NovaBay Pharmaceuticals, Inc.
Form 10-K
March 31, 2009

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

FORM 10-K

(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 to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

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

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

PART I

ITEM 1. BUSINESS

Overview

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 entered a human 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.

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. Galderma will be responsible for the development costs of the acne and other indications, except in Japan, where they will be shared, 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 exclusive rights to 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.

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 are 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. Our formulation of NVC-422 for nasal applications is trademarked as AgaNase® and is currently in Phase II clinical trials.

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 trademark and design in the United States, and the Aganocide trademark in the United States, the European Community and Japan. We have allowed trademark applications in the United States for AgaNase, NeutroPhase, and NovaBay. We have registered the NovaBay trademark in Australia, the AgaNase trademark in Australia, the European Community and Japan, the NeutroPhase trademark in Australia, Ireland and the United Kingdom, and applications for these same trademarks pending in a number of other foreign countries. We recently applied for the AgaDerm trademark in the United States.

We have three issued patents, six pending utility applications, and have filed three provisional applications in the United States. We also have two pending international applications filed under the Patent Cooperation Treaty, one issued patent each in China, Hong Kong, Israel, India, Mexico, and South Korea, and 46 pending foreign national applications in Europe, Argentina, Australia, Brazil, Canada, China, Hong Kong, Israel, India, Japan, South Korea, Mexico, Singapore, New Zealand, Taiwan and South Africa.

The subject matter of our patents and patent applications cover 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, 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. Our second issued patent in the U.S. provides coverage for a method of disinfecting open wounds and burns, promoting wound healing and providing ocular disinfection using a specific range of formulations of NVC-101. This patent was issued on July 1, 2008 and will expire in 2024. 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.

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 FIE Tax Proposals (as defined in “Material Canadian Federal Income Tax Considerations—Foreign Investment Entity Status”), 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 FIE Tax Proposals, there may be certain adverse tax consequences for our Canadian investors.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive offices and our research and development and administrative operations are located in Emeryville, California. In total, we lease approximately 18,100 square feet of office space in the facility pursuant to five lease agreements expiring on various dates through October 31, 2015.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

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PART II

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

Market Information

Since October 25, 2007, our common stock has been listed on the NYSE Amex, formerly American Stock Exchange, and the Toronto Stock Exchange (TSX) under the symbol "NBY." Prior to such time, there was no established public trading market for our common stock. On December 31, 2008, we notified the TSX our intent to voluntarily remove our listing of common stock from the TSX in order to consolidate trading on the NYSE Amex. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported by the NYSE Amex:

	High	Low
2008		
First Quarter	2.41	2.15
Second Quarter	2.10	2.09
Third Quarter	1.70	1.57
Fourth Quarter	1.14	1.02

On March 20, 2009, the last reported sale price of our common stock on the American Stock Exchange was $1.60.

Holders

As of March 20, 2008, there were approximately 343 holders of record of our common stock. This figure does not reflect persons or entities that hold their stock in nominee or "street" name through various brokerage firms.

Dividend Policy

We have not paid cash dividends on our common stock since our inception. We currently expect to retain earnings primarily for use in the operation and expansion of our business, and therefore, do not anticipate paying any cash dividends in the near future. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements, restrictions under any existing indebtedness and other factors the Board of Directors deems relevant.

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Performance Graph(1)

The following graph compares our total stockholder returns for the past 14 months to two indices: the Amex Composite Index and the RDG MicroCap Biotechnology Index. The total return for each index assumes the reinvestment of all dividends, if any, paid by companies included in these indices and are calculated as of December 31 of each year.

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

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

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

(2) Shows the cumulative return on $100 invested on 10/26/07 in stock or 9/30/07 in index, including reinvestment of dividends. Fiscal year ending December 31.

Sales of Unregistered Securities

The following is a summary of our recent transactions involving sales of our securities that were not registered under the Securities Act of 1933, as amended (the “Securities Act”):

(1) In April 2008, we issued a two year warrant and a four year warrant to purchase an aggregate of 300,000 of common stock to PM Holdings Ltd. as part of our consideration for the revision of the agreement dated February 13, 2007 with PM Holdings. Under the terms of the original agreement, we agreed to pay PM Holdings $28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminates the monthly cash payment obligation and instead provides for a one-time, upfront cash payment of $264,000 and the issuance of warrants to purchase 300,000 of common stocks at an exercise price of $4.00 per share.

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(2) In July 2008, we issued total of 15,000 shares of common stock to the principals of The Investor Relations Group as compensation for services rendered to us.

The issuance of securities in the transaction described in paragraph 1 above was effected without registration under the Securities Act in reliance on Section 4(2) thereof and Rule 506 of Regulation D thereunder based on the status of such investors as accredited investors as defined under the Securities Act. The transaction described in paragraph 1 above was also exempt from registration under the Securities Act pursuant to Rule 903 of Regulation S thereunder as an offer and sale of securities that occurred outside the United States. The sale of securities was made in an offshore transaction, did not involve any directed selling efforts within the United States, and involved only purchasers who were outside the United States and were non-U.S. persons.

The issuance of securities in the transaction described in paragraph 2 above was effected without registration under the Securities Act in reliance on Section 4(2) thereof based on the company's belief that such investors were accredited investors as defined under the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchaser

We did not repurchase any of our outstanding equity securities during the most recent quarter covered by this report.

Use of Proceeds from Sales of Registered Securities

On October 24, 2007, a Registration Statement on Form S-1 (File. No. 333-140714) relating to our initial public offering was declared effective by the SEC. The closing was held October 31, 2007. The net proceeds to us from the offering were approximately $17.1 million. From the effective date of the registration statement until December 31, 2008, we estimate we had used $6.6 million for research and development, $2.0 million for working capital and $3.1 million for other general purposes. The remaining estimated $5.4 million have been invested in various interest-bearing money market accounts and marketable securities.

The amounts reflected above included expenditures for: the Phase I and II clinical development of NVC-422 in pre-surgical nasal preparation; pre-clinical, Phase I and initial Phase II studies of NVC-422 in the prevention of catheter associated urinary tract infections; and pre-clinical studies to select among additional indications to be taken into development. These expenditures did not represent a material change from the use of proceeds described in the prospectus related to the offering.

ITEM 6. SELECTED FINANCIAL DATA

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

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	Year Ended December 31,				
	2004	2005	2006	2007	2008
	(in thousands, except per share data)				
Statements of Operations Data:					
Revenue	$ -	$ -	$ 1,533	$ 5,913	$ 6,722
Operating expenses:					
Research and development	1,481	1,952	4,087	7,421	9,595
General and administrative	1,345	1,617	2,972	4,368	5,636
Total operating expenses	2,826	3,569	7,059	11,789	15,231
Other income (expense), net	22	106	240	488	397
Net loss before income taxes	(2,804)	(3,463)	(5,286)	(5,388)	(8,112)
Provision for income taxes	-	-	-	(12)	(2)
Net loss	$ (2,804)	$ (3,463)	$ (5,286)	$ (5,400)	$ (8,114)
Net loss per share:					
Basic and diluted	$ (0.64)	$ (0.71)	$ (0.92)	$ (0.60)	$ (0.38)
Shares used in per share calculations:					
Basic and diluted	4,378	4,852	5,715	8,974	21,312

	Year Ended December 31,				
	2004	2005	2006	2007	2008
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 4,047	$ 3,212	$ 11,086	$ 22,353	$ 12,099
Working capital	3,908	2,985	7,926	18,194	8,033
Total assets	4,359	3,562	11,866	23,922	13,969
Capital lease obligation—current and non-current	20	-	-	86	49
Equipment loan—current and non-current	-	-	-	716	836
Deferred revenue—current and non-current	-	-	9,167	7,517	4,167
Convertible notes payable	-	-	-	-	-
Convertible preferred stock	164	175	192	-	-
Common stock and additional paid-in capital	9,127	10,869	14,683	32,797	33,933
Total stockholders' equity	4,093	3,252	1,813	14,320	7,345

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included in Part II, Item 8 of this report. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section entitled "Risk Factors" in Item 1A and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical stage biopharmaceutical company focused on developing innovative product candidates for the treatment or prevention of a wide range of infections in hospital and non-hospital environments. Many of these infections have become increasingly difficult to treat because of the rapid rise in drug resistance. We have discovered and are developing a class of non-antibiotic anti-infective compounds, which we have named Aganocide compounds. These compounds are based upon small molecules that are naturally generated by white blood cells when defending the body against invading pathogens. 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 and viral infections. In laboratory testing, our Aganocide compounds have demonstrated the ability to destroy all bacteria against which they have been tested. Furthermore, because of their mechanism of action, we believe that bacteria are unlikely to develop resistance to our Aganocide compounds.

In August 2006, we entered into a collaboration and license agreement with Alcon, to license to Alcon the exclusive 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 solution. 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. Alcon has the right to terminate the agreement in its entirety upon nine months' notice, or terminate portions of the agreement upon 135 days' notice, subject to certain provisions. Both parties have the right to terminate the agreement for breach upon 60 days' notice.

Alcon is responsible for all of the costs that it incurs in developing the products using the Aganocide compounds. We announced the clearance of an Investigational New Drug (IND) application submitted by Alcon to the FDA to permit the clinical development of Novabay's NVC-422 for infection of the eye. The IND clearance has triggered the immediate payment of the first milestone of $1,000,000 from Alcon to Novabay. The achievement of the milestones and product commercialization is subject to many risks and uncertainties, including, but not limited to Alcon's ability to obtain regulatory approval from the FDA and Alcon's ability to execute its clinical initiatives. Therefore, we cannot predict when, if ever, the milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized product.

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. Galderma will be responsible for the

development costs of the acne and other indications, except in Japan, where they will be shared, 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 exclusive rights to 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 this agreement then NovaBay will receive royalties whose rates escalate as sales increase.

Our business model is to develop our Aganocide compounds and enter into collaboration and license agreements with other entities for different indications using our Aganocide compounds. For example, in June 2007, we entered into a license agreement with KCI, under which KCI paid to us a non-refundable technology access fee of $200,000. If products covered by the license are commercially launched, we will also receive royalty payments based on net revenues from sales by KCI of such products. We have not received any milestone or other payments under this agreement since the initial technology access fee.

To date, we have generated no revenue from product sales, and we have financed our operations and internal growth primarily through the sale of our capital stock, and the technology access fee from Alcon. We are a development stage company and have incurred significant losses since commencement of our operations in July 2002, as we have devoted substantially all of our resources to research and development. As of December 31, 2008, we had an accumulated deficit of $26.6 million. Our accumulated deficit resulted from research and development expenses and general and administrative expenses. We expect to continue to incur net losses over the next several years as we continue our clinical and research and development activities and as we apply for patents and regulatory approvals.

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Recent Events

In March 2008, we amended the Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 with PM Holdings Ltd. Under the terms of the original agreement, we agreed to pay PM Holdings $28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminated the monthly cash payment obligation and instead provided for a one-time, upfront cash payment of $264,000 and the issuance of warrants to purchase 300,000 common shares at an exercise price of $4.00 per share. Under the amended agreement, no further cash or equity amounts are payable during the duration of the agreement through February 2010. We paid the upfront cash amount and issued the warrants during April 2008.

