NEOGEN CORP
Form 10-K
July 29, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year Ended May 31, 2016

¨ **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 0-17988

NEOGEN CORPORATION

(Exact name of registrant as specified in its charter)

MICHIGAN	**38-2367843**
(State or other jurisdiction of incorporation or organization)	***(I.R.S. Employer Identification No.)***

620 Lesher Place

Lansing, Michigan 48912

(Address of principal executive offices, including zip code)

517-372-9200

(Registrant s telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

COMMON STOCK, $0.16 par value per share

(Title of Class)

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

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Indicate by 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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

(Check one):

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

Based on the closing sale price on November 30, 2015 the aggregate market value of the voting stock held by non-affiliates of the registrant was $2,211,000,000. For these purposes, the registrant considers its Directors and executive officers to be its only affiliates.

The number of outstanding shares of the registrant s Common Stock was 37,574,890 on June 30, 2016.

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DOCUMENTS INCORPORATED BY REFERENCE

The Registrant s definitive proxy statement to be prepared pursuant to Regulation 14a and filed in connection with solicitation of proxies for its October 6, 2016 annual meeting of shareholders is incorporated by reference into part III of this Form 10-K.

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Subsidiaries	
Consent of independent registered public accounting firm	BDO USA, LLP
Section 302 Certification of Chief Executive Officer	
Section 302 Certification of Chief Financial Officer	
Section 1350 Certification pursuant to Section 906	

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

Forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, are made throughout this Annual Report on Form 10-K, including statements relating to management s expectations regarding new product introductions; the adequacy of the Company s sources for certain components, raw materials and finished products; and the Company s ability to utilize certain inventory. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words believes, anticipates, plans, expects, seeks, estimates, and similar expressions are intended to identify forward-looking statements. There a number of important factors that could cause Neogen Corporation s results to differ materially from those indicated by such forward-looking statements, including those detailed in ITEM 1A. RISK FACTORS and under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations, Critical Accounting Policies and Estimates, and Future Operating Results.

In addition, any forward-looking statements represent management s views only as of the day this Annual Report on Form 10-K was first filed with the Securities and Exchange Commission and should not be relied upon as representing management s views as of any subsequent date. While management may elect to update forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, even if its views change.

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PART I.

ITEM 1. BUSINESS

Neogen Corporation and subsidiaries (Neogen or the Company) develop, manufacture and market a diverse line of products dedicated to food and animal safety. The Company s Food Safety segment consists primarily of diagnostic test kits and complementary products (e.g., dehydrated culture media) sold to food producers and processors to detect dangerous and/or unintended substances in human food and animal feed, such as foodborne pathogens, spoilage organisms, natural toxins, food allergens, genetic modifications, ruminant by-products, meat speciation, drug residues, pesticide residues and general sanitation concerns. The diagnostic test kits are generally less expensive, easier to use and provide greater accuracy and speed than conventional diagnostic methods. The majority of the tests are disposable, single-use, immunoassay and DNA detection products that rely on the Company s proprietary antibodies and RNA and DNA testing methodologies to produce rapid and accurate test results. The Company s expanding line of food safety products also includes bioluminescence-based diagnostic technology.

Neogen s Animal Safety segment is engaged in the development, manufacture, marketing and distribution of pharmaceuticals, rodenticides, disinfectants, vaccines, veterinary instruments, topicals, diagnostic products for the worldwide animal safety market, and genomic testing services. The majority of these consumable products are marketed through a network of national and international distributors, as well as a number of large farm supply retail chains in the United States and Canada. The Company s USDA-licensed facility in Lansing, Michigan, produces immunostimulant products for horses and dogs, and a unique equine botulism vaccine. The Company s line of drug detection products is sold worldwide for the detection of abused and therapeutic drugs in animals and animal products.

Neogen s products are marketed by Company sales personnel in North America, the United Kingdom and other parts of Europe, Mexico, Brazil, China and India and by distributors throughout the rest of the world.

Neogen s mission is to be the leading company in the development and marketing of solutions for food and animal safety. To meet this vision, a growth strategy consisting of the following elements has been developed: (i) increasing sales of existing products; (ii) introducing new products and product lines; (iii) expanding international sales; and (iv) acquiring businesses and forming strategic alliances. The Company has been historically successful at increasing product sales organically and maintains an active acquisition program to identify and capitalize on opportunities to acquire new products and/or businesses.

Neogen Corporation was formed as a Michigan corporation in June 1981 and actual operations began in 1982. The Company s principal executive offices are located at 620 Lesher Place, Lansing, Michigan 48912-1595 and its telephone number is (517) 372-9200.

Neogen s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports are available free of charge via our Internet website (www.neogen.com) as soon as reasonably practicable after such information is filed with, or furnished to, the United States Securities and Exchange Commission.

PRODUCTS

Product trademarks and registered trademarks owned by Neogen include: **CORPORATE:** Neogen®, Neogen flask logo®; **FOOD SAFETY:** AccuClean®, AccuPoint®, AccuScan®, Acumedia®, Agri-Screen®, Alert®, ANSR®, BetaStar®, BioLumix®, Centrus®, F.A.S.T.®, GeneQuence®, GENE-TRAK®, Harlequin , ISO-GRID®, Lab M®,

NeoCare , NeoColumn , NeoFilm®, NeoSeek , NEO-GRID®, Nutritone®, Penzyme®, Pinnacle®, Reveal®, Revive®, Soleris®, µPREP , Veratox®, Simple. Accurate. Supported. Food Safety Solutions℠; **LIFE SCIENCES:** Alert®, K-Blue®, K-Blue Substrate®, K-Gold®, NeoSal®, **ANIMAL SAFETY**: Acid-A-Foam , Aero-ssault , Ag-Tek®, AluShield , AquaPrime®, Assault®, Barnstorm , BioCres , BioPhene , BioQuat , Bot Bar®, BreederSleeve®, Bromethalin One Meal Is All It Takes (design)®, Calf Eze , Chem-Tech, Ltd. , Chem-Tech s CT logo (with circle) , Chlor-A-Foam , Companion , Cowboy Syringe®, CT-511®, Cykill , D3 , DC&R®, DeciMax®, Di-Kill®, Dr. Frank s®, Dy-Fly®, Dyne-O-Might , Earth City Resources (design)®, ElectroJac®, ELISA Technologies (design)®, EqStim®, EquiSleeve®, E-Z Bond , E-Z Catch®, Farmphene , Final-Fly-T®, Fly-Die Defense , Fura-Zone®, GenQuat , Gold Nugget®, Horse Sense®, Ideal®, ImmunoRegulin®, Insectrin®, Insight , Iodis , Jo-Ad®, LD-44®, LD-44T , Maxi Sleeve®, MaxKlor , MegaShot , MycAseptic , NeedleGard , NFZ , Nu-Dyne , One Bac Pac®, PCA®, PanaKare , Pantek , ParlorMint , Parvo-Place® Pack®, PolyPetite , PolyShield , Poly-Sleeve®, Poridon®, Preserve , Prima®, Prima BMV®, Prima Marc , Prima Tech®, Prima Tech logo®, Pro-Fix®, Pro-Flex®, Pro-Shot , PRO-TECT 6 MIL®, PRO-TECT 6 MIL logo®, Prozap®, Prozap (stylized mark w/fancy Z) , PY-75 , Ram-Lik®, Rat & Mouse-A-Rest II®, RenaKare , Rodent Elimination Station , Rodex , Rot-Not , Safe-T-Flex , Siloxycide , Spectrasol , Spec-Tuss , Spurricide®, Stress-Dex®, SureBond®, SureKill®, Synergize , SyrVet®, SyrVet logo®, Tetrabase , Tetracid , Tetradyne , ThyroKare , TopHoof , Tri-Heal®, Tri-Heal Seal , Tryad®, Turbocide®, Turbocide Gold®, Udder Shield®, Uniprim®, UriKare , VAP-5 , VAP-20 , Vet-Tie , Vita-15 , War-Paint®, We keep em movin®, X-185 , Zipcide®, **AGRIGENOMICS:** Deoxi , GeneSeek®, Genomic Profiler , Genomic Solutions for Food Security®, Igenity®, SeekGain , SeekSire , SeekTrace , Tru-Point®, and **LOGOTYPES:** BioSentry barn logo®, BioSentry chicken logo®, BioSentry pig logo®, TurboCide® (stylized).

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Neogen operates in two primary business areas: the Food Safety segment, which develops and markets products for the detection of pathogens, natural toxins, allergens and other unwanted substances in food and feed products; and the Animal Safety segment, which develops and markets products and services dedicated to animal health. See Notes to Consolidated Financial Statements elsewhere in this Form 10-K for financial information about the Company s business segments and international operations.

FOOD SAFETY SEGMENT

Neogen s Food Safety segment is primarily engaged in the production and marketing of diagnostic test kits and complementary products marketed to food and feed producers and processors to detect dangerous and/or unintended substances in food and animal feed, such as foodborne pathogens, spoilage organisms, natural toxins, food allergens, genetic modifications, meat speciation, drug residues, pesticide residues and general sanitation concerns.

Neogen s test kits are used to detect potential hazards in food and animal feed by testers ranging from small local grain elevators to the largest, best-known food and feed processors in the world, and numerous regulatory agencies. Neogen s products include tests for:

Mycotoxins. Grain producers and processors of all types and sizes use the Company s Veratox, Agri-Screen, Reveal, Reveal Q+ and Reveal Q+ MAX tests for mycotoxins, including aflatoxin, deoxynivalenol, fumonisin, ochratoxin, zearalenone and T-2/HT-2 toxin, to help ensure product safety and quality.

Food allergens. The world s largest producers of cookies, crackers, candy, ice cream and many other foods, use the Company s Veratox, Alert, Reveal, Reveal 3-D and BioKits testing products for food allergens to help protect their food-allergic customers from the inadvertent contamination of products with food allergens, such as peanut, milk, egg, almond, gliadin (gluten), soy and hazelnut residues.

Dairy antibiotics. Dairies are the primary users of Neogen s BetaStar, BetaStar Combo, BetaStar 4D and Penzyme diagnostic tests to detect the presence of beta-lactam and tetracycline antibiotics in milk. The presence of these drugs in milk is a public health hazard and an economic risk to processors as it limits the milk s further processing.

Foodborne pathogens. Meat and poultry processors, seafood processors, fruit and vegetable producers and many other market segments are the primary users of Neogen s ANSR and Reveal tests for foodborne bacteria, including *E. coli* O157:H7, *Salmonella*, *Listeria* and *Campylobacter*. Neogen s ANSR pathogen detection system is an isothermal amplification reaction test method which exponentially amplifies the DNA of any bacteria present in food and environmental samples to detectable levels in 10 minutes. Combined with ANSR s single enrichment step, Neogen s pathogen detection method provides DNA-definitive results in a fraction of the time of other molecular detection methods. Reveal s lateral flow device combines an immunoassay with chromatography for a rapid and accurate one-step result.

Spoilage microorganisms. Neogen s Soleris and BioLumix products are used by food processors to identify the presence of spoilage organisms (e.g., yeast and mold) and other microbiological contamination. The systems measure microbial growth by monitoring biochemical reactions that generate a color change in the media as microorganisms grow. The sensitivity of the system allows detection in a fraction of the time needed for traditional methods, with less labor and handling time.

Sanitation monitoring. Neogen manufactures and markets its AccuPoint Advanced rapid sanitation test for adenosine triphosphate (ATP), a chemical found in all living cells. This easy-to-use and inexpensive test uses bioluminescence to quickly determine if a food contact surface has been completely sanitized. When ATP comes into contact with the

reagents contained in the test device, a reaction takes place that produces light. More light is indicative of higher levels of ATP and a need for more thorough sanitation. The Company s worldwide customer base for its ATP sanitation testing products includes food and beverage processors, the food service and healthcare industries, as well as many other users.

Dehydrated culture media. Neogen s Acumedia and Lab M subsidiaries offer dehydrated culture media for varied purposes, including traditional bacterial testing, and growing beneficial bacteria, such as cultures for sausages and beer. The Company s customers for dehydrated culture media also include commercial and research laboratories and producers of pharmaceuticals, cosmetics and veterinary vaccines.

Seafood contaminants. Neogen s specialty products for the seafood market include tests for histamine, a highly allergenic substance that occurs when certain species of fish begin to decay; chloramphenicol, a banned antibiotic in most of the world, but still used by some shrimp farmers to improve the yield of their products; sulfite, an effective but potentially allergenic shrimp preservative; and shellfish toxins.

The majority of Neogen s food safety test kits use immunoassay technology to rapidly detect target substances. The Company s ability to produce high quality antibodies sets its products apart from immunoassay test kits produced and sold by other companies. The Company s kits are available in microwell formats, which allow for automated and rapid processing of a large number of samples, and lateral flow and other similar devices that provide distinct visual results. Typically, test kits use antibody-coated test devices and chemical reagents to indicate a positive or negative result for the presence of a target substance in a test sample; the simplicity of the tests makes them accessible to all levels of food producers, processors and handlers. Neogen also offers other test methods and products to complement its immunoassay tests.

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The Company s kits are generally based on internally developed technology, licensed technology, or technology that is acquired in connection with acquisitions. In fiscal 2016, the Food Safety segment incurred royalty expense totaling $1,329,000 for licenses and royalties for technology used in the Company s products, including expense of $737,000 for allergen products, $134,000 for the pathogen product line and $122,000 for licenses related to the dairy antibiotics product line. Generally, the Company s royalty rates are in the range of 2% to 10% of revenues on products containing the licensed technology. Some licenses involve technology that is exclusive to Neogen s use while others are nonexclusive and involve technology licensed to multiple licensees.

