Ruthigen, Inc.
Form 10-K
June 30, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended March 31, 2014

OR

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

For the transition period from _____ to _____

Commission file number: 001-36199

RUTHIGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-1821392**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

2455 Bennett Valley Rd., Suite C116
Santa Rosa, California 95404
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(707) 525-9900**

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 Par Value Per Share	The NASDAQ Capital Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ 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. x

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

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

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

The aggregate market value of the registrant’s voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of June 15, 2014 was $18,900,915. The registrant has provided this information as of June 15, 2014 because its common stock was not publicly traded as of the last business day of its most recently completed second fiscal quarter.

As of June 15, 2014, the registrant had 4,804,290 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the 2014 Annual Meeting of Stockholders.

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PART I

Forward-Looking Statements

This Annual Report contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this Annual Report may not occur. Generally these statements relate to business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results. The words “may,” “will,” “expect,” “believe,” “anticipate,” “projec “plan,” “intend,” “estimate,” and “continue,” and their opposites and similar expressions are intended to identify forward-looking statements. We caution you that these statements are not guarantees of future performance or events and are subject to a number of uncertainties, risks and other influences, many of which are beyond our control, that may influence the accuracy of the statements and the projections upon which the statements are based. Factors which may affect our results include, but are not limited to, the risks and uncertainties discussed in Item 1A of this Annual Report.

Any one or more of these uncertainties, risks and other influences could materially affect our results of operations and whether forward-looking statements made by us ultimately prove to be accurate. Our actual results, performance and achievements could differ materially from those expressed or implied in these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether from new information, future events or otherwise.

As used in this Annual Report on Form 10-K, or this Annual Report, references to the “Company”, “we”, “us”, or “our” refer to Ruthigen, Inc.

Item 1. BUSINESS.

Overview

We are a biopharmaceutical company focused on the discovery, development, and commercialization of pharmaceutical-grade hypochlorous acid, or HOCl, based therapeutics designed to prevent and treat infection in invasive applications. Our lead drug candidate, RUT58-60, is a broad spectrum anti-infective that we are developing for the prevention and treatment of infection in surgical and trauma procedures. We are focusing RUT58-60 for use initially to prevent infections in abdominal surgery due to the large addressable market, high rate of post-surgical infection associated with abdominal surgery, the high-impact opportunity that abdominal surgery offers us in the

clinical trial setting to expose multiple internal organs to RUT58-60 at one time, and feedback from surgeons identifying post-surgical infection in abdominal surgery (relative to other surgeries) as a significant unmet medical need. We were incorporated in January 2013 as a wholly-owned subsidiary of Oculus Innovative Sciences, Inc., or Oculus or the Former Parent, and we were operated as a wholly-owned subsidiary of Oculus until the completion of our initial public offering, or IPO, in March 2014. We currently have no products approved for sale. We submitted our Investigational New Drug Application, or IND, for RUT58-60 to the United States Food and Drug Administration, or FDA, in early May 2014. In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60.

Our goal is to become the first company to market RUT58-60 as a drug containing HOCl for the prevention and treatment of infection in invasive surgeries in the United States. We believe that RUT58-60 has the potential to significantly reduce the