In May 2008, we completed our Phase I safety study of our lead Aganocide compound, NVC-422, as a lavage solution for catheterized patients. The study showed that NVC-422 was well tolerated in the bladder in the Phase I trial. This study was designed to evaluate the safety and tolerability of NVC-422 in the bladder, and upon completion of the Phase I, the lavage solution for catheterized patients showed no adverse events. This Phase I study supports the development of the product as a candidate to treat or prevent catheter associated urinary tract infections (CAUTI).

In May 2008, NovaBay completed its Phase IIa study of NVC-422 for nasal decolonization of Staphylococcus aureus, including MRSA (Methicillin Resistant Staphylococcus Aureus). In this study, two concentrations of a prototype nasal spray formulation of NVC-422 was tested to decolonize the lower nasal passages and were both found to be well tolerated. Based on a statistical analysis the higher dose treatment group provided consistent S. aureus reduction below the baseline score throughout the treatment period.

In July 2008, we received our second issued patent in the U.S. The patent provides coverage for a method of disinfecting open wounds and burns, promoting wound healing and providing ocular disinfection using a specific range of formulations of NVC-101. This patent was issued on July 1, 2008 and will expire in 2024

In July 2008, we completed a successful testing of our formulation of our lead Aganocide compound for dermatological uses, known as AgaDerm, in a challenging animal model of dermatophyte infection. The study showed that the AgaDerm formulation delivered an Aganocide compound effectively when applied on the surface of the skin and enhanced its penetration into hair follicles. The infectious agent was a dermatophyte, Trichophyton mentagrophytes, a parasitic fungus that causes infections of the nails, hair and skin, including ringworm. The Aganocide compound in the AgaDerm formulation was shown to be highly effective not only on the skin surface, but also showed potent ability to kill organisms invading the hair.

In November 2008, we commenced patient enrollment in a Phase II Exploratory Study of hospitalized patients who are catheterized and have bacteriuria. This Phase II study is to explore the feasibility of developing NVC-422 as a product candidate to treat or prevent catheter-associated urinary tract infections (CAUTI).

In December 2008, we notified the Toronto Stock Exchange (TSX) of our intent to voluntarily remove our listing of common stock from the TSX in order to consolidate trading on the NYSE Amex.

In December 2008, we received our third issued patent in the U.S. The patent 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.

On March 25, 2009, we announced that we have entered into an agreement with Galderma S.A. to develop and commercialize our novel proprietary Aganocide® compounds. The exclusive agreement is worldwide in scope, except in certain Asian markets, and covers acne and impetigo and potentially other major dermatological conditions, excluding onychomycosis (nail fungus) and orphan drug indications.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements giving due consideration to materiality. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, income taxes, intangible assets, long-term service contracts and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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While our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of certain milestones and royalties on net product sales. In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and recognized over the performance obligation period. We recognize revenue in accordance with SEC Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements", as amended by SAB No. 104 (together, SAB 104). In accordance with SAB 104, revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectibility is reasonably assured.

Assuming the elements meet the EITF No. 00-21 criteria for separation and the SAB 104 requirements for recognition, the revenue recognition methodology prescribed for each unit of accounting is summarized below:

Upfront Fees—We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology licensed has no utility to the licensee. If we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement.

Funded Research and Development—Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. The full-time equivalent amount can vary each year if the contracts allow for a percentage increase determined by relevant salary surveys, if applicable. Reimbursements from collaborative partners for agreed upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical studies are classified as revenue in accordance with EITF Issue No. 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent," and recognized in the period the reimbursable expenses are incurred. Payments received in advance are recorded as deferred revenue until the research and development services are performed or costs are incurred.

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

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

Research and Development Costs

We charge research and development costs to expense as incurred. These costs include salaries and benefits for research and development personnel, costs associated with clinical trials managed by contract research organizations, and other costs associated with research, development and regulatory activities. We use external service providers to conduct clinical trials, to manufacture supplies of product candidates and to provide various other research and development-related products and services. Research and development costs may vary depending on the type of item or service incurred, location of performance or production, or lack of availability of the item or service, and specificity required in production for certain compounds.

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Patent Costs

We expense patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included as general and administrative expenses in our statements of operations. Patent costs may vary depending on the location, domestic of foreign, in which the patent is being secured.

Stock-Based Compensation

On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share-Based Payment". SFAS No. 123R replaced SFAS No. 123 and superseded Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations. Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. We were required to utilize the prospective application method prescribed by SFAS No. 123R, under which prior periods are not revised for comparative purposes. Under SFAS No. 123R, forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. Under the prospective application transition method, non-public entities that previously used the minimum value method of SFAS No. 123 should continue to account for non-vested equity awards outstanding at the date of adoption of SFAS No. 123R in the same manner as they had been accounted for prior to adoption. SFAS No. 123R specifically prohibits pro forma disclosures for those awards valued using the minimum value method. The valuation and recognition provisions of SFAS No. 123R apply to new awards and to awards outstanding as of the adoption date that are subsequently modified. The adoption of SFAS No. 123R had a material effect on our financial position and results of operations. See Note 10 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

Prior to the adoption of SFAS No. 123R, we valued our stock-based awards using the minimum value method and provided pro-forma information regarding stock-based compensation and net income required by SFAS No. 123. We did not recognize stock-based compensation expense in our statements of operations for option grants to our employees or directors for the periods prior to our adoption of SFAS No. 123R because the exercise price of options granted was generally equal to the fair market value of the underlying common stock on the date of grant.

We account for stock compensation arrangements with non-employees in accordance with SFAS No. 123R and EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", which require that such equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

The adoption of SFAS No.123R had a material effect on our financial position and results of operations. See Note 10 of the Notes to Consolidated Financial Statements, included in Part II, Item 8 of this report, for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

Income Taxes

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets

and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recognized if it is more likely than not that some portion or all of the deferred tax asset will not be recognized.

Recent Accounting Pronouncements

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities”. SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities by requiring enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities,” and how derivative instruments and related hedged items affect an entity’s operating results, financial position, and cash flows.

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SFAS No. 161 is effective for fiscal years beginning after November 15, 2008. Early adoption is permitted. We are currently reviewing the provisions of SFAS No. 161 and have not yet adopted the statement. However, as the provisions of SFAS No. 161 are only related to disclosure of derivative and hedging activities, we do not believe the adoption of SFAS No. 161 will have a material impact on our consolidated operating results, financial position, or cash flows.

In April 2008, the FASB issued FSP FAS 142-3, Determination of the Useful Life of Intangible Assets or FSP FAS 142-3. FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. The intent of the position is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the intangible asset. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. We are assessing the potential impact that the adoption of FSP FAS 142-3 may have on our consolidated financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles or SFAS No. 162. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement shall be effective 60 days following the Securities and Exchange Commission’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. We do not believe that implementation of this standard will have a material impact on our consolidated financial position, results of operations or cash flows.

In June 2008, the FASB issued FSP No. EITF 03-6-1, “Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities,” (FSP EITF 03-6-1). FSP EITF 03-6-1 states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. Management has determined that the adoption of FSP EITF 03-6-1 will not have an impact on the Financial Statements.

Results of Operations

Comparison of Years Ended December 31, 2007 and December 31, 2008

License and Collaboration Revenue

Total license and collaboration revenue was $5.9 million for the year ended December 31, 2007, compared to $6.7 million for the year ended December 31, 2008. License and collaboration revenue consisted almost exclusively of amounts earned under the license and collaboration agreement with Alcon for amortization of the upfront technology access fees and amounts that have been or will be reimbursed for the funding of research and development activities performed during the period. The upfront technology access fee of $10.0 million from Alcon is being amortized into revenue on a straight-line basis over the four year funding term of the agreement, through August 2010. The upfront technology access fee from KCI of $200,000 has been amortized on a straight-line basis over 18 months through December 2008.

To the extent we earn milestone payments under the Alcon and Galderma collaborations, we would expect revenues to increase. We expect to receive approximately $4 million under the Galderma agreement, and received the initial portion in March 2009. However, we cannot predict if and when we will receive any milestone payments from these collaborations.

Research and Development

Total research and development expenses increased by 29% to $9.6 million for the year ended December 31, 2008 from $7.4 million for the year ended December 31, 2008. This increase was due in part to an increase in related employee costs of $0.5 million, as the average number of research and development personnel increased for most of 2008. Research expenses increased by 26% to $0.6 million, as a result of increased contract studies in bio-sciences and discovery research, and an increase in related lab services and supplies. Development expenses increased by 92% to $1.4 million, mainly due to an increase in process development, method development, and formulation studies. In addition, $0.7 million of overhead expenses were allocated to research and development.

We expect to incur ongoing research and development expenses in 2009 and in subsequent years as we continue to increase our focus on developing product candidates, both independently and in collaboration with Alcon. In particular, we expect to incur ongoing clinical, chemistry, and manufacturing expenses during 2009 in connection with the common cold, dermatology, and catheter associated urinary tract infections programs.

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General and Administrative

General and administrative expenses increased by 29% to $5.6 million for the year ended December 31, 2008 from $4.4 million for the year ended December 31, 2007. This increase was due in part to an increase in employee costs of 53%, to $2.5 million. The increase in employee costs was mainly due to a 53% increase in salaries and wages to $1.4 million and related increases in other employee benefits and recruiting expenses, due primarily to increased headcount.

We expect that general and administrative expenses will increase during 2009 and in subsequent years due to increasing public company expenses and business development costs and our expanding operational infrastructure. In particular, we expect to incur increasing legal, accounting, investor relations, equity administration and insurance costs in order to operate as a public company.

Other Income, Net

Other income, net decreased to $397,000 for the year ended December 31, 2008 from $487,000 for the year ended December 31, 2007. This decrease was primarily attributable to increased interest expense related to borrowings secured by capital equipment, due to paying interest for the full year instead of a partial year. The decrease was also attributed to increased finance and service charges related to increased borrowings on the line of credit secured by the capital equipment loan. Interest income relates primarily to interest earned on cash, cash equivalents and investments in marketable securities. See “Note 3-Short Term Investments.”

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

Comparison of Years Ended December 31, 2006 and December 31, 2007

License and Collaboration Revenue

Total license and collaboration revenue was $1.5 million for the year ended December 31, 2006, compared to $5.9 million for the year ended December 31, 2007. License and collaboration revenue consisted primarily of amounts earned under the license and collaboration agreements with Alcon for amortization of the upfront technology access fees and amounts that have been or will be reimbursed for the funding of research and development activities performed during the period. The increase in revenue during 2007 as compared to 2006 is attributable to the timing of the Alcon and KCI agreements, which were entered into in August 2006 and June 2007, respectively. The upfront technology access fee of $10.0 million from Alcon is being amortized into revenue on a straight-line basis over the four year funding term of the agreement, through August 2010. The upfront technology access fee from KCI of $200,000 has been amortized on a straight-line basis over 18 months through December 2008.

