clinical study is currently underway with results expected to be available in the second half of 2013.

- Ophthalmology - NovaBay is developing an eye drop formulation of auriclosene (NVC-422) for treating adenoviral conjunctivitis, for which there is currently no FDA-approved treatment. The company expects to complete a global Phase 2b clinical study for this indication in the second half of 2013. The company expects to initiate a proof-of-concept study for bacterial conjunctivitis in the second quarter of 2013 with the same auriclosene (NVC-422) formulation.

- Urology – NovaBay's urinary catheter irrigation solution containing auriclosene (NVC-422) is currently in Phase 2 clinical studies, with the goal of reducing the incidence of urinary catheter blockage and encrustation (UCBE) and the associated urinary tract infections. The company reported positive data from Part A of this study and expects to announce interim top-line results from Part B of this study in the second quarter of 2013.

NeutroPhase®

NovaBay has developed NeutroPhase, which is a different class of molecule from the Aganocides. NeutroPhase is an FDA 510(k)-cleared Skin and Wound Cleanser. With a distinct mechanism of action from Aganocides, NeutroPhase is a patented pure hypochlorous acid solution and has the potential to be best suited 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.

NovaBay has begun securing commercial partnerships for NeutroPhase. In January 2012, NovaBay announced it had entered into a strategic marketing agreement for China with Pioneer Pharma Co., Ltd., a Shanghai-based company that markets high-end pharmaceutical products into China. In September 2012, the collaboration with Pioneer Pharma was expanded to include other Asian markets, excluding S. Korea and Japan. NovaBay expects to announce additional marketing agreements in select geographic markets around the world during 2013.

Our Technology and Research

In 2002, the World Health Organization predicted that within ten years we will enter a “post-antibiotic” era, where there will be infections for which there will be no effective antibiotic treatments. This prediction is proving to be true as there are now more multi-drug resistant bacteria (Superbugs) appearing, and even a few pan-resistant species. Antibiotic compounds are naturally produced by microorganisms for billions of years as a way to defend against other invasive microorganisms. The 1st commercially available antibiotic, Penicillin was discovered by Sir Alexander Fleming in 1928. He found that the juice generated in certain molds killed Staph bacteria. This ushered the golden age of antibiotics, leading to synthesis and isolation of over 150 antibiotics. Within 20 years of wide use of penicillin, penicillin resistant staph had reached 80%. It is of no surprise that all of our 150 antibiotic have shown resistance to one or more bacteria. After all, bacteria have dealt with antibiotic assault for billions of years. They have adapted, survived and thrived and will continue to do so in the future. Many of the animal species including mammals with circulatory systems have evolved to be able to protect themselves by developing a unique series of molecules that are based on the chemistry of Chlorine, such as chlorotaurines. Over millions of years, no resistant has been seen with the class of compounds. Aganocide compounds being developed by NovaBay are a synthetic analog of this evolutionary compound produced by mammal’s innate immune systems.

The more antibiotics are thrown into the environment, the more resistance will be generated and reported. NovaBay’s Aganocide compound have the potential of replacing a number of topical non-systemic antibiotics, hence reducing selective pressure put on bacteria in the environment.

Furthermore sub-lethal exposure of antibiotic to pathogen produces a rapid rise to resistance after several passages, while in established peer reviewed passage studies, no such resistance can be developed to our lead Aganocide, auriclosene (NVC-422). All antibiotics will develop resistance at different rates. Aganocides, by virtue of their novel mechanism of action, are unlikely to develop resistance. We have subjected our lead compound auriclosene (NVC-422) to such serial passage with a number of pathogens and have confirmed that no resistance develops even after many passages. As expected, antibiotics tested in parallel all developed resistance.

In preclinical studies, the Aganocide compounds have demonstrated efficacy against bacteria in biofilm. Biofilm is a cocoon-like shield that forms around a colony of bacteria. Once the biofilm is formed, bacteria go into dormancy. Dormant bacteria in biofilm reproduce slowly and are protected from attack by the body’s killer cells by their biofilm shield. We now understand that biofilm is a natural, ever present defense mechanism of bacteria. Single free floating bacteria are much easier to kill than colonies consisting of millions of bacteria as found in biofilm. Antibiotics are generally more effective against fast reproducing bacteria as opposed to bacteria colonized in biofilm. We continue to expand our understanding of Aganocide action on biofilm. In controlled laboratory studies,

our Aganocide compounds were found to be effective at killing bacteria in biofilm. Furthermore, in animal studies our Aganocide compounds have been found to be more effective against biofilm colonization than mupirocin, a widely used topical antibiotic. We believe efficacy of Aganocide compounds in biofilm would be an important property that may contribute to their utility in many commercial applications.

Our Business Segments

Beginning in 2012, we began reporting our financial data for four reportable segments, coinciding with our four business units: dermatology, ophthalmology, urology and wound care. For financial information regarding our business segments, see Note 13 of the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report.

Our Target Indications and Product Candidates

Our goal is to advance our product candidates through confirmatory Phase 2 proof of concept trials, after which we will evaluate further advancing each program on our own or entering a co-development collaboration or licensing agreement with a proven market leader. In the event that we enter into a co-development collaboration or licensing agreement with a proven market leader, this strategy provides the benefit of their product development expertise and proven commercial capabilities. In these collaborations, our strategy has been to defray the development costs while retaining participation in the long-term commercial economics of our products. This strategy enhances our probability of success in product and commercial development. In many instances, we believe we can build upon the safety data generated in one indication to accelerate early development of other indications. We are also learning from our own and our partners' experience in developing appropriate formulations and usage of our compounds. The more development programs that are undertaken by our partners and by us, the greater product development synergy we expect to achieve.

By virtue of their anti-microbial versatility, the Aganocide compounds offer NovaBay an opportunity to potentially address a wide variety of topical, non-systemic indications in large, underserved markets. Topical indications include treatment and prevention of infections on any surface that may harbor pathogens, such as skin, bladder, sinus, ears, lungs, the eye, as well as medical devices such as catheters. We are currently focusing on four major market opportunities: ophthalmology, dermatology, urology and hospital infections. Our strategy is to build four distinct business units around these markets in the years to come.

Ophthalmology

Based on the findings in the Phase 2a study announced in May 2011, NovaBay is continuing the clinical development of auriclosene (NVC-422) by conducting a global Phase 2b clinical trial in adenoviral conjunctivitis. Enrollment into this study began in the U.S. during May 2012, in India during December 2012 and will begin in Brazil during the first quarter 2013.

NovaBay is using top-tier contract research organizations (CROs) to manage the trial: Quintiles Research Ltd. (India), Chiltern International (Brazil) and Symbio, LLC (United States).

Globally, adenoviral conjunctivitis remains a significant unmet medical need across all ocular infections. NovaBay believes auriclosene (NVC-422) could represent a significant advancement in the treatment of this condition, particularly in treating sight-threatening epidemic keratoconjunctivitis, or EKC.

In view of the fact that auriclosene (NVC-422) possesses potent in vitro anti-bacterial activity in addition to its potent in vitro anti-viral activity, NovaBay plans to conduct a proof-of-concept bacterial conjunctivitis clinical study beginning during the second quarter of 2013.

Dermatology

We are focused on developing products that will potentially eliminate the need to use antibiotic-based products in the dermatology market. Our technology goes beyond antibiotics: we are focused on developing non-antibiotic anti-microbial products which would be effective against drug-resistant pathogens. As resistance to antibiotics becomes a critical public health issue, NovaBay intends to aggressively pursue the development of non-antibiotic anti-microbials that are unlikely to cause resistance, as a first-line treatment for a range of topical infections.

Galderma Collaboration

On March 25, 2009, we entered into a collaboration and license agreement with Galderma S.A. to develop and commercialize our Aganocide compounds, which covers acne and impetigo and potentially other major dermatological conditions, excluding onychomycosis (nail fungus), orphan drug indications and most post surgical use and use in wound care. We amended this agreement in December 2009 and again in December 2010. Based on the Impetigo Phase 2a clinical trial results, in December 2010, NovaBay and Galderma S.A., agreed to expand their partnership to focus on the development of NovaBay's Aganocide compound auriclosene (NVC-422) for the topical treatment of impetigo. This expansion is intended to provide NovaBay with the additional funding and resources required for the clinical development of its auriclosene (NVC-422) proprietary topical formulation for impetigo and other topical infections. Galderma is currently evaluating auriclosene (NVC-422) in a global Phase 2b clinical study, with the potential to move into Phase 3 development in 2014.

The 2nd amendment of the distinguished the territory for impetigo and other collaboration products. Galderma has exclusive and worldwide jurisdiction over impetigo products with the exception of the Middle East and worldwide exclusive jurisdiction for other collaboration products with the exception of the Middle East and the Asia Pacific, as described in the next paragraph.

Galderma is responsible for the development costs of product candidate compounds, except for costs incurred in Japan. In Japan, Galderma has the option to request that we share such development costs. Under the original agreement, we were supporting the ongoing development program for impetigo; however under the second amendment, entered into on December 2, 2010, Galderma has exercised its option and increased its support to cover the cost of development for this indication. Upon the achievement of a specified milestone, Galderma will reimburse NovaBay for specified, previously incurred expenses related to the development of the impetigo program and Galderma has reimbursed the expenses in September 2012 NovaBay retains the right to co-market products resulting from the agreement in Japan. In addition, NovaBay has retained all rights to co-promote the products developed under the agreement in hospitals and other healthcare institutions in North America.

From the inception of the agreement to December 31, 2012, we have received $21.5 million from Galderma including a technology access fee, continuation fee, milestone payments and research and development funding. NovaBay has the potential to receive up to $62.0 million in predetermined fees, including milestones and personnel reimbursement, with additional funding available to cover product and clinical development. We are entitled to royalties ranging from 10% to 30% on cumulative net sales of products once commercialized, subject to some reductions based on any development costs incurred directly by Galderma. Upon the termination of the agreement under certain circumstances, Galderma will grant NovaBay certain technology licenses which would require NovaBay to make royalty payments to Galderma for such licenses with royalty rates in the low- to mid-single digits.

Impetigo

Impetigo is a highly contagious superficial bacterial infection of the skin that affects mostly children. Most cases are caused by Staphylococcus aureus, Streptococcus pyogenes, or a mixture of both organisms. Methicillin-resistant S. aureus (MRSA) is being observed with increasing frequency in this population. Impetigo is currently being treated with antibiotic ointments, though reports of drug resistant bacteria in Impetigo are increasing.

Under the terms of the second amendment to the agreement with Galderma, for the research and development of impetigo and acne, Galderma has exercised its option to advance the clinical development of the impetigo program and paid a $3.25 million continuation fee together with additional research and development funding through the development of the program.

We believe that there is a significant market for the treatment of impetigo, with approximately 13 million prescriptions for the treatment of impetigo annually in US, Europe, Japan and Brazil, and 1.3 million prescriptions in the U.S. alone.

Urology

It is estimated that there are greater than 300,000 chronically catheterized patients in the U.S. alone. Auriclosene (NVC-422) catheter irrigation solution may provide significant clinical benefit by reducing the risk of complications associated with UCBE, thereby greatly enhancing the quality of life for patients and their caregivers.

Previously, NovaBay announced positive results from a Phase 2a clinical study of its irrigation solution containing auriclosene (NVC-422), the company's lead Aganocide compound. Auriclosene demonstrated activity against uropathogens that form biofilm on urinary catheter surfaces and can cause UCBE due to formation of bladder stones and crystals that block the catheter. These results were supported recently by interim data from a Phase 2 clinical study, which demonstrated preliminary proof of concept for auriclosene catheter irrigation solution in preventing UCBE and maintaining catheter patency.