Revenues from Neogen s Food Safety segment accounted for 45.4%, 46.5% and 47.0% of the Company s total revenues for fiscal years ended May 31, 2016, 2015 and 2014, respectively.

ANIMAL SAFETY SEGMENT

Neogen s Animal Safety segment is primarily engaged in the development, manufacture and marketing of veterinary instruments, pharmaceuticals, vaccines, topicals, a full suite of agricultural biosecurity products, such as rodenticides, insecticides, cleaners and disinfectants, genomic services and diagnostic products.

Veterinary instruments. Neogen markets a broad line of veterinary instruments and animal health delivery systems under the Ideal brand name. Approximately 250 different products are offered, many of which are used to deliver animal health products, such as antibiotics and vaccines. Ideal s D3 Needles are stronger than conventional veterinary needles and are uniquely detectable by common meat processing facility metal detectors a big market advantage in the safety-conscious beef and swine industries. Neogen s Prima Tech product line is designed around highly accurate devices used by farmers, ranchers, and veterinarians to inject animals, provide topical applications and to use for oral administration. Prima Tech is also a supplier of products used in artificial insemination in the swine industry. Other products include animal identification and handling equipment.

Veterinary pharmaceuticals. Animal Safety s NeogenVet product line provides innovative, value-added, high quality products to the veterinary market. Top NeogenVet products include PanaKare, a digestive aid that serves as a replacement therapy where digestion of protein, carbohydrate and fat is inadequate due to exocrine pancreatic insufficiency; Natural Vitamin E-AD, which aids in the prevention and treatment of vitamin deficiencies in swine, cattle and sheep; and RenaKare, a supplement for potassium deficiency in cats and dogs. Other products sold under the NeogenVet brand include Vita-15 and Liver 7, which are used in the treatment and prevention of nutritional deficiencies. The Company also manufactures Uniprim, a leading veterinary antibiotic.

Veterinary biologics. Neogen s BotVax B vaccine has successfully protected thousands of high-value horses and foals against Type B botulism, commonly known as Shaker Foal Syndrome. The Company s product is the only USDA-approved vaccine for the prevention of Type B botulism in horses. Years of research and many thousands of doses have proven Neogen s EqStim immunostimulant to be safe and effective as a veterinarian-administered adjunct to conventional treatment of equine bacterial and viral respiratory infections. The Company s ImmunoRegulin product uses similar immunostimulant technology to aid in the treatment of pyoderma (a bacterial skin inflammation) in dogs.

Veterinary OTC products. Animal Safety products offered by Neogen to the retail over-the-counter (OTC) market include Ideal brand veterinary instruments packaged for the retail market. OTC products also include Stress-Dex, an oral electrolyte replacer for performance horses, and Fura-Zone, for the prevention and treatment of surface bacterial infections in wounds, burns and cutaneous ulcers. Ag-Tek and other hoof care, disposables and artificial insemination supplies are marketed to the dairy and veterinary industries.

Rodenticides. Neogen s comprehensive line of proven rodenticides, sold under brand names such as Ramik and Havoc, effectively address rodent problems of any size and serve as a critical component of an overall biosecurity plan for major agricultural operations. Neogen offers several rodenticide active ingredients including diphacinone, bromethalin, brodifacoum, and zinc phosphide formulated with food grade ingredients to generate the highest acceptance and most palatable bait possible.

Cleaners and disinfectants. Used in animal and food production facilities, Neogen s cleaners and disinfectants, including DC&R, 904 Disinfectant, Acid-A-Foam, Preserve, Tetradyne and FarmFluid S, can stop a disease outbreak before it starts. The products also are used in the veterinary clinic market to maintain sanitary conditions and limit the potential hazards of bacteria, fungi and viruses.

Insecticides. Neogen s highly effective Chem-Tech insecticides utilize environmentally friendly technical formulas, and several are approved for use in food establishments. The company s Prozap insecticide brand is well known in the large animal production industry, particularly with dairy and equine producers.

Animal genomics services. Neogen s animal genomics businesses, GeneSeek and Igenity, provide value-added services to leading agricultural genetics providers, large national cattle associations, companion animal breed registries, university researchers, and numerous commercial cattle producers. With both state-of-the-art genetics laboratories and the comprehensive bioinformatics to interpret genetic test results, Neogen offers identity and trait determination and analysis. GeneSeek s technology employs high-resolution DNA genotyping for identity and trait analysis in a variety of important animal and agricultural plant species. Igenity s extensive bioinformatics system identifies and predicts an animal s positive or negative traits based on DNA test results. This information has helped livestock producers make significant improvements in genetics and improve overall quality of their animals.

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Life sciences. Neogen s line of approximately 100 drug detection immunoassay test kits is sold worldwide for the detection of approximately 300 abused and therapeutic drugs in farm animals and racing animals, and for detection of drug residues in meat and meat products. The test kits are also used for human forensic toxicology drug screening applications. This line includes tests for narcotics, analgesics, stimulants, depressants, tranquilizers, anesthetics, steroids and diuretics. Neogen also has several products used by researchers for the detection of biologically active substances.

Many of the products and services in the Animal Safety segment use licensed technology. Animal Safety incurred royalty expense totaling $640,000 for licenses and royalties in fiscal 2016 for technology used in the segment s products and services, including expense of $304,000 for licenses related to the genomics services line.

Revenues from Neogen s Animal Safety segment accounted for 54.6%, 53.5% and 53.0% of the Company s total revenues for fiscal years ended May 31, 2016, 2015 and 2014, respectively.

GENERAL SALES AND MARKETING

Neogen is organized under two segments Food Safety and Animal Safety. Within these segments, the Company s sales efforts are generally organized by specific markets, rather than by products or geography. During the fiscal year that ended May 31, 2016, the Company had approximately 22,000 customers for its products. Since many customers for animal safety products are distributors, and certain animal safety products are offered to the general retail market, the total number of end users of the Company s products is considerably greater than 22,000. As of May 31, 2016, a total of 348 employees were assigned to sales and marketing functions within the Company, compared to 305 at the end of May 2015. During the years ended May 31, 2016, 2015 and 2014, no single customer or distributor accounted for 10% or more of the Company s revenues.

DOMESTIC SALES AND MARKETING

FOOD SAFETY

To reach each customer and prospect with expertise and experience, Neogen has a staff of specialized food safety sales and technical service representatives assigned to specific markets. This staff sells Company products directly to end users, and also handles technical support issues that arise with customers in the United States and Canada.

Neogen s food safety markets are primarily comprised of: milling and grain, including grain elevators, feed mills, pet food manufacturers, and grain inspection companies; meat and poultry, including meat and poultry processors, producers of ready-to-eat meat and poultry products; and the USDA s Food Safety Inspection Service (FSIS); grocery products, including flour millers, malters, bakeries, candy and confection manufacturers, manufacturers of prepared meals, nuts, spices, cookies, crackers and other snack foods; fruits and vegetables, including growers and processors of juice and packaged fresh cut grocery items; seafood, including harvesters and processors of a wide variety of seafood products; dairy and beverage, including milk processors and soft drink bottlers; healthcare, including hospitals and distributors to the healthcare industry; traditional culture media markets, including commercial and research laboratories and producers of pharmaceuticals, cosmetics and veterinary vaccines; food service and retail, including fast food service establishments and retail grocery market chains, and nutraceuticals, including producers and marketers of a wide variety of nutritional and holistic consumer products.

ANIMAL SAFETY

Neogen markets a broad range of pharmaceuticals, vitamin injectables, wound care products, topicals, instruments, genomics services and biologicals to the veterinary market. The product range is focused on the food (e.g., cattle, swine and poultry) and companion (e.g., horses, dogs and cats) animal markets. Neogen s sales group works directly with veterinarians, clinics and universities and markets through established ethical distributors by supporting the efforts of over 1,000 domestic distributor sales representatives calling on 35,000 plus veterinarians. Neogen further supports its veterinary distribution channel through product training, field support, promotions and technical service.

The Company believes the OTC animal health market offers growth opportunities for Neogen and its products. Neogen offers a broad range of products including well-recognized brands of rodenticides, disinfectants, insecticides, instruments and horse care products. To reach the OTC market, Neogen s sales team works with a large network of animal health distributors including marketing groups, traditional two-step distributors, catalogers and large retail chains. Support includes product training, field support, planogram solutions, promotions and advertising.

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As a commercial laboratory, GeneSeek provides services direct to large-herd beef and dairy cattle, swine, poultry and sheep producers, universities and other research organizations, and various livestock and canine breed associations.

INTERNATIONAL SALES AND MARKETING

Neogen maintains eight Company-owned locations outside of the United States to provide a direct presence in regions of particular importance to the Company, and maintains an extensive network of distributors to reach countries where the Company does not have a direct presence.

Neogen Europe. Neogen Europe, Ltd., located in Ayr, Scotland, provides the Company access to the European Union (E.U.), and sells products and services to its network of customers and distributors throughout the E.U. Customers in the United Kingdom, France, Germany and the Netherlands are served by Company employees. In other European regions, customers are generally serviced by distributors managed by Neogen Europe personnel. Neogen Europe s research and development team continues to be a strong asset in the development of products tailored to meet the unique requirements of the European market.

Lab M Holdings. In August 2015, Neogen acquired the stock of Lab M Holdings (Lab M), a developer, manufacturer and supplier of microbiological culture media and diagnostic systems located in Heywood, England. Lab M s extensive range of microbiological culture media, supplements, immunomagnetic separation techniques and proficiency testing systems are used in laboratories around the world.

Neogen Latinoamérica. The Company s subsidiary in Mexico, Neogen Latinoamérica, is headquartered in Mexico City and distributes Neogen s products throughout Mexico and Central America. Neogen Latinoamérica manages the Company s business activities throughout the region to animal and crop producers, and food processors.

Neogen do Brasil and Deoxi. Neogen do Brasil (translated as Neogen of Brazil), headquartered near São Paulo, distributes Neogen s products throughout Brazil. Brazil is one of the world leaders in the export of numerous food commodities, including beef, poultry, soybeans, coffee, sugar and orange juice, and this operation gives the Company direct sales representation to these important markets. Neogen also owns Deoxi Biotecnologia Ltda, a genomics testing laboratory located in Aracatuba, Brazil, which it purchased in April 2016.

Neogen China. Noegen s Chinese subsidiary, with locations in Shanghai and Beijing, employs sales representatives who sell directly to Chinese customers. China s burgeoning middle class, with its rapidly growing demand for higher quality meat and dairy products, makes the country a substantial growth opportunity for Neogen products both for animal production on the country s farms, and in processing plants throughout China s food processing and distribution industry.

Neogen India. In June 2015, Neogen acquired the assets of Sterling Test House, a leading commercial food testing laboratory based in southwest India, to serve as a base for the Company s new operations in India. Sterling Test House was incorporated in 1990, and its business has grown to include most of the food safety and water quality testing for major hotels and restaurants in its home region, as well as safety and quality analysis for the country s expanding nutraceutical market, and growing food export businesses. The laboratory is located in Cochin in the state of Kerala, which is India s leading region for the export of spices, tea, and fresh fruits and vegetables. In late fiscal 2016, Neogen transferred sales responsibility for its Food Safety products directly to sales representatives at Neogen India.

Neogen Canada. In September 2015, Neogen opened a Canadian location in Guelph, Ontario. Currently, this office is used for genomics sales and sample reception.

Dairy antibiotics distributor. Neogen s dairy antibiotics diagnostic products are distributed outside of North America, Brazil and China by Denmark based Chr. Hansen, an international supplier of natural ingredient solutions for the food, health and nutritional industries.

Other distributor partners. Outside of the Company locations and dairy antibiotics distributor mentioned above, Neogen uses its own sales managers to work closely with and coordinate the efforts of a network of approximately 140 distributors in more than 100 countries. The distributors provide local training and technical support, perform market research and promote Company products within designated countries around the world.

Animal Safety products distribution. Animal Safety has a strong presence in several key international markets with rodenticides, disinfectants, instruments, diagnostics and veterinary products. Utilizing Company personnel in Brazil, Mexico and China, as well as in-country distributors and U.S.-based exporters, these markets include Canada, Mexico and Central America, South America, the Caribbean, Australia, Europe and Asia.

Sales to customers outside the United States accounted for 33.5%, 36.7% and 38.8% of the Company s total revenues for fiscal years ended May 31, 2016, 2015 and 2014, respectively.

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RESEARCH AND DEVELOPMENT

Management maintains a strong commitment to Neogen s research and development activities. The Company s product development efforts are focused on the enhancement of existing product lines and in the development of new products that fit its business strategy. As of May 31, 2016, the Company employed 85 individuals in its worldwide research and development group, including immunologists, chemists and microbiologists. Research and development costs were approximately $9.9 million, $9.6 million and $8.3 million representing 3.1%, 3.4% and 3.4% of total revenues in fiscal years 2016, 2015 and 2014, respectively. Management currently expects the Company s future research and development expenditures to approximate 3% to 4% of total revenues.

Neogen has ongoing development projects for new diagnostic tests and other complementary products for both the food safety and animal safety markets. Management expects that a number of these products will be commercially available at various times during fiscal years 2017 to 2019.

