NovaBay Pharmaceuticals, Inc.
Form 10-K/A
August 04, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A
Amendment No. 1

(Mark One)
T ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2008

OR

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

For the transition period from to

Commission file number 001-33678

NOVABAY PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

California	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 Amex

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes £ No T

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

Act. Yes £ No T

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 T No £

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

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

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

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

As of June 30, 2008, 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 American Stock Exchange (now the NYSE Amex), was approximately $36,535,032. Excludes an aggregate of 3,938,952 shares of common stock held by officers and directors and by each person known by the registrant to own 5% or more of the outstanding common stock as of June 30, 2008. 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 19, 2009, there were 21,647,388 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2009 Annual Meeting of Stockholders 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, 2008

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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.

EXPLANATORY NOTE

We are filing this amendment to our Annual Report on Form 10-K, originally filed with the Securities and Exchange Commission on March 31, 2009 (the “Form 10-K”). for the purpose of amending (i) Item 1 to revise the description of our agreement with Galderma, and to revise the disclosure under “Intellectual Property,” (ii) amending Item 1A to remove a cross-reference in the last risk factor and (iii) to revise the Exhibit Index to correct a typographical error. This amendment only changes the cover page and Item 1 and Item 1A and the Exhibit Index of the Form 10-K and, as a result of this filing includes additional Exhibits 31.1 and 31.2.

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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

We are a mid-stage biopharmaceutical company developing first-in-class, novel, and synthetic anti-infective product candidates to treat and prevent a wide range of infections, without developing resistance, in hospital and non-hospital environments. Many of these infections are increasingly difficult to treat because of the rapid and growing rise in drug resistance. Our proprietary Aganocide® compounds are synthetic forms of N-chlorinated antimicrobial molecules, which are highly effective and rapidly-acting anti-infective molecules produced by white blood cells when defending the body against invading pathogens. We have specifically designed our Aganocide class of compounds to mimic the human body's natural defense against infection. Importantly, this new class of highly differentiated compounds may deliver the same or better efficacy as currently used antibiotics, but without contributing to the growing, global epidemic of drug-resistant bacteria. In preclinical testing, our Aganocide compounds have demonstrated the ability to destroy all bacteria against which they have been tested. We believe that our Aganocide compounds could form a platform on which to create a variety of products to address differing needs in the treatment and prevention of bacterial, viral and fungal infections.

We were incorporated under the laws of the State of California on January 19, 2000 as NovaCal Pharmaceuticals, Inc. We had no operations until July 1, 2002, on which date we acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, we changed our name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, we formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which may conduct research and development in Canada, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which may explore and pursue dermatological opportunities.

Our Target Indications and Product Candidates

We have developed a two-pronged development strategy to maximize the clinical and commercial potential of our Aganocide compounds. Our goal is to advance our product candidates to confirmatory Phase II proof of concept trials, after which we will evaluate further advancing each program on our own or entering a co-development collaboration with a proven market leader to benefit from their expertise and proven capabilities, as well as to defray costs, while retaining participation in long-term commercial economics. We believe that this strategy is appropriate because of the significant breadth of product opportunities that can be developed from our technology base. 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 dosing and usage of our compounds. The more development programs that are undertaken by our partners and by ourselves, the greater the synergy in our activities.

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Eye, Ear, Sinus and Contact Lens Solution

In August 2006, we entered into a collaboration and license agreement with Alcon Manufacturing Ltd. ("Alcon"), an affiliate of Alcon, Inc., that provides Alcon with the exclusive rights to develop, manufacture and commercialize products incorporating our Aganocide compounds for the treatment of eye, ear and sinus infections as well as for use in contact lens solutions. Under the terms of the agreement, Alcon agreed to pay an up-front, non-refundable, non-creditable technology access fee of $10.0 million upon the effective date of the agreement. In addition to the technology access fee, we are entitled to receive semi-annual payments from Alcon to support on-going research and development activities over the four-year funding term of the agreement. The research and development support payments include amounts to fund a specified number of personnel engaged in collaboration activities and to reimburse for qualified equipment, materials and contract study costs. As product candidates are developed and proceed through clinical trials and approval, we will receive milestone payments. If the products are commercialized, we will also receive royalties on any sales of products containing the Aganocide compounds. From the inception of the agreement to December 31, 2008, we have received $17.9 million from Alcon including the technology access fee, the payments for personnel engaged in collaboration activities, the reimbursement for shared costs and contributions towards the purchase of capital equipment.