Part 2 of the Phase 2 study is currently underway, with interim top-line results expected in the second quarter of 2013. Part 2 uses a more potent formulation, which could reduce the number of required catheter irrigations from the current standard of care of 14 to 21 per week to only 2 treatments per week.

NovaBay is evaluating the potential of building a commercial team in the U.S. to market this product along with other complementary products for the urology and neurology markets. NovaBay believes that the potential market for the treatment of spinal cord injury patents with bacterial colonization of the catheter and bladder, specifically Proteus mirabilis infections, may be approximately $180 million annually.

Advanced Wound Care

NovaBay has begun marketing its FDA-cleared NeutroPhase skin and wound cleanser for the chronic non-healing wound market, which represents a promising worldwide commercial opportunity. Potential applications for NeutroPhase that are covered by its three FDA 510(k) clearances include diabetic ulcers, venous stasis ulcers and pressure ulcer stages I-IV as well as surgical wounds and burns. NovaBay's marketing strategy for NeutroPhase is to collaborate with wound care companies with optimal infrastructure to maximize its commercial potential in each territory around the world.

In January 2012, NovaBay announced it had entered into a distribution agreement with Pioneer Pharma Co. Ltd., with a value of up to $1.3 million in pre-commercialization milestones related to the launch of NeutroPhase in mainland China, excluding Hong Kong, Macau and Taiwan. The agreement is for a term of five years and thereafter may be renewed for additional five years. The collaboration with Pioneer Pharma was expanded in September 2012 to include the Asian markets, Hong Kong, Macau, Taiwan, Singapore, Malaysia, Indonesia, Myanmar, Philippines, Thailand, Vietnam, Brunei, Cambodia and Laos. Pioneer Pharma has access to 7,500 hospitals and 40,000 pharmacies with over 1,000 sales representatives. NovaBay is actively pursuing additional partnerships in other territories.

The cost of treating chronic wounds is estimated at $5 billion to $7 billion in the U.S., and the occurrence of these wounds is increasing at a rate of 10% per year. NovaBay is currently seeking commercial partners for NeutroPhase to cover the North and South American, European, African, Middle Eastern, S. E. Asian, Australia /New Zealand and Japanese markets.

Research and Development

As of December 31, 2012, we had 18 employees dedicated to research and development. Our research and development expenses consist primarily of personnel-related expenses, laboratory supplies and contract research services provided to our research, development and clinical groups. We expense our research and development costs as they are incurred. Research and development expenses for 2012, 2011 and 2010 were $9.3 million, $9.9 million, and $8.6 million, respectively. All of our research and development employees are engaged in drug research and development activities, including those related to the Galderma agreement as described above. We expect to incur significant research and development expenses for the foreseeable future.

Intellectual Property

We rely on a combination of patent, trademark, copyright and trade secret laws in the U.S. and other jurisdictions, as well as confidentiality procedures and contractual provisions, to protect our proprietary technology. We also enter into confidentiality and invention assignment agreements with our employees and consultants and confidentiality agreements with other third parties, and we rigorously control access to our proprietary technology.

We are the assignee of record of five (5) issued patents in the U.S. and twenty-one (21) issued patents in foreign countries. In addition to our issued patents, we own or co-own thirteen (13) patent applications in various stages of prosecution in the U.S. and thirty-five (35) applications pending in foreign countries and regions including Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Mexico, Singapore, South Korea, Taiwan, New Zealand, South Africa, and Japan. Additional applications will enter the foreign national phase once they pass through the international phase of the Patent Cooperation Treaty.
The subject matter of our patents and patent applications covers four types of technologies: methods relating to the manufacture and use of our hypochlorous acid solution NeutroPhase (NVC-101), compositions of matter of our Aganocide compounds, methods of treating or preventing microbial ailments utilizing NeutroPhase and/or our Aganocide compounds, and formulations. In April of 2009 we entered into an exclusive worldwide license to certain patent applications relating to methods of use of N-chlorotaurine. These applications are pending in the U.S. and abroad.

U.S. Patent No. 6,424,066 provides coverage for a method of treating burns or promoting wound healing, tissue repair or tissue regeneration using a specific range of formulations of hypochlorous acid. This patent was issued on July 30, 2002, and will expire on January 12, 2020, with payment of maintenance fees. Corresponding patents have been issued in Australia, China, India, Israel, Hong Kong, Mexico and South Korea. U.S. Patent No. 7,393,522 provides coverage for a method of disinfecting open wounds and burns, promoting wound healing or providing ocular

disinfection using a specific range of formulations of hypochlorous acid. This patent was issued on July 1, 2008, and will expire on October 27, 2020, with payment of maintenance fees.

U.S. Patent No. 7,462,361 provides composition-of-matter coverage of our lead development candidate, auriclosene (NVC-422), and other Aganocide compounds. This patent was issued on December 9, 2008, and will expire on August 17, 2024, with payment of maintenance fees. U.S. Patent No. 7,893,109 is a continuation application of U.S. Patent No. 7,462,361 and provides composition-of-matter coverage of additional N,N-dichloroamine compounds related to auriclosene (NVC-422). This patent was issued on February 22, 2011, and will expire in 2024. Corresponding patents were issued in Australia, Canada, Japan, Singapore, Taiwan, New Zealand, China, India, Korea and Mexico. Corresponding applications are pending in Argentina, Brazil, Europe, Hong Kong, and Israel.

U.S. Patent No. 7,846,971 provides composition-of-matter coverage of additional Aganocide compounds. This patent was issued on December 7, 2010, and will expire on January 25, 2026, with the payment of maintenance fees. Corresponding patents have been issued in Singapore, Australia, and South Africa and corresponding applications are pending in, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Mexico, and Taiwan.

NovaBay®, NovaBay Pharma®, AgaNase®, Aganocide®, AgaDerm® and NeutroPhase® are registered U.S. trademarks of NovaBay Pharmaceuticals, Inc. In addition to the U.S. registrations, NovaBay is registered in the European Community, Israel, Mexico, Australia, Canada and Brazil while an additional application is pending in India; AgaNase is registered in the European Community, Australia, Canada, Israel, Japan, Mexico, India, China, South Korea, and Taiwan and a application pending in Brazil; NeutroPhase is registered in Australia, the European Community, India, Great Britain and Northern Ireland and the United Kingdom and applications are pending in Canada and China; and Aganocide is registered in the European Community and Japan. Applications for registration of the trademarks Baynovation, Dermnovation, Urovation, OmniPhase, Phase One and Going Beyond Antibiotics™ are pending in the U.S.

Competition

The market for topical, non-systemic anti-infective drugs is highly competitive. If developed, and commercialized, our Aganocide products would compete against a wide variety of existing products, products and technologies that are currently in development, and products and technologies that could be developed and reach the market before or after our products. In particular, we would be competing against existing topical antibiotics and anti-infective products that are sold by many major pharmaceutical companies, or generic equivalents that are being distributed, typically at low prices.

NeutroPhase is competing in a crowded skin and wound cleanser market with many old and low priced products with similar indications for use. However, we believe there is currently no dominant product in this indication.

Potential competitors for our Aganocides and for NeutroPhase include large and small pharmaceutical and medical device companies, such as Pfizer, Inc., Johnson & Johnson, Abbott Grp. Plc., GlaxoSmithKline Plc, Sanofi-Aventis SA, Novartis AG, Smith & Nephew Plc, C.R. Bard, Molnlycke, Lohman and Roucher, Johnson and Johnson, 3M, Puricore and Oculus Innovative Sciences.

We believe the principal competitive advantage of our products in our target markets include their effectiveness in killing bacteria, fungi and viruses, including bacteria in biofilm, very low potential for the development of resistance, fast time to kill bacteria, wide safety margin, low side effect profile and cost effectiveness. We believe that our Aganocide compounds may, if approved by the regulatory authorities, have significant advantages over existing compounds and compounds in development of which we are aware, because our Aganocide compounds could be used to prevent infections or to treat infections with bacterial and viral components such as conjunctivitis.

Manufacturing and Supply

We do not currently operate manufacturing facilities for clinical or commercial production, as we rely on and leverage the manufacturing and distribution infrastructure of third parties. We have no plans to establish our own manufacturing facilities in the future. Third party vendors supply us with the Active Pharmaceutical Ingredient (API) of auriclosene (NVC-422) and the finished clinical trials materials for NeutroPhase, which are required to be manufactured in compliance with the FDA's "Current Good Manufacturing Practice", or CGMP, regulations. NeutroPhase is a medical device and is manufactured for us by third parties that are required to comply with FDA's Quality Systems Regulations (QSR).We also intend to work with third parties for future clinical trial materials and commercial supplies of auriclosene (NVC-422) and our other Aganocide compounds.

The Galderma agreement provides for the manufacture by Galderma of finished dosage forms of products incorporating Aganocide compounds for sale under our label in those markets where we have retained marketing rights.

Sales and Marketing

Our lead Aganocide product candidate, auriclosene (NVC-422), as well as many of the product candidates we expect to develop in the future, is primarily intended to address a variety of different non-systemic, anti-infective market segments, some of which are large, primary care markets. We do not currently have, nor do we intend in the near term to create, a commercialization organization capable of marketing, selling and distributing our targeted product candidates to large, primary care markets. This applies to markets in both the U.S. and elsewhere. Rather, we intend to establish commercialization partnerships with pharmaceutical, biotechnology or other leading organizations with the experience and resources to bring our products to market. In some cases, we may enter into agreements with these organizations during the development stage of a product candidate to further benefit from their clinical development,

regulatory, market research, pre-marketing and other expertise, as is the case with Galderma. In other cases, we may enter into a distribution agreement, as we have done with Pioneer Pharma. As appropriate, we may establish a specialty sales force with expertise in marketing and selling any future approved products to specialty physicians for specific target indications. We may also establish other complementary capabilities related to marketing and selling targeted medicines, particularly where those capabilities may not currently exist at other organizations. In 2012, 2011 and 2010, substantially all of our revenues have been generated from Galderma and Alcon. Following the termination of the agreement with Alcon (located in Switzerland), we rely on Galderma for a significant portion of our revenues for the foreseeable future; Galderma is located in France. Substantially all of our long-lived assets are located in the U.S. Galderma accounted for 91%, 54% and 22% of our revenues, and Alcon accounted for 0%, 46% and 78% of our revenues, in 2012, 2011 and 2010, respectively. Additional information on our revenues, profit and loss and total assets is set forth in our financial statements included in Item 8 of this Annual Report on form 10-K.

Government Regulation

The testing, manufacturing, labeling, advertising, promotion, distribution, export and marketing of our product candidates are subject to extensive regulation by the FDA, state agencies and comparable regulatory authorities in other countries. Because our programs involve product candidates that are considered as drugs and others that are medical devices, we intend to submit applications to regulatory agencies for approval or clearance of both drug and medical device product candidates.

U.S. Government Regulation

In the U.S., the FDA regulates drugs and medical devices under the Federal Food, Drug, and Cosmetic Act and the agency's implementing regulations. If we fail to comply with the applicable U.S. requirements at any time during the product development process, clinical testing, and the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

Our products are classified by the FDA as a drug or a medical device depending upon the mechanism of action and indications for use or claims. NeutroPhase skin and wound cleanser is FDA cleared as a medical device. Preparations of auriclosene (NVC-422) in clinical trials are currently being reviewed by the FDA as drugs.

Drug Approval Process

The process required by the FDA before a drug may be marketed in the U.S. generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies, toxicology and formulation studies all performed in accordance with the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an Investigational New Drug (IND) application for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication; these clinical trials must be conducted in accordance with Good Clinical Practice (GCP) Guidelines, including Institutional Review Board oversight of the consent of subjects and registration of applicable studies with clinicaltrials.gov; clinical trials generally progress through Phase 1, 2 and 3, testing, respectively, initial safety, population and dose finding, and finally, testing of the anticipated commercial dose, formulation and indication at multiple sites in randomized, placebo-controlled studies that must provide replicate evidence of safety and effectiveness;
  - submission to the FDA of a New Drug Application (NDA) including payment of substantial User Fees;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third-parties, at which the product is produced to assess compliance with strictly enforced current GMP regulations, as well as FDA audit for GCP compliance of one or more clinical investigator sites; and
  - FDA review and approval of the NDA before any commercial marketing, sale or shipment of the product.