Portions of certain technologies utilized in some products manufactured and marketed by Neogen were acquired from or developed in collaboration with affiliated partnerships, independent scientists, governmental units, universities and other third parties. The Company has entered into agreements with these parties that provide for the payment of license fees and royalties based upon sales of products that utilize the pertinent technology. License fees and royalties expensed under these agreements amounted to $1,969,000, $2,189,000 and $2,278,000 in fiscal years 2016, 2015 and 2014, respectively.

PROPRIETARY PROTECTION AND APPROVALS

Neogen uses trade secrets as proprietary protection in many of its food and animal safety products. In many cases, the Company has developed unique antibodies capable of detecting microorganisms and residues at minute levels. The supply of these antibodies, and the proprietary techniques utilized for their development, may offer better protection than the filing of patents. Such proprietary reagents are maintained in secure facilities and stored in more than one location to reduce exposure to complete destruction by natural disaster or other means.

Patent and trademark applications are submitted whenever appropriate. Since its inception, Neogen has acquired and received numerous patents and trademarks, and has several pending patents and trademarks. The patents expire at various times over the next 23 years.

A summary of patents by product categories follows:

	USA	International	Expiration
Natural Toxins, Allergens & Drug Residues	4	35	2018-2038
Bacterial & General Sanitation	18	37	2017-2028
Life Science	0	7	2024
Vaccine	2	0	2018-2028
Veterinary Instruments & Other	11	35	2017-2039
Genomics	6	2	2021-2028

The Company does not expect the near-term expiration of any patent to have a significant effect on future results of operations.

Management believes that Neogen has adequate protection as to proprietary rights for its products. However, it is aware that substantial research has taken place at universities, governmental agencies and other companies throughout the world and that numerous patents have been applied for and issued for technologies which may be used in the Company s products. To the extent some of the Company s products may now, or in the future, embody technologies protected by patents, copyrights or trade secrets of others, licenses to use such technologies may need to be obtained in order to continue to sell the products. These licenses may not be available on commercially reasonable terms. Failure to obtain any such licenses may delay or prevent the sale of certain new or existing products. In addition, patent litigation is not uncommon. Accordingly, there can be no assurance that the Company s existing patents will be sufficient to completely protect its proprietary rights.

One of the major areas affecting the success of biotechnology development involves the time, cost and uncertainty surrounding regulatory approvals. Neogen products requiring regulatory approval, which the Company currently has in place, include BotVax B, EqStim, ImmunoRegulin, Uniprim and BetaStar. The Company s general strategy is to select technical and proprietary products that do not require mandatory approval to be marketed. Neogen s rodenticide, disinfectant and insecticide products are subject to registration in the United States and internationally.

Neogen utilizes third-party validations on many of its disposable test kits as a marketing tool to provide its customers with the proper assurances. These include validation by the AOAC International, independently administered third-party, multi-laboratory collaborative studies and approvals by the U.S. Federal Grain Inspection Service and the USDA Food Safety Inspection Service for the use of Company products in their operations.

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PRODUCTION AND SUPPLY

Neogen manufactures its products in Michigan, Kentucky, Wisconsin, North Carolina, Iowa, Tennessee, California and the United Kingdom and provides genomics services in Nebraska, Scotland and Brazil. As of May 31, 2016, there were approximately 577 full-time employees assigned to manufacturing and providing of services in these locations, operating on one or two shifts; with occasional 24/7 production during high demand periods; future demand increases could be accommodated by adding shifts. Management believes it could increase the current output of its primary product lines by more than 50% using the current space available; however, to do so could require investment in additional capital equipment.

Food safety diagnostics. Manufacturing of diagnostic tests for the detection of natural toxins, pathogens, food allergens, dairy antibiotics, spoilage organisms and pesticides, final kit assembly, quality assurance and shipping takes place in the Company s facilities in Lansing, Michigan. Proprietary monoclonal and polyclonal antibodies for Neogen s diagnostic kits are produced on a regular schedule in the Company s immunology laboratories in Lansing. Generally, final assembly and shipment of diagnostic test kits to customers in Europe is performed in the Company s Ayr, Scotland facility. Assembly and shipment of electronic readers and disposable single-use samplers takes place in the Company s facilities in Lansing. Soleris instrument readers are produced by third party vendors, quality tested in Lansing, and then shipped to customers. Dehydrated culture media products are manufactured in a FDA-registered facility in Lansing and and also at Lab M in Heywood, England. Products are blended following strict formulations or custom blended to customer specification and shipped directly to customers from Lansing and Heywood.

Animal health products. Manufacturing of animal health products, pharmacological diagnostic test kits and test kits for drug residues takes place in the Company s FDA-registered facilities in Lexington, Kentucky. In general, manufacturing operations including reagent manufacturing, quality assurance, final kit assembly and packaging are performed by Neogen personnel. Certain animal health products and veterinary instruments that are purchased finished or that are toll manufactured by third party vendors are warehoused and shipped from the Company s Lexington facilities. Other veterinary instruments are produced in the Company s facilities in Lansing, and are generally then shipped to Lexington, for distribution to customers. Manufacturing and shipment of devices used for animal injections, topical applications and oral administration takes place in a Company-owned facility in Kenansville, North Carolina.

Veterinary biologics. Neogen maintains a Lansing-based USDA-approved manufacturing facility devoted to the production of the biologic products EqStim and ImmunoRegulin. *P. acnes* seed cultures are added to media and then subjected to several stages of further processing resulting in a finished product that is filled and packaged within the facility. The Company s BotVax B vaccine is also produced in the Lansing facility utilizing Type B botulism seed cultures and a traditional fermentation process. All completed biologic products are then shipped to Neogen s Lexington facilities for inventory and distribution to customers.

Agricultural genomic services. Neogen offers agricultural genomics laboratory services and bioinformatics at its locations in Nebraska, Scotland and Brazil. Through its laboratory services and bioinformatics (primarily in beef and dairy cattle, pigs, sheep, poultry, horses and dogs), GeneSeek empowers its customers to speed genetic improvement efforts, as well as identify economically important diseases. The Company renovated a building during fiscal 2014 to meet its current and near-term future domestic needs, and added to its processing capabilities in Scotland in fiscal 2016, while also purchasing a genomics business in Brazil to enhance its presence there.

Cleaners, disinfectants and rodenticides. Manufacturing of rodenticides and certain cleaners and disinfectants takes place in the following locations: Randolph, Wisconsin; Memphis, Tennessee; and Turlock, California. Manufacturing of rodenticides consists of blending technical material (active ingredient) with bait consisting principally of various

grains. Certain cleaners and disinfectants are manufactured in Neogen facilities, while others are purchased from other manufacturers for resale, or toll manufactured by third parties.

Pesticides. Chem-Tech Ltd. manufactures insecticides and other pesticides at its facility in Pleasantville, Iowa.

Neogen purchases component parts and raw materials from more than 800 suppliers. Though many of these supplies are purchased from a single source in order to achieve the greatest volume discounts, the Company believes it has identified acceptable alternative suppliers for most of its key components and raw materials where it is economically feasible to do so. There can be no assurance that the Company would avoid a disruption of supply in the event a supplier discontinues shipment of product. Shipments of products are generally accomplished within a 48-hour turnaround time. As a result of this quick response time, Neogen s backlog of unshipped orders at any given time has historically not been significant.

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COMPETITION

Although competitors vary in individual markets, management knows of no competitor that is pursuing Neogen s fundamental strategy of developing and marketing a broad line of products, ranging from disposable tests and dehydrated culture media to veterinary pharmaceuticals and instruments for a large number of food safety and animal safety concerns. For each of its individual products, the Company faces intense competition from companies ranging from small businesses to divisions of large multinational companies. Some of these organizations have substantially greater financial resources than the Company. Neogen competes primarily on the basis of ease of use, speed, accuracy and other similar performance characteristics of its products. The breadth of the Company s product line, the effectiveness of its sales and customer service organizations, and pricing are also components in management s competitive plan.

Future competition may become even more intense, including the development of changing technologies, which could affect the marketability and profitability of Neogen s products. The Company s competitive position will also depend on management s ability to develop proprietary products, attract and retain qualified scientific and other personnel, develop and implement production and marketing plans and obtain patent protection. Additionally, the Company must have adequate capital resources to execute its strategy.

FOOD SAFETY:

With a large professional sales organization offering a comprehensive catalog of food safety solutions, management believes the Company maintains a general competitive advantage over competitors offering only limited product lines. In most cases, Neogen sales and technical service personnel can offer unique insight into a customer s numerous safety and quality challenges, and offer testing and other solutions to help the customer overcome those challenges.

Competition for pathogen detection products includes traditional methods and antibody and genetic-based platforms. Neogen s product offerings compete across the entire spectrum of methods. Competition for natural toxins and allergen detection products include instrumentation and antibody-based tests. While the Company s offerings will not always compete on all platforms in all markets, the products that are offered provide tests that can be well utilized by most customers to meet their testing needs.

Besides its extensive product offerings and robust distribution network, the Company focuses its competitive advantage in the areas of customer service, product performance, speed and ease of use of its products. Additionally, by aggressively maintaining itself as a low-cost producer, Neogen believes that it can be competitive with new market entrants that may choose a low pricing strategy in an attempt to gain market share.

ANIMAL SAFETY:

Neogen s Animal Safety segment faces no one competitor across the products and markets it serves. In the racing industry market, the Company believes it holds a leading market share position. In the life sciences and forensics markets, the Company competes against several other diagnostic and reagent companies with similar product offerings.

In the veterinary market, Neogen markets BotVax B, the only USDA-approved vaccine for the prevention of botulism Type B in horses. The Company competes on other key products through differentiated product performance and superior customer and technical support. With some of its products, the Company provides solutions as a lower cost alternative and offers a private label option for its distributors.

Competition in the rodenticide market includes several companies of comparable size that offer products into similar market segments. The rodenticide retail market is not dominated by a single brand. While the technical materials used by competing companies are similar, Neogen uses manufacturing and bait formula techniques which the Company believes better attracts rodents to the product and thereby improves overall product performance.

Within the insecticide market, Chem-Tech products specifically focus on the area of insect control for food and animal safety applications. There are several competitors offering similar products, however, the Company has a proprietary formulation chemistry that optimizes the delivery and safe application of insecticides at the customer s location. These products are currently only sold in the U.S. through a combination of direct sales and distributors.

Several companies compete for sales in the cleaner and disinfectant product segment. Neogen s products are sold through its distributor network around the world, primarily to assist in the cleaning and disinfecting of animal production facilities.

In addition to the Company s extensive portfolio of Animal Safety products, Neogen also competes in the retail market by providing solutions to common retail problems, such as stock outs, wasted floor space and inconsistent brand identity. The Company offers planograms and reordering systems to maximize turns and profitability for its retail customers.

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GeneSeek, the leading commercial agricultural genomics laboratory in the U.S., employs cutting-edge technology in the area of genomics. The result of this technology allows the acceleration of natural selection through selective breeding of traits such as disease resistance and meat quality. Competition comes mainly from service providers whose primary focus are the human and pharmaceutical industries, as well as several smaller companies offering genomics services. GeneSeek is not involved in cloning or the development of transgenic animals.

GOVERNMENT REGULATION

A significant portion of Neogen s products and revenues are affected by the regulations of various domestic and foreign government agencies, including the U.S. Department of Agriculture, the Environmental Protection Agency, and the U.S. Food and Drug Administration. Changes in these regulations could affect revenues and/or costs of production and distribution.

Neogen s development and manufacturing processes involve the use of certain hazardous materials, chemicals and compounds. Management believes that the Company s safety procedures for handling and disposing of such commodities comply with the standards prescribed by federal, state and local regulations; however, changes in such regulations or rules could involve significant costs to the Company and could be materially adverse to its business.

The rodenticides, insecticides, cleaners, disinfectants and sanitizers manufactured and distributed by Neogen are subject to Environmental Protection Agency and various state regulations. In general, any international sale of the product must also comply with similar regulatory requirements in the country of destination. Each country has its own individual regulatory construct with specific requirements (e.g., label in the language of the importing country). To the best of the Company s knowledge, Neogen products are in compliance with applicable regulations in the countries where such products are sold.

Dairy products used in National Conference on Interstate Milk Shipments (NCIMS) and other milk monitoring programs are regulated by the FDA. Before products requiring FDA approval can be sold in the U.S., extensive product performance data must be submitted in accordance with the FDA approved protocol administered by AOAC Research Institute (AOAC RI). Following approval of a product by the FDA, the product must also be approved by NCIMS, an oversight body that includes federal, state and industry representatives. The Company s BetaStar U.S. dairy antibiotic residue testing product has been approved by the FDA, NCIMS, and AOAC RI. While some foreign countries accept AOAC RI approval as part of their regulatory approval processes, many countries have their own regulatory requirements.

Many of the food safety diagnostic products to detect allergens and spoilage organisms do not require direct government approval. However, the Company has pursued AOAC approval for many of the products to enhance their marketability. Products for mycotoxin detection, which are used by federal inspectors, must be approved by the USDA. Neogen has obtained and retained the necessary approvals to conduct its current operations.

Neogen s veterinary vaccine products and one pharmaceutical product require government approval to allow for lawful sales. The vaccine products are approved by United States Department of Agriculture, Center for Veterinary Biologics (USDA-CVB) and the pharmaceutical product is approved by the FDA. The products, and the facilities in which they are manufactured, are in a position of good standing with both agencies. The Company has had no warning letters based on any review or inspection, no recalls on any of these products, and knows of no reason why it could not manufacture and market such products in the future.