Research and Development

Research and development expenses increased by 82% to $7.4 million for the year ended December 31, 2007 from $4.1 million for the year ended December 31, 2006. This increase was due in part to an increase in salary and benefits expense of $1.5 million, as the average number of research and development personnel increased by 77% from 2006 to 2007, and included the hiring of several senior personnel. In connection with this increase in hiring, recruiting and relocation costs increased by $110,000 due to an increased reliance on outside personnel recruitment firms and the funding of relocation benefits. Also, during the last three quarters of 2007, we conducted Phase I and Phase II clinical studies for the pre-surgical nasal preparation indication, which caused our clinical expenses for the year ended December 31, 2007 to increase by $730,000 over the year ended December 31, 2006. Additionally, increased efforts

around the chemistry, manufacturing and controls related to NVC-422 resulted in an increase of $538,000 from the year ended December 31, 2006 to the year ended December 31, 2007 as we produced more drug substance to support our internal research programs and Alcon collaboration requirements. Costs for outside consultants increased by $245,000 during the year ended December 31, 2007 as a result of increased regulatory activity associated with the IND filings for the pre-surgical nasal preparation and catheter associated urinary tract infection indications and the filing of the 510(k) application related to our NVC-101 compound, as well as due to increased usage of manufacturing and formulation consultants in connection with the KCI agreement. The amortization of stock-based compensation increased by $121,000 from 2006 to 2007 as a result of an increased number of grants becoming subject to the SFAS No. 123R guidance.

General and Administrative

General and administrative expenses increased by 47% to $4.4 million for the year ended December 31, 2007 from $3.0 million for the year ended December 31, 2006. This increase was due in part to an increase in salary and benefits expense of $494,000 as the average number of general and administrative personnel grew by 27% from 2006 to 2007. The increase in general and administrative expenses during the year ended December 31, 2007 was also attributable to the issuance of $360,000 in cash and stock to a consultant for investor relations and financial advisory services and cash and stock payments of $114,000 made to our non-employee directors upon the closing of the IPO and for ongoing director compensation. Rent expense increased by $209,000 during the year ended December 31, 2007 compared to the same period in the prior year because we leased additional space in late 2006 and during the second and fourth quarters of 2007 to accommodate our increased personnel and expanded laboratory facilities. Accounting expenses increased by $97,000 from the 2006 to the 2007 period as audit and tax activities increased in preparation for becoming a public company.

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Other Income, Net

Other income, net increased to $488,000 for the year ended December 31, 2007 from $240,000 for the year ended December 31, 2006. This increase was primarily attributable to increased interest income earned due to higher average cash balances as a result of the $10.0 million upfront cash amount received from Alcon in August 2006 and the $17.1 million received upon the closing of the IPO in October 2007.

Liquidity and Capital Resources

We have incurred cumulative net losses of $26.6 million since inception through December 31, 2008. We do not expect to generate significant revenue from product candidates for several years. Since inception, we have funded our operations primarily through the private placement of our preferred stock. We raised total net proceeds of $12.6 million from sales of our preferred stock in 2002 through 2006. In October 2007, we completed our IPO in which we raised a total of $20.0 million, or approximately $17.1 million in net cash proceeds after deducting underwriting discounts and commissions of $1.4 million and other offering costs of $1.5 million.

In August 2006, we entered into a collaboration and license agreement with Alcon. Under the terms of this agreement, we received an up-front technology access fee of $10.0 million in September 2006. Additionally, we are entitled to receive semi-annual payments each January and July over the four year term of the agreement to support on-going research and development efforts. In both January and July 2007, we received a payment of $1.4 million to support the performance of research and development activities throughout 2007. The Alcon agreement also provides for milestone payments upon the achievement of specified milestones in each field of use and royalty payments upon the sale of commercialized products. The aggregate milestone payments payable in connection with the ophthalmic, otic and sinus fields are $19 million, $12 million and $39 million, respectively. As of December 31, 2008, we have not achieved any milestone nor has any product been commercialized to date. The achievement of the milestones and product commercialization is subject to many risks and uncertainties, including, but not limited to Alcon’s ability to obtain regulatory approval from the FDA and Alcon’s ability to execute its clinical initiatives. Therefore, we cannot predict when, if ever, the milestones specified in the Alcon agreement will be achieved or when we will receive royalties on sales of commercialized products.

During April 2007, we entered into a master security agreement to establish a $1.0 million equipment loan facility with a financial institution. The purpose of the loan is to finance equipment purchases, principally in the build-out of our laboratory facilities. Borrowings under the loan are secured by eligible equipment purchased from January 2006 through April 2008 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. There are no loan covenants specified in the agreement. As of December 31, 2008, we had an outstanding equipment loan balance of $716,000 carrying a weighted-average interest rate of 10.57%. The principal and interest due under the loan will be repaid in equal monthly installments through April 2011. As of December 31, 2008 there was $206,000 available for borrowing under this equipment loan facility.

In March 2009, we entered into a license agreement with Galderma. Under the terms of the agreement, we have received an initial upfront payment. In addition, Galderma will pay to Novabay certain upfront fees, ongoing fees, reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide® compounds.

Cash and Cash Equivalents

As of December 31, 2008, we had cash, cash equivalents, and short-term investments of $12.1 million compared to $22.4 million at December 31, 2007, and $11.1 million at December 31, 2006.

Cash Provided by (Used in) Operating Activities

For the years ended December 31, 2008 and 2007, cash used in operating activities of $9.9 million $6.3 million, respectively, was primarily attributable to our research and development and general administrative expenses in running our company, and lack of any meaningful cash inflow, as the revenue we recognized was primarily related to amortization of the $10.0 million upfront technology access fee received from Alcon in 2006.

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For the year ended December 31, 2006, cash provided by operating activities of $4.7 million was attributable primarily to an increase in deferred revenue related to the $10.0 million upfront technology access fee received from Alcon and an increase in accounts payable and accrued liabilities reflecting amounts that were expensed during the period but not paid until after December 31, 2006. This amount was offset by our net loss of $5.3 million, excluding the amounts recognized for stock-based compensation and depreciation, which are non-cash expenses.

Cash Used in Investing Activities

For the year ended December 31, 2008, cash provided by investing activities of $10.9 million was attributable to sales of short-term investments (net of purchases) of $11.5 million and purchases of property and equipment of $610,000.

For the year ended December 31, 2007, cash used in investing activities of $5.7 million was attributable to purchases of short-term investments (net of maturities or sales) of $5.0 million and purchases of property and equipment of $663,000.

For the year ended December 31, 2006, cash used in investing activities of $5.5 million was attributable to purchases of short-term investments (net of maturities or sales) of $5.2 million and purchases of property and equipment of $362,000.

Cash Provided by Financing Activities

Net cash provided by financing activities of $236,000 for the year ended December 31, 2008 was primarily attributable to the $422,000 increase in proceeds from borrowings under our equipment loan, net of payments on the outstanding balance.

Net cash provided by financing activities of $18.0 million for the year ended December 31, 2007 was primarily attributable to the net proceeds of $17.1 million received upon the close of the IPO and $794,000 in proceeds from borrowings under our equipment loan.

Net cash provided by financing activities of $3.5 million for the year ended December 31, 2006 was attributable to sales of preferred stock of $2.6 million and proceeds from option and warrant exercises of $1.0 million, partially offset by $93,000 of costs incurred in preparation for our initial public offering.

Quarterly Results of Operations

The following table presents unaudited quarterly results of operations for the eight quarters ended December 31, 2008. This information has been derived from our unaudited financial statements and has been prepared by us on a basis consistent with our audited annual financial statements and includes all adjustments, consisting only of normal recurring adjustments, which management considers necessary for a fair presentation of the information for the periods presented.

	Quarter Ended (1)							
	March 31, 2007	June 30, 2007	Sept. 30, 2007	Dec. 31, 2007	March 31, 2008	June 30, 2008	Sept. 30, 2008	Dec. 31, 2008
	(in thousands, except per share data)							
Statements of Operations Data:								
Revenue	$ 1,483	$ 1,465	$ 1,444	$ 1,521	$ 1,492	$ 1,442	$ 1,592	$ 2,196
Operating expenses:								

Research and development	1,463	2,066	2,051	1,841	2,647	2,173	1,443	2,541
General and administrative	1,035	1,069	1,021	1,243	1,684	1,773	1,715	1,255
Total operating expenses	2,498	3,135	3,072	3,084	4,331	3,946	3,158	3,796
Other income (expense), net	122	113	72	181	163	94	77	64
Net loss before income taxes	(893)	(1,557)	(1,556)	(1,382)	(2,676)	(2,410)	(1,489)	(1,536)
Provision for income taxes	-	-	-	(12)	(2)	-	-	-
Net loss	$ (893)	$ (1,557)	$ (1,556)	$ (1,394)	$ (2,678)	$ (2,410)	$ (1,489)	$ (1,536)
Net loss per share:								
Basic and diluted	$ (0.14)	$ (0.24)	$ (0.24)	$ (0.09)	$ (0.13)	$ (0.11)	$ (0.07)	$ (0.07)
Shares used in per share calculations:								
Basic and diluted	6,416	6,500	6,564	16,332	21,288	21,334	21,443	21,469

(1) The 2008 and 2007 amounts were computed independently for each quarter, and the sum of the quarters may not total the annual amounts.

Net Operating Losses and Tax Credit Carryforwards

As of December 31, 2008 we had net operating loss carryforwards for both federal and state income tax purposes of $20 million. If not utilized, the federal and state net operating loss carryforwards will begin expiring at various dates between 2014 and 2028.

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Current federal and California tax laws include substantial restrictions on the utilization of net operating loss carryforwards in the event of an ownership change of a corporation. Accordingly, our ability to utilize net operating loss carryforwards may be limited as a result of such ownership changes. Such a limitation could result in the expiration of carryforwards before they are utilized

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented, and we do not expect it to have a material impact in the near future. There can be no assurances, however, that our business will not be affected by inflation.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Contractual Obligations

Our contractual cash commitments as of December 31, 2008 were as follows:

Contractual Obligations	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 years
			(in thousands)		
Operating leases	$ 6,594	$ 860	$ 2,787	$ 2,947	$ -
Capital lease	52	45	7	-	-
Equipment loan	945	440	505	-	-
	$ 7,591	$ 1,344	$ 3,300	$ 2,947	$ -

Our commitments under the operating leases shown above consist of payments relating to five leases for laboratory and office space in one office building in Emeryville, California. These leases expire on various dates through October 31, 2015.

Our commitment under the capital lease shown above consists of the total payments due under one lease of laboratory equipment. This amount includes $12,581 of interest payments over the remaining term of the lease.

Our commitment under the equipment loan shown above consists of the total payments due under the loan facility. This amount includes $108,690 of interest payments over the remaining term of the loan.

We believe our cash balance at December 31, 2008 is sufficient to fund our projected operating requirements through at least the next twelve months. However, we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress and cost of our pre-clinical studies and clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;

- the cost and timing of regulatory approvals;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risk consists principally of interest rate risk on our cash, cash equivalents, and short-term investments. Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in interest rates, particularly because the majority of our investments are in short-term debt securities.

Our investment policy restricts our investments to high-quality investments and limits the amounts invested with any one issuer, industry, or geographic area. The goals of our investment policy are as follows: preservation of capital; assurance of liquidity needs; best available return on invested capital; and minimization of capital taxation. Some of the securities in which we invest may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with an interest rate fixed at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. To minimize this risk, in accordance with our investment policy, we maintain our cash and cash equivalents in short-term marketable securities, including money market mutual funds, Treasury bills, Treasury notes, commercial paper, and corporate and municipal bonds. The risk associated with fluctuating interest rates is limited to our investment portfolio. Due to the short term nature of our investment portfolio, we believe we have minimal interest rate risk arising from our investments. We do not use derivative financial instruments in our investment portfolio. We do not hold any instruments for trading purposes.