There is continuing and pervasive FDA regulation of drug product manufacturing, labeling, distribution, advertising and promotion once approved, and approval may be subject to additional required clinical studies or risk evaluation and mitigation strategies, or REMS.

Medical Devices

NeutroPhase is cleared by the FDA as a medical device. Unless an exception applies, each medical device we wish to commercialize in the U.S. will require either prior 510(k) clearance or premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempt from this requirement. Any post-clearance modifications made to a 510(k) device may require the submission of a new 510(k) notification prior to commercialization. Devices deemed by the FDA to pose the greatest risk, such

as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring human clinical study prior to premarket approval. The 510(k) process is undergoing programmatic change at FDA and our ability to obtain 510(k) clearance for future device products may be adversely impacted by such regulatory changes.

Continuing Food and Drug Administration Regulation of Medical Devices

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include:

- the FDA's Quality Systems Regulations (QSRs), which require manufacturers to follow stringent design, testing, production, control, labeling, packaging, storage, shipping, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations which impose restrictions on labeling and promotional activities, and FDA prohibitions against the promotion of products for uncleared, unapproved, or "off-label" uses;

- post-market surveillance requirements which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA Medical Device Reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- notices of correction or removal, and recall regulations.

In addition, we are required to register our facility and list our products with the FDA, and are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services to determine compliance with the QSRs and other regulations, and these inspections may include the manufacturing facilities of our subcontractors.

International Regulation

In addition to being subject to the laws and regulations in the U.S., we will be subject to a variety of laws and regulations in those other countries in which we seek to study and commercialize products. European and Canadian regulatory requirements and approval processes are similar in principle to those in the U.S. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of the European Union, European countries, Canada and other countries before we can commence clinical trials or marketing of the product in those respective countries. The approval process may be longer or shorter than that required for FDA approval. The requirements governing pricing, reimbursement, clinical trials, and to a lesser extent, product licensing vary from country to country.

Third Party Reimbursement and Pricing Controls

In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third party payers, such as government and private insurance plans. Third party payers are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payers. Aganocide products from which we may receive revenue in the future may not be considered cost-effective, and reimbursement may not be available or sufficient to allow these products to be sold on a competitive and profitable basis.

Anti-Kickback and False Claims Laws

In the U.S., we are subject to various federal and state laws pertaining to healthcare “fraud and abuse,” including anti-kickback and false claims laws. The federal Anti-Kickback Law makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, offer, receive or pay any remuneration, directly or indirectly, in exchange for, or to induce, the referral of business, including the purchase, order or prescription of a particular drug or device, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. Violations of the law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the federal Anti-Kickback Law. Some of these state prohibitions apply to referral of patients for healthcare services reimbursed by any source, not only the Medicare and Medicaid programs. Due to the breadth of these laws, it is possible that our future sales and marketing practices or our future relationships with physicians might be challenged under anti-kickback laws, which could harm us.

False claims laws prohibit anyone from knowingly presenting, or causing to be presented, for payment to third party payers (including Medicare and Medicaid) claims for reimbursed items or services, including drugs and medical

devices, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our future activities relating to the reporting of prices for our products, the reporting of Medicaid rebate information and other information affecting federal, state and third party reimbursement of our products, and the sale and marketing of our products, will be subject to scrutiny under these laws. In addition, pharmaceutical and medical device companies have been prosecuted under the federal False Claims Act in connection with their off-label promotion of products. Suits filed under the False Claims Act, known as “qui tam” actions, can be brought by any individual on behalf of the government and such individuals (known as relators or, more commonly, as whistleblowers) may share in the amounts paid by the entity to the government in fines or settlement.

Employees

As of December 31, 2012, we had 26 full-time employees and 4 part-time employees, including 8 with doctoral degrees. Of our workforce, 18 employees were engaged in research and development, and 12 in finance, legal and administration. 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.

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.novabaypharma.com, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (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. 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 not important may also impair our business operations. 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.

Risks Relating to Our Business

Current worldwide economic conditions may limit our access to capital, adversely affect our business and financial condition, as well as further decrease our stock price.

General worldwide economic conditions have continued to be depressed due to the effects of the subprime lending crisis, general credit market crisis, the Greek debt crises and the effects that it has had on the Eurozone, collateral effects on the finance and banking industries, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. Although the impact of the downturn on our business is uncertain at this time, downturn may adversely affect our business and operations in a number of ways, including making it more difficult for us to raise capital as well as making it more difficult to enter into collaboration agreements with other parties. Like many other stocks, our stock price has been subject to fluctuations in recent months. Our stock price could decrease due to concerns that our business, operating results and financial condition will be negatively impacted by a worldwide economic downturn.

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.

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. 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 any of our 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 Galderma, 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 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.

We do not currently have any commitments for future external funding. 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 December 31, 2012, with the exception of 2009. For the years ended December 31, 2012, 2011 and 2010, we had net losses of approximately $7.0 million, $5.1 million and 4.3 million, respectively, and for the year ended December 31, 2009, we had net income of $2.7 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 agreement and, as a result, may not be able to achieve or maintain profitability in the future. Through December 31, 2012, we had an accumulated deficit of approximately $40.3 million. We have been, and expect to remain for the foreseeable future, mostly in a research and development stage as we proceed through clinical trials. We have incurred substantial research and development expenses, which were approximately $9.3 million, $9.9 million and $8.6 million for the years ended December 31, 2012, 2011 and 2010, respectively. 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 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 develop, obtain regulatory approval for and commercialize our drug product candidates, either independently or with partners, we will not be able to generate such revenues or 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 aganocide product candidates 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.

We currently only have one marketable products, and if we are unable to develop and obtain regulatory approval for products that we develop, we may never generate product revenues.

To date, our revenues have been derived mainly from research and development collaboration and license agreements. We have generated limited revenues from sales of NeutroPhase and we cannot guarantee that we will have substantial marketable drugs or other products. 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. 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.

We have one commercialized product, NeutroPhase and if NeutroPhase does not gain market acceptance, our business will suffer.

A number of factors may affect the market acceptance of 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;
- our ability to find the right distributor; and
- the effectiveness of the sales and marketing efforts of our dof our Dright De that we will emaceuticals, Inc. to manufacture NeutroPhase. istributor.

If our products do not gain market acceptance, we may not be able to support funding of our future operations, including developing, testing and obtaining regulatory approval for new product candidates, which would cause our business to suffer.

We have limited experience in developing drugs and medical devices, and we may be unable to commercialize some of the products we develop.

Development and commercialization of drugs and medical devices involves a lengthy and complex process. We have limited experience in developing products and have only one commercialized product in the market. In addition, no one has ever developed or commercialized a product based on our Aganocide compounds, and we cannot assure you that it is possible to develop, obtain regulatory approval for or commercialize any products based on these compounds or that we will be successful in doing so.

Before we can develop and commercialize any new products, we will need to expend significant resources to:

- undertake and complete clinical trials to demonstrate the efficacy and safety of our product candidates;
- maintain and expand our intellectual property rights;
- obtain marketing and other approvals from the FDA and other regulatory agencies; and
- select collaborative partners with suitable manufacturing and commercial capabilities.

The process of developing new products takes several years. Our product development efforts may fail for many reasons, including:

- the failure of our product candidates to demonstrate safety and efficacy;
- the high cost of clinical trials and our lack of financial and other resources; and
- our inability to partner with firms with sufficient resources to assist us in conducting clinical trials.

Success in early clinical trials often is not replicated in later studies, and few research and development projects result in commercial products. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical trials, which would eliminate or adversely impact the timing for revenues from those product candidates. If a clinical study fails to demonstrate the safety and effectiveness of our product candidates, we may abandon the development of the product or product feature that was the subject of the clinical trial, which could harm our business.

Even if we develop products for commercial use, these products may not be accepted by the medical and pharmaceutical marketplaces or be capable of being offered at prices that will enable us to become profitable. We cannot assure you that our products will be approved by regulatory authorities or ultimately prove to be useful for commercial markets, meet applicable regulatory standards, or be successfully marketed.

Our current research collaboration with Galderma may fail, resulting in a decrease in funding and inhibition of our ability to continue developing products.

We have entered into an agreement with Galderma S.A. to develop and commercialize our Aganocide compounds, which covers acne and impetigo and potentially other major dermatological conditions, excluding onychomycosis (nail fungus) and orphan drug indications. With the termination of our collaboration with Alcon, our collaboration with Galderma is our only collaboration, and so unless and until we enter into additional collaborations or are able to market products on our own, we will be dependent on Galderma for all of our revenues.

We cannot assure you that our collaboration with Galderma will be successful, or that we will receive the full amount of research funding, milestone payments or royalties, or that any commercially valuable intellectual property will be created, from this arrangement. If Galderma were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully and in a timely manner, the research contemplated by our collaboration with them could be delayed or terminated and our costs of performing studies may increase.

Our research collaboration with Alcon has ended, which will result in a decrease in funding and may impede our ability to develop our Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions unless we are able to enter into a new collaboration with another collaboration partner.

In June 2011, we and Alcon terminated our collaboration and license agreement. Under the terms of the collaboration and license agreement prior to termination, we received semi-annual payments to support on-going research and development activities over the term of the agreement, which payments were reduced beginning in 2011. During 2010 we received $6.0 million in funding payments from Alcon, and in the first five months of 2011 we received $2.1 million in funding payments from Alcon. We received a payment of approximately $3.0 million in connection with the termination, but will not receive any additional payments from Alcon. As a result, we expect our revenues to be significantly less than we have recognized in previous years. Further, as we continue the development of auriclosene (NVC-422) for application in connection with the eye, ear and sinus and for use in contact lens solutions, we have to fund such development unless we are able to enter into a new collaboration with another collaboration partner, which we may not be able to do. If we are not able to enter into a new collaboration with another collaboration partner and we continue the development of auriclosene (NVC-422) for application in connection with the eye, ear and sinus and for use in contact lens solutions, we will need to rely on our own funds, and any additional funds we may raise. If we are not able to enter into a new collaboration with another collaboration partner or are not able to raise additional funds, we may not be able to develop auriclosene (NVC-422) for these applications.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and if we do enter into collaborations, these collaborations may not be successful. Our current and future success depends in part on our ability to enter into successful collaboration arrangements and maintain the collaboration arrangement we currently have with Galderma. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;
- our shortage of capital resources may impact a willingness on the part of potential companies to collaborate with us;
- our contracts for collaborative arrangements may be terminable for convenience on written notice and may otherwise expire or terminate, and we may not have alternative funding available;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we do not have day-to-day control over the activities of our partners and have limited control over their decisions;
- our ability to receive milestones and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements.

If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our

product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital. Consequently, if we are unable to enter into, maintain or extend successful collaborations, our business may be harmed.

Our long-term success depends upon the successful development and commercialization of other products from our research and development activities.

Our long-term viability and growth will depend upon the successful development and commercialization of other products from our research and development activities. Product development and commercialization is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in early stage clinical trials or preclinical work does not ensure that later stage or larger scale clinical trials will be successful. Even if later stage clinical trials are successful, the risk remains that unexpected concerns may arise from additional data or analysis or that obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with our view of the data or require additional data or information or additional studies.

Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials, and compliance with extensive current good clinical practice requirements. We are in many cases using the services of third-party contract clinical trial providers. If we fail to adequately manage the design, execution and regulatory aspects of our clinical trials, our studies and ultimately our regulatory approvals may be delayed or we may fail to gain approval for our product candidates altogether.