We recently announced that Alcon has completed its Phase I clinical trial for the treatment of viral conjunctivitis, a very common and highly contagious condition for which we believe there are currently no approved treatment options and is beginning its Phase II study.

Dermatology

We are focused on developing products that will potentially eliminate the need to use antibiotic-based products in the dermatology market. In laboratory testing, we have shown that our lead Aganocide compound NVC-422 kills P. acne, the bacterium responsible for the infection in inflamed acne breakouts, and other dermal bacteria. We have been in advanced preclinical development of a variety of formulations for use in the treatment of skin infections. These studies have confirmed the ability to deliver NVC-422 in therapeutic formulations, suitable for use in skin conditions. We are currently in advanced planning stages to bring these formulations into proof of concept clinical development for the treatment of impetigo in order to enhance their value as we explore partnering opportunities. Impetigo is a highly contagious bacterial skin infection and one of the most common skin diseases among children. It is becoming more serious because it is increasingly being caused by MRSA (methacillin resistant Staph. aureus). Even recently approved drugs like GSK's Altabax® have not been shown to be clinically efficacious against MRSA.

On March 25, 2009, we announced that we 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. The agreement is exclusive and worldwide in scope, with the exception of Asian markets, where we have commercialization rights, and North America, where we have an option to exercise co-promotion rights. Galderma will be responsible for the development costs of the acne and other indications, except in Japan, in which Galderma has the option to request that we share such development costs, and for the ongoing development program for impetigo, upon the achievement of a specified milestone. Galderma will also reimburse NovaBay for the use of its personnel in support of the collaboration. NovaBay retains the right to co-market products resulting from the agreement in Japan. In addition, NovaBay has retained all rights in other Asian markets outside Japan, and has the right to co-promote the products developed under the agreement in the hospital and other healthcare institutions in North America.

Galderma will pay to NovaBay certain upfront fees, ongoing fees, reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide® compounds. If products are commercialized under

the agreement, NovaBay's royalties will escalate as sales increase. 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.

Pre-Surgical Nasal Preparation

Staphylococcus aureus is a major cause of surgical site infections (“SSI”). SSIs are a significant concern because of the risk to the patient and because of the resulting increase in the cost of post-surgical treatment. It has been shown that surgical patients who carry S. aureus in their nasal passages are at a significantly higher risk of developing SSIs. Conventional body washing with an antiseptic preparation does not deal with nasal passages, which are a major area of S. aureus colonization in the body. If the strain of S. aureus that causes the SSI is an antibiotic-resistant variant known as methicillin-resistant S. aureus (“MRSA”), the treatment options become extremely limited and increasingly problematic. We have formulated NVC-422 as a nasal spray and were developing it for the decolonization of S. aureus (including MRSA) from the nasal passages. Studies show that when combined with an antiseptic body wash, nasal decolonization leads to a significant reduction in SSIs. We are not moving forward with this program at this time.

Common Cold

Acute viral nasopharyngitis, or acute coryza, usually known as the common cold, is a highly contagious, viral infectious disease of the upper respiratory system, primarily caused by picornaviruses (including rhinoviruses) or coronaviruses. Common symptoms are sore throat, runny nose, nasal congestion, sneezing and cough; sometimes accompanied by 'pink eye', muscle aches, fatigue, malaise, headaches, muscle weakness, and/or loss of appetite.

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Catheter Associated Urinary Tract Infections

Urinary tract catheters have become a routine part of the management of patients in intensive care and long-term care settings with an estimated five million patients undergoing catheterization each year. Catheter associated urinary tract infections ("CAUTI") are the major source of hospital-acquired infections, accounting for more than 40% of all hospital infections, or 800,000 infections per year. These infections generally prolong hospitalization, require intensive antibiotic therapy and greatly increase the cost of treatment. A contributing factor in CAUTIs is the formation of bacterial biofilm within the catheter. This biofilm provides an on-going reservoir of bacteria that can cause infection. We are developing a formulation of NVC-422 that may destroy bacteria in the bladder as well as controlling bacteria that have formed biofilm within the catheter. We successfully completed Phase I clinical trials that established the safe and well-tolerated nature of our CAUTI formulation. We are currently in Phase II clinical trials to explore the therapeutic potential of NVC-422 for the treatment of bacteruria in the bladder under different dosing regimens.