To date, we have operated exclusively in the United States and have not had any material exposure to foreign currency rate fluctuations. We have recently formed a wholly-owned subsidiary, which is incorporated under the laws of British Columbia (Canada), which may conduct research and development activities in Canada. To the extent we conduct operations in Canada, fluctuations in the exchange rates of the U.S. and Canadian currencies may affect our operating results.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item 8 are set forth below. Our quarterly financial information is set forth in Item 7 of this report and is hereby incorporated into this Item 8 by reference.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of NovaBay Pharmaceuticals, Inc. (a development stage company) as at December 31, 2007 and 2008 and the related consolidated statements of operations, cash flows and stockholders' equity for the years ended December 31, 2006, 2007 and 2008 and for the period from July 1, 2002 (date of development stage inception) to December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as at December 31, 2007 and 2008 and the results of its operations and its cash flows for the years ended December 31, 2006, 2007 and 2008 and for the period from July 1, 2002 (date of development stage inception) to December 31, 2008 in conformity with generally accepted accounting principles in the United States of America.

/s/ Davidson & Company LLP
Chartered Accountants

Vancouver, Canada
March 24, 2009

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

	December 31, 2007	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,941	$ 12,099
Short-term investments (Note 3)	11,412	-
Prepaid expenses and other current assets	419	414
Total current assets	22,772	12,513
Property and equipment, net (Note 4)	1,150	1,456
TOTAL ASSETS	$ 23,922	$ 13,969
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Accounts payable	$ 142	$ 406
Accrued liabilities (Note 5)	1,141	1,166
Capital lease obligation (Note 6)	37	42
Equipment loan (Note 7)	219	366
Deferred revenue	3,039	2,500
Total current liabilities	4,578	4,480
Capital lease obligation - non-current (Note 6)	49	7
Equipment loan - non-current (Note 7)	497	470
Deferred revenue - non-current	4,478	1,667
Total liabilities	9,602	6,624
Stockholders' Equity:		
Common stock, $0.01 par value; 65,000 and 65,000 shares authorized at December 31, 2007 and December 31, 2008, respectively, 21,269 and 21,471 shares issued and outstanding at December 31, 2007 and December 31, 2008, respectively.	212	215
Additional paid-in capital	32,585	33,718
Accumulated other comprehensive income (loss)	(3)	-
Accumulated deficit during development stage	(18,474)	(26,588)
Total stockholders' equity	14,320	7,345
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 23,922	$ 13,969

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

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

	Year Ended December 31,			Cumulative Period from July 1, 2002 (date of development stage inception) to December 31,
	2006	2007	2008	2008
REVENUE				
License and collaboration revenue	$ 1,533	$ 5,913	$ 6,722	$ 14,168
Total revenue	1,533	5,913	6,722	14,168
EXPENSES				
Operating Expenses:				
Research and development	4,087	7,421	9,595	25,007
General and administrative	2,972	4,368	5,636	16,964
Total operating expenses	7,059	11,789	15,231	41,971
Other income, net	240	488	397	1,229
Net loss before income taxes	(5,286)	(5,388)	(8,112)	(26,574)
Provision for income taxes	-	(12)	(2)	(14)
Net loss	$ (5,286)	$ (5,400)	$ (8,114)	$ (26,588)
Net loss per share:				
Basic and diluted	$ (0.92)	$ (0.60)	$ (0.38)	
Shares used in per share calculations:				
Basic and diluted	5,715	8,974	21,312	

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

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated Deficit During Development	Total Stockholders'
	Shares	Amount	Capital	(Loss)	Stage	Equity
Balance at July 1, 2002	-	$ -	$ -	$ -	$ -	$ -
Comprehensive loss:						
Net loss	-	-	-	-	(544)	(544)
Total comprehensive loss						(544)
Issuance of Series A preferred stock and common stock for acquisition of LLC	3,902	39	462	-	-	528
Stock-based compensation expense related to non-employee stock options	-	-	15	-	-	15
Sale of stock warrants	-	-	10	-	-	10
Balance at December 31, 2002	3,902	39	487	-	(544)	9
Comprehensive loss:						
Net loss	-	-	-	-	(977)	(977)
Total comprehensive loss						(977)
Issuance of Series A preferred stock	-	-	192	-	-	197
Issuance of Series B preferred stock net of issuance costs of $86	-	-	1,413	-	-	1,446
Issuance of stock	25		7	-	-	7
Issuance of stock for option exercises	40	1	7	-	-	8
Issuance of stock for warrant exercises	137	1	109	-	-	110
Stock-based compensation expense related to non-employee stock options	-	-	2	-	-	2
Balance at December 31, 2003	4,104	41	2,217	-	(1,521)	802
Comprehensive loss:						
Net loss	-	-	-	-	(2,804)	(2,804)
Total comprehensive loss						(2,804)
Issuance of Series B preferred stock net of issuance costs of $127	-	-	1,112	-	-	1,139
	-	-	420	-	-	429

Issuance of Series B preferred stock upon conversion of notes						
Issuance of Series C preferred stock net of issuance costs of $123	-	-	5,178	-	-	4,368
Issuance of stock for option exercises	5	-	1	-	-	1
Issuance of stock for warrant exercises	31	-	37	-	-	37
Issuance of stock for Series B offering costs	368	4	106	-	-	110
Issuance of stock for services	15	-	4	-	-	4
Stock-based compensation expense related to non-employee stock options	-	-	7	-	-	7
Balance at December 31, 2004	4,523	45	9,082	-	(4,325)	4,093
Comprehensive loss:						
Net loss	-	-	-	-	(3,463)	(3,463)
Change in unrealized gains (losses) on investments	-	-	-	(4)	-	(4)
Total comprehensive loss						(3,467)
Issuance of Series C preferred stock net of issuance costs of $140	-	-	158	-	-	162
Issuance of Series D preferred stock net of issuance costs of $36	-	-	1,070	-	-	1,077
Issuance of stock for option exercises	50	-	12	-	-	12
Issuance of stock for warrant exercises	292	3	324	-	-	327
Issuance of stock and options for Series C offering costs	164	2	101	-	-	103
Issuance of stock for services	20	-	17	-	-	17
Stock-based compensation expense related to non-employee stock options	-	-	55	-	-	55
Proceeds from stock subscription receivable	-	-	-	-	-	873
Balance at December 31, 2005	5,049	50	10,819	(4)	(7,788)	3,252
Comprehensive loss:						
Net loss	-	-	-	-	(5,286)	(5,286)
Change in unrealized gains (losses) on investments	-	-	-	16	-	16
Total comprehensive loss						(5,270)
Issuance of Series D preferred stock net of issuance costs of $114	-	-	2,477	-	-	2,494

Issuance of stock for option exercises	80	1	22	-	-	23
Issuance of stock for warrant exercises	1,148	12	964	-	-	976
Issuance of stock and options for Series D offering costs	31	-	64	-	-	64
Issuance of stock for services	3	-	5	-	-	5
Initial public offering costs	-	-	(93)	-	-	(93)
Stock-based compensation expense related to employee and director stock options	-	-	313	-	-	313
Stock-based compensation expense related to non-employee stock options	-	-	49	-	-	49
Balance at December 31, 2006	6,311	63	14,620	12	(13,074)	1,813

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

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Accumulated Deficit During Development	Total Stockholders'
	Shares	Amount	Capital	(Loss)	Stage	Equity
Balance at December 31, 2005	5,049	50	10,819	(4)	(7,788)	3,252
Comprehensive loss:						
Net loss	-	-	-	-	(5,286)	(5,286)
Change in unrealized gains (losses) on investments	-	-	-	16	-	16
Total comprehensive loss						(5,270)
Issuance of Series D preferred stock net of issuance costs of $114	-	-	2,477	-	-	2,494
Issuance of stock for option exercises	80	1	22	-	-	23
Issuance of stock for warrant exercises	1,148	12	964	-	-	976
Issuance of stock and options for Series D offering costs	31	-	64	-	-	64
Issuance of stock for services	3	-	5	-	-	5
Initial public offering costs	-	-	(93)	-	-	(93)
Stock-based compensation expense related to employee and director stock options	-	-	313	-	-	313
Stock-based compensation expense related to non-employee stock options	-	-	49	-	-	49
Balance at December 31, 2006	6,311	63	14,620	12	(13,074)	1,813
Comprehensive loss:						
Net loss	-	-	-	-	(5,400)	(5,400)
Change in unrealized gains (losses) on investments	-	-	-	(15)	-	(15)
Total comprehensive loss						(5,415)
Conversion of preferred stock to common stock in connection with IPO	9,614	96	96	-	-	-
Issuance of stock and warrants in connection with IPO, net of offering costs	5,000	50	17,120	-	-	17,170
	298	3	111	-	-	114

Issuance of stock for option exercises						
Issuance of stock for services	38	-	92	-	-	92
Issuance of stock for director compensation	8	-	29	-	-	29
Stock-based compensation expense related to employee and director stock options	-	-	399	-	-	399
Stock-based compensation expense related to non-employee stock options	-	-	118	-	-	118
Balance at December 31, 2007	21,269	212	32,585	(3)	(18,474)	14,320
Comprehensive loss:						
Net loss	-	-	-	-	(8,114)	(8,114)
Realized gains (losses)				35		35
Change in unrealized gains (losses) on investments	-	-	-	(32)	-	(32)
Total comprehensive loss						(8,111)
Conversion of preferred stock to common stock in connection with IPO	-	-	-	-	-	-
Issuance of warrants			67			67
Issuance of stock for option exercises	123	1	148	-	-	149
Issuance of stock for services	30	1	84	-	-	85
Issuance of stock for director compensation	49	1	123	-	-	124
Stock-based compensation expense related to employee and director stock options	-	-	721	-	-	721
Stock-based compensation expense related to non-employee stock options	-	-	(11)	-	-	(11)
Tax benefit from stock plans	-	-	1	-	-	1
Balance at December 31, 2008	21,471	$ 215	$ 33,718	$ -	$ (26,588)	$ 7,345

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

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NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,			Cumulative Period from July 1, 2002 (date of development stage inception) to December 31,
	2006	2007	2008	200
Cash flows from operating activities:				
Net loss	$ (5,286)	$ (5,400)	$ (8,114)	$ (26,588)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	74	183	304	704
Accretion of discount on short-term investments	(32)	(246)	(23)	(301)
Net realized (gain) loss on sales of short-term investments	20	-	(35)	(3)
Loss on disposal of property and equipment	1	-	-	121
Stock-based compensation expense for options issued to employees and directors	313	428	721	1,462
Compensation expense for warrants & stock issued for services	-	-	100	100
Stock-based compensation expense for options and stock issued to non-employees	54	210	162	525
Taxes paid by LLC	-	-		1
Changes in operating assets and liabilities:				
Decrease (increase) in prepaid expenses and other assets	(143)	(193)	5	(409)
Increase in accounts payable and accrued liabilities	576	397	289	1,597
Increase (decrease) in deferred revenue	9,167	(1,650)	(3,351)	4,166
Net cash provided by (used in) operating activities	4,744	(6,271)	(9,942)	(18,625)
Cash flows from investing activities:				
Purchases of property and equipment	(362)	(663)	(610)	(2,160)
Proceeds from disposal of property and equipment	1	1	-	44
Purchases of short-term investments	(11,293)	(49,197)	(32,097)	(94,544)
Proceeds from maturities and sales of short-term investments	6,141	44,199	43,571	94,847
Cash acquired in purchase of LLC	-	-	-	516
Net cash provided by (used in) investing activities	(5,513)	(5,660)	10,864	(1,297)
Cash flows from financing activities:				
Proceeds from preferred stock issuances	2,558	-	-	11,160