If we do not successfully execute our growth initiatives through the acquisition, partnering and in-licensing of products, technologies or companies, our future performance could be adversely affected.

In addition to our internal development projects, we anticipate growing through external growth opportunities, which include the acquisition, partnering and in-licensing of products, technologies and companies or the entry into strategic alliances and collaborations. If we are unable to complete or manage these external growth opportunities successfully, we may not be able to grow our business in the way that we currently expect. The availability of high quality opportunities is limited and we are not certain that we will be able to identify suitable candidates or complete transactions on terms that are acceptable to us. To pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. The availability of such financing is limited by the recent tightening of the global credit markets.

We may acquire other businesses or form joint ventures or in-license compounds that could disrupt our business, harm our operating results, dilute your ownership interest in us, or cause us to incur debt or significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, and enter into technology or pharmaceutical compound licensing arrangements. We also may pursue strategic alliances that leverage our core technology and industry experience to enhance our ability to commercialize our product candidates and expand our product offerings or distribution. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of commercial partnering agreements, strategic alliances, joint ventures or in-licensing of compounds. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. If we in-license any additional compounds, we may fail to develop the product candidates, and spend significant resources before determining whether a compound we have in-licensed will produce revenues. Any future acquisitions or in-licensing by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for acquisitions by incurring indebtedness. Additional funds may not be available on terms that are favorable to us, or at all.

We do not have our own manufacturing capacity, and we plan to rely on partnering arrangements or third-party manufacturers for the manufacture of our potential products.

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. We have no experience in drug formulation or manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. As a result, we have

partnered and expect to partner with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute product supplies for our clinical trials. Any performance failure on the part of our commercial partners or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and reducing or delaying product revenues.

Our products, if developed and commercialized, will require precise, high quality manufacturing. The failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers and partners often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. These manufacturers and partners are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current Good Manufacturing Practice and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party compliance with these regulations and standards. If any of our manufacturers or partners fails to maintain compliance, the production of our products could be interrupted, resulting in delays, additional costs and potentially lost revenues.

In addition, if the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we will need to manufacture them in larger quantities. Significant scale-up of manufacturing will require validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product, the regulatory approval or commercial launch of any drugs may be delayed or there may be a shortage in supply and our business may be harmed as a result.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on the skills, experience and efforts of our officers, especially our Chief Executive Officer, Chief Financial Officer, Sr. Vice President for Ophthalmic Drug Development, Sr. Vice President for Advanced Wound Care, Chief Alliance Officer and Vice President of Product Development, Vice President of Medical Affairs, Sr. Vice President of Business and Corporate Development and other key employees. The efforts of each of these persons is critical to us as we continue to develop our technologies and as we attempt to transition into a company with commercial products. Any of our officers and other key employees may terminate their employment at any time. The loss of any of our senior management team members could weaken our management expertise and harm our ability to compete effectively, develop our technologies and implement our business strategies.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. Our research and development programs and collaborations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We have also encountered difficulties in recruiting qualified personnel from outside the San Francisco Bay Area, due to the high housing costs in the area.

If we grow and fail to manage our growth effectively, we may be unable to execute our business plan.

Our future growth, if any, may cause a significant strain on our management, and our operational, financial and other resources. Our ability to grow and manage our growth effectively will require us to implement and improve our operational, financial and management information systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management information systems could have a material adverse effect on our business, financial condition, and results of operations.

If our facilities become inoperable, we will be unable to perform our research and development activities, fulfill the requirements under our collaboration agreement and continue developing products and, as a result, our business will be harmed.

We do not have redundant laboratory facilities. We perform substantially all of our research, development and testing in our laboratory located in Emeryville, California. Emeryville is situated on or near active earthquake fault lines. Our facility and the equipment we use to perform our research, development and testing would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and testing for some period of time. The inability to perform our research and development activities may result in the loss of partners or harm our reputation, and we may be

unable to regain those partnerships in the future. Our insurance coverage for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses, including the loss of time as well as the costs of lost opportunities, and may not continue to be available to us on acceptable terms, or at all.

Obtaining regulatory approval in the United States does not ensure we will obtain regulatory approval in other countries.

We will aim to obtain regulatory approval in the U.S. as well as in other countries. To obtain regulatory approval to market our proposed products outside of the U.S., we and any collaborator must comply with numerous and varying regulatory requirements in other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ significantly from that required to obtain FDA approval. The regulatory approval process in other countries includes all of the risk associated with FDA approval as well as additional, presently unanticipated risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects associated with regulatory approval in the U.S., including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product may be marketed. In addition, failure to comply with applicable regulatory requirements in other countries can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution.

If we are unable to design, conduct and complete clinical trials successfully, we will not be able to obtain regulatory approval for our products.

To obtain FDA approval for our drug product candidates, we must submit to the FDA a New Drug Application, or NDA, demonstrating that the product candidate is safe and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials.

Any clinical trials we conduct or that are conducted by our partners may not demonstrate the safety or efficacy of our product candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. Even if the results of one or more of our clinical trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical studies or clinical trials before we can submit NDAs or obtain FDA approvals for our product candidates, and positive results of a clinical trial may not be replicated in subsequent trials.

Clinical trials are very expensive and difficult to design and implement. The clinical trial process is also time-consuming. Furthermore, if participating patients in clinical studies suffer drug-related adverse reactions during the course of such trials, or if we or the FDA believe that participating patients are being exposed to unacceptable health risks, we will have to suspend or terminate our clinical trials. Failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon clinical trials or to repeat clinical studies. Further, because our product candidates are all in the same class of compounds, failure in one clinical trial may cause us or our partners to have to suspend or terminate other clinical trials. For example, if toxicity issues were to arise in one clinical trial, it could indicate that all of our product candidates have toxicity issues.

In addition, the completion of clinical trials can be delayed by numerous factors, including:

- delays in identifying and agreeing on acceptable terms with prospective clinical trial sites;
- slower than expected rates of patient recruitment and enrollment;
- increases in time required to complete monitoring of patients during or after participation in a trial; and
- unexpected need for additional patient-related data.

Any of these delays, if significant, could impact the timing, approval and commercialization of our product candidates and could significantly increase our overall costs of drug development.

Even if our clinical trials are completed as planned, their results may not support our expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our products are safe and effective for indicated uses. Such failure would cause us to abandon a product candidate for some indications and could delay development of other product candidates.

Government agencies may establish usage guidelines that directly apply to our proposed products or change legislation or regulations to which we are subject.

Government usage guidelines typically address matters such as usage and dose, among other factors. Application of these guidelines could limit the use of products that we may develop. In addition there can be no assurance that government regulations applicable to our proposed products or the interpretation thereof will not change and thereby prevent the marketing of some or all of our products for a period of time or permanently. The FDA’s policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. 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.

Our product candidates may be classified as a drug or a medical device, depending on the mechanism of action or indication for use and prior precedent, and a change in the classification may have an adverse impact on our revenues or our ability to obtain necessary regulatory approvals.

Several potential indications for our product candidates may be regulated under the medical device regulations of the FDA administered by the Center for Devices and Radiological Health and the same physical product may be regulated by the FDA's Center for Drug Evaluation and Research for another indication. Alternatively the products could be classified as combination products, in which case both the device and drug centers jointly review the submission. The products may be designated by the FDA as a drug or a medical device depending upon the regulatory definition of a drug and a device, their primary mode of action and the indications for use or product claims.

The use of NeutroPhase as a solution for cleansing and debriding wounds was cleared as a Class I medical device. The determination as to whether a particular indication is considered a drug or a device is also based in part upon precedent. A reclassification by the FDA of an indication from a device to a drug indication during our development for that indication could have a significant adverse impact due to the more rigorous and lengthy approval process required for drugs, as compared to medical devices. Such a change in classification can significantly increase development costs and prolong the time for development and approval, thus delaying revenues. A reclassification of an indication after approval from a drug to a device could result in a change in classification for reimbursement. In many cases, reimbursement for devices is significantly lower than for drugs and there could be a significant negative impact on our revenues.

We and our collaborators are and will be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and which may limit our ability to commercialize our medical device and drug products and candidates.

Any regulatory approvals that we receive may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The FDA may require us to commit to perform lengthy Phase IV post-approval studies, for which we would have to expend additional resources, which could have an adverse effect on our operating results and financial condition. In addition, if the FDA approves any of our drug product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drugs, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drugs or the withdrawal of the drugs from the market. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing any products we may develop and our business could suffer.

Conducting clinical trials of our product candidates may expose us to expensive liability claims, and we may not be able to maintain liability insurance on reasonable terms or at all.

The risk of clinical trial liability is inherent in the testing of pharmaceutical and medical device products. If we cannot successfully defend ourselves against any clinical trial claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our product candidates. Our inability to obtain sufficient clinical trial insurance at an acceptable cost to protect us against potential clinical trial claims could prevent or inhibit the commercialization of our product candidates. Our current clinical trial insurance covers individual and aggregate claims up to $5.0 million. This insurance may not cover all claims and we may not be able to obtain additional insurance coverage at a reasonable cost, if at all, in the future. In addition, if our agreements with any future corporate collaborators entitle us to indemnification against product liability losses and clinical trial liability, such indemnification may not be available or adequate should any claim arise.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages. Compliance with environmental regulations can be expensive, and noncompliance with these regulations may result in adverse publicity and potentially significant monetary damages and fines.

Our activities currently require the controlled use of potentially harmful biological materials and other hazardous materials and chemicals and may in the future require the use of radioactive compounds. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject, on an ongoing basis, to U.S. federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations might be significant and could negatively affect our operating results. In addition, if more stringent laws and regulations are adopted in the future, the costs of compliance with these new laws and regulations could be substantial or could impose significant changes in our testing and production process.

The pharmaceutical and biopharmaceutical industries are characterized by patent litigation and any litigation or claim against us may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation.

There has been substantial litigation in the pharmaceutical and biopharmaceutical industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. For the most part, these lawsuits relate to the validity, enforceability and infringement of patents. Generic companies are encouraged to challenge the patents of pharmaceutical products in the United States because a successful challenger can obtain six months of exclusivity as a generic product under the Hatch-Waxman Act. We expect that we will rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know-how or require us to license such patents and pay significant fees or royalties to produce our products. In addition, future patents may issue to third parties which our technology may infringe. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products may infringe.

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If such a dispute were to be resolved against us, we may be required to pay substantial damages, including treble damages and attorney's fees if we were to be found to have willfully infringed a third party's patent, to the party claiming infringement, develop non-infringing technology, stop selling any products we develop, cease using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent us from selling any products we develop, which could harm our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees may have been previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could severely harm our business.

If product liability lawsuits are brought against us, they could result in costly litigation and significant liabilities.

The product candidates we are developing or attempting to develop will, in most cases, undergo extensive clinical testing and will require approval from the applicable regulatory authorities prior to sale. However, despite all reasonable efforts to ensure safety, it is possible that we or our collaborators will sell products which are defective, to which patients react in an unexpected manner, or which are alleged to have side effects. The manufacture and sale of such products may expose us to potential liability, and the industries in which our products are likely to be sold have been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our collaborators and make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend significant financial and managerial resources.

Failure to obtain sufficient quantities of products and substances necessary for research and development, pre-clinical trials, human clinical trials and product commercialization that are of acceptable quality at reasonable prices or at all could constrain our product development and have a material adverse effect on our business.