Wound Care

Wound infections prevent wounds from healing and can cause serious bloodstream infections. We have developed NVC-101, a proprietary solution of hypochlorous acid that we have trademarked as NeutroPhase, to address this major problem. We have received clearance from the FDA for the marketing of this product as a wound cleanser and debriding agent. We continue to explore the potential for NVC-101 and the Aganocide compounds in woundcare.

Our Technology and Research

We have developed our lead compounds by understanding the nature of the antimicrobial molecules that are produced by the human body's white blood cells to kill pathogens such as bacteria, viruses and fungi. Once the body's defense system detects these pathogens, white blood cells produce small, highly active molecules that kill the pathogens in an extremely efficient manner. These molecules are not readily usable as pharmaceutical products because our body produces them "on demand" and the molecules are not naturally stable. We have discovered ways to stabilize one of these naturally occurring molecules, which we call NVC-101 or NeutroPhase. Through the modification of another of these natural molecules, we have created NVC-422, which is our lead Aganocide compound. NVC-422 is a stable analog of naturally occurring N-chlorotaurine ("NCT"). We believe NVC-422 is safer and more potent than the naturally occurring NCT molecule. We have made significant discoveries over the past year that have enhanced our understanding of why the naturally generated molecules cannot be kept stable and used as drugs. We have also been exploring different Aganocide compounds that have been invented by NovaBay's scientists with the aim of creating molecules that can penetrate different tissues more effectively, or that can enhance the duration of antimicrobial activity. We have also made great progress in developing different formulations that can enhance the penetration of the Aganocide molecules.

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. It is beginning to look as if that prediction may have been overoptimistic as there are more multidrug resistant bacteria appearing, and even a few pan-resistant species. By using nature's blueprint for the development of new anti-infective products, we start with the intent that the natural molecules do not allow pathogens to develop resistance. Extensive laboratory studies appear to confirm that the Aganocide compounds should exhibit this characteristic. The intended ability of our Aganocide compounds to be effective without developing resistance would be critical in a situation where bacteria are continuing to develop ever more sophisticated mechanisms for protecting themselves from antibiotics.

Additionally, we continue to expand our understanding of the activity of the Aganocide compounds against bacteria in biofilm. Just as bacteria are found everywhere, we now understand that biofilm is a natural, ever present defense mechanism of bacteria. Biofilm is a cocoon-like shield that forms around a colony of bacteria. Once the biofilm is

formed, bacteria go into dormancy. Dormant bacteria reproduce once every few days, while an active bacteria reproduces every 30 to 60 minutes. Antibiotics are generally only effective against fast reproducing bacteria. In controlled laboratory studies, our Aganocide compounds were found to be highly effective at killing bacteria in biofilm. We believe their activity in biofilm is a critical element of their success, particularly in the prevention of catheter associated urinary tract infections.

Research and Development

As of December 31, 2008, we had 22 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 2006, 2007, and 2008 were $4.1 million, $7.4 million, and $9.6 million, respectively. All of our research and development employees are engaged in drug research and development activities, including those related to the Alcon agreement described above. We expect to incur significant research and development expenses for the foreseeable future.

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Intellectual Property

We rely on a combination of patent, trademark, copyright and trade secret laws in the United States 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 have registered the NovaBay Pharma and Design trademark in the United States, the NovaBay trademark in the European Community, Israel, Mexico, and Australia, the Neutro Phase trademark in Australia, the European Community, Ireland and the United Kingdom, the Aganocide trademark in the United States, the European Community and Japan and the AgaNase trademark in Australia, the European Community, Israel, Japan, Mexico, South Korea, and Taiwan, and have applications for these same trademarks pending in a number of other foreign countries. We have allowed trademark applications in the United States for Agaderm, AgaNase, NeutroPhase, and NovaBay.