Other animal safety and food safety products generally do not require additional registrations or approvals. However, Neogen s regulatory staff routinely monitors amendments to current regulatory requirements to ensure compliance.

EMPLOYEES

As of May 31, 2016, the Company employed 1,235 full-time persons worldwide. None of the employees are covered by collective bargaining agreements. There have been no work stoppages or slowdowns due to labor-related problems, and management believes that its relationship with its employees is generally good. Employees having access to proprietary information have executed confidentiality agreements with the Company.

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ITEM 1A. RISK FACTORS

An investment in Neogen Corporation s common shares involves a high degree of risk. The risks described below are not the only ones that an investor faces. Additional risks that are not yet known to us or that we currently think are immaterial could also impair our business, financial condition or results of operations. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected.

Risks Relating to Our Business

Our business strategy is dependent on successfully promoting internal growth and identifying and integrating acquisitions.

Our business has grown significantly over the past several years as a result of both internal growth and acquisitions of existing businesses and their products. Management initiatives may be attempted to augment internal growth, such as strengthening our presence in select markets, reallocating research and development funds to higher growth potential products, development of new applications for our technologies, enhancing our service offerings, continuing key customer efforts, and finding new markets for our products. Failure of these management initiatives may have a material adverse effect on our operating results and financial condition.

Identifying and pursuing acquisition opportunities, integrating these acquisitions into our business and managing their growth requires a significant amount of management s time and skill. We cannot assure that we will be effective in identifying, integrating or managing future acquisition targets. Our failure to successfully integrate and manage a future acquisition may have a material adverse effect on our operating results and financial condition.

In addition, if we continue to experience growth in our business, such growth could place a significant strain on our management, customer service, operations, sales and administrative personnel, and other resources. To serve the needs of our existing and future customers we will be required to recruit, train, motivate and manage qualified employees. We have incurred and will continue to incur significant costs to retain qualified management, sales and marketing, engineering, production, manufacturing and administrative personnel, as well as expenses for marketing and promotional activities. Our ability to manage our planned growth depends upon our success in expanding our operating, management, information and financial systems, which might significantly increase our operating expenses.

We may not be able to effectively manage our future growth, and if we fail to do so, our business, financial condition and results of operations could be adversely affected.

We rely significantly on our information systems and telecommunications infrastructure to support our operations and a security breach of the Company s information systems could damage the Company s reputation and have an adverse effect on operations and results.

We rely on information systems and telecommunications infrastructure to integrate departments and functions, to enhance our ability to service customers, to improve our control environment and to manage our cost reduction initiatives. Any issues involving our critical business applications and infrastructure may adversely impact our ability to manage operations and the customers we serve. In addition, if the Company s security and information systems are compromised, or employees fail to comply with the applicable laws and regulations and this information is obtained by unauthorized persons or used inappropriately, it could adversely affect the Company s reputation, as well as results of operations, and could result in litigation, the imposition of penalties, or significant expenditures to remediate any damage to persons whose personal information has been compromised.

Disruption of our manufacturing and service operations could have an adverse effect on our financial condition and results of operations.

We manufacture our products at several manufacturing facilities located in the following locations: Lansing, Michigan; Lexington, Kentucky; Randolph, Wisconsin; Kenansville, North Carolina; Pleasantville, Iowa; Memphis, Tennessee; Turlock, California; Heywood, England; and Ayr, Scotland. We offer genomics services from facilities located in: Lincoln, Nebraska; Ayr, Scotland; and Aracatuba, Brazil. These facilities and our distribution systems are subject to catastrophic loss due to fire, flood, terrorism or other natural or man-made disasters. If any of these facilities were to experience a catastrophic loss, it could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair or replace the facility and/or distribution system. If such a disruption were to occur, we could breach agreements, our reputation could be harmed, and our business and operating results could be adversely affected. Although we carry insurance for property damage and business interruption, we do not carry insurance or financial reserves for interruptions or potential losses arising from terrorism. Economic conditions and uncertainties in global markets may adversely affect the cost and other terms upon which we are able to obtain third party insurance. If our third party insurance coverage is adversely affected, or to the extent we have elected to self-insure, we may be at greater risk that our operations will be harmed by a catastrophic loss.

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Our dependence on suppliers could limit our ability to sell certain products or negatively affect our operating results.

We rely on third party suppliers to provide components in our products, manufacture products that we do not manufacture ourselves and perform services that we do not provide ourselves, including package delivery services. Because these suppliers are independent third parties with their own financial objectives, actions taken by them could have a negative effect on our results of operations. The risks of relying on suppliers include our inability to enter into contracts with third party suppliers on reasonable terms, inconsistent or inadequate quality control, relocation of supplier facilities, supplier work stoppages and suppliers failure to comply with their contractual obligations. In addition, we currently purchase some raw materials and products from sole or single sources. Some of the products that we purchase from these sources are proprietary and, therefore, cannot be readily or easily replaced by alternative sources. Problems with suppliers could negatively impact our ability to supply the market, substantially decrease sales, lead to higher costs or damage our reputation with our customers.

We rely heavily on third party package delivery services, and a significant disruption in these services or significant increases in prices may disrupt our ability to ship products, increase our costs and lower our profitability.

We ship a significant portion of our products to our customers through independent package delivery companies, such as UPS, Federal Express and DHL. We also ship our products through other carriers, including national and regional trucking firms, overnight carrier services and the U.S. Postal Service. If one or more of these third party package delivery providers were to experience a major work stoppage, preventing our products from being delivered in a timely fashion or causing us to incur additional shipping costs we could not pass on to our customers, our costs could increase and our relationships with some of our customers could be adversely affected. In addition, if one or more of our third party package delivery providers were to increase prices, and we were not able to find comparable alternatives or make adjustments in our delivery network, our profitability could be adversely affected.

Our business sells many products through distributors, which present risks that could negatively affect our operating results.

We sell many of our products, both within and outside of the U.S., through distributors. As a result, we are dependent on these distributors to sell our products and assist us in promoting and creating a demand for our products. Our distributors sometimes offer products from several different companies, and those distributors may carry our competitors products and promote our competitors products over our own products. We have limited ability, if any, to cause our distributors to devote adequate resources to promoting, marketing, selling and supporting our products. We cannot assure that we will be successful in maintaining and strengthening our relationships with our distributors or establishing relationships with new distributors who have the ability to market, sell and support our products effectively. We may rely on one or more key distributors for a product or region, and the loss of one or more of these distributors could reduce our revenue. Distributors may face financial difficulties, including bankruptcy, which could harm our collection of accounts receivable and financial results. In addition, violations of anti-corruption laws or similar laws by our distributors could have a material impact on our business, and any termination of a distributor relationship may result in increased competition in the applicable jurisdiction. Failing to manage the risks associated with our use of distributors may reduce sales, increase expenses and weaken our competitive position, which could have a negative effect on our operating results.

The development of new products entails substantial risk of failure due to the production of non-viable products, lack of properly identifying market potential, and competitors better serving the marketplace.

Our growth strategy includes significant investment in and expenditures for product development. To execute this strategy, we are continually developing new products for which we believe there should be significant market demand. We cannot assure that we will successfully develop commercially viable products, that the products will be developed on a timely basis to meet market demand or that the relevant market will be properly identified. Our competitors may also adapt more quickly, and deliver superior technologies, price and/or service to better fit our customers requirements. If we expend substantial resources in developing an unsuccessful product, whether that lack of success is the result of our production of a non-viable product, a misidentified market, or a competitor s superior ability to meet our customers requirements, operating results could be adversely affected.

Our international operations are subject to different product standards as well as other operational risks.

In fiscal 2016, sales to customers outside of the U.S. accounted for 33.5% of the Company s total revenue. We expect that our international business will continue to account for a significant portion of our total revenue. Foreign regulatory bodies may establish product standards different from those in the U.S. and with which the Company s current products do not comply. Our potential inability to design products that comply with foreign standards could have a material adverse effect on our future growth. Other risks related to our sales to customers outside of the U.S. include possible disruptions in transportation, difficulties in building and managing foreign distribution, fluctuation in the value of foreign currencies, changes in import duties and quotas and unexpected economic and political changes in foreign markets. These factors could adversely affect international sales and our overall financial performance.

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The markets for our products are extremely competitive, and our competitors may be able to utilize existing resource advantages to our detriment.

The markets in which the Company competes are subject to rapid and substantial changes in technology and are characterized by extensive research and development and intense competition. Many of our competitors and potential competitors have greater financial, technical, manufacturing, marketing, research and development and management resources than we do. These competitors might be able to use their resources, reputations and ability to leverage existing customer relationships to give them a competitive advantage over us. They might also succeed in developing products that are more reliable and effective than our products, make additional measurements, are less costly than our products or provide alternatives to our products.

We are dependent on the agricultural marketplace, which is affected by factors beyond our control.

Our primary customers are in the agricultural and food production industries. Economic conditions affecting agricultural industries are cyclical and are dependent upon many factors outside of our control, including weather conditions, changes in consumption patterns or commodity prices. Any of these factors in the agricultural marketplace could affect our sales and overall financial performance.

Our quarterly operating results are subject to significant fluctuations.

We have experienced, and may experience in the future, significant fluctuations in our quarterly operating results. The mix of products sold and the acceptance of new products, in addition to other factors, could contribute to this quarterly variability. We operate with relatively little backlog and have few long-term customer contracts. Substantially all of our product revenue in each quarter results from orders received in that quarter. In addition, our expense levels are based, in part, on our expectation of future revenue levels. A shortfall in expected revenue could, therefore, result in a disproportionate decrease in our net income.

Our success is highly dependent on our ability to obtain protection for the intellectual property utilized in our products.

Our success and ability to compete depends in part upon our ability to obtain protection in the United States and other countries for our products by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. Patent applications filed by the Company may not result in the issuance of patents or, if issued, may not be issued in a form that will be commercially advantageous to us. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of time we may have patent protection for our products. We also cannot assure that our nondisclosure agreements, together with trade secrets and other common law rights, will provide meaningful protection for the Company s trade secrets and other proprietary information. Moreover, the laws of some foreign jurisdictions may not protect intellectual property rights to the same extent as in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights domestically or in foreign jurisdictions, we may incur substantial costs and our business, including our business prospects, could be substantially harmed.

From time to time, the Company has received notices alleging that the Company s products infringe third party proprietary rights. Whether the manufacture, sale or use of current products, or whether any products under development would, upon commercialization, infringe any patent claim will not be known with certainty unless and until a court interprets the patent claim in the context of litigation. When an infringement allegation is made against

us, we may seek to invalidate the asserted patent claim and/or to allege non-infringement of the asserted patent claim. In order for us to invalidate a U.S. patent claim, we would need to rebut the presumption of validity afforded to issued patents in the United States with clear and convincing evidence of invalidity, which is a high burden of proof. The outcome of infringement litigation is subject to substantial uncertainties, and also the testimony of experts as to technical facts upon which experts may reasonably disagree. Our defense of an infringement litigation lawsuit could result in significant expense. Regardless of the outcome, infringement litigation could significantly disrupt our marketing, development and commercialization efforts, divert management s attention and consume our financial resources. In the event that we are found to infringe any valid claim in a patent held by a third party, we may, among other things, be required to:

- Pay damages, including up to treble damages and the other party s attorneys fees, which may be substantial;
- Cease the development, manufacture, importation, use and sale of products that infringe the patent rights of others, through a court-imposed injunction;
- Expend significant resources to redesign our technology so that it does not infringe others patent rights, or develop or acquire non-infringing intellectual property, which may not be possible;
- Discontinue manufacturing or other processes incorporating infringing technology; and/or
- Obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

Any development or acquisition of non-infringing products, technology or licenses could require the expenditure of substantial time and other resources and could have a material adverse effect on our business and financial results. If we are required to, but cannot, obtain a license to valid patent rights held by a third party, we would likely be prevented from commercializing the relevant product, or from further manufacture, sale or use of the relevant product.

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We are subject to substantial governmental regulation.