We have relied and will continue to rely on contract manufacturers for the foreseeable future to produce quantities of products and substances necessary for research and development, pre-clinical trials, human clinical trials and product

commercialization. It will be important to us that such products and substances can be manufactured at a cost and in quantities necessary to make them commercially viable. At this point in time, we have not attempted to identify, and do not know whether there will be, any third party manufacturers which will be able to meet our needs with respect to timing, quantity and quality for commercial production. In addition, if we are unable to contract for a sufficient supply or required products and substances on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our research and development, pre-clinical and clinical testing would be delayed, thereby delaying the submission of product candidates for regulatory approval or the market introduction and subsequent sales of products. Any such delay may have a material adverse effect on our business, financial condition and results of operations.

Because our clinical development activities rely heavily on sensitive and personal information, an area which is highly regulated by privacy laws, we may not be able to generate, maintain or access essential patient samples or data to continue our research and development efforts in the future on reasonable terms and conditions, which may adversely affect our business.

As a result of our clinical development, we will have access to very sensitive data regarding the patients enrolled in our clinical trials. This data will contain information that is personal in nature. The maintenance of this data is subject to certain privacy-related laws, which impose upon us administrative and financial burdens, and litigation risks. For instance, the rules promulgated by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act, or HIPAA, creates national standards to protect patients' medical records and other personal information in the U.S. These rules require that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health care information of the patient to companies like NovaBay. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (i.e., for use in research and in submissions to regulatory authorities for product approvals). As such, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities, and to ensure such information is used only as authorized by the patient. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity, and could harm our ability to initiate and complete clinical studies required to support regulatory applications for our proposed products. In addition, HIPAA does not replace federal, state, or other laws that may grant individuals even greater privacy protections. We can provide no assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks may prove too great for us to reasonably bear, and may adversely affect our ability to function profitably in the future.

We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.

Our business and future growth depend on the development, use and ultimate 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.

There is a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales and marketing activities may constitute the promotion of our products for a non-FDA-approved use in violation of applicable law. We also face the risk that the FDA or other regulatory authorities might pursue enforcement 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 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 would likely be required to substantially change our sales, promotion, grant and educational activities. In addition, were any enforcement actions against us or our senior officers to arise, we could be excluded from participation in U.S. government healthcare programs such as Medicare and Medicaid.

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.

NovaBay aggressively protects and enforces its patent rights worldwide. However, certain risks remain. There is no assurance that patents will issue from any of our applications or, for those patents we have or that do issue, that the claims will be sufficiently broad to protect our proprietary rights, or that it will be economically possible to pursue sufficient numbers of patents to afford significant protection. For example, we do not have any composition of matter patent directed to the NeutroPhase composition. If a potential competitor introduces a similar method of using NeutroPhase with a similar composition that does not fall within the scope of the method of treatment claims, then we or a potential marketing partner would be unable to rely on the allowed claims to protect its market position for the method of using the NeutroPhase composition, and any revenues arising from such protection would be adversely impacted.

In addition, there is no assurance that any patents issued to us or licensed or assigned to us by third parties will not be challenged, invalidated, found unenforceable or circumvented, or that the rights granted there under will provide competitive advantages to us. If we or our collaborators or licensors fail to file, prosecute 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. The laws of the State prevent 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.

If our competitors develop products similar to NeutroPhase, we may need to modify or alter our business strategy, which may delay the achievement of our goals.

Competitors may develop products with similar characteristics to NeutroPhase. Such similar products marketed by larger competitors can hinder our efforts to penetrate the market. As a result, we may be forced to modify or alter our business and regulatory strategy and sales and marketing plans, as a response to changes in the market, competition and technology limitations, among others. Such modifications may pose additional delays in achieving our goals.

If bacteria develop resistance to Aganocide compounds, our revenues could be significantly reduced.

Based on our understanding of the hypothesis of the mechanism of action of our Aganocide compounds, we do not expect bacteria to be able to develop resistance to Aganocide compounds. However, we cannot assure you that one or more strains of bacteria will not develop resistance to our compounds, either because our hypothesis of the mechanism of action is incorrect or because a strain of bacteria undergoes some unforeseen genetic mutation that permits it to survive. Since we expect lack of resistance to be a major factor in the commercialization of our product candidates, the discovery of such resistance would have a major adverse impact on the acceptability and sales of our products.

If physicians and patients do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Even if the FDA approves product candidates that we develop, physicians and patients may not accept and use them. Acceptance and use of our products may depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- published studies demonstrating the cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of any of our products to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to develop our own sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, or at all, revenues from any products we develop could be disappointing.

We currently have no internal sales, marketing or distribution capabilities. To commercialize any product candidates approved by the FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us, such as Pioneer Pharma Co. Ltd. If we decide to commercialize any products we develop such as NeutroPhase, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations which are capable of successfully launching new products and generating sufficient product revenues. In addition, establishing such operations will take time and involve significant expense.

If we decide to enter into co-promotion or other licensing arrangements with third parties, we may be unable to identify acceptable partners because the number of potential partners is limited and because of competition from others for similar alliances with potential partners. Even if we are able to identify one or more acceptable partners, we may not be able to enter into any partnering arrangements on favorable terms, or at all. If we enter into any partnering arrangements, our revenues are likely to be lower than if we marketed and sold our products ourselves.

In addition, any revenues we receive would depend upon our partners' efforts which may not be adequate due to lack of attention or resource commitments, management turnover, and change of strategic focus, further business combinations or other factors outside of our control. Depending upon the terms of our agreements, the remedies we have against an under-performing partner may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement partner on acceptable terms, or at all.

If we cannot compete successfully for market share against other companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval and are launched they will compete with a number of existing and future drugs, devices and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products are unable to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete for market share against fully integrated pharmaceutical and medical device companies or other companies that develop products independently or collaborate with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, have substantially greater capital resources, larger research and development staffs and facilities, and greater financial resources than we do, as well as significantly greater experience in:

- developing drugs and devices;
- conducting preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of product candidates;
- formulating and manufacturing products; and
- launching, marketing, distributing and selling products.

Our competitors may:

- develop and patent processes or products earlier than we will;
- develop and commercialize products that are less expensive or more efficient than any products that we may develop;
- obtain regulatory approvals for competing products more rapidly than we will; and
- improve upon existing technological approaches or develop new or different approaches that render any technology or products we develop obsolete or uncompetitive.

We cannot assure you that our competitors will not succeed in developing technologies and products that are more effective than any developed by us or that would render our technologies and any products we develop obsolete. If we are unable to compete successfully against current or future competitors, we may be unable to obtain market acceptance for any product candidates that we create, which could prevent us from generating revenues or achieving profitability and could cause the market price of our common stock to decline.

Our ability to generate revenues from any products we develop will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement for our products from healthcare payers.

Our ability to commercialize our product candidates will depend, in part, on the extent to which health insurers, government authorities and other third-party payers will reimburse the costs of products which may be developed by

us or our partners. We expect that a portion of our economic return from partnering arrangements with pharmaceutical companies and other collaborators will be derived from royalties, fees or other revenues linked to final sales of products that we or our partners develop. Newly-approved pharmaceuticals and other products which are developed by us or our partners will not necessarily be reimbursed by third-party payers or may not be reimbursed at levels sufficient to generate significant sales. Government and other third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs or medical devices. Cost control initiatives such as these could adversely affect our or our collaborators' ability to commercialize products. In addition, real or anticipated cost control initiatives for final products may reduce the willingness of pharmaceutical companies or other potential partners to collaborate with us on the development of new products.

Significant uncertainty exists as to the reimbursement status of newly-approved healthcare products. Healthcare payers, including Medicare, health maintenance organizations and managed care organizations, are challenging the prices charged for medical products or are seeking pharmacoeconomic data to justify formulary acceptance and reimbursement practices. We currently have not generated pharmacoeconomic data on any of our product candidates. Government and other healthcare payers increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs and medical devices, and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has or has not granted labeling approval. Adequate third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for our products, market acceptance of our product candidates could be limited.

Health care reform measures could limit the prices we or our collaborative partners can obtain for our potential products, or impose additional costs on us.

In March 2010, the U.S. Congress adopted and President Obama signed into law comprehensive health care reform legislation through the passage of the Patient Protection and Affordable Health Care Act. While we anticipate that this legislation may, over time, increase the number of patients who have insurance coverage for pharmaceutical products, it also imposes cost containment measures that may adversely affect the amount of reimbursement for pharmaceutical products. In addition, such legislation contains a number of provisions designed to generate the revenues necessary to fund the coverage expansion, including new fees or taxes on certain health-related industries.

Many of the details of the new law will be included in new and revised regulations, which have not yet been promulgated, and require additional guidance and specificity to be provided by the Department of Health and Human Services, Department of Labor and Department of the Treasury. Accordingly, while it is too early to understand and predict the ultimate impact of the new legislation on our business, the legislation could have a material adverse effect on our business.

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 results of preclinical or clinical trials relating to our product candidates;
- the announcement of new products by us or our competitors;
- 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 the recent volatility in the financial markets and 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 risk of high volatility.

The number of shares of our common stock being traded may be very low. Any stockholder wishing to sell his/her stock may cause a significant fluctuation in the price of our stock. 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 directors, executive officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2012, our officers and directors collectively controlled approximately 4,465,922 shares of our outstanding common stock (and approximately 7,412,927 shares of our common stock when including options held by

them which were exercisable as of or within 60 days from December 31, 2012). Furthermore, as of December 31, 2012, our largest stockholder is Dr. Ramin Najafi, our Chairman and Chief Executive Officer. Dr. Najafi individually, and through his family trust which he jointly controls with his wife Mrs. Farideh Najafi, owns 3,870,845 shares, or 10.5 % of our outstanding common stock (including 500,477 options held by Dr. Najafi which are exercisable as of or within 60 days from December 31, 2012). As a result, Dr. Najafi, can significantly influence the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

Our limited operating history may make it difficult for you to evaluate our business and to assess our future viability.

Our operations to date have been limited to organizing and staffing our company, developing our technology, researching and developing our compounds, and conducting preclinical studies and early-stage clinical trials of our compounds. We have not demonstrated the ability to succeed in achieving clinical endpoints, obtain regulatory approvals, formulate and manufacture products on a commercial scale or conduct sales and marketing activities. Consequently, any predictions you make about our future success or viability are unlikely to be as accurate as they could be if we had a longer operating history.

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, 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 Delaware General Corporation Law 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our principal executive offices and our research and development and administrative operations are located in Emeryville, California. In total, we lease approximately 14,544 square feet of office space in the facility pursuant to a lease agreement expiring on October 31, 2020.

ITEM 3. LEGAL PROCEEDINGS

We are currently not a party to, nor is our property the subject matter of, any pending or, to our knowledge, contemplated material legal proceedings. From time to time, we may become party to litigation and subject to claims arising in the ordinary course of our business.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the NYSE Mkt, under the symbol "NBY." The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported by the NYSE Mkt:

	2012		2011	
	High	Low	High	Low
First Quarter	1.70	1.20	2.36	1.67
Second Quarter	1.36	0.90	2.35	1.04
Third Quarter	1.56	1.12	1.09	0.67
Fourth Quarter	1.76	1.05	1.38	0.84

Holders

As of March 11, 2013, there were approximately 315 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, and therefore, do not anticipate paying any cash dividends in the near 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.

Purchase of Equity Securities by the Issuer

During the fourth quarter of 2012, the Company repurchased 10,116 shares from employees to satisfy the statutory withholding tax liability upon the vesting of restricted share-based awards.

Performance Graph(1)

The following graph compares our total stockholder returns for the past five years to two indices: the NYSE Mkt and the RDG MicroCap Biotechnology Index. The total return for each index assumes the reinvestment of all dividends, if any, paid by companies included in these indices and are calculated as of December 31 of each year.