We are the assignee on record for three issued patents, seven pending utility applications, and have filed three provisional applications in the United States. In addition to our U.S. patents and applications, we seek patent protection in key foreign countries. We have one issued patent in China, Hong Kong, Israel, India, Mexico, and South Korea, and pending applications filed under the Patent Cooperation Treaty in various stages of examination .

The subject matter of our patents and patent applications covers four key areas: methods relating to the manufacture and use of NVC-101, compositions of matter of the Aganocide compounds, methods of treatment utilizing the Aganocide compounds, and formulations.

Our first issued patent in the U.S. provides coverage for a method of treating burns or promoting wound healing or tissue repair or tissue regeneration using a specific range of formulations of NVC-101. This patent was issued on July 30, 2002 and will expire in 2020 with payment of maintenance fees. Our second issued patent in the U.S. 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 NVC-101. This patent was issued on July 1, 2008 and will expire in 2020 with payment of maintenance fees. Our third issued patent in the U.S. provides composition-of-matter coverage of our lead development candidate, NVC-422, and other Aganocide compounds. This patent was issued on December 9, 2008 and will expire in 2026 with payment of maintenance fees.

Competition

The market for drugs and medical devices designed to treat or prevent bacterial infections is highly competitive. If developed, and commercialized, our 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 any products that we develop may be introduced. In particular, we would be competing against existing antibiotics that are sold by many major pharmaceutical companies, or generic equivalents that are being distributed, typically at low prices. NeutroPhase, if launched for use in wound management, will be competing against multiple products with similar indications for use. However, we believe there is currently no dominant product in this indication.

Our potential competitors include large and small pharmaceutical and medical device companies, such as Pfizer, Inc., Johnson & Johnson, Abbot Grp. Plc., GlaxoSmithKline Plc, Sanofi-Aventis SA, Smith & Nephew Plc, and Novartis AG. Some of these competitors may have far greater resources and experience in the area than we do and may develop and patent processes or products earlier than we are able to, 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 are able to, and improve upon existing technological approaches or develop new or different approaches that render any technology or products we develop obsolete or uncompetitive.

We believe the principal competitive factors for products in our target markets include their effectiveness in killing bacteria, including bacteria in biofilm, very low potential for the development of resistance, time to kill bacteria, safety, side effects and cost effectiveness. We believe that our 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 and NVC-101 compounds could be used to prevent infections or to treat infections where speed of action, action against bacteria in biofilm, action in topical indications or action against multi-drug resistant bacteria is important.

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 NVC-422 and the finished clinical trials materials for NVC-101, which are manufactured in compliance with the FDA’s “Current Good Manufacturing Practice”, or CGMP, regulations. We also intend to work with third parties for future clinical trial materials and commercial supplies of NVC-422.

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The Alcon and Galderma agreements provide for the manufacture by Alcon and 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 product candidate, NVC-422, as well as many of the product candidates we expect to develop in the future, are intended to address a variety of different 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 United States 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 Alcon and Galderma. 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.

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 United States, 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 United States 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 may be classified by the FDA as a drug or a medical device depending upon the mechanism of action and indications for use or claims. The use of NVC-101 as a solution for cleansing and debriding wounds is considered a medical device. Similarly, NVC-422 may be classified as a medical device depending on the indication for use. For example, we believe if the indication is for bladder lavage, it would be classified as a medical device, whereas we believe it would be considered a drug when it is indicated for the prevention of urinary tract infection. The determination as to whether a particular product and indication is considered a drug or a device is based in part upon prior precedent.

Drug Approval Process

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

- preclinical laboratory tests, animal studies 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;

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- submission to the FDA of a New Drug Application ("NDA") including payment of substantial UserFees;

- 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, advertising and promotion once approved.

Medical Devices

NeutroPhase, as well as some of our product candidates, may be regulated as medical devices. Unless an exception applies, each medical device we wish to commercialize in the United States 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 premarket approval.

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 be 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 United States, 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 United States. 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 United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors 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 payors. 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.