A portion of our products and facilities are regulated by various domestic and foreign government agencies, including the U.S. Department of Agriculture, the U.S. Food and Drug Administration and the Environmental Protection Agency. Although less than 10% of our revenue is currently derived from products requiring government approval prior to sale, a significant por style="DISPLAY: inline; FONT-FAMILY: times new roman; FONT-SIZE: 10pt">Net loss (4,009) (2,531) (44,320)

Change in unrealized gains (losses) on available-for-sale securities 2 2 (11)

Comprehensive loss $(4,007) $(2,529) $(44,331)

Net loss per share:

Basic and diluted $(0.11) $(0.09)

Shares used in per share calculations:

Basic and diluted 36,756 28,572

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

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

(in thousands)	Three Months Ended March 31, 2013	2012	Cumulative Period from July 1, 2002 (inception) to March 31, 2013
Cash flows from operating activities:			
Net loss	$(4,009)	$(2,531)	$(44,320)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	81	91	2,351
Accretion of discount on short-term investments	—	—	(252)
Net realized loss on sales of short-term investments	9	12	125
Loss on disposal of property and equipment	—	30	313
Stock-based compensation expense for options and stock issued to employees and directors	215	342	6,256
Compensation expense for warrants issued for services	3	20	203
Stock-based compensation expense for options, warrants and stock issued to non-employees	47	127	1,289
Non-cash loss (gain) on increase (decrease) in fair value of warrants	520	35	(187)
Taxes paid by LLC	—	—	1
Changes in operating assets and liabilities:			
(Increase) decrease in accounts receivable	27	(1,006)	(916)
Purchase of inventory	(38)	—	(61)
(Increase) decrease in prepaid expenses and other assets	80	24	(616)
Increase (decrease) in accounts payable and accrued liabilities	(222)	167	1,996
Increase (decrease) in deferred revenue	(405)	(47)	1,836
Net cash used in operating activities	(3,692)	(2,736)	(31,982)
Cash flows from investing activities:			
Purchases of property and equipment	(9)	—	(3,370)
Proceeds from disposal of property and equipment	—	1	52
Purchases of short-term investments	(2,127)	(712)	(115,545)
Proceeds from maturities and sales of short-term investments	1,450	1,175	110,799
Cash acquired in purchase of LLC	—	—	516
Net cash provided by (used in) investing activities	(686)	464	(7,548)
Cash flows from financing activities:			
Proceeds from preferred stock issuances, net	—	—	11,160
Proceeds from common stock issuances	15	—	3,207
Proceeds from exercise of options and warrants	15	36	2,121
Proceeds from initial public offering, net of costs	—	—	17,077
Proceeds from shelf offering, net of costs	—	—	13,231

Proceeds from stock subscription receivable	—	—	873
Proceeds from issuance of notes	—	—	405
Principal payments on capital lease	—	—	(157)
Proceeds from short-term borrowing	—	—	88
Principal payment on short-term borrowing	—	(71)	(88)
Proceeds from borrowings under equipment loan	—	—	1,216
Principal payments on equipment loan	—	—	(1,216)
Net cash provided by (used in) financing activities	30	(35)	47,917
Net increase (decrease) in cash and cash equivalents	(4,348)	(2,307)	8,387
Cash and cash equivalents, beginning of period	12,735	8,428	—
Cash and cash equivalents, end of period	$8,387	$6,121	$8,387

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

NOVABAY PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

NOTE 1. ORGANIZATION

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

Aganocide® Compounds
NovaBay's first-in-class Aganocide® compounds, led by auriclosene (NVC-422), are patented, synthetic molecules with a broad spectrum of activity against bacteria, viruses and fungi. Mimicking the mechanism of action that human white blood cells use against infections, Aganocides possess a reduced likelihood that bacteria or viruses will be able to develop resistance, which is critical for advanced anti-infectives. Having demonstrated therapeutic proof-of-concept in three Phase 2 clinical studies, these compounds are well suited to treat and prevent a wide range of local, non-systemic infections. NovaBay is currently focused in three large therapeutic markets:

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

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

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

NeutroPhase®
NovaBay is also developing another class of molecule, NeutroPhase®, which is an FDA 510(k)-cleared product for advanced wound care. With a distinct mechanism of action from Aganocides, we believe that NeutroPhase is the only patented pure hypochlorous acid solution available and has the potential to be best suited to treat the six-million-patients in the U.S. who suffer from chronic non-healing wounds, such as pressure, venous stasis and diabetic ulcers.

NovaBay has begun securing commercial partnerships for NeutroPhase. In January 2012, NovaBay announced it had entered into a strategic marketing agreement with Pioneer Pharma Co., Ltd., a Shanghai-based company that markets high-end pharmaceutical products into China, to market NeutroPhase in China. In September 2012, the collaboration with Pioneer Pharma was expanded to include the Asian markets Hong Kong, Macau, Taiwan, Singapore, Malaysia, Indonesia, Myanmar, Philippines, Thailand, Vietnam, Brunei, Cambodia and Laos. NovaBay expects to announce additional marketing agreements in select geographic markets around the world during 2013.

The Company was incorporated under the laws of the State of California on January 19, 2000, as NovaCal Pharmaceuticals, Inc. The Company had no operations until July 1, 2002, on which date it acquired all of the operating assets of NovaCal Pharmaceuticals, LLC, a California limited liability company. In February 2007, the

Company changed its name from NovaCal Pharmaceuticals, Inc. to NovaBay Pharmaceuticals, Inc. In August 2007, it formed two subsidiaries—NovaBay Pharmaceuticals Canada, Inc., a wholly-owned subsidiary incorporated under the laws of British Columbia (Canada), which was formed to conduct research and development in Canada but was dissolved in July 2012, and DermaBay, Inc., a wholly-owned U.S. subsidiary, which may explore and pursue dermatological opportunities. In June 2010, the Company changed the state in which it is incorporated (the Reincorporation), and is now incorporated under the laws of the State of Delaware. All references to "we," "us," "our," or "the Company" herein refer to the California corporation prior to the date of the Reincorporation, and to the Delaware corporation on and after the date of the Reincorporation. The Company currently operate in four business segments; see Note 10 for further details.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited consolidated financial statements of NovaBay Pharmaceuticals, Inc. have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") for interim reporting including the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. These statements do not include all disclosures for annual audited financial statements required by accounting principles generally accepted in the United States of America ("U.S. GAAP") and should be read in conjunction with the Company's audited consolidated financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012. The consolidated balance sheet at December 31, 2012, has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements.

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

The Company believes these consolidated financial statements reflect all adjustments (consisting only of normal, recurring adjustments) that are necessary for a fair presentation of the financial position and results of operations for the periods presented. Results of operations for the interim periods presented are not necessarily indicative of results to be expected for the year.

The financial statements have been prepared under the guidelines for Development Stage Entities. 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 March 31, 2013, we continued to conduct clinical trials and had not commenced our planned principal operations.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, NovaBay Pharmaceuticals Canada, Inc. (prior to its dissolution in July 2012) and DermaBay, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization period for payments received from product development and license agreements as they relate to revenue recognition, assumptions for valuing options and warrants, and income taxes. Actual results could differ from those estimates.

Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid instruments with a stated maturity of three months or less at the date of purchase to be cash and cash equivalents. Cash and cash equivalents are stated at cost, which approximates their fair value. As of March 31, 2013, the Company’s 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.

The Company classifies all highly liquid investments with a stated maturity of greater than three months at the date of purchase as short-term investments. Short-term investments generally consist of municipal and corporate debt securities. The Company has classified its short-term investments as available-for-sale. The Company does 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, the Company occasionally sells 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. The interest income and realized gains and losses are included in other income (expense), net within the consolidated statements of operations and comprehensive loss. Interest income is recognized when earned.

Concentrations of Credit Risk and Major Partners

Financial instruments which potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains 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. The Company does not believe it is exposed to significant credit risk due to the financial position of the financial institutions in which these deposits are held. Additionally, the Company has established guidelines regarding diversification and investment maturities, which are designed to maintain safety and liquidity.

During the three months ended March 31, 2013, revenues were derived from two collaboration partners, two distribution partners and service revenues. During the three months ended March 31, 2012, the majority of the Company’s operating revenues were derived from one collaborative partner.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

As of March 31, 2013, 94% of accounts receivable was derived from one collaboration and one distribution partner. As of March 31, 2012, the majority of the Company's accounts receivable was from one collaborative partner.

Comprehensive Income (Loss)

ASC 220, Comprehensive Income requires that an entity's change in equity or net assets during a period from transactions and other events from non-owner sources be reported. The Company reports unrealized gains and losses on its available-for-sale securities as other comprehensive income (loss).

Fair Value of Financial Assets and Liabilities

Financial instruments, including cash and cash equivalents and short-term investments, 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 their carrying amounts because the obligations bear market rates of interest.

The Company measures the fair value of financial assets and liabilities based on U.S. GAAP guidance which defines fair value, establishes a framework for measuring fair value, and requires disclosures about fair value measurements.

Under U.S. GAAP, fair value is defined 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. A fair value hierarchy is also established, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. There are 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).

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 over the shorter of seven years or 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

The Company accounts for long-lived assets in accordance with U.S. GAAP, 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. Determination of recoverability is based on the estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values and the loss is recognized in the statements of operations.

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

Revenue Recognition

License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of the Company's 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 revenue recognition criteria under U.S. GAAP, the Company analyzes its multiple element arrangements to determine whether the elements can be separated. The Company performs its analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables are accounted for as a single unit of accounting and revenue is recognized over the performance obligation period. Revenue is recognized when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable; and collectability is reasonably assured.

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

Upfront Fees—The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology licensed has no utility to the licensee. If it has performance obligations through research and development services that are required because its know-how and expertise related to the technology is proprietary to it, or can only be performed by it, then such up-front fees are deferred and recognized over the period of the performance obligations. The Company bases the estimate of the period of performance on factors in the contract. Actual time frames could vary and could result in material changes to its results of operations.

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

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

Royalties—The Company recognizes royalty revenues from licensed products upon the sale of the related products.

Research and Development Costs

The Company charges 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. The Company uses 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 expenses under the collaborative agreements approximate the revenue recognized, excluding milestone and upfront payments received under such arrangements.

Patent Costs

Patent costs, including legal expenses, are expensed in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of ASC 718, Compensation-Stock Compensation. Under the fair value recognition provisions, 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. Non-employee stock-based compensation charges are amortized over the vesting period on a straight-line basis. For stock options granted, the fair value of the stock options is estimated using a Black-Scholes-Merton option pricing model. See Note 8 for further information regarding stock-based compensation expense and the assumptions used in estimating that expense.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Income Taxes

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

Common Stock Warrant Liabilities

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

Net Income (Loss) per Share

The Company computes net income (loss) per share by presenting both basic and diluted earnings (loss) per share (EPS).

Basic EPS is computed by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period including stock options and warrants, using the treasury stock method, 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 since their effect would be anti-dilutive. During the three months ended March 31, 2013, and 2012, there is no difference between basic and diluted net loss per share due to the Company’s net losses. The following table sets forth the calculation of basic EPS and diluted EPS:

	Three Months Ended March 31,	
(in thousands, except per share amounts)	2013	2012
Net loss	$(4,009)	$(2,531)
Basic shares	36,756	28,572
	—	—

Add: shares issued upon assumed exercise of stock options		
Diluted shares	36,756	28,572
Basic and diluted net loss per share	$(0.11)	$(0.09)

The following outstanding stock options and stock warrants were excluded from the diluted net loss per share computation as their effect would have been anti-dilutive:

	Three Months Ended March 31,	
(In thousands)	2013	2012
Stock options	6,683	5,958
Stock warrants	11,210	4,923
	17,893	10,881

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Recent Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 2013, as compared to the recent accounting pronouncements described in the Company's Form 10-K for the year ended December 31, 2012, that are of significance or potential significance to the Company.

NOTE 3. INVESTMENTS

Short-term investments at March 31, 2013, and December 31, 2012 consisted of the following:

	March 31, 2013			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Corporate bonds	$ 482	$ —	$ (3)	$ 479
Municipal bonds	305	—	(4)	301
Certificates of deposit	$ 4,029	$ —	$ (4)	$ 4,025
	$ 4,816	$ —	$ (11)	$ 4,805

	December 31, 2012			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Corporate bonds	$ 514	$ —	$ (9)	$ 505
Municipal bonds	$ 305	—	(2)	303
Certificates of deposit	3,329	—	(2)	3,327
	$ 4,148	$ —	$ (13)	$ 4,135

All short-term investments at March 31, 2013 and December 31, 2012 mature in less than one year. Unrealized holding gains and losses classified as available-for-sale are recorded in accumulated other comprehensive loss.

The Company recognized realized losses of $9,000 and $12,000, for the three months ended March 31, 2013 and 2012, respectively.

NOTE 4. FAIR VALUE MEASUREMENTS

The Company's cash equivalents and investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities. The types of investments that are generally classified within Level 2 of the fair value hierarchy include corporate securities and certificates of deposits.

The Company’s warrant liabilities are classified within level 3 of the fair value hierarchy because the value is calculated using significant judgment based on our own assumptions in the valuation of these liabilities.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2013:

(in thousands)	Balance at March 31, 2013	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash equivalents	$ 8,387	$ 8,387	$ —	$ —
Short-term investments:				
Corporate bonds	479	—	479	—
Municipal bonds	301	—	301	
Certificates of deposit	4,025	—	4,025	—
Total short-term investments	4,805	—	4,805	—
Total assets	$ 13,192	$ 8,387	$ 4,805	$ —
Liabilities				
Warrant liability	$ 1,802	$ —	$ —	$ 1,802
Total liabilities	$ 1,802	$ —	$ —	$ 1,802

For the three month period ended March 31, 2013, as a result of the fair value adjustment of the warrant liability, the Company recorded a non-cash loss on an increase in the fair value of $520,000 in its consolidated statement of operations and comprehensive loss. See Note 6 for further discussion on the calculation of the fair value of the warrant liability.

(in thousands)	Warrant liability
Fair value of warrants at December 31, 2012	$1,282
Adjustment to fair value at March 31, 2013	520
Total warrant liability at March 31, 2013	$1,802

NOTE 5. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases laboratory facilities and office space under an operating lease which will expire on October 31, 2020. Rent expense was approximately $219,000 and $259,000 for the three months ended March 31, 2013 and 2012, respectively.

The Company's monthly rent payments fluctuate under the master lease agreement. In accordance with U.S. GAAP, the Company recognizes rent expense on a straight-line basis. The Company records deferred rent for the difference between the amounts paid and recorded as expense.

Directors and Officers Indemnity

As permitted under Delaware law and in accordance with its bylaws, the Company shall indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving at its request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director or officer insurance policy that limits its exposure and may enable them to recover a portion of any future payments. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, no liability has been recorded for these agreements as of March 31, 2013.