As a member of the NYSE Mkt Composite Index, we are required under applicable regulations to use this index as a comparator, and we believe the RDG MicroCap Biotechnology Index is a relevant comparator since it is composed of peer companies in lines-of-business similar to ours.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

(1) This section is not “soliciting material,” is not deemed “filed” with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

	12/07	12/08	12/09	12/10	12/11	12/12
NovaBay Pharmaceuticals, Inc.	100.00	27.13	54.80	44.16	35.65	30.06
NYSE MKT Composite	100.00	62.15	82.82	104.10	112.59	121.01
RDG MicroCap Biotechnology	100.00	48.62	59.56	55.44	43.40	35.89

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial information as of and for the dates and periods indicated have been derived from our audited consolidated financial statements. The information set forth below is not necessarily indicative of results of future operations, and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this report and our consolidated financial statements and related notes included elsewhere in this report.

	Year Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Statements of Operations Data:					
Revenue:					
License, collaboration and distribution revenue	$ 6,855	$ 10,993	$ 9,754	$ 15,684	$ 6,722
Other revenues	92	26	—	—	—
Total revenue	6,947	11,019	9,754	15,684	6,722
Operating expenses:					
Research and development	9,275	9,911	8,616	7,337	9,595
Selling, general and administrative	5,981	5,429	5,654	5,607	5,636
Total operating expenses	15,256	15,340	14,270	12,944	15,231
Operating income (loss)	(8,309)	(4,321)	(4,516)	2,740	(8,509)
Non-cash gain (loss) on change in fair value of warrants	1,439	(732)	—	—	—
Other income (expense), net	(155)	(30)	258	(36)	397
Income (loss) before income taxes	(7,025)	(5,083)	(4,258)	2,704	(8,112)
Provision for income taxes	(2)	(2)	(50)	(7)	(2)
Net income (loss)	$ (7,027)	$ (5,085)	$ (4,308)	$ 2,697	$ (8,114)
Net income (loss) per share:					
Basic	$ (0.24)	$ (0.20)	$ (0.18)	$ 0.12	$ (0.38)
Diluted	$ (0.24)	$ (0.20)	$ (0.18)	$ 0.12	$ (0.38)
Shares used in computing net income (loss) per share:					
Basic	29,448	25,773	23,326	22,404	21,312
Diluted	29,448	25,773	23,326	23,115	21,312

	Year Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands)				
Balance Sheet Data:					
	$ 16,870	$ 14,138	$ 12,806	$ 11,292	$ 12,099

Cash, cash equivalents and short-term investments					
Working capital	15,108	11,720	11,031	11,568	8,033
Total assets	19,235	15,963	15,516	17,523	13,969
Capital lease obligation—current and non-current	—	—	—	7	49
Equipment loan—current and non-current	—	—	106	470	836
Deferred revenue—current and non-current	1,892	2,250	3,689	2,167	4,167
Common stock and additional paid-in capital	54,373	42,672	38,703	37,236	33,933
Total stockholders' equity	14,049	9,344	10,490	13,345	7,345

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. As a result of many factors, such as 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.

Overview

NovaBay Pharmaceuticals is a clinical-stage biotechnology company focused on addressing the large unmet therapeutic needs of the global anti-infective market with its two distinct categories of products.

Aganocide® Compounds
NovaBay's 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. Having demonstrated therapeutic proof-of-concept in three Phase 2 clinical studies, these compounds are well suited to treat and prevent a wide range of local, non-systemic infections. NovaBay is currently focused in three large therapeutic markets:

- Dermatology - Partnered with Galderma, a leading dermatology company, the companies are developing a gel formulation of auriclosene (NVC-422) for treating the highly contagious skin infection, impetigo. A global Phase 2b clinical study is currently underway with results expected to be available in the second half of 2013.

- Ophthalmology - NovaBay is developing an eye drop formulation of auriclosene (NVC-422) for treating adenoviral conjunctivitis, for which there is currently no FDA-approved treatment. The company expects to complete a global Phase 2b clinical study for this indication in the last half of 2013. The company expects to initiate a proof-of-concept study for bacterial conjunctivitis in the second quarter of 2013 with the same auriclosene (NVC-422) formulation.

- Urology – NovaBay's urinary catheter irrigation solution containing auriclosene (NVC-422) is currently in Phase 2 clinical studies, with the goal of reducing the incidence of urinary catheter blockage and encrustation (UCBE) and the associated urinary tract infections. The company reported positive data from Part A of this study and expects to announce interim top-line results from Part B of this study in the second quarter of 2013.

NeutroPhase®
NovaBay has developed NeutroPhase, which is a different class of molecule from the Aganocides. NeutroPhase is an FDA 510(k)-cleared Skin and Wound Cleanser. With a distinct mechanism of action from Aganocides, NeutroPhase is a patented pure hypochlorous acid solution and has the potential to be "best in class" skin and wound cleanser for wound care and is suited 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, surgical wound and burn.

NovaBay has begun securing commercial partnerships for NeutroPhase. In January 2012, NovaBay announced it had entered into a strategic marketing agreement with Pioneer Pharma Co., Ltd., a Shanghai-based company that markets high-end pharmaceutical products into China. In September 2012, the collaboration with Pioneer Pharma was expanded to include the Asian markets, Hong Kong, Macau, Taiwan, Singapore, Malaysia, Indonesia, Myanmar, Philippines, Thailand, Vietnam, Brunei, Cambodia and Laos. NovaBay expects to announce additional marketing

agreements in select geographic markets around the world during 2013.

To date, we have generated very little revenue from product sales, and we have financed our operations and internal growth primarily through the sale of our capital stock, and the fees received from Galderma and Alcon, prior to termination of our collaboration with Alcon Manufacturing Ltd. (Alcon), an affiliate of Alcon, Inc., in June 2011. As we are a development stage company, we have incurred significant losses since commencement of our operations in July 2002, since we have devoted substantially all of our resources to research and development. As of December 31, 2012, we had an accumulated deficit of $40.3 million. This deficit resulted from research and development expenses as well as general and administrative expenses. We expect to incur net losses over the next several years as we continue our clinical and research and development activities and as we apply for patents and regulatory approvals.

Significant Events in 2012 and 2013

In February 2013, we announced that the World Health Organization (WHO) has approved the international nonproprietary name (INN) “auriclosene” (pronounced awr-rih-CLO-zeen) for our lead Aganocide® compound auriclosene (NVC-422). INNs facilitate the identification of active pharmaceutical ingredients, and each INN is a globally recognized unique name.

In February 2013, we announced that our partner Galderma S.A., a global leading pharmaceutical company exclusively focused on dermatology, had initiated the South African arm of its Phase 2b clinical study of a proprietary topical formulation of auriclosene (NVC-422) for the treatment of impetigo.

In January 2013 we announced that the first patients had been enrolled in India into our global Phase 2b BAYnovation clinical study, investigating auriclosene (NVC-422) Ophthalmic Solution as a treatment of adenoviral conjunctivitis, a highly contagious form of “pink eye” for which there is an unmet ocular medical need.

In December 2012, we closed an underwritten public offering of an aggregate of 5,900,000 shares of our common stock, at a price to the public of $1.25 per share, and one-year warrants to purchase up to an aggregate of 4,425,000 shares of common stock at an exercise price of $1.50 per share. The net offering proceeds we received from this offering were approximately $6.6 million, after deducting underwriting discounts and commissions and other estimated offering expenses, but excluding the exercise of any warrants. If the warrants are exercised in full we will receive additional proceeds of approximately $6.64 million.

In September 2012, we announced we received $2.6 million from our partner Galderma S.A., a global leading pharmaceutical company exclusively focused on dermatology. The payment is associated with the clinical advancement of NovaBay's “non-antibiotic, anti-infective” Aganocide® compound auriclosene (NVC-422) as a topical formulation moving to replace traditional antibiotics for the impetigo treatment, a highly contagious skin infection caused by common bacteria such as methicillin-resistant Staphylococcus aureus (MRSA).

In September 2012, we announced that the first patients have been enrolled in the Company’s Phase 2b clinical study of a proprietary topical formulation of auriclosene (NVC-422) for the treatment of impetigo. The study is expected to enroll over 300 patients at 24 clinical sites in four countries worldwide and aims to confirm efficacy and evaluate 2 different dosage regimens.

In September 2012, we announced that we have expanded our distribution agreement with Naqu Area Pioneer Pharma Co., Ltd., a Shanghai-based company that markets high-end pharmaceutical products into China, for the commercialization of NeutroPhase Skin and Wound Cleanser in select Asian markets in addition to China.

In September 2012, we announced NeutroPhase Skin and Wound Cleanser in combination with negative pressure wound therapy (NPWT) is featured in a case study as a new therapeutic technique for the management of necrotizing fasciitis. The case study titled, “Treatment of Acute Necrotizing Fasciitis Using Adjunctive Pure Hypochlorous Acid,” was presented at the 2012 Fall Symposium on Advanced Wound Care (SAWC), in Baltimore, Md.

In August 2012, we announced that we received 510(k) clearance from the Food and Drug Administration (FDA) to market NeutroPhase® Skin and Wound Cleanser under widened indications including the moistening and debriding of graft and donor sites. Concurrently, the FDA cleared NeutroPhase to be administered through a new convenient spray pump.

In May 2012, we announced that we had enrolled the first patients in our global Phase 2b clinical study, evaluating our lead compound, auriclosene (NVC-422), for treating adenoviral conjunctivitis, a highly contagious form of “pink eye.” After providing suggestions and insight into the design of the trial at an End-of-Phase 2A meeting, the Food and Drug Administration (FDA) confirmed that the trial has all the design elements (controls, sample size, end-points) of a pivotal trial.

In April 2012, we announced that our pure hypochlorous acid (HOCl) wound cleanser, NeutroPhase, in combination with commercially available wound dressings, has been found to support healing when treating chronic non-healing wounds in three new patient case studies. The studies were presented in a poster at the 2012 Spring Symposium on

Advanced Wound Care (SAWC) in conjunction with the 22nd Annual Meeting of the Wound Healing Society, in Atlanta, Ga.

In March 2012, we announced that we had entered into a feasibility and option agreement with Virbac Animal Health for the development and potential commercialization of Aganocides for a number of veterinary uses. Under the terms of the agreement, NovaBay received an upfront payment and is entitled to additional support for research and development. Virbac will conduct veterinary studies using NovaBay's Aganocide compounds to assess feasibility for treating several veterinary indications.

In January 2012, we announced that we had entered into a commercial partnership agreement with Pioneer Pharma Co., Ltd., a Shanghai-based company that markets high-end pharmaceutical products into China, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, we received an upfront payment of over $300,000, with the potential for additional payments totaling approximately $1 million that may be triggered by certain pre-commercial launch regulatory milestones.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP). The preparation of these 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 financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements 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, common stock warrant liabilities and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements, 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.

Revenue Recognition

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of certain milestones and royalties on net product sales. In accordance with authoritative guidance, we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and revenue is recognized over the performance obligation period. Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured. If these factors were to vary the resulting change could have a material effect on our revenue recognition and on our results of operations.

Assuming the elements meet the revenue recognition guidelines, the revenue recognition methodology prescribed for each unit of accounting is summarized below:

Upfront Fees—We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology licensed has no utility to the licensee. If we have continuing performance obligations through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the estimated period of the performance obligation. We base the estimate of the period of performance on factors in the contract. Actual time frames could vary and could result in material changes to our results of operations. When our collaboration partners request us to continue performing the research and development services in collaboration beyond the initial period of performance, the remaining unamortized deferred revenue and any new continuation or license fees are recognized over the extended period of performance.

Funded Research and Development—Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. The full-time equivalent amount can vary each year if the contracts allow for a percentage increase determined by relevant salary surveys, if applicable. Reimbursements from collaborative partners

for agreed upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical studies are classified as revenue and recognized in the period the reimbursable expenses are incurred. Payments received in advance are recorded as deferred revenue until the research and development services are performed or costs are incurred.