Proceeds from common stock issuances	-	-	-	17
Proceeds from exercise of options and warrants	999	114	153	1,761
Proceeds from initial public offering, net of costs	(93)	17,170	-	17,077
Proceeds from stock subscription receivable	-	-	-	873
Proceeds from issuance of notes	-	-	-	405
Payments on capital lease	-	(31)	(37)	(108)
Proceeds from borrowings under equipment loan	-	794	422	1,216
Payments on equipment loan	-	(78)	(302)	(380)
Tax benefit from stock plans	-	-	-	-
Net cash provided by financing activities	3,464	17,969	236	32,021
Net increase in cash and cash equivalents	2,695	6,038	1,158	12,099
Cash and cash equivalents, beginning of period	2,208	4,903	10,941	-
Cash and cash equivalents, end of period	$ 4,903	$ 10,941	$ 12,099	$ 12,099

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

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NOVABAY PHARMACEUTICALS, INC.
(a development stage company)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,			Cumulative Period from July 1, 2002 (date of development stage inception) to December 31,
	2006	2007	2008	2008
Supplemental disclosure of cash flow information:				
Interest paid	$ 2	$ 34	$ 102	$ 146
Income taxes paid	$ -	$ -	$ -	$ -
Non-cash activities:				
Issuance of stock, options and warrants for stock offering costs	$ 64	$ 524	$ -	$ 801
Property and equipment acquired under capital lease obligation	$ -	$ 117	$ 62	$ 219

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NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION

NovaBay Pharmaceuticals, Inc. (the "Company") is a clinical stage biopharmaceutical company focused on developing innovative product candidates for the treatment or prevention of a wide range of infections in hospital and non-hospital environments. Many of these infections have become increasingly difficult to treat because of the rapid rise in drug resistance. We have discovered and are developing a class of non-antibiotic anti-infective compounds, which we have named Aganocide compounds. These compounds are based upon small molecules that are naturally generated by white blood cells when defending the body against invading pathogens. 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 and viral infections. In laboratory testing, our Aganocide compounds have demonstrated the ability to destroy all bacteria against which they have been tested. Furthermore, because of their mechanism of action, we believe that bacteria are unlikely to develop resistance to our Aganocide compounds.

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. We currently operate in one business segment.

In October 2007, we completed an initial public offering of our common stock ("IPO") in which we sold and issued 5,000,000 shares of our common stock at a price to the public of $4.00 per share. We raised a total of $20.0 million from the IPO, or approximately $17.1 million in net cash proceeds after deducting underwriting discounts and commissions of $1.4 million and other offering costs of $1.5 million. Upon the closing of the IPO, all shares of convertible preferred stock outstanding automatically converted into 9,613,554 shares of common stock. In connection with the IPO, we also issued warrants to the underwriters to purchase an aggregate of 350,000 shares of common stock at an exercise price of $4.00 per share. The warrants are exercisable on or after October 31, 2008 and expire on October 31, 2010.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements include our accounts and the accounts of our wholly owned subsidiaries. Intercompany transactions and balances have been eliminated. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and are expressed in U.S. dollars. The financial statements have been prepared under the guidelines of Statement of Financial Accounting Standard ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises". A development stage enterprise is one in which planned principal operations have not commenced, or if its operations have commenced, there have been no significant revenues therefrom. As of December 31, 2008, we had not commenced our planned principal operations.

Certain amounts for prior periods have been reclassified to conform to current period presentation.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, NovaBay Pharmaceuticals Canada, Inc. and DermaBay, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

Reverse Stock Split

On August 10, 2007, we filed an amendment to our articles of incorporation to effect a 1-for-2 reverse stock split of our common stock. All share and per share amounts relating to the common stock, stock options and warrants and the conversion ratios of preferred stock included in the financial statements and footnotes have been restated to reflect the reverse stock split.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents and Short-Term Investments

We consider all highly liquid instruments with a stated maturity of three months or less to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximate their fair value. As of December 31, 2008, our cash and cash equivalents were held in financial institutions in the United States and include deposits in money market funds, which were unrestricted as to withdrawal or use.

We classify all highly liquid investments with a stated maturity of greater than three months as short-term investments. Short-term investments generally consist of United States government, municipal and corporate debt securities. We have classified our short-term investments as available-

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NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

for-sale. We do not intend to hold securities with stated maturities greater than twelve months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, we occasionally sell these securities prior to their stated maturities. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. A decline in the market value below cost of any available-for-sale security that is determined to be other than temporary results in a revaluation of its carrying amount to fair value and an impairment charge to earnings, resulting in a new cost basis for the security. No such impairment charges were recorded for the periods presented. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. The amortization and accretion, interest income and realized gains and losses are included in other income, net within the consolidated statements of operations. Interest income is recognized when earned.

Concentrations of Credit Risk

Financial instruments which potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. We maintain deposits of cash, cash equivalents and short-term investments with three highly-rated, major financial institutions in the United States.

Deposits in these banks may exceed the amount of federal insurance provided on such deposits. We do not believe we are exposed to significant credit risk due to the financial position of the financial institutions in which these deposits are held. Additionally, we have established guidelines regarding diversification and investment maturities, which are designed to maintain safety and liquidity.

Fair Value of Financial Assets and Liabilities

Financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The fair value of capital lease obligations and equipment loans approximates its carrying amounts as a market rate of interest is attached to their repayment.

The Company measures the fair value of financial assets and liabilities based on the guidance of Statement of Financial Accounting Standards No. 157, Fair Value Measurements (“Statement No. 157”) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. Effective January 1, 2008, the Company adopted the provisions of Statement No. 157 for financial assets and liabilities, as well as for any other assets and liabilities that are carried at fair value on a recurring basis. The adoption of the provisions of Statement No. 157 did not materially impact the Company’s consolidated financial position and results of operations.

Statement No. 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Statement No. 157 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Statement No. 157 describes three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities
Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable
Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

At December 31, 2008 there were no assets or liabilities subject to additional disclosure under Statement No. 157.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets of five to seven years for office and laboratory equipment, three years for software and seven years for furniture and fixtures. Leasehold improvements are depreciated on the shorter of seven years or the life of the lease term. Depreciation of assets recorded under capital leases is included in depreciation expense.

The costs of normal maintenance, repairs, and minor replacements are charged to operations when incurred.

Impairment of Long-Lived Assets

We account for long-lived assets in accordance with SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of”, which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets and has determined that there was no impairment as of all periods presented. Should there be impairment in the future, we would recognize the amount of the impairment based on the expected future cash flows from the impaired assets. The cash flow estimates would be based on management’s best estimates, using appropriate and customary assumptions and projections at the time.

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Accumulated Other Comprehensive Income

Accumulated other comprehensive income consists of unrealized gains and losses on short-term investments classified as available-for-sale.

Revenue Recognition

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreements typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of certain milestones and royalties on net product sales. In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables", we analyze our multiple element arrangements to determine whether the elements can be separated. We perform our analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and recognized over the performance obligation period. We recognize revenue in accordance with SEC Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements", as amended by SAB No. 104 (together, "SAB 104"). In accordance with SAB 104, revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectibility is reasonably assured.

Assuming the elements meet the EITF No. 00-21 criteria for separation and the SAB 104 requirements for recognition, the revenue recognition methodology prescribed for each unit of accounting is summarized below:

Upfront Fees—We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology licensed has no utility to the licensee. If we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement.

Funded Research and Development—Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. Reimbursements from collaborative partners for agreed upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical studies are classified as revenue in accordance with EITF Issue No. 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent," and recognized in the period the reimbursable expenses are incurred. Payments received in advance are recorded as deferred revenue until the research and development services are performed or costs are incurred.

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

recognized as revenue over the term of the arrangement as we complete our performance obligations.

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

Advertising Costs

There were no advertising costs incurred for any of the periods presented.

Research and Development Costs

We charge research and development costs to expense as incurred. These costs include salaries and benefits for research and development personnel, costs associated with clinical trials managed by contract research organizations, and other costs associated with research, development and regulatory activities. We use external service providers to conduct clinical trials, to manufacture supplies of product candidates and to provide various other research and development-related products and services.

Patent Costs

We expense patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included as general and administrative expenses in our statements of operations.

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Stock-Based Compensation

On January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123R, “Share-Based Payment”. SFAS No. 123R replaced SFAS No. 123 and superseded Accounting Principles Board (“APB”) Opinion No. 25, “Accounting for Stock Issued to Employees” and related interpretations. Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation expense is measured at the grant date for all stock-based awards to employees and directors and is recognized as expense over the requisite service period, which is generally the vesting period. We were required to utilize the prospective application method prescribed by SFAS No. 123R, under which prior periods are not revised for comparative purposes. Under the prospective application transition method, non-public entities that previously used the minimum value method of SFAS No. 123 should continue to account for non-vested equity awards outstanding at the date of adoption of SFAS No. 123R in the same manner as they had been accounted for prior to adoption. SFAS No. 123R specifically prohibits pro forma disclosures for those awards valued using the minimum value method. The valuation and recognition provisions of SFAS No. 123R apply to new awards and to awards outstanding as of the adoption date that are subsequently modified. The adoption of SFAS No.123R had a material effect on our financial position and results of operations. See Note 10 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

Prior to the adoption of SFAS No. 123R, we valued our stock-based awards using the minimum value method and provided pro-forma information regarding stock-based compensation and net income required by SFAS No. 123. We did not recognize stock-based compensation expense in our statements of operations for option grants to our employees or directors for the periods prior to our adoption of SFAS No. 123R because the exercise price of options granted was generally equal to the fair market value of the underlying common stock on the date of grant.

We account for stock compensation arrangements with non-employees in accordance with SFAS No. 123R and EITF Issue No. 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services”, which require that such equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted to non-employees, the fair value of the stock options is estimated using a Black-Scholes-Merton valuation model.

Income Taxes

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recognized if it is more likely than not that some portion or all of the deferred tax asset will not be recognized.

Net Income (Loss) per Share

We compute net income (loss) per share in accordance with SFAS No. 128, “Earnings per Share” which requires presentation of both basic and diluted earnings (loss) per share (“EPS”).

Basic EPS is computed by dividing net income (loss) available to common shareholders (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period including stock options and stock warrants, using the treasury stock method, and convertible preferred stock, using the if-converted method. In computing diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted EPS computation in net loss periods as their effect would be anti-dilutive. There is no difference between basic and diluted net loss per share for all periods presented due to the Company’s net losses.