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Anti-Kickback and False Claims Laws

In the United States, 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 payors (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 wholesaler or estimated retail 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, 2008, we had 31 full-time employees, including 13 with doctoral degrees. Of our full time workforce, 22 employees were engaged in research and development, and 9 in finance and administration. None of our employees is 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 experienced a downturn due to the effects of the subprime lending crisis, general credit market crisis, 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 it more difficult for us to raise capital as well as make it more difficult to enter into collaboration agreements with other parties. Like many other stocks, our stock price has been subject to fluctuations and has decreased substantially in recent months. Our stock price could further decrease due to concerns that our business, operating results and financial condition will be negatively impacted by a worldwide economic downturn.

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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.

We expect our capital outlays and operating expenditures to substantially increase over at least the next several years as we expand our product pipeline and increase research and development efforts and 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 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 and the credit crisis, 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 shareholders' ownership percentage would be diluted and new investors may demand rights, preferences or privileges senior to those of existing shareholders. 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. We expect to incur net losses for the foreseeable future and we may never achieve or maintain profitability.

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We have incurred net losses since our inception. For the years ended December 31, 2006, 2007 and 2008 we had net losses of approximately $5.3 million, $5.4 million, and $8.1 million, respectively. Through December 31, 2008, we had an accumulated deficit of approximately $26.6 million. We have been, and expect to remain for the foreseeable future, mostly in a research and development stage. Since our inception, we have not generated revenue, except for modest revenue in 2006, 2007, and 2008 relating to two research and development collaboration and license agreements. We have incurred substantial research and development expenses, which were approximately $4.1 million, $7.4 million, and $9.6 million for the years ended December 31, 2006, 2007, and 2008, 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 do not expect any of our current product candidates to be commercialized within the next several years, if at all. We expect to continue to incur substantial losses for the foreseeable future, and we may never become profitable. We anticipate that our expenses will increase substantially in the foreseeable future as we:

- conduct pre-clinical studies and clinical trials for our product candidates in different indications;
- 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 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 very limited data on the use of our products in humans and will need to perform costly and time consuming clinical trials in order to bring our products to market.

Most of the data that we have on our products is from in-vitro (laboratory) studies or in-vivo animal studies and our human data is from Phase I safety studies or small-scale Phase IIa exploratory- studies. We will need to conduct Phase I, II and III human clinical trials to confirm such results in order to obtain approval from the FDA of our drug product candidates. Often, positive in-vitro or in-vivo animal studies arc not followed by positive results in human clinical trials, and we may not be able to demonstrate that our products arc safe and effective for indicated uses in humans. In addition, for each indication, we estimate that it will take between three and five years to conduct the necessary clinical trials.

We currently do not have any 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 solely from research and development collaboration and license agreements. We have never generated revenues from sales of products and we cannot guarantee that we will ever have 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. Before proceeding with clinical trials, we will conduct pre-clinical studies, which may, or may not be, valid predictors of potential outcomes in humans. If pre-clinical studies are favorable, we will then begin clinical trials. 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 products will be derived from sales of products that may not be commercially available for at least the next several years, if at all.

We have limited experience in developing drugs and medical devices, and we may be unable to commercialize any 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 never commercialized, any of our product candidates. 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.

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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.

We must maintain and expand expensive finance and accounting systems, procedures and controls in order to grow our business and organization, which will increase our costs and require additional management resources.

We completed our initial public offering, or IPO, in October 2007. As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC and Canadian securities regulatory authorities, including expanded disclosure and accelerated reporting requirements and more complex accounting rules. We are also required to comply with marketplace rules and the heightened corporate governance standards of the NYSE Amex. Compliance with these rules has been expensive, and there are additional rules with which we have not yet needed to comply but which we will need to comply with in the future. For example, for this Form 10-K we are not required to have our independent auditors audit our internal control over financial reporting, but next year we will be required to do so. If our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of our Annual Report on Form 10-K for 2009, or our business grows and we are not able to comply with accelerated reporting obligations, our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed with the SEC and with Canadian securities regulatory authorities. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

If we do not maintain our current research collaborations with Alcon and Galderma, and enter into additional collaborations, a portion of our funding may decrease and inhibit our ability to develop new products.