Milestones—Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

Royalties—We recognize royalty revenues from licensed products upon the sale of the related products.

Research and Development Costs

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

Stock-Based Compensation

Stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. See Note 10 of the Notes to Consolidated Financial Statements for further information regarding stock-based compensation expense and the assumptions used in estimating that expense. For stock options granted to employees, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model.

Stock-based compensation arrangements with non-employees are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model.

Income Taxes

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recognized if it is more likely than not that some portion or the entire deferred tax asset will not be recognized. Valuation allowances are based, in part, on estimates that management must make as to our results in future periods. The actual outcome may not be consistent with our estimate, which would require that we make changes in our valuation allowance.

Common Stock Warrant Liabilities

For warrants where there is a deemed possibility that we may have to settle the warrants in cash, we records the fair value of the issued warrants as a liability at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss in the consolidated statement of operations. The fair values of these warrants have been determined using the Binomial Lattice (“Lattice”) valuation model, and the changes in the fair value are recorded in the consolidated statement of operations. The Lattice model provides for assumptions regarding volatility, call and put features and risk-free interest rates within the total period to maturity. These values are subject to a significant degree of judgment on the part of management.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income (ASU 2011-05). Under the amended guidance, all changes in the components of net income and the components of other comprehensive income are to be presented either in a single continuous statement of comprehensive income, or in two separate but consecutive financial statements. In December 2011, the FASB issued Accounting Standards Update No. 2011-12, Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05 (ASU 2011-12). ASU 2011-12 defers the effective date of the requirement in ASU 2011-05 to disclose on the face of the financial statements the effects of

reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income. All other requirements of ASU 2011-05 are not affected by ASU 2011-12. The changes were effective January 1, 2012, with early adoption permitted. This change did not have an impact to our consolidated financial results as it is a change in presentation only.

In May 2011, the FASB issued ASU No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS, which amends the current fair value measurement and disclosure guidance. These changes were effective January 1, 2012, on a prospective basis. Early application is not permitted. This change did not have a material impact to our consolidated financial results.

Results of Operations

Comparison of Years Ended December 31, 2012, 2011 and 2010

License, Collaboration and Distribution Revenue

Total license, collaboration and distribution revenue was $6.9 million for the year ended December 31, 2012, compared to $11.0 million for the year ended December 31, 2011, and $9.8 million for the year ended December 31, 2010.

License, collaboration and distribution revenue over the years ended December 31, 2012, 2011 and 2010 is due to six different agreements entered into by NovaBay. Those agreements are:

- a license and collaboration agreement entered into with Galderma in 2009,
- a license and collaboration agreement with Alcon entered into in 2006 and terminated in 2011,
- a distribution agreement covering China entered into with Pioneer Pharma in Jan 2012,
- a second distribution agreement with Pioneer Pharma covering SE Asia along with a stock purchase agreement,
- a private label distribution agreement entered into with a U.S.-based marketer of healthcare products and;
- a feasibility and option agreement with an animal health company.

Under the terms of the agreement entered into with Galderma in March 2009, Galderma will pay to NovaBay certain upfront fees, ongoing fees, reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide compounds. We received an upfront technology access fee from Galderma of $1.0 million in 2009, which was amortized on a straight-line basis into revenue over the initial 20 month period of the contract. In December 2010 we received a $3.25 million continuation fee and $500,000 license fee which are being amortized on a straight-line basis into revenue over the additional three year funding term pursuant to the December 2010 amendment to the contract. In 2012, we recognized $1.3 million of the upfront technology access fee, continuation fee and license fee under the agreement and we also recognized $1.6 million in ongoing research and development fees and $3.5 million in materials, equipment and contract study costs under the agreement. In 2011, we recognized $1.3 million of the upfront technology access fee, continuation fee and license fee under the agreement and we also recognized $1.6 million in ongoing research and development fees and $2.6 million in materials, equipment and contract study costs and $500,000 in milestone payments under the agreement. In 2010, we recognized $786,000 of the upfront technology access fee, continuation fee and license fee under the agreement and we also recognized $850,000 in ongoing research and development fees and $470,000 in materials, equipment and contract study costs under the agreement.

In August 2006, we entered into a collaboration and license agreement with Alcon, which was terminated in 2011. The upfront technology access fee of $10.0 million from Alcon was amortized into revenue on a straight-line basis over the four year funding term of the agreement, through August 2010. We recognized no revenue under this agreement during the year ended December 31, 2012. In 2011 we recognized a $2.0 million termination payment in addition to $2.8 million in ongoing research and development fees and $246,000 in reimbursements for materials, equipment and contract study costs under the agreement. In 2010, we recognized $1.7 million of the upfront technology access fee and we also recognized $5.4 million in ongoing research and development fees and $562,000 in reimbursements for materials, equipment and contract study costs under the agreement. As a result of the termination of the Alcon agreement, we will recognize no further revenue under this agreement.

In January 2012, we entered into a distribution agreement with Pioneer Pharma Co., Ltd., a Shanghai-based company that markets high-end pharmaceutical products into China, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, we received an upfront payment of $312,500, which is recorded in

deferred revenue until the final MAA approval is received as the payment is refundable if the SFDA does not provide MAA approval. The distribution agreement provides that Pioneer Pharma Co., Ltd. is entitled to receive cumulative purchase discounts of up to $500,000 upon the purchase of the NeutroPhase product. The deferred revenue will be recognized as the purchase discounts are earned, with the remaining deferred revenue recognized ratably over the product distribution period. We also received $312,500 in November 2012, related to the submission of the first marketing approval for the product to the SFDA. The deferred revenue will be recognized as the purchase discounts are earned, with the remaining deferred revenue recognized ratably over the product distribution period.

In September 2012, we entered into two agreements with Pioneer Pharma Co., Ltd. (“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, we agreed to grant to Pioneer over a period of 5.5 years the right to distribute Neutrophase, upon MAA Approval from a Regulatory Authority, in certain territories in Asia (other than China). Upon execution of the Distribution Agreement, we received an upfront payment of $250,000 from Pioneer, which was initially recorded as deferred revenue; an additional $350,000 was due to us in December 2012. This amount was initially recorded as deferred revenue at December 31, 2012 and was received in early January 2013. Pioneer is also obligated to make certain additional payments to us upon receipt of the MAA Approval. The Distribution Agreement further provides that Pioneer is entitled to a cumulative credit not to exceed $500,000 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 Pioneer for the purchase of restricted units (comprising 1 share of common stock and a warrant for the purchase of 1 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 share. 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 a fair value of the warrants based on the Black-Scholes Merton option pricing model. Because the aggregate fair value of the units on the dates of purchase exceeded the $2.5 million in proceeds received from the unit purchase by approximately $1 million, we were required to reallocate the amounts received or earned, totaling $600,000, from deferred revenue to stockholders’ equity as consideration for the purchase of the units.

In April 2012, we entered into a feasibility and option agreement with an animal health company for the development and potential commercialization of Aganocides for a number of veterinary uses. Under the terms of the agreement, we received an upfront payment of $150,000 and we are entitled to additional support for research and development. The company will conduct veterinary studies using NovaBay's Aganocide compounds in order to assess feasibility for treating several veterinary indications.

In October 2012, NovaBay entered into a private label distribution agreement with a US based marketer of healthcare products. Under the terms of that agreement NovaBay received an upfront payment and will receive an additional payment upon the first shipment under the agreement. In addition, NovaBay is entitled to additional support for research and development and product payments.

We did not recognize any other significant revenues in 2012, 2011 and 2010.

Research and Development

At the end of 2010 NovaBay adopted a strategy of focusing on specific healthcare markets as we develop our compounds. NovaBay is developing commercial opportunities for its Aganocide portfolio of anti-infectives in four distinct healthcare markets: dermatology, ophthalmology, urology and hospital infections. Each of these market segments are underserved by current products and therefore the opportunity exists for improved treatments. NovaBay's strategy is to address these market opportunities either through partnerships and collaborations or by building an internal organization to strategically market its own products when appropriate from a commercial standpoint.

Historically, as we were developing our focus, we did not track our research and development costs by market or indication. Our research and development efforts crossed multiple programs and our programs were not clearly defined, making the tracking of program costs impractical. During 2011 we set up processes to allow us to track our costs based on these four specific healthcare markets and we began providing investors with detailed financial information pertaining to our efforts in each of these markets in 2012.

Total research and development expenses decreased by 6% to $9.3 million for the year ended December 31, 2012, from $9.9 million for the year ended December 31, 2011. This decrease was primarily due to the reduction of costs associated with the termination of Alcon in 2011, partially offset by the increase in costs in our conjunctivitis and UCBE trials.

Total research and development expenses increased by 15% to $9.9 million for the year ended December 31, 2011, from $8.6 million for the year ended December 31, 2010. This increase was primarily due to increases in our clinical costs as we conducted clinical trials in 2011.

We expect to incur increasing research and development expenses in 2013 and in subsequent years as we continue to increase our focus on developing product candidates, both independently and in collaboration with our partners. In particular, we expect to incur ongoing clinical, chemistry, and manufacturing expenses related to four healthcare markets in which we are pursuing opportunities: ophthalmology, dermatology, urology and advanced wound care.

General and Administrative

General and administrative expenses were $6.0 million in 2012 compared to $5.4 million in 2011 and $5.7 million in 2010. This increase in 2012 reflects an increase in marketing and gearing up for increased clinical trials and support for the distribution of NeutroPhase. We expect general and administrative to increase slightly as we continue to support trials and market our NeutroPhase product in 2013.

Non-Cash Gain (Loss) on Change in Fair Value of Warrants

The non-cash gain (loss) on the change in fair value of warrants relates to the fair value adjustment to the warrants issued with our July 2011 registered direct offering of common stock and warrants. This balance will fluctuate with market conditions and the price of our stock.

Other Income (Expense), Net

Other income (expense), net was an expense of $155,000 for the year ended December 31, 2012; an expense of $30,000 for the year ended December 31, 2011 and an income of $258,000 for the year ended December 31, 2010. The income in 2010 was primarily due to the receipt of $244,000 related to the Qualified Therapeutic Discovery Project grant from the IRS and a decrease of $46,000 in interest expense in 2010 as we paid down our capital lease and debt balances.

We expect that other income (expense), net will vary based on fluctuations in our cash balances and borrowings under equipment loans and the interest rate paid on such balances and borrowings.

Liquidity and Capital Resources

We have incurred cumulative net losses of $40.3 million since inception through December 31, 2012. We do not expect to generate significant revenue from product candidates for several years. Since inception, we have funded our operations primarily through the sales of our stock and funds received under our collaboration agreements. We raised total net proceeds of $11.2 million from sales of our preferred stock in 2002 through 2006. In October 2007, we completed our IPO in which we raised a total of $20.0 million, or approximately $17.1 million in net cash proceeds after deducting underwriting discounts and commissions of $1.4 million and other offering costs of $1.5 million. In August 2009, we completed a registered direct offering and had net proceeds of $1.9 million. In July 2011 we completed a second registered direct offering with gross proceeds of $5.2 million, or approximately $4.6 million in net proceeds after deducting underwriting commissions of $288,000 and other offering costs of $244,000. In December 2012, we completed a public offering with gross proceeds of $7.4 million, or approximately $6.6 million in net proceeds after deducting underwriting commissions of $479,000 and other offering costs of $240,000. Additionally, cash received from our collaboration partners have totaled $61.4 million. Under the terms of our collaboration and license agreement with Galderma, Galderma will pay to NovaBay reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide compounds. We believe the capital generated through these sources is sufficient to fund our planned operations into 2013. Our capital requirements going forward will depend on numerous factors including:

- the number and characteristics of product development programs we pursue and the pace of each program;
- the scope, rate of progress, results and costs of clinical trials;
- the time, cost and outcome involved in seeking regulatory approvals;
- our ability to establish and maintain strategic collaborations or partnerships for clinical trials, manufacturing and marketing of our product candidates; and
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop.