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

	Year Ended December 31,		
(in thousands)	2006	2007	2008
Convertible preferred stock	9,614	-	-
Stock options	2,401	2,896	3,371
Stock warrants	-	350	650

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Recent Accounting Pronouncements

In December 2007, the Emerging Issues Task Force (EITF") met and ratified EITF No.07-01, Accounting for

Collaborative Arrangements, in order to define collaborative arrangements and to establish reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. This EITF is effective for financial statements issued for fiscal years beginning after December15, 2008, and interim periods within those fiscal years. This EITF is to be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. We are currently assessing the impact of this EITF to our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities". SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities by requiring enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," and how derivative instruments and related hedged items affect an entity's operating results, financial position, and cash flows.

SFAS No. 161 is effective for fiscal years beginning after November 15, 2008. Early adoption is permitted. We are currently reviewing the provisions of SFAS No. 161 and have not yet adopted the statement. However, as the provisions of SFAS No. 161 are only related to disclosure of derivative and hedging activities, we do not believe the adoption of SFAS No. 161 will have a material impact on our consolidated operating results, financial position, or cash flows.

In April 2008, the FASB issued FSP FAS 142-3, Determination of the Useful Life of Intangible Assets or FSP FAS 142-3. FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. The intent of the position is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the intangible asset. FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008. We are assessing the potential impact that the adoption of FSP FAS 142-3 may have on our consolidated financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles or SFAS No. 162. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement shall be effective 60 days following the Securities and Exchange Commission's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. We do not believe that implementation of this standard will have a material impact on our consolidated financial position, results of operations or cash flows.

In June 2008, the FASB issued FSP No. EITF 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities," (FSP EITF 03-6-1). FSP EITF 03-6-1 states that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the

two-class method. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008. Management has determined that the adoption of FSP EITF 03-6-1 will not have an impact on the Financial Statements.

NOTE 3. SHORT-TERM INVESTMENTS

Short-term investments at December 31, 2007 and 2008 consisted of the following:

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	December 31, 2007			
(in thousands)	Amortized Cost	Gross Unrealized/Realized Gains	Gross Unrealized/Realized Losses	Market Value
Corporate bonds	$ 5,362	$ -	$ (4)	$ 5,358
U.S. Agencies	5,553	1	-	5,554
Municipal Bonds	500	-	-	500
Certificates of Deposit	-	-	-	-
Other Fixed Income	-	-	-	-
	$ 11,415	$ 1	$ (4)	$ 11,412

	December 31, 2008			
(in thousands)	Amortized Cost	Gross Unrealized/Realized Gains	Gross Unrealized/Realized Losses	Market Value
Corporate bonds	$ -	$ -	$ -	$ -
U.S. Agencies	-	-	-	-
Municipal Bonds	-	-	-	-
Certificates of Deposit	-	-	-	-
Other Fixed Income	-	-	-	-
	$ -	$ -	$ -	$ -

Contractual maturities of short-term investments as of December 31, 2007 and 2008 were as follows:

	December 31, 2007	
(in thousands)	Amortized Cost	Market Value
Due in one year or less	$ 9,915	$ 9,912
Due after 10 years	1,500	1,500
Total	$ 11,415	$ 11,412

	December 31, 2008	
(in thousands)	Amortized Cost	Market Value
Due in one year or less	$ -	$ -
Due after 10 years	-	-
Total	$ -	$ -

During the years ended December 31, 2006, 2007, and 2008 we recognized a net realized gain/ (loss) of $(20,000), $0 and $35,000 respectively. For the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2008, we recognized a net realized gain of $3,000. Short-term investments were liquidated in the fourth quarter, resulting in no amounts to report.

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NOTE 4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

(in thousands)	December 31, 2007	December 31, 2008
Office and laboratory equipment	$ 1,243	$ 1,728
Furniture and fixtures	96	113
Software	72	110
Leasehold improvement	73	143
Total property and equipment, at cost	1,484	2,094
Less: accumulated depreciation	(334)	(638)
Total property and equipment, net	$ 1,150	$ 1,456

Depreciation expense was $74,000, $183,000 and $304,000 for the years ended December 31, 2006, 2007 and 2008, respectively and $704,000 for the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2008.

NOTE 5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following:

(in thousands)	December 31, 2007	December 31, 2008
Research and development	$ 178	$ 509
Employee payroll and benefits	688	423
Professional fees	197	182
Other	78	52
Total accrued liabilities	$ 1,141	$ 1,166

NOTE 6. CAPITAL LEASE OBLIGATION

During the first quarter of 2007, we commenced a lease for a portion of our laboratory equipment. This arrangement is being accounted for as a capital lease. Assets under capital leases that are included in property and equipment are as follows:

(in thousands)	December 31, 2007	December 31, 2008
Office and laboratory equipment	$ 166	$ 229
Less: accumulated depreciation	(19)	(47)
Capital lease assets, net	$ 147	$ 182

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Future minimum lease payments under capital leases were as follows at December 31, 2008:

(in thousands)	Lease Commitment
Year ending December 31,	
2009	$ 45
2010	7
2011	-
2012	-
2013	-
Total minimum lease payments	52
Less: amount representing interest	(3)
Present value of minimum lease payments	$ 49

NOTE 7. EQUIPMENT LOAN

During April 2007, we entered into a master security agreement to establish a $1.0 million equipment loan facility with a financial institution. The purpose of this loan is to finance equipment purchases, principally in the build-out of our laboratory facilities. Borrowings under the loan are secured by eligible equipment purchased from January 2006 through April 2008 and will be repaid over 40 months at an interest rate equal to the greater of 5.94% over the three year Treasury rate in effect at the time of funding or 10.45%. There are no loan covenants specified in the agreement.

As of December 31, 2008, we had an outstanding equipment loan balance of $836,291 carrying a weighted-average interest rate of 10.95%. At December 31, 2008, there was $216,253 available for borrowing under this equipment loan facility.

Future minimum loan payments under equipment loans were as follows at December 31, 2008:

(in thousands)	Loan Commitment
Year ending December 31:	
2009	$ 440
2010	396
2011	109
2012	-
2013	-
Total minimum loan payments	$ 945
Less: amount representing interest	(109)
Present value of minimum loan payments	$ 836

NOTE 8. COMMITMENTS AND CONTINGENCIES

Operating Leases

We lease laboratory facilities and office space under operating leases which expire at various dates through 2015. Rent expense was $317,000, $526,000, and $620,532 for the years ended December 31, 2006, 2007 and 2008, respectively, and $1,941,532 for the cumulative period from July 1, 2002 (date of development stage inception) to December 31, 2008.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The future minimum lease payments under non-cancellable operating leases were as follows as of December 31, 2008:

(in thousands)	Lease Commitment
Year ending December 31:	
2009	$ 860
2010	893
2011	929
2012	965
2013	1,004
2014	1,044
2015	899
Total lease commitment	$ 6,594

Legal Matters

From time to time, we may be involved in various legal proceedings arising in the ordinary course of business. There are no matters at December 31, 2008 that, in the opinion of management, would have a material adverse effect on our financial position, results of operations or cash flows.

NOTE 9. STOCKHOLDERS' EQUITY

Preferred Stock

In 2002 and 2003, we issued 3.2 million shares of Series A Convertible Preferred Stock for net proceeds of $647,000. In 2003 and 2004, we issued 6.9 million shares of Series B Convertible Preferred Stock for net proceeds of $3.0 million. In 2004 and 2005, we issued 6.7 million shares of Series C Convertible Preferred Stock for net proceeds of $5.4 million. In 2005 and 2006, we issued 2.5 million shares of Series D Convertible Preferred Stock for net proceeds of $3.6 million. All outstanding shares of convertible preferred stock automatically converted into 9.6 million shares of common stock upon the closing of our IPO in October 2007. In connection with the IPO, we amended our articles of incorporation to provide for the issuance of up to 5,000,000 shares of preferred stock in such series and with such rights and preferences as may be approved by the board of directors. As of December 31, 2008, there were no shares of preferred stock outstanding.

Common Stock

Under our amended articles of incorporation, we are authorized to issue 65,000,000 shares of $0.01 par value common stock. Each holder of common stock has the right to one vote but does not have cumulative voting rights. Shares of common stock are not subject to any redemption or sinking fund provisions, nor do they have any preemptive, subscription or conversion rights. Holders of common stock are entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends have been declared or paid as of December 31, 2008. In August 2007, we filed an amendment to our articles of incorporation to effect a 1-for-2 reverse stock split of our common stock. All share and per share amounts relating to the common stock, stock options and warrants and the

conversion ratios of preferred stock included in the financial statements and footnotes have been restated to reflect the reverse stock split. In October 2007, we completed an initial public offering of our common stock in which we sold and issued 5,000,000 shares of our common stock at a price to the public of $4.00 per share. We raised a total of $20.0 million from the IPO, or approximately $17.1 million in net cash proceeds after deducting underwriting discounts and commissions of $1.4 million and other offering costs of $1.5 million.

Stock Warrants

Warrants to acquire shares of common stock were issued in connection with the sales of the Series A and Series B Convertible Preferred Stock and certain convertible notes. Additionally, in October 2007, warrants were issued to the underwriters in connection with the IPO. The significant terms of the Series A, Series B, Note, and Underwriter warrants were as follows:

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Series A Warrants—The warrants issued with the sale of Series A Preferred Stock were issued on the basis of 0.20 of a warrant for every share of Series A Preferred Stock purchased. The exercise price of these warrants was $1.20 per share. We extended a limited-time offer to holders of the warrants to exercise them at a price of $0.80 per share. The warrants expired on July 1, 2005, except for warrants issued in connection with later purchases of the Series A Preferred Stock for which the expiration date was extended to July 1, 2006.

Series B Warrants—The warrants issued with the sale of Series B Preferred Stock were issued on the basis of 0.175 of a warrant for every share of Series B Preferred Stock purchased. The exercise price of these warrants was $0.80 per share. The warrants expired on June 30, 2006.

Note Warrants—Warrants were granted in connection with promissory notes issued to certain of our shareholders in 2002 and 2003. The warrants issued to these shareholders had an exercise price of $1.20 per share. The warrants expired on June 30, 2006.

Underwriter Warrants—In connection with the IPO, we issued warrants to the underwriters to purchase an aggregate of 350,000 shares of common stock at an exercise price of $4.00 per share. The warrants are exercisable on or after October 31, 2008 and expire on October 31, 2010. The warrants were valued at approximately $524,000 using the Black-Scholes-Merton option-pricing model based upon the following assumptions: (1) expected price volatility of 50.0%, (2) a risk-free interest rate of 3.94% and (3) a contractual life of 3 years. We accounted for the fair value of the Underwriter Warrants as an expense of the IPO resulting in a charge to stockholders' equity.

Advisory Services Warrants - In April 2008, we issued a two year warrant and a four year warrant to purchase an aggregate of 300,000 shares of common stock to PM Holdings Ltd. as part of our consideration for the revision of the agreement dated February 13, 2007 with PM Holdings. Under the terms of the original agreement, we agreed to pay PM Holdings $28,000 per month through February 2010 for financial and investor relations advisory services. The amendment to this agreement eliminates the monthly cash payment obligation and instead provides for a one-time, upfront cash payment of $264,000 and the issuance of warrants to purchase 300,000 shares of common stock at an exercise price of $4.00 per share.