In the normal course of business, the Company provides indemnifications of varying scope under agreements with other companies, typically its clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, the Company generally indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties in connection with use or testing of its products or product candidates or with any U.S. patent or any copyright or other intellectual property infringement claims by any third party with respect to their products. The term of these indemnification agreements is generally perpetual. The potential future payments the Company could be required to make under these indemnification agreements is unlimited. Historically, costs related to these indemnification provisions have been immaterial. The Company also maintains various liability insurance policies that limit its exposure. As a result, the Company believes the fair value of these indemnification agreements is minimal. Accordingly, no liabilities have been recorded for these agreements as of March 31, 2013.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Legal Matters

From time to time, the Company may be involved in various legal proceedings arising in the ordinary course of business. There are no matters at March 31, 2013, that, in the opinion of management, would have a material adverse effect on the Company's financial position, results of operations or cash flows.

NOTE 6. WARRANT LIABILITY

In July 2011, the Company sold common stock and warrants in a registered direct financing. As part of this transaction, 3,488,005 warrants were issued with an exercise price of $1.33 and were exercisable on January 1, 2012, and expire on July 5, 2016. The terms of the warrants require registered shares to be delivered upon each warrant's exercise and also require possible cash payments to the warrant holders (in lieu of the warrant's exercise) upon specified fundamental transactions involving the Company's common stock, such as in an acquisition of the Company. Under ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480"), the Company's ability to deliver registered shares upon an exercise of the warrants and the Company's potential obligation to cash-settle the warrants if specified fundamental transactions occur are deemed to be beyond the Company's control. The warrants contain a provision where the warrant holder would have the option to receive cash, equal to the Black Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480 requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Binomial Lattice ("Lattice") valuation model, and the changes in the fair value are recorded in the consolidated statement of operations and comprehensive loss. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. In addition, after January 5, 2012, and if the closing bid price per share of the common stock on the principal market equals or exceeds $2.66 for any ten trading days (which do not need to be consecutive) in a period of fifteen consecutive trading days, the Company has the right to require the exercise of one-third of the warrants then held by the warrant holders, which would result in gross proceeds to the Company of approximately $1.5 million.

The key assumptions used to value the warrants were as follows:

	March 31,	
Assumption	2013	2012
Expected price volatility	55 %	80 %
Expected term (in years)	3.26	4.26
Risk-free interest rate	0.41 %	0.84 %
Dividend yield	0.00 %	0.00 %
Weighted-average fair value of warrants	$0.52	$0.79

NOTE 7. STOCKHOLDERS' EQUITY

On July 5, 2011, the Company closed a registered direct offering for the sale of 4,650,675 units (The "July 2011 Registered Direct Financing"), each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.75 of a share of common stock (or a total of 3,488,005 shares), at a purchase price of $1.11 per unit. The warrants will be exercisable 180 days after issuance for $1.33 per share and will expire five years from the date of issuance. All of the shares of common stock and warrants issued in the offering (and the shares of common stock

issuable upon exercise of the warrants) were offered pursuant to a shelf registration statement filed with, and declared effective by, the Securities and Exchange Commission. The shares of common stock and the warrants were immediately separable and were issued separately, but were purchased together in the July 2011 Registered Direct Offering. The Company raised a total of $5.2 million from the July 2011 Registered Direct Financing, or approximately $4.6 million in net proceeds after deducting underwriting commissions of $288,000 and other offering costs of $244,000.

On December 6, 2012, the Company closed a public offering for the sale of 5,900,000 units, each unit consisting of (i) one share of common stock and (ii) one warrant to purchase 0.75 of a share of common stock (or a total of 4,425,000 shares), at a purchase price of $1.25 per unit. The warrants were immediately exercisable for $1.50 per share and will expire one year from the date of issuance. All of the shares of common stock and warrants issued in the offering (and the shares of common stock issuable upon exercise of the warrants) were offered pursuant to a shelf registration statement filed with, and declared effective by, the Securities and Exchange Commission. The shares of common stock and the warrants were immediately separable and were issued separately, but were purchased together. The Company raised a total of $7.4 million from this offering, or approximately $6.6 million in net proceeds after deducting underwriting commissions of $479,000 and other offering costs of $240,000.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock Warrants

At March 31, 2013, there were outstanding warrants to purchase 1,225,000 shares of common stock with an exercise price of $2.75 per share expiring on August 21, 2014. These outstanding warrants were exercisable at March 31, 2012.

In July 2011, 3,488,005 warrants were issued in connection with our July 2011 Registered Direct Financing. These warrants were issued with an exercise price of $1.33 and expire on July 5, 2016. These outstanding warrants were exercisable at March 31, 2012. During 2012, 22,500 of these warrants were exercised and the Company received $30,000 in cash for the warrants.

In January 2012, warrants to purchase 60,000 shares were issued to a vendor. These warrants were issued with an exercise price of $2.50 per share for 30,000 of the shares and $3.75 per share for the remaining 30,000 shares and became exercisable monthly through June 30, 2012, and expire on January 2, 2016. The warrants were valued at approximately $34,000 using the Black-Scholes-Merton option-pricing model based upon the following assumptions: (1) expected price volatility of 75% and 89%, respectively, (2) a risk-free interest rate of 0.30% and 0.36% respectively and (3) an expected life of 2.36 and 2.98 years, respectively. The Company accounts for the fair value of these warrants as an expense amortized over the vesting period of the warrants. The Company recognized $0 and $20,000 in expense during the three months ended March 31, 2013, and 2012, respectively, related to these warrants.

In September 2012 and October 2012, warrants to purchase 800,000 and 1,200,000 shares, respectively, were issued to Pioneer Pharma Co., Ltd as part of a unit purchase agreement that was accounted for along with an expanded distribution agreement. These warrants were issued with an exercise price of $1.50 per share, are immediately exercisable, and expire on August 31, 2013. The warrants were valued at approximately $360,000 and $330,000, respectively, using the Black-Scholes-Merton option-pricing model based upon the following assumptions: (1) expected price volatility of 79% and 71%, respectively, (2) a risk-free interest rate of 0.17% and 0.17%, respectively and (3) an expected life of 0.96 and 0.83 years, respectively. Due to the combined accounting of this agreement along with the expanded distribution agreement, the Company accounted for the fair value of the common stock and warrants as equity.

In October 2012, warrants to purchase 15,000 shares were issued to a vendor. These warrants were issued with an exercise price of $2.50 per share and 5,000 shares became exercisable on each of October 30, 2012, November 30, 2012, and December 30, 2012, and they all expire on September 30, 2014. The warrants were valued at approximately $4,000 using the Black-Scholes-Merton option-pricing model based upon the following assumptions: (1) expected price volatility of 72%, (2) a risk-free interest rate of 0.27% and (3) an expected life of 2.00 years. The Company accounts for the fair value of these warrants as an expense amortized over the vesting period of the warrants. The Company recognized $0 in expense during the three months ended March 31, 2013, and 2012, related to these warrants.

On December 6, 2012, 4,425,000 warrants were issued in connection with our July public offering. These warrants were issued with an exercise price of $1.50 and expire on December 6, 2013. These outstanding warrants were exercisable at March 31, 2013.

In January 2013, warrants to purchase 20,000 shares were issued to a vendor. These warrants were issued with an exercise price of $1.50 per share for 10,000 of the shares and $1.75 per share for the remaining 10,000 shares, became

exercisable immediately, and expire on August 31, 2013, and December 31, 2013, respectively. The warrants were valued at approximately $3,000 using the Black-Scholes-Merton option-pricing model based upon the following assumptions: (1) expected price volatility of 69.82% and 69.40%, respectively, (2) a risk-free interest rate of 0.11% and 0.14%, respectively and (3) an expected life of 0.64 and 0.97 years, respectively. The Company accounts for the fair value of these warrants as an expense amortized over the vesting period of the warrants. The Company recognized $3,000 and $0 in expense during the three months ended March 31, 2013, and 2012, respectively, related to these warrants.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The details of all outstanding warrants as of March 31, 2013, is as follows:

(in thousands, except per share data)	Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2012	11,190	$ 1.59
Warrants issued	20	$ 1.63
Outstanding at March 31, 2013	11,210	$ 1.59

NOTE 8. EQUITY-BASED COMPENSATION

Equity Compensation Plans

Prior to our Initial Public Offering (IPO), the Company 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, the Company 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. As of March 31, 2013, there were 836,821 shares available for future grant 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 the Company's 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. The Company issues new shares to satisfy option exercises under the plans.

Stock Option Summary

The following table summarizes information about the Company's stock options outstanding at March 31, 2013, and activity during the three-month period then ended:

(in thousands, except years and per share data)	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2012	6,222	$ 1.62		
Options granted	772	$ 1.16		
Options exercised	(14)	$ 1.09		
Restricted stock unit vested	(173)	$ —		
Options forfeited/cancelled	(124)	$ 1.51		

Outstanding at March 31, 2013	6,683	$	1.61	6.85	$	1,104
Vested and expected to vest at March 31, 2013	6,499	$	1.63	6.80	$	1,044
Vested at March 31, 2013	4,727	$	1.78	6.00	$	573
Exercisable at March 31, 2013	4,727	$	1.78	6.00	$	573

Stock Options and Awards to Employees and Directors

The Company grants options to purchase common stock to its employees and directors at prices equal to or greater than the market value of the stock on the dates the options are granted. The Company has estimated the value of stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing model using the single-option valuation approach. The 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 the Company applied to value its stock-based awards.

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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:

	Three Months Ended March 31,			
Assumption	2013		2012	
Expected price volatility	87	%	94	%
Expected term (in years)	4.95		4.32	
Risk-free interest rate	0.80	%	0.72	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of options granted during the period	$0.78		$0.93	

For the three months ended March 31, 2013 and 2012, the Company recognized stock-based compensation expense of $215,000 and $342,000, respectively, for option awards to employees and directors. As of March 31, 2013, total unrecognized compensation cost related to unvested stock options was $1.3 million. This amount is expected to be recognized as stock-based compensation expense in the Company's consolidated statements of operations and comprehensive loss over the remaining weighted average vesting period of 2.58 years.

Stock-Based Awards to Non-Employees

During the three months ended March 31, 2013 and 2012, the Company granted options to purchase an aggregate of 62,000 and 55,000 shares of common stock, respectively, to non-employees in exchange for advisory and consulting services. Additionally, during the three months ended March 31, 2013 and 2012, the Company issued 11,856 and 60,527 shares of common stock, respectively, to non-employees. 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:

	Three Months Ended March 31,			
Assumption	2013		2012	
Expected price volatility	77	%	88	%
Expected term (in years)	8.88		8.79	
Risk-free interest rate	1.65	%	1.82	%
Dividend yield	0.00	%	0.00	%
Weighted-average fair value of options granted during the period	$0.98		$1.17	

For the three months ended March 31, 2013 and 2012, the Company recognized stock-based compensation expense of $47,000 and $127,000, respectively, related to non-employee stock and option grants.

Summary of Stock-Based Compensation Expense

Stock-based compensation expense is classified in the consolidated statements of operations and comprehensive loss in the same expense line items as cash compensation. Since the Company continues to operate at a net loss, it does not expect to realize any current tax benefits related to stock options.

A summary of the stock-based compensation expense included in the consolidated statement of operations and comprehensive loss for the options and stock discussed above is as follows:

	Three Months Ended March 31,	
(in thousands)	2013	2012
Research and development	$179	$125
General and administrative	86	364
Total stock-based compensation expense	$265	$489

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

NOTE 9. LICENSE, COLLABORATION AND DISTRIBUTION AGREEMENTS

Galderma

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

This agreement is exclusive and worldwide in scope, with the exception of Asian markets and North America, as described in the next paragraph.

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

Galderma will pay to NovaBay certain upfront fees, ongoing fees, reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide compounds. If products are commercialized under the agreement, NovaBay's royalties will escalate as sales increase. The Company received a $1.0 million upfront technology access fee payment in the first quarter of 2009 and a $3.25 million continuation fee and a $500,000 fee to expand the license to include the Asia-Pacific Territory in December 2010. These fees were recorded as deferred revenues and recognized as earned on a straight-line basis over the Company's expected performance period. The initial upfront technology access fee was recognized over the initial 20 month funding term of the agreement through October 2010, and the continuation and license fees are being recognized over the additional three year funding term of the agreement through November 2013.

Revenue has been recognized under the Galderma agreement as follows:

	Three Months Ended March 31,	
(in thousands)	2013	2012
Amortization of Upfront Technology Access Fee	$315	$315
On-going Research and Development (FTE)	409	401
Materials, Equipment, and Contract Study Costs	11	589

Total	$735	$1,305

The Company had deferred revenue balances of $631,000 and $957,000 at March 31, 2013 and December 31, 2012, respectively, related to the Galderma agreement, which consisted of the unamortized balances on the upfront technology and access fee and the continuation and license fee and support for ongoing research and development. As of March 31, 2013, the Company has earned $4.25 million in milestone payments. As of March 31, 2013, the Company has not earned or received any royalty payments under the Galderma agreement.

Pioneer Pharma Co., Ltd.

In January 2012, the Company entered into a distribution agreement with Pioneer Pharma Co., Ltd., a Shanghai-based company that markets high-end pharmaceutical products into China, for the commercialization of NeutroPhase in this territory. Under the terms of the agreement, NovaBay received an upfront payment of $312,500. NovaBay also received $312,500 in January 2013, related to the submission of the first marketing approval for the product to the CFDA (formerly the SFDA, State Food and Drug Administration), which was submitted in December 2012. The distribution agreement provides that Pioneer Pharma Co., Ltd is entitled to receive cumulative purchase discounts of up to $500,000 upon the purchase of NeutroPhase product. The deferred revenue will be recognized as the purchase discounts are earned, with the remaining deferred revenue recognized ratable over the product distribution period. In addition, NovaBay is entitled to receive $625,000 upon receipt of an MAA approval of the product from the CFDA.