Cash and Cash Equivalents

As of December 31, 2012, we had cash, cash equivalents, and short-term investments of $16.9 million, compared to $14.1 million and $12.8 million at December 31, 2011 and 2010, respectively.

Cash Used in Operating Activities

For the year ended December 31, 2012, cash used in operating activities was $6.5 million compared to $3.1 million for the year ended December 31, 2011. The increase in 2012 of cash used in operating activities is primarily due to increased clinical activity in 2012.

For the year ended December 31, 2011, cash used in operating activities was $3.1 million compared to cash provided by operating activities of $2.0 million for the year ended December 31, 2010. The cash used in operating activities is primarily due to increased clinical activity and a decrease in deferred revenues and the cash provided by operating activities is due to the collection of a $3.8 million receivable that was outstanding in 2009 and an increase in deferred revenue.

Cash Provided by (Used in) Investing Activities

For the year ended December 31, 2012, cash provided by investing activities of $1.4 million was attributable to the net effect of purchases of short-term investments and sales and maturities.

For the year ended December 31, 2011, cash used in investing activities of $4.7 million was attributable to purchases of short-term investments offset, in part, by sales and maturities resulting in $4.5 million used, and purchases of property and equipment of $119,000.

For the year ended December 31, 2010, cash used in investing activities of $1.2 million was attributable to purchases of short-term investments, offset by maturities and sales, resulting in $991,000 used and purchases of property and equipment of $203,000.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities of $9.4 million for the year ended December 31, 2012, was primarily attributable to the $6.7 million provided by our December 2012 financing and $2.8 provided by stock sales to Pioneer Pharma.

Net cash provided by financing activities of $4.7 million for the year ended December 31, 2011, was primarily attributable to the $4.6 million provided by our July 2011 registered direct financing.

Net cash used in financing activities of $292,000 for the year ended December 31, 2010, was primarily attributable to $364,000 in principal payments on our equipment loan partially offset by cash received on stock option exercises of $81,000.

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, 2012. This information has been derived from our unaudited financial statements and has been prepared by us on a basis consistent with our audited annual 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							
	Dec. 31, 2012	Sept. 30, 2012	June 30, 2012	March 31, 2012	Dec. 31, 2011	Sept. 30, 2011	June 30, 2011	March 31, 2011
	(in thousands, except per share data)							
Statements of Operations Data:								
Revenue:								
License, collaboration and distribution revenue	$ 1,067	$3,617	$856	$1,315	$1,214	$2,762	$4,527	$2,490
Other revenue	47	25	15	5	16	10	—	—
Total revenue	1,114	3,642	871	1,320	1,230	2,772	4,527	2,490
Operating expenses:								
Research and development	2,119	2,514	2,378	2,264	2,199	2,023	2,769	2,920
Selling, general and administrative	1,838	1,234	1,368	1,541	1,499	1,097	1,318	1,515
Total operating expenses	3,957	3,748	3,746	3,805	3,698	3,120	4,087	4,435
Operating income (loss)	(2,843)	(106)	(2,875)	(2,485)	(2,468)	(348)	440	(1,945)
Non-cash gain (loss) on change in fair value of warrants	637	209	628	(35)	(1,185)	453	—	—
Other income (expense), net	(160)	(17)	27	(5)	6	6	(11)	(31)
Income (loss) before income taxes	(2,366)	86	(2,220)	(2,525)	(3,647)	111	429	(1,976)
Provision for (benefit from) income taxes	16	(6)	(6)	(6)	19	(5)	(4)	(12)
Net income (loss)	$ (2,350)	$80	$(2,226)	$(2,531)	$(3,628)	$106	$425	$(1,988)
Net income (loss) per share:								
Basic	$ (0.07)	$0.00	$(0.08)	$(0.09)	$(0.13)	$0.00	$0.02	$(0.08)

Diluted	$ (0.07)	$0.00	$(0.08)	$(0.09)	$(0.13)	$0.00	$0.02	$(0.08)
Shares used in computing net income (loss) per share:								
Basic	31,671	28,861	28,671	28,572	28,214	27,902	23,480	23,428
Diluted	31,671	29,284	28,671	28,572	28,214	27,902	23,480	23,428

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2012, we had net operating loss carryforwards for federal and state income tax purposes of $33.8 million and 35.5 million, respectively. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2015 and 2032. As of December 31, 2012, we also had tax credit carryforwards for federal income tax purposes of $58,000.

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, though, there can be no assurances that our business will not be affected by inflation in the future.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2012.

Contractual Obligations

Our contractual cash commitments as of December 31, 2012, were as follows (in thousands):

Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating leases	$ 4,512	$ 520	$ 1,086	$ 1,153	$ 1,753
	$ 4,512	$ 520	$ 1,086	$ 1,153	$ 1,753

Our commitments under the operating leases shown above consist of payments relating to our lease of laboratory and office space in one office building in Emeryville, California. This lease expires on October 31, 2020.

We believe our cash balance at December 31, 2012, is sufficient to fund our projected operating requirements through at least the next twelve months. However, we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our future capital requirements will depend on many factors, including:

- 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 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.

We do not anticipate that we will generate significant product revenue for a number of years. Until we can generate sufficient product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances and short-term investments. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience dilution. In addition, debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations for some of our technologies or product candidates that we would otherwise seek to develop on our own. Such collaborations may not be on favorable terms or they may require us to relinquish rights to our technologies or product candidates.

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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 the majority of our investments are in short-term debt securities.

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, 2012 and 2011, a 10% change in interest rates would have had an immaterial effect on the value of our short-term marketable securities. We do not use derivative financial instruments in our investment portfolio. We do not hold any instruments for trading purposes.

To date, we have operated exclusively in the U.S. and 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

To the Board of Directors and Stockholders of
NovaBay Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of NovaBay Pharmaceuticals, Inc. (a development stage company) as of December 31, 2012 and 2011 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, 2012 and for the period from July 1, 2002 (date of inception) to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The cumulative statements of operations and comprehensive loss, stockholders' equity and cash flows for the period from July 1, 2002 (date of inception) to December 31, 2009 were audited by other auditors. Our report, insofar as it relates to the amounts included for the period from July 1, 2002 to December 31, 2009, is based solely on the report of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of NovaBay Pharmaceuticals, Inc. (a development stage company) as of December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012 and for the period from July 1, 2002 (date of inception) to December 31, 2012, in conformity with U.S. generally accepted accounting principles.

/s/ OUM & CO. LLP

San Francisco, California
March 11, 2013

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders of
NovaBay Pharmaceuticals Inc.
(a development stage company)

We have audited the accompanying consolidated statements of operations, stockholders' equity and cash flows for the period from July 1, 2002 (date of development stage inception) to December 31, 2009 of NovaBay Pharmaceuticals Inc. (a development stage company). NovaBay Pharmaceuticals Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of its operations and its cash flows for the period from July 1, 2002 (date of development stage inception) to December 31, 2009 of NovaBay Pharmaceuticals Inc. (a development stage company) in conformity with accounting principles generally accepted in the United States of America.

/S/ Davidson & Company LLP
Chartered Accountants

Vancouver, Canada

March 11, 2013

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31, 2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$12,735	$8,428
Short-term investments	4,135	5,710
Accounts receivable	943	3
Inventory	23	—
Prepaid expenses and other current assets	445	417
Total current assets	18,281	14,558
Property and equipment, net	891	1,270
Other assets	63	135
TOTAL ASSETS	$19,235	$15,963
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$455	$472
Accrued liabilities	1,497	1,061
Deferred revenue	1,221	1,305
Total current liabilities	3,173	2,838
Deferred revenue - non-current	671	945
Deferred rent	60	115
Warrant liability	1,282	2,721
Total liabilities	5,186	6,619
Stockholders' Equity:		
Preferred stock, $0.01 par value; 5,000 shares authorized; none outstanding at December 31, 2012 and 2011	—	—
Common stock, $0.01 par value; 65,000 shares authorized; 36,915 and 28,587 shares issued and outstanding at December 31, 2012 and 2011, respectively	369	286
Additional paid-in capital	54,004	42,386
Accumulated other comprehensive loss	(13)	(44)
Accumulated deficit during development stage	(40,311)	(33,284)
Total stockholders' equity	14,049	9,344
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$19,235	$15,963

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

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Year Ended December 31,			Cumulative Period from July 1, 2002 (inception) to December 31,
	2012	2011	2010	2012
Revenue:				
License, collaboration and distribution revenue	$6,855	$10,993	$9,754	$57,454
Other revenues	92	26	—	118
Total revenue	6,947	11,019	9,754	57,572
Operating expenses:				
Research and development	9,275	9,911	8,616	60,146
Selling, general and administrative	5,981	5,429	5,654	39,635
Total operating expenses	15,256	15,340	14,270	99,781
Operating loss	(8,309)	(4,321)	(4,516)	(42,209)
Non-cash gain (loss) on change in fair value of warrants	1,439	(732)	—	707
Other income (expense), net	(155)	(30)	258	1,266
Loss before income taxes	(7,025)	(5,083)	(4,258)	(40,236)
Provision for income taxes	(2)	(2)	(50)	(75)
Net loss	(7,027)	(5,085)	(4,308)	(40,311)
Other comprehensive income (loss):				
Change in unrealized gains (losses) on available-for-sale securities	31	(30)	(14)	(13)
Total comprehensive loss	$(6,996)	$(5,115)	$(4,322)	$(40,324)
Net loss per share:				
Basic and diluted	$(0.24)	$(0.20)	$(0.18)	
Shares used in per share calculations:				
Basic and diluted	29,448	25,773	23,326	

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

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit During Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at July 1, 2002	—	$—	—	$—	$ —	$ —	$ —	$ —
Cumulative net loss for the period from July 1, 2002 through December 31, 2008	—	—	—	—	—	—	(23,891)	(23,891)
Issuance of preferred stock and common stock	19,227	192	3,927	39	12,489	—	—	12,720
Conversion of preferred stock to common stock in connection with IPO	(19,227)	(192)	9,614	96	96	—	—	—
Issuance of stock and warrants in connection with IPO, net of offering costs	—	—	6,225	62	18,959	—	—	19,021
Issuance of stock for preferred stock offering costs	—	—	563	6	271	—	—	277
Issuance of stock for director compensation	—	—	57	1	152	—	—	153
Issuance of stock for option exercises	—	—	715	7	374	—	—	381
Issuance of stock for services	—	—	106	1	202	—	—	203
Issuance of stock for warrant exercises	—	—	1,608	16	1,434	—	—	1,450
Sale of stock warrants	—	—	—	—	10	—	—	10
Compensation expense for warrants issued for	—	—	—	—	155	—	—	155

services								
Stock-based compensation expense related to employee and director stock options	—	—	130	1	2,352	—	—	2,353
Stock-based compensation expense related to non-employee stock options	—	—	309	4	504	—	—	508
Tax benefit from stock plans	—	—	—	—	5	—	—	5
Balance at December 31, 2009	—	—	23,254	233	37,003	—	(23,891)	13,345

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY – (Continued)
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit During Development Stage	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2009	23,254	233	37,003	—	(23,891)	13,345
Net loss	—	—	—	—	(4,308)	(4,308)
Change in unrealized losses on investments	—	—	—	(14)		(14)
Costs related to shelf offering	—	—	(2)	—	—	(2)
Compensation expense for warrants issued for services	—	—	7	—	—	7
Issuance of stock for option exercises	105	1	80	—	—	81
Stock-based compensation expense related to employee and director stock options	—	—	1,129	—	—	1,129
Stock-based compensation expense related to non-employee stock and stock options	33	—	263	—	—	