At December 31, 2008, there were outstanding warrants to purchase 650,000 shares of common stock at a weighted-average exercise price of $4.00 per share. None of the warrants were exercisable at December 31, 2008.

NOTE 10. EQUITY-BASED COMPENSATION

Equity Compensation Plans

Prior to the IPO, we had two equity plans in place: the 2002 Stock Option Plan and the 2005 Stock Option Plan. Upon the closing of the IPO in October 2007, we adopted the 2007 Omnibus Incentive Plan (the "2007 Plan") to provide for the granting of stock awards, such as stock options, unrestricted and restricted common stock, stock units, dividend equivalent rights, and stock appreciation rights to employees, directors and outside consultants as determined by the board of directors. In conjunction with the adoption of the 2007 Plan, no further option awards may be granted from the 2002 or 2005 Stock Option Plans and any option cancellations or expirations from the 2002 or 2005 Stock Option Plans may not be reissued. At the inception of the 2007 Plan, 2,000,000 shares were reserved for issuance under the Plan. As of December 31, 2008, there were 741,502 shares available for future grants under the 2007 Plan.

Under the terms of the 2007 Plan, the exercise price of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and , if granted to an owner of more than 10% of our stock, then not less than 110%. Stock options granted under the 2007 Plan expire no later than ten years from the date of grant. Stock options granted to employees generally vest over four years while options granted to directors and consultants typically vest over a shorter period, subject to continued service. All of the options granted prior to October 2007 include early exercise provisions that allow for full exercise of the option prior to the option vesting, subject to certain repurchase provisions. We issue new shares to satisfy option exercises under the plans.

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Stock Option Summary

The following table summarizes information about our stock options outstanding at December 31, 2008 and activity during the year then ended:

(in thousands, except per share data)	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2006	2,401	$ 0.83		
Options granted	814	$ 3.31		
Options exercised	(298)	$ 0.38		
Options forfeited/cancelled	(21)	$ 1.52		
Outstanding at December 31, 2007	2,896	$ 1.57		
Options granted	903	$ 2.39		
Options exercised	(122)	$ 1.18		
Options forfeited/cancelled	(306)	$ 2.66		
Outstanding at December 31, 2008	3,371	$ 1.70	6.8	$ 767
Vested and expected to vest at December 31, 2008	3,217	$ 1.66	6.7	$ 767
Vested at December 31, 2008	2,112	$ 1.15	5.4	$ 763
Exercisable at December 31, 2008	2,470	$ 1.41	5.8	$ 767

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of our common stock as quoted on the American Stock Exchange as of December 31, 2008. We received cash payments for the exercise of stock options in the amount of $23,000, $114,000 and $149,000 during the years ended December 31, 2006, 2007 and 2008, respectively. The aggregate intrinsic value of stock option awards exercised was $126,000, $571,000 and $108,000 for the years ended December 31, 2006, 2007 and 2008, respectively, as determined at the date of option exercise.

The options outstanding and vested by exercise price at December 31, 2008 were as follows (number of options in thousands):

	Options Outstanding			Options Vested	
Range of Exercise Prices	Number Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Number Vested	Weighted-Average Exercise Price
$0.20	544	$ 0.20	3.2	544	$ 0.20
$0.30	318	$ 0.30	5.0	318	$ 0.30
$0.56	192	$ 0.56	5.4	184	$ 0.56

$0.94 - $1.20	253	$	1.15	4.2	229	$ 1.14
$1.70 - $1.97	1,157	$	1.82	8.4	548	$ 1.70
$2.00 - $2.48	217	$	2.21	8.2	96	$ 2.21
$3.56 - $4.00	690	$	3.71	8.7	193	$ 3.73
	3,371	$	1.71	6.8	2,112	$ 1.15

Stock Option Awards to Employees and Directors

We grant options to purchase common stock to some of our employees and directors at prices equal to or greater than the market value of the stock on the dates the options are granted. We have estimated the value of certain stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing valuation model using the single-option valuation approach. The

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NOVABAY PHARMACEUTICALS, INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

application of this valuation model involves assumptions that are judgmental and subjective in nature. See Note 2 for a description of the accounting policies that we applied to value our stock-based awards.

The weighted average assumptions used in determining the value of options granted and a summary of the methodology applied to develop each assumption are as follows:

	Year Ended December 31,		
Assumption	2006	2007	2008
Expected price volatility	74.0%	68.9%	70.3%
Expected term (in years)	5.7	6	6.1
Risk-free interest rate	4.8%	4.1%	3.1%
Dividend yield	0.0%	0.0%	0.0%
Weighted-average fair value of options granted during the period	$ 1.06	$ 2.17	$ 1.56

Expected Price Volatility—This is a measure of the amount by which the stock price has fluctuated or is expected to fluctuate. Prior to the adoption of SFAS No. 123R, we assumed 0% price volatility in accordance with the minimum value method requirements of SFAS No. 123. Under SFAS No. 123R, which we adopted on January 1, 2006, the computation of expected volatility was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization data. An increase in the expected price volatility will increase the value of the option granted and the related compensation expense.

Expected Term—This is the period of time over which the options granted are expected to remain outstanding. Because there is insufficient historical information available to estimate the expected term of the stock-based awards, we adopted the simplified method for estimating the expected term pursuant to SAB No. 107. On this basis, we estimated the expected term of options granted by taking the average of the vesting term and the contractual term of the option. An increase in the expected life will increase the value of the option granted and the related compensation expense.

Risk-Free Interest Rate—This is the U.S. Treasury rate for the week of the grant having a term approximating the expected life of the option. An increase in the risk-free interest rate will increase the value of the option granted and the related compensation expense.

Dividend Yield—We have not made any dividend payments nor do we have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease the value of the option granted and the related compensation expense.

Forfeiture Rate—Under SFAS No. 123R, forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. For the years ended December 31, 2006 and 2007, we applied an estimated forfeiture rate of 5% to employee grants and 0% to director grants. Due to employee turnover in 2008 we applied an estimated forfeiture rate of 20% to employee grants and 0% to director grants.

For the years ended December 31, 2006, 2007 and 2008, we recognized stock-based compensation expense of $313,000 $399,000 and $721,000, respectively, for option awards to employees and directors. As of December 31, 2008, total unrecognized compensation cost related to unvested stock options granted or modified on or after January

1, 2006 was $1.7 million. This amount is expected to be recognized as stock-based compensation expense in our statements of operations over the remaining weighted average vesting period of 2.8 years.

Common Stock Awards to Directors

In connection with the close of the IPO in October 2007, we adopted a new plan to compensate the independent members of the Board of Directors for their services. Under the terms of the Director Compensation Plan, each independent member is entitled to a combination of cash and unrestricted common stock for each board and committee meeting attended, up to specified annual maximums. In accordance with these provisions, we issued 50,971 shares of common stock to independent directors during the year ended December 31, 2008. These shares were issued out of the 2007 Plan. The fair market value of the stock issued to directors was recorded as an operating expense in the period in which the meeting occurred, resulting in total compensation expense of $123,735 for

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NOVABAY PHARMACEUTICALS, INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

common stock awards to directors during the year ended December 31, 2008.

Summary of Stock-Based Compensation Expense Under SFAS No. 123R

Upon the adoption of SFAS No. 123R on January 1, 2006, we began recognizing stock-based compensation expense in the statements of operations for all employee and director equity awards granted or modified on or after the adoption date. Stock-based compensation expense is classified in the statements of operations in the same expense line items as cash compensation. Since we continue to operate at a net loss, we do not expect to realize any current tax benefits related to stock options.

A summary of the stock-based compensation expense included in results of operations for the option and stock awards to employees and directors discussed above is as follows:

	Year Ended December 31,		
(in thousands)	2006	2007	2008
Research and Development	227	206	412
General and Administrative	86	222	432
Total stock-based compensation expense	$ 313	$ 428	$ 844

Stock-Based Awards to Non-Employees

During the years ended December 31, 2006, 2007 and 2008, we granted options to purchase an aggregate of 58,000, 69,000 and 16,000 shares of common stock, respectively, to non-employees in exchange for advisory and consulting services. The stock options are recorded at their fair value on the measurement date and recognized over the respective service or vesting period. The fair value of the stock options granted was calculated using the Black-Scholes-Merton option pricing model based upon the following assumptions:

	Year Ended December 31,		
Assumption	2006	2007	2008
Expected price volatility	74.0%	71.0%	70.0%
Expected term (in years)	5.3	5.3	6.1
Risk-free interest rate	4.4%	4.7%	3.1%
Dividend yield	0.0%	0.0%	0.0%
Weighted-average fair value of options granted during the period	$ 0.78	$ 1.70	$ 1.26

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

For the years ended December 31, 2006 and 2007, we recognized stock-based compensation expense of $49,000, and $118,000, respectively, related to non-employee option grants. For the year ended December 31, 2008 we reversed previously recognized expense of $13,000 due to the required revaluation of unvested non-employee grants.

NOTE 11. COLLABORATION AND LICENSE AGREEMENTS

Alcon Manufacturing, Ltd.

In August 2006, we entered into a collaboration and license agreement with Alcon Manufacturing, Ltd. (“Alcon”) to license to Alcon the exclusive 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 solution. 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. This up-front fee was recorded as deferred revenue and is being amortized into revenue on a straight-line basis over the four-year funding term of the agreement, through August 2010. Additionally, we will receive semi-annual payments 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. Our obligation to perform research and development activities under the agreement expires at the end of the four year funding term. 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 compound. Alcon has the right to terminate the agreement in its entirety upon nine months’ notice, or terminate portions of the agreement upon 135 days’ notice, subject to certain provisions. Both parties have the right to terminate the agreement for breach upon 60 days’ notice.

Revenue has been recognized as follows:

	Year Ended December 31,		
	2006	2007	2008
(in thousands)			
Amortization of Upfront Technology Access Fee	$ 800	$ 2,500	$ 2,500
On-going Research and Development	700	2,700	2,700
Materials, Equipment, and Contract Study Costs	-	700	1,500
	$ 1,500	$ 5,900	$ 6,700

At December 31, 2007 and 2008, we had deferred revenue balances of $7.4 million and $4.2 million, respectively, related to the Alcon agreement which was comprised of $6.7 million and $4.2 million, respectively, for the upfront technology access fee and $0.7 million and $0, respectively, for other prepaid reimbursements. As of December 31, 2008, we had not received any milestone or royalty payments under the Alcon agreement.

KCI International VOF GP

In June 2007, we entered into a license agreement with an affiliate of Kinetic Concepts, Inc. (“KCI”), under which we granted KCI the exclusive rights to develop, manufacture and commercialize NVC-101, or NeutroPhase, as well as

other products containing hypochlorous acid as the principal active ingredient, worldwide for use in wound care in humans, other than products or uses intended for the eye, ear or nose. Under the terms of the agreement, KCI paid to us a non-refundable technology access fee of $200,000. The up-front technology access fee was recorded as deferred revenue and has been amortized into revenue on a straight-line basis over the 18-month performance obligation period, through December 2008. Under the agreement, we are also entitled to receive reimbursements for qualified consulting, materials and contract study costs. In addition, we are entitled to receive payments of up to $1.25 million if certain milestones are met. If products covered by the license are commercially launched, we will also receive royalty payments based on net revenues from sales by KCI of such products. KCI has the right to terminate the agreement without penalty upon 60 days' notice. We have the right to terminate the agreement if KCI has not commercially launched a product incorporating NVC-101, or any other product containing hypochlorous acid, within 18 months of the date of the agreement. Both parties have the right to terminate the agreement for breach upon 60 days' notice.