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In September 2012, we entered into two agreements with Pioneer Pharma Co., Ltd. (“Pioneer”): (1) an international distribution agreement (“Distribution Agreement”) and (2) a unit purchase agreement (“Purchase Agreement”). These agreements were combined and accounted for as one arrangement with one unit of accounting for revenue recognition purposes.
Pursuant to the terms of the Distribution Agreement. Pioneer has the right to distribute Neutrophase, upon MAA Approval from a Regulatory Authority, in certain territories in Asia (other than China). Upon execution of the Distribution Agreement, we received an upfront payment of $250,000 from Pioneer, which was initially recorded as deferred revenue; an additional $350,000 was due to us as of December 2012. This amount was recorded as deferred revenue at December 31, 2012 and was received in early January 2013. Pioneer is also obligated to make certain additional payments to us upon receipt of the MAA Approval. The Distribution Agreement further provides that Pioneer is entitled to a cumulative purchase discount not to exceed $500,000 upon the purchase of NeutroPhase product, payable in NovaBay unregistered restricted common stock.

Pursuant to the Purchase Agreement, we also received $2.5 million from Pioneer for the purchase of restricted units (comprising 1 share of common stock and a warrant for the purchase of 1 share of common stock). The unit purchase was completed in two tranches: (1) 800,000 units in September 2012 and (2) 1,200,000 units in October 2012, with both tranches at a purchase price of $1.25 per share. The fair value of the total units sold was $3.5 million, based upon the trading price of our common stock on the dates the units were purchased and fair value of the warrants based on the Black-Scholes Merton option pricing model. Because the aggregate fair value of the units on the dates of purchase exceeded the $2.5 million in proceeds received from the unit purchase by approximately $1 million, we reallocated $600,000 from deferred revenue to stockholders’ equity as consideration for the purchase of the units.

During the three months ended March 31, 2013 and 2012, we recognized $0 and $10,000, respectively, related to the these agreements.

At March 31, 2013 and December 31, 2012, the Company had a deferred revenue balance of $583,000 related to the Pioneer partnership agreements.

Animal Health Agreement

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

Revenue has been recognized under the agreement as follows:

	Three Months Ended March 31,	
(in thousands)	2013	2012
Amortization of Upfront Technology Access Fee	$38	$—
On-going Research and Development (FTE)	87	—
Total	$125	$—

The Company had deferred revenue balances of $0 and $125,000, respectively, at March 31, 2013 and December 31, 2012, related to this agreement, which consisted of the unamortized balances on the upfront technology and access fee and the support for ongoing research and development.

Private Label Agreement

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Revenue has been recognized under the agreement as follows:

	Three Months Ended March 31,	
(in thousands)	2013	2012
Amortization of Upfront Technology Access Fee	$10	$—
On-going Research and Development (FTE)	44	—
Total	$54	$—

The Company had deferred revenue balances of $273,000 and $226,000, respectively, at March 31, 2013 and December 31, 2012, related to this agreement, which consisted of the unamortized balances on the upfront technology and access fee and the support for ongoing research and development.

NOTE 10. SEGMENT INFORMATION

Beginning in 2012, the Company is reporting financial data for four reportable segments, coinciding with its four business units: dermatology, ophthalmology, urology and wound care. The dermatology segment includes all aspects of its business around the dermatology arena including the collaboration with Galderma and their impetigo clinical trial. The ophthalmology segment includes its clinical trial on ophthalmology which it is conducting on its own at this time. This segment also includes its i-case product which is currently in development phases. The urology segment covers its UCBE trials. The wound care segment encompasses the business around its NeutroPhase product, which went on the market in December 2012. Its remaining activities are immaterial and are shown as an aggregate.

The Company discloses information about its reportable segments based on the measures it uses in assessing the performance of each segment. The Company uses “segment net income (loss)” to measure the performance of its business units. Segment net income (loss) includes the allocation of certain corporate expense. These expenses have been allocated based on the FTE allocations to each individual segment or business unit.

The Company does not segregate specific assets to each business unit as we do not have a reasonable way to allocate the corporate assets to each unit and the Company does not use this as a measure of segment performance.

	Three Months Ended March 31,	
(in thousands)	2013	2012
Revenues:		
DermaBay (dermatology)	$735	$1,305
EyeBay (ophthalmology)	—	—
UroBay (urology)	—	—
MediBay (wound care)	117	11
Other	168	5
	$1,020	$1,321
Segment net income (loss):		
DermaBay (dermatology)	$4	$595
EyeBay (ophthalmology)	(1,348)	(733)

UroBay (urology)	(892)	(889)
MediBay (wound care)	(883)	(808)
Other	(368)	(650)
	$(3,487)	$(2,485)

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

A reconciliation of total segment net loss to consolidated net loss is as follows:

(in thousands)	Three Months ended March 31, 2013	2012
Segment net income (loss)	$(3,487)	(2,485)
Non-cash gain on change in fair value of warrants of warrants	(520)	(35)
Other income (expense), net	—	(5)
Provision for income taxes	(2)	(6)
Net loss	$(4,009)	$(2,531)

NOTE 11. SUBSEQUENT EVENTS

On March 29, 2013, the Company agreed to sell an aggregate of 300,000 shares of the Company's common stock to an accredited investor at a purchase price of $375,000, the shares were transferred and the cash was collected in April 2013.

We evaluated subsequent events through the issuance date of the consolidated financial statements. We are not aware of any significant events, other than those disclosed above, that occurred subsequent to the balance sheet date but prior to the filing of this Quarterly Report on Form 10-Q that would have a material impact on our consolidated financial statements.

ITEM 2. 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 I, Item 1 of this report, and with our consolidated financial statements and related notes, and Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2012, which was filed with the Securities and Exchange Commission on March 14, 2013. This discussion contains forward-looking statements that involve risks and uncertainties. Words such as "expects," "anticipated," "will," "may," "goals," "plans," "belie "estimates," variations of these words, and similar expressions are intended to identify these forward-looking statements. As a result of many factors, such as those set forth under the section entitled "Risk Factors" in Part II, Item 1A and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements Readers are cautioned that these forward-looking statements are only predictions based upon assumptions made that we believed to be reasonable at the time, and are subject to risks and uncertainties. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements.

Overview

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

Aganocide® Compounds
NovaBay's first-in-class Aganocide® compounds, led by auriclosene (NVC-422), are patented, synthetic molecules with a broad spectrum of activity against bacteria, viruses and fungi. Mimicking the mechanism of action that human white blood cells use against infections, Aganocides possess a reduced likelihood that bacteria or viruses will be able to develop resistance, which is critical for advanced anti-infectives. Having demonstrated therapeutic proof-of-concept in three Phase 2 clinical studies, these compounds are well suited to treat and prevent a wide range of local, non-systemic infections. NovaBay is currently focused in three large therapeutic markets:

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

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

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

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

wound care and is suited to treat the six-million-patients in the U.S. who suffer from chronic non-healing wounds, such as pressure, venous stasis and diabetic ulcers, surgical wound and burn.

NovaBay has begun securing commercial partnerships for NeutroPhase. In January 2012, NovaBay announced it had entered into a strategic marketing agreement with Pioneer Pharma Co., Ltd., a Shanghai-based company that markets high-end pharmaceutical products into China. In September 2012, the collaboration with Pioneer Pharma was expanded to include the Asian markets, Hong Kong, Macau, Taiwan, Singapore, Malaysia, Indonesia, Myanmar, Philippines, Thailand, Vietnam, Brunei, Cambodia and Laos. NovaBay expects to announce additional marketing agreements in select geographic markets around the world during 2013.

To date, we have generated very little revenue from product sales, and we have financed our operations and internal growth primarily through the sale of our capital stock, and the fees received from Galderma and Alcon, prior to the termination of our collaboration with Alcon Manufacturing Ltd. (Alcon), an affiliate of Alcon, Inc., in June 2011. As we are a development stage company, we have incurred significant losses since commencement of our operations in July 2002, since we have devoted substantially all of our resources to research and development. As of March 31, 2013, we had an accumulated deficit of $44.3 million. This deficit resulted from research and development expenses as well as general and administrative expenses. We expect to incur net losses over the next several years as we continue our clinical and research and development activities and as we apply for patents and regulatory approvals.

Recent Events

In April 2013, Shin Poong Pharmaceutical Co., Ltd. announced that it signed an exclusive distribution agreement for Shin Poong Pharma to commercialize NeutroPhase®, Skin and Wound Cleanser in South Korea for acute and chronic wounds.

In April 2013, we announced the enrollment of the first patients in Brazil into our global Phase 2b clinical trial, BAYnovation. The trial is investigating Auriclosene (NVC-422) Ophthalmic Solution as a treatment for adenoviral conjunctivitis, a highly contagious form of “pink eye” for which there is no approved treatment anywhere in the world.

In March 2013, we announced that Keith R. Bley, Ph.D., has joined NovaBay as Senior Vice President of Product Development, effective March 4, 2013. Dr. Bley has more than 20 years of experience in the pharmaceutical industry, management positions with increasing responsibility in research and product development.

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

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

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

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States for interim reporting. The preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. In preparing these consolidated financial statements, management has made its best

estimates and judgments of certain amounts included in the financial statements giving due consideration to materiality. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, research and development costs, patent costs, stock-based compensation, income taxes 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.

Our significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements (unaudited), included in Part I, Item 1 of this report, and are also described in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2012. We have not materially changed these policies from those reported in our Annual Report on Form 10-K for the year ended December 31, 2012.

Recent Accounting Pronouncements

See Note 2 to the accompanying unaudited consolidated financial statements included in Part I, Item 1 of this quarterly report on Form 10-Q for information on recent accounting pronouncements.

Results of Operations

Comparison of the Three Months Ended March 31, 2013, and March 31, 2012

License, Collaboration and Distribution Revenue

Total license, collaboration and distribution revenue was $914,000 for the three months ended March 31, 2013, compared to $1.3 million for the three months ended March 31, 2012.

License, collaboration and distribution revenue over the three months ended March 31, 2013, and 2012, is due to five different agreements entered into by NovaBay. Those agreements are:

- a license and collaboration agreement entered into with Galderma in 2009,
- a distribution agreement covering China entered into with Pioneer Pharma in Jan 2012,
- a private label distribution agreement entered into with a U.S.-based marketer of healthcare products and;
- a feasibility and option agreement with an animal health company.

The decrease in license, collaboration and distribution revenue was related to a decrease in reimbursable support costs from Galderma for support of the Impetigo trial as the trial progresses. We did not recognize any other significant revenues in for the three months ended March 31, 2013 and 2012.

Research and Development

Total research and development expenses increased by 29% to $2.9 million for the three months ended March 31, 2013, from $2.3 million for the three months ended March 31, 2012. The increase relates to the increase in clinical activities as we continue to conduct our BAYNovation for viral conjunctivitis and UCBE trials and scale up our production in anticipation of the Phase 3 impetigo trial to be conducted by Galderma. This increase in production will be partially reimbursed by Galderma in the future.

We expect to incur increasing research and development expenses throughout 2013 and in subsequent years as we continue to increase our focus on clinical trials and developing product candidates, both independently and in collaboration with Galderma. In particular, we expect to incur ongoing clinical and manufacturing expenses during 2013 in connection with our dermatology, ophthalmology and urology programs.

General and Administrative

General and administrative expenses remained relatively flat at $1.5 million for the three months ended March 31, 2013 and 2012. We expect general and administrative expenses to continue to remain relatively flat for the remainder of 2013 in comparison to 2012.

Non-Cash Loss on Increase in Fair Value of Warrants

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

Other Income (Expense), Net

Other income (expense), net was an expense of $0 for the three months ended March 31, 2013, compared to $5,000 for the three months ended March 31, 2012. This change was primarily attributable to fluctuation in the returns on our investments.

We expect that other income (expense), net will fluctuate based on our cash balances and the fluctuation in interest rates.

Liquidity and Capital Resources

As of March 31, 2013, we had cash, cash equivalents, and short-term investments of $13.2 million, compared to $16.9 million at December 31, 2012. We have incurred cumulative net losses of $44.3 million since inception through March 31, 2013. We do not expect to generate significant revenue from product candidates for several years. Since inception, we have funded our operations primarily through the sales of our stock and warrants and funds received under our collaboration agreements. We raised $47.9 million through sales of our equity through March 31, 2013. Our last public offering was in December 2012, in which we sold our common stock and warrants with gross proceeds of $7.4 million, or approximately $6.6 million in net proceeds after deducting underwriting commissions of $479,000 and other offering costs of $240,000. Additionally, cash received from our collaboration partners have totaled $62.0 million through March 31, 2013. Under the terms of our collaboration and license agreement with Galderma, Galderma will pay to NovaBay reimbursements, and milestone payments related to achieving development and commercialization of its Aganocide compounds. We believe the capital generated through these sources is sufficient to fund our planned operations into 2014. Our capital requirements going forward will depend on numerous factors including:

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

Cash Used in Operating Activities

For the three months ended March 31, 2013 cash used in operating activities of $3.7 million was primarily attributable to our research and development and general administrative expenses of operating the company.