We have entered into a collaborative arrangement with Alcon, and we rely on Alcon for joint intellectual property creation and for substantially all of our near-term revenues. Under the agreement, we licensed to Alcon the exclusive rights (except for certain retained marketing rights) to develop, manufacture and commercialize products incorporating the Aganocide compounds for application in connection with the eye, ear and sinus and for use in contact lens solutions. We also recently 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.

We cannot assure you that our collaborations with Alcon or Galderma or any other collaborative arrangement 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 these arrangements. If Alcon or 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. We plan on entering into additional collaborations and licensing arrangements. We may not be able to negotiate additional collaborations on acceptable terms, if at all, and 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. If we are unable to enter into, maintain or extend successful collaborations, our business may be harmed.

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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 the expansion of our pipeline through spending on 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. In order 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.

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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 NeutroPhase and other product candidates. We have no experience in drug formulation or manufacturing, and we lack the resources and the capabilities to manufacture NeutroPhase or 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 the potential for 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, Vice President of Research and Development, Vice President of Medical Affairs, 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 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 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.

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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 United States as well as in other countries. To obtain regulatory approval to market our proposed products outside of the United States, 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 include 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 United States, 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.

In order 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.

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.

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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 United States or in other countries.

Our product candidates may be classified as a drug or a medical device, depending on the mechanism of action, 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. Our products may be classified by the FDA as a drug or a medical device depending upon their mechanism of action, indications for use or claims. For example, for NVC-422, if the indication is for bladder lavage, we believe it would be classified as a medical device, whereas we believe it would be considered a drug when it is indicated for the prevention of urinary tract infection. Similarly, the use of NVC-101 as a solution for cleansing and debriding wounds is considered a medical device. The determination as to whether a particular indication is considered a drug or a device is based in part upon prior 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 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 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 (as further described below), 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 $3 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.

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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 nine months of exclusivity as a generic product under the Waxman-Hatch 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 in order 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 attorneys 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.

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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 United States. 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.

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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 United States 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 NVC-101 composition. If a potential competitor introduces a similar method of using NVC-101 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 NVC-101 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 thereunder 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 United States. 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 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:

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- 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. In order 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. If we decide to commercialize any products we develop, 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, 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

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- 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.

Risks Relating to Owning Our Common Stock

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

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;

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- announcements by us related to litigation;
- changes in our earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earning 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 shareholder 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 shareholders have significant voting power and may take actions that may not be in the best interests of our other shareholders.

As of December 31, 2008, our officers and directors collectively controlled approximately 3,979,097 shares of our outstanding common stock (and approximately 5,183,520 shares of our common stock when including options held by them which were exercisable as of or within 60 days of December 31, 2008). Furthermore, as of December 31, 2008, our largest shareholder, a family trust established and controlled by Dr. Ramin Najafi, our Chairman and Chief Executive Officer, beneficially owned 3,126,700 shares or 14.6% of our outstanding common stock. As a result, Dr. Najafi can significantly influence the management and affairs of our company and most matters requiring shareholder 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 shareholders.

Future sales of shares by our shareholders could cause the market price of our common stock to drop significantly, even if our business is doing well.

Up to 2,972,275 shares held by certain of our officers and directors will become eligible for sale in the public market over the period ending October 25, 2009, as the shares are released from lock-up agreements with the underwriters in our initial public offering.

In addition, at any time and without public notice, we and the underwriters may release, at our respective discretions, all or some of the securities subject to our respective lock-up agreements, subject to applicable regulatory requirements. As restrictions on resale end, the market price of our stock could drop significantly if the holders of those shares sell them or are perceived by the market as intending to sell them. These declines in our stock price could occur even if our business is otherwise doing well.

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 articles of incorporation and bylaws and California law, contain provisions that could discourage a third party from making a takeover offer that is beneficial to our shareholders.

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

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- 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 shareholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without shareholder approval; and
- the ability of our Board of Directors to issue up to 5,000,000 shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

In addition, as a California corporation, we are subject to California 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 California Corporations Code 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 shareholders 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.

We may be considered a “foreign investment entity” which may have adverse Canadian tax consequences for our Canadian investors.