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NOVABAY PHARMACEUTICALS, INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Revenue has been recognized as follows:

	Year Ended December 31,		
	2006	2007	2008
(in thousands)			
Amortization of Upfront Technology Access Fee	$ -	$ 72	$ 128
On-going Research and Development	-	29	8
Materials, Equipment, and Contract Study Costs	-	-	-
	$ -	$ 101	$ 136

We had deferred revenue balances of $128,000 and $0, respectively, at December 31, 2007 and 2008, related to the KCI agreement, which consisted of the remaining amount to be amortized for the upfront technology access fee. As of December 31, 2008, we had not earned or received any milestone or royalty payments under the KCI agreement.

NOTE 12. EMPLOYEE BENEFIT PLAN

We have a 401(k) plan covering all eligible employees. We are not required to contribute to the plan and have made no contributions through December 31, 2008.

NOTE 13. INCOME TAXES

Net loss before provision for income taxes consisted of the following (in thousands):

	Year Ending December 31		
	2006	2007	2008
United States	$ (5,126)	$ (5,388)	$ (8,112)
International	-	-	-
	$ (5,126)	$ (5,388)	$ (8,112)

The federal and state income tax provision (benefit) is summarized as follows (in thousands):

	Year Ending December 31		
	2006	2007	2008
Current			
Federal	$ -	$ -	$ -
State	-	12	2
Other			
Total Current Tax Expense	-	12	2
Deferred			
Federal	-	-	-
State	-	-	-
Other	-	-	-
Total Deferred Tax Expense	-	-	-

Total Tax Expense	$ -	$ 12	$ 2

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The tax effects of significant items comprising the Company's deferred taxes as of December 31 are as follows:

		Year Ending December 31	
		2007	2008
Deferred Tax Assets:			
	Accruals	$ 264	$ 409
	Deferred Revenue	2,655	1,660
	Net Operating Losses	4,040	7,946
	Stock Options	310	176
	Other Deferred Tax Assets	25	45
	Total Deferred Tax Assets	$ 7,294	$ 10,236
Deferred Tax Liabilities:			
	Property, Plant & Equipment	(88)	(228)
	Total Deferred Tax Liabilities	(88)	(228)
Valuation Allowance		(7,206)	(10,008)
Net Deferred Taxes		$ -	$ -

SFAS No. 109 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of future tax benefits is dependent on the Company’s ability to generate sufficient taxable income within the carryforward period. Because of the Company’s recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance.

The valuation allowance increased by the following amounts

2006	2007	2008
	(In thousands)	
$ 2,111	$ 1,997	$ 2,978

We track the portion of our federal and state net operating loss carryforwards attributable to stock option benefits in a separate memo account pursuant to FAS 123R. Therefore, these amounts are not included in gross or net deferred tax assets.
Pursuant to FAS 123R, the benefit of these net operating loss carryforwards will only be recorded to equity when they reduce cash taxes payable.

Net operating losses and tax credit carryforwards as of December 31, 2008 are as follows:

In thousands		Amount	Expiration Years
Net operating losses, federal	$	19,972	2024 - 2028
Net operating losses, state	$	19,797	2014 - 2028
Tax credits, federal	$	-	
Tax credits, state	$	8,223	N/A

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows (in thousands):

	Year Ending December 31		
	2006	2007	2008
Statutory Rate	$ (1,743)	$ (1,832)	$ (2,758)
State Tax	(297)	(274)	(435)
ISO Related Expense for GAAP	-	81	207
Change in Valuation Allowance	2,111	1,997	2,978
Other	(71)	40	10
			-
			-
			-
Total	$ -	$ 12	$ 2

Uncertain Income Tax Positions

In July 2006, the FASB released Interpretation No. 48 “Accounting for Uncertainty in Income Taxes” (“FIN 48”). FIN 48 prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease within a twelve month period.

We adopted the provisions of FIN 48 on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. We have no unrecognized tax benefit as of December 31, 2008, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of income tax expense. We are subject to income tax examinations for U.S. incomes taxes and state income taxes from 2002 forward. We do not anticipate that total unrecognized tax benefits will significantly change prior to December 31, 2009.

NOTE 14. SUBSEQUENT EVENTS

In January 2009, the FDA approved the Investigational New Drug application (IND) submitted by Alcon to permit the clinical development of our NVC-422 for infections of the eye. The IND clearance has triggered the immediate payment of the first milestone of $1,000,000 from Alcon.

On February 2, 2009, the Company filed a registration statement on Form S-8 to register an aggregate of 858,766 additional shares of the Company’s common stock to be issued under the Company’s 2007 Omnibus Incentive Plan, as amended and restated.

In January 2009, the Company issued refresh grants of incentive stock options to its employees.

On March 25, 2009, the Company announced that it has entered into an agreement with Galderma S.A. to develop and commercialize the Company’s novel proprietary Aganocide® compounds. The exclusive agreement is worldwide in

scope, except in certain Asian markets, and covers all major dermatological conditions, excluding onychomycosis (nail fungus) and orphan drug indications.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Not applicable.

ITEM 9A(T). CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 and 15d-15 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

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A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Assessing the costs and benefits of such controls and procedures necessarily involves the exercise of judgment by management. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework. Our management has concluded that, as of December 31, 2008, our internal control over financial reporting was effective based on these criteria.

This annual report does not include an attestation report of the company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the company to provide only management's report in this annual report.

This report shall not be deemed to be filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, unless the registrant specifically states that the report is to be considered "filed" under the Exchange Act or incorporates it by reference into a filing under the Securities Act or the Exchange Act.

Changes in Internal Control Over Financial Reporting

During the fourth quarter of 2008, there were no changes in our internal control over financial reporting, identified by our Chief Executive Officer or our Chief Financial Officer in connection with the evaluation of the effectiveness of our disclosure controls and procedures, which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item with respect to Executive Officers may be found under the caption, "Executive Compensation and Other Information" appearing in the definitive Proxy Statement to be delivered to NovaBay's stockholders in connection with the solicitation of proxies for NovaBay's 2009 Annual Meeting of Stockholders (the "Proxy Statement"). The information required by this Item with respect to Directors, including information with respect to our audit committee, audit committee financial experts and procedures for Board nominations, is incorporated herein by reference from the information under the caption, "Proposal One: Election of Directors" appearing in the Proxy Statement.

Section 16(a) Beneficial Ownership Reporting Compliance

The information required by this Item with respect to compliance with Section 16(a) of the Exchange Act is incorporated herein by reference from the section captioned “Section 16(a) Beneficial Ownership Reporting Compliance” contained in the Proxy Statement.

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Code of Ethics and Business Conduct

The information required by this Item with respect to our code of ethics and business conduct is incorporated herein by reference from the section captioned “Proposal 1: Election of Directors – Code of Ethics and Business Conduct” contained in the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is set forth in the Proxy Statement under the caption, “Executive Compensation and Other Information.” Such information is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item with respect to security ownership of certain beneficial owners and management is set forth in the Proxy Statement under the caption, “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information.” Such information is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is set forth in the Proxy Statement under the headings “Proposal 1: Election of Directors” and “Certain Relationships and Related Transactions.” Such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is set forth in the Proxy Statement under the heading “Fees Paid to Independent Registered Public Accounting Firm.” Such information is incorporated herein by reference.

Consistent with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, we are responsible for listing the non-audit services approved by our Audit Committee to be performed by Davidson & Company LLP, our external auditor. Non-audit services are defined as services other than those provided in connection with an audit or a review of our financial statements. Our Audit Committee has approved our recurring engagements of non-audit services of Moss Adams, LLP for the preparation of tax returns, and tax advice in preparing for and in connection with such filings.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report:

(1) Financial Statements. The following financial statements of NovaBay Pharmaceuticals, Inc. are included in Item 8 of this Annual Report on Form 10-K commencing on the pages referenced below:

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or the required information is included in our consolidated financial statements and notes thereto.

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(3) Exhibits.

See the Exhibit Index which follows the signature page of this Annual Report on Form 10-K, which is incorporated herein by reference.

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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 report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 31, 2009

NOVABAY PHARMACEUTICALS, INC.
By: /S/ RAMIN NAJAFI
Ramin (“Ron”) Najafi
Chief Executive Officer and President

POWER OF ATTORNEY

We, the undersigned officers and directors of NovaBay Pharmaceuticals, Inc., do hereby constitute and appoint Ramin (“Ron”) Najafi and Thomas J. Paulson, and each of them, our true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby, ratifying and confirming all that each of said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report on Form 10-K has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated:

Signature	Title	Date
/S/ RAMIN NAJAFI Ramin (“Ron”) Najafi	Chairman of the Board, Chief Executive Officer and President (principal executive officer)	March 30, 2009
/S/ THOMAS PAULSON Thomas J. Paulson	Chief Financial Officer and Treasurer (principal financial and accounting officer)	March 31, 2009
/S/ CHARLES J. CASHION Charles J. Cashion	Director	March 31, 2009
/S/ ANTHONY DAILLEY Anthony Dailley, DDS	Director	March 30, 2009
/S/ PAUL FREIMAN Paul E. Freiman	Director	March 30, 2009
/S/ ALEX MCPHERSON Alex McPherson, MD, Ph.D.	Director	March 30, 2009
/S/ ROBERT R. TUFTS Robert R. Tufts	Director	March 30, 2009

/S/ TONY WICKS Tony Wicks	Director	March 30, 2009
/S/ HARRY F. HIXSON, JR., PhD Harry F. Hixson	Director	March 30, 2009

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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 (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.), and forms of agreements thereto.)
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
10.10*	Office Lease dated June 3, 2004 by and between the Registrant and Emery Station Associates II, LLC, as amended
10.11	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 10.19 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.)
10.12	

	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.)
10.13*	License Agreement dated June 11, 2007 by and between the Registrant and KCI International VOF GP
10.14*	Financial Advisory and Investor Relations Consulting Agreement dated February 13, 2007 by and between the Registrant and PM Holdings Ltd
10.15*	Director Compensation Plan
10.11*†	Collaboration and License Agreement dated August 29, 2006 by and between the Registrant and Alcon Manufacturing, Ltd.
10.16*	Master Security Agreement dated April 23, 2007 by and between the Registrant and General Electric Capital Corporation
10.17*	Form of Common Stock Purchase Warrant by and between the Registrant and the underwriters
23.1	Consent of Davidson & Company LLP
24.1	Power of Attorney (included on the signature pages hereto)
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
32.2	Certification of the chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Incorporated by reference to the exhibit of the same number from the Company's registration statement of Form S-1 (File No. 333-138379) initially filed with the Securities and Exchange Commission on November 2, 2006, 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.