Cash Used in Investing Activities

For the three months ended March 31, 2013, cash used by investing activities of $686,000 was attributable to net effect of purchases of short-term investments and sales and maturities.

Cash Provided by Financing Activities

Net cash provided by financing activities of $30,000 for the three months ended March 31, 2013, was primarily attributable proceeds from stock option exercises.

Net Operating Losses and Tax Credit Carryforwards

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

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

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented, and we do not expect it to have a material impact in the near future. 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 commitments at March 31, 2013, consist of an operating lease. The operating lease consists of payments relating to the lease for various laboratory and office space in one office building in Emeryville, California. This lease expires on October 31, 2020, and the total commitment as of March 31, 2013 is $4.3 million due over the lease term, compared to $4.5 million as of December 31, 2012.

ITEM 3. 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. As of March 31, 2013, and December 31, 2012, a 10% change in interest rates would have had an immaterial effect on the value of our short-term marketable securities. We do not use derivative financial instruments in our investment portfolio. We do not hold any instruments for trading purposes.

To date, we have operated exclusively in the United States and have not had any material exposure to foreign currency rate fluctuations.

ITEM 4. 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 at the reasonable assurance level 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.

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.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended March 31, 2013, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

The risk factors facing our company have not changed materially from those set forth in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2012, as filed with the SEC on March 14, 2013, which risk factors are set forth below.

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

Risks Relating to Our Business

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

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

We may be unable to raise additional capital on acceptable terms in the future which may in turn limit our ability to develop and commercialize products and technologies.

While we have reduced our staff levels and reduced both our research and general expenditures, we expect our capital outlays and operating expenditures to increase over at least the next several years as we expand our clinical and regulatory activities. Conducting clinical trials is very expensive, and we expect that we will need to raise additional

capital, through future private or public equity offerings, strategic alliances or debt financing, before we achieve commercialization of any of our Aganocide compounds. In addition, we may require even more significant capital outlays and operating expenditures if we do not continue to partner with third parties to develop and commercialize our products.

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

- the extent to which we receive milestone payments or other funding from Galderma, if any;
- the scope, rate of progress and cost of our pre-clinical studies and clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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

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

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

We have incurred net losses each year since our inception through December 31, 2012, with the exception of 2009. For the years ended December 31, 2012, 2011 and 2010, we had net losses of approximately $7.0 million, $5.1 million and 4.3 million, respectively, and for the year ended December 31, 2009, we had net income of $2.7 million. We were able to record a profit in 2009 due to our receipt of a $3.75 million milestone payment under our agreement with Galderma; however, there is no assurance that we will receive any additional large milestone payments under this agreement and, as a result, may not be able to achieve or maintain profitability in the future. We had a net loss of $4.0 million in the quarter ended March 31, 2013. Through March 31, 2013, we had an accumulated deficit of approximately $44.3 million. We have been, and expect to remain for the foreseeable future, mostly in a research and development stage as we proceed through clinical trials. We have incurred substantial research and development expenses, which were approximately $2.9 million, $9.3 million, $9.9 million and $8.6 million for the three months ended March 31, 2013, and the years ended December 31, 2012, 2011 and 2010, respectively. We

expect to continue to make, for at least the next several years, significant expenditures for the development of products that incorporate our Aganocide compounds, as well as continued research into the biological activities of our Aganocide compounds, which expenditures are accounted for as research and development expenses. We expect to incur substantial losses for the foreseeable future, and we may never achieve or maintain sustained profitability. We anticipate that our expenses related to our clinical trials and regulatory activities will increase substantially in the foreseeable future as we:

- conduct pre-clinical studies and clinical trials for our product candidates in different indications;
- develop, formulate, manufacture and commercialize our product candidates either independently or with partners;
- pursue, acquire or in-license additional compounds, products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional qualified personnel.

We will need to generate significant revenues to achieve and maintain profitability. If we cannot successfully develop, obtain regulatory approval for and commercialize our drug product candidates, either independently or with partners, we will not be able to generate such revenues or achieve or maintain profitability in the future. Our failure to achieve and subsequently maintain profitability could have a material adverse impact on the market price of our common stock.

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

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

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

To date, our revenues have been derived mainly from research and development collaboration and license agreements. We have generated limited revenues from sales of NeutroPhase and we cannot guarantee that we will have substantial marketable drugs or other products. Satisfaction of all regulatory requirements applicable to our product candidates typically takes many years, is dependent upon the type, complexity, novelty and classification of the product candidates, and requires the expenditure of substantial resources for research and development and testing. We must demonstrate that our product candidates satisfy rigorous standards of safety and efficacy before we can submit for and gain approval from the FDA and regulatory authorities in other countries. In addition, to compete effectively, our products will need to be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. We cannot be certain that the clinical development of any of our current product candidates or any other product that we may develop in the future will be successful, that they will receive the regulatory approvals required to commercialize them, or that any of our other in-licensing efforts or pre-clinical testing will yield a product suitable for entry into clinical trials. Our commercial revenues from sales of Aganocide products will be derived from sales of products that may not be commercially available for at least the next several years.

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

A number of factors may affect the market acceptance of NeutroPhase or any other products we develop or acquire, including, among others:

- the price of our products relative to other products for the same or similar treatments;
- the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our products for their indicated applications and treatments;
- our ability to find the right distributor; and
- the effectiveness of the sales and marketing efforts of our dof our Dright De that we will emaceuticals, Inc. to manufacture NeutroPhase. istributor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We do not have redundant laboratory facilities. We perform substantially all of our research, development and testing in our laboratory located in Emeryville, California. Emeryville is situated on or near active earthquake fault lines. Our facility and the equipment we use to perform our research, development and testing would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and testing for some period of time. The inability to perform our research and development activities may result in the loss of partners or harm our reputation, and we may be unable to regain those partnerships in the future. Our insurance coverage for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses, including the loss of time as well as the costs of lost opportunities, and may not continue to be available to us on acceptable terms, or at all.

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

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

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

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

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

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

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

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

- unexpected need for additional patient-related data.

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

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

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

Government usage guidelines typically address matters such as usage and dose, among other factors. Application of these guidelines could limit the use of products that we may develop. In addition there can be no assurance that government regulations applicable to our proposed products or the interpretation thereof will not change and thereby prevent the marketing of some or all of our products for a period of time or permanently. The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U.S. or in other countries.

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

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

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

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

Any regulatory approvals that we receive may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The FDA may require us to commit to perform lengthy Phase IV post-approval studies, for which we would have to expend additional resources, which could have an adverse effect on our operating results and financial condition. In addition,

if the FDA approves any of our drug product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drugs, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drugs or the withdrawal of the drugs from the market. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing any products we may develop and our business could suffer.

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

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

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

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

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

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

Intellectual property litigation, regardless of outcome, is expensive and time-consuming, could divert management’s attention from our business and have a material negative effect on our business, operating results or financial condition. If such a dispute were to be resolved against us, we may be required to pay substantial damages, including treble damages and attorney’s fees if we were to be found to have willfully infringed a third party’s patent, to the party

claiming infringement, develop non-infringing technology, stop selling any products we develop, cease using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. Modification of any products we develop or development of new products thereafter could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. In addition, parties making infringement claims may be able to obtain an injunction that would prevent us from selling any products we develop, which could harm our business.

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

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

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

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

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

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

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

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

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

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

Our business and future growth depend on the development, use and ultimate sale of products that are subject to FDA regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA.

There is a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales and marketing activities may constitute the promotion of our products for a non-FDA-approved use in violation of applicable law. We also face the risk that the FDA or other regulatory authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to substantially change our sales, promotion, grant and educational activities. In addition, were any enforcement actions against us or our senior officers to arise, we could be excluded from participation in U.S. government healthcare programs such as Medicare and Medicaid.

If we are unable to protect our intellectual property, our competitors could develop and market products similar to ours that may reduce demand for our products.

Our success, competitive position and potential future revenues will depend in significant part on our ability to protect our intellectual property. We rely on the patent, trademark, copyright and trade secret laws of the U.S. and other countries, as well as confidentiality and nondisclosure agreements, to protect our intellectual property rights. We apply for patents covering our technologies as we deem appropriate.

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

In addition, there is no assurance that any patents issued to us or licensed or assigned to us by third parties will not be challenged, invalidated, found unenforceable or circumvented, or that the rights granted there under will provide competitive advantages to us. If we or our collaborators or licensors fail to file, prosecute or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of any products we develop, and demand for our products could decline as a result. Further, although we have taken steps to protect our intellectual property and proprietary technology, third parties may be able to design around our patents or, if they do infringe upon our technology, we may not be successful or have sufficient resources in pursuing a claim of infringement against those third parties. Any pursuit of an infringement claim by us may involve substantial expense and diversion of management attention.

We also rely on trade secrets and proprietary know-how that we seek to protect by confidentiality agreements with our employees, consultants and collaborators. If these agreements are not enforceable, or are breached, we may not have adequate remedies for any breach, and our trade secrets and proprietary know-how may become known or be independently discovered by competitors.

We operate in the State of California. The laws of the State prevent us from imposing a delay before an employee who may have access to trade secrets and proprietary know-how can commence employment with a competing company. Although we may be able to pursue legal action against competitive companies improperly using our proprietary information, we may not be aware of any use of our trade secrets and proprietary know-how until after significant damage has been done to our company.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors, including generic manufacturers, could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our competitors may:

- develop and patent processes or products earlier than we will;

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

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

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

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

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

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

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

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

Risks Relating to Owning Our Common Stock

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

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

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

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

The number of shares of our common stock being traded may be very low. Any stockholder wishing to sell his/her stock may cause a significant fluctuation in the price of our stock. In addition, low trading volume of a stock increases the possibility that, despite rules against such activity, the price of the stock may be manipulated by persons acting in their own self-interest. We may not have adequate market makers and market making activity to prevent manipulation.

Our directors, executive officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of March 31, 2013, our officers and directors collectively controlled approximately 4,769,868 shares of our outstanding common stock (and approximately 7,663,105 shares of our common stock when including options held by them which were exercisable as of or within 60 days from March 31, 2013). Furthermore, as of March 31, 2013, our largest stockholder is Dr. Ramin Najafi, our Chairman and Chief Executive Officer. Dr. Najafi individually, and through his family trust which he jointly controls with his wife Mrs. Farideh Najafi, owns 4,039,143 shares, or 10.2 % of our outstanding common stock (including 668,775 options held by Dr. Najafi which are exercisable as of or within 60 days from March 31, 2013). As a result, Dr. Najafi, can significantly influence the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

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

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

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

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

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

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In October 2012, NovaBay issued warrants to purchase 15,000 shares to a vendor. These warrants were issued with an exercise price of $2.50 per share and 5,000 shares became exercisable on each of October 30, 2012, November 30, 2012, and December 30, 2012, and they all expire on September 30, 2014.

On January 10, 2013, NovaBay issued two separate warrant agreements, each to purchase 10,000 shares of its common stock, to Neil Kohlhaas, a vendor, for consulting services. These warrants were issued with an exercise price of $1.50 per share and $1.75 per share, respectively, and became exercisable immediately. The warrants expire on August 31, 2013, and December 31, 2013, respectively.

On March 29, 2013, the Company sold an aggregate of 300,000 shares of the Company’s common stock to an accredited investor at a purchase price of $375,000, this cash was collected in April 2013.

These sales were made in reliance upon Section 4(2) of the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

ITEM 6. EXHIBITS

See the Exhibit Index which follows the signature page of this Quarterly Report on Form 10-Q, which is incorporated here by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 1, 2013	NOVABAY PHARMACEUTICALS, INC.
	/s/ Ramin Najafi Ramin (“Ron”) Najafi Chairman and Chief Executive Officer (duly authorized officer)
Date: May 1, 2013	/s/ Thomas J. Paulson Thomas J. Paulson Chief Financial Officer (principal financial officer)

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation of NovaBay Pharmaceuticals, Inc., a Delaware corporation (Incorporated by reference to the exhibit of the same number from the Company's current report on Form 8-K, as filed with the SEC on June 29, 2010 (SEC File No. 001-33678))
3.2	Amended and Restated Bylaws of registrant (Incorporated by reference to the exhibit of the same number from the Company's current report on Form 8-K as filed with the SEC on June 29, 2010 (SEC File No. 001-33678).)
4.1	Specimen common stock certificate (Incorporated by reference to the exhibit of the same description from the Company's registration statement of Form S-1 (File No. 333-140714) initially filed with the Securities and Exchange Commission on February 14, 2007, as amended)
4.2	Form of Warrant issued in the August 2009 offering. (Incorporated by reference to the exhibit with the same description from the Company's current report on Form 8-K, as filed with the SEC on August 21, 2009 (SEC File No. 001-33678).)
4.3	Form of Warrant issued in the July 2011 offering. (Incorporated by reference to the exhibit with the same description from the Company's current report on Form 8-K, as filed with the SEC on June 29, 2011 (SEC File No. 001-33678).)
4.4	Form of Form of Common Stock Purchase Warrant issued in December 2012 (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K as filed with the SEC on December 6, 2012 (SEC File No. 001-33678)).
10.1	2012 Executive Bonuses for Named Executive Officers (Incorporated by reference to the disclosure in Item 5.02 of the Company's Current Report on Form 8-K as filed with the SEC on February 15, 2013 (SEC File No. 001-33678)).
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.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document

101.LAB* XBRL Taxonomy Extension Label Linkbase Document

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

* XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.