Although we believe that we are not currently a “foreign investment entity” within the meaning of the Canadian tax laws, no assurances can be given in this regard or as to our status in the future. If we become a “foreign investment entity” within the meaning of the Canadian tax laws, there may be certain adverse tax consequences for our Canadian investors.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this amendment report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 4, 2009

NOVABAY PHARMACEUTICALS, INC.
By: /S/ THOMAS J. PAULSON
THOMAS J. PAULSON
Chief Financial Officer and Treasurer

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EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Articles of Incorporation of registrant (Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.)
3.2	Amended and Restated Bylaws of registrant (Incorporated by reference to the exhibit of the same number from the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2007 as filed with the SEC on November 15, 2007.)
4.1*	Specimen common stock certificate
4.2**	Form of Registration Rights Agreement by and between the Registrant and the underwriters
10.1*+	2002 Stock Option Plan, and forms of agreements thereto
10.2*+	2005 Stock Option Plan, and forms of agreements thereto
10.3*+	2007 Omnibus Incentive Plan, and forms of agreements thereto (the Plan is incorporated by reference to Exhibit 10.1 from the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2008 as filed with the SEC on August 14, 2008, and the forms of agreements thereto are incorporated by reference to the exhibit referencing the Plan from the Company's amendment to registration statement of Form S-1 (File No. 333-140714) filed with the Securities and Exchange Commission on May 29, 2007, as amended.)
10.4*+	Employment Agreement dated January 1, 2007 by and between the Registrant and Ramin ("Ron") Najafi
10.5*+	Employment Agreement dated January 1, 2007 by and between the Registrant and John ("Jack") O'Reilly
10.6*+	Employment Agreement dated January 1, 2007 by and between the Registrant and Behzad Khosrovi
10.7*+	Employment Agreement dated January 1, 2007 by and between the Registrant and Colin Scott
10.8+	Employment Agreement dated January 9, 2008 by and between the Registrant and Thomas J. Paulson (Incorporated by reference to Exhibit 10.18 from the company's annual report on Form 10-K for the year end December 31, 2007 as filed with the SEC on March 14, 2008.)
10.9+	Retirement and Consulting Agreement dated January 1, 2009 by and Between the Registrant and John ("Jack") O'Reilly (previously filed with the original filing of this Form 10-K)
10.10*	Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended
10.11*†	Collaboration and License Agreement dated August 29, 2006 by and between the Registrant and Alcon Manufacturing, Ltd.

10.12*	Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 by and between the Registrant and PM Holdings Ltd
10.13*	Director Compensation Plan
10.14*	Master Security Agreement dated April 23, 2007 by and between the Registrant and General Electric Capital Corporation
10.15*	License Agreement dated June 11, 2007 by and between the Registrant and KCI International VOF GP
10.16*	Form of Common Stock Purchase Warrant by and between the Registrant and the underwriters
10.17	Fifth Amendment dated November 20, 2007 to Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended (Incorporated by reference to Exhibit 10.20 from the Company's annual report on Form 10-K for the year ended December 31, 2007 as filed with the SEC on March 14, 2008.)
10.18	Sixth Amendment to Lease between Emery Station Office II, LLC and Novacal Pharmaceuticals, Inc., effective September 1, 2008. (Incorporated by reference to Exhibit 10.1 from the Company's quarterly report on Form 10-Q/A for the quarter ended September 30, 2008 as filed with the SEC on November 14, 2008.)
23.1 ††	Consent of Davidson & Company LLP
24.1	Power of Attorney (included on the signature pages of the Form 10-K as previously filed)
31.1	Certification of the principal executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the chief executive officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (previously filed with the original filing of this Form 10-K)
32.2	Certification of the chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (previously filed with the original filing of this Form 10-K)

* Incorporated by reference to the exhibit of the same number from the Company's registration statement of Form S-1 (File No. 333-140714) initially filed with the Securities and Exchange Commission on February 14, 2007, as amended.

** Incorporated by reference Exhibit 10.7 from the Company's registration statement of Form S-1 (File No. 333-140714) initially filed with the Securities and Exchange Commission on February 14, 2007, as amended.

+ Indicates a management contract or compensatory plan or arrangement.

† NovaBay Pharmaceuticals, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been separately filed with the Securities and Exchange Commission.

††Previously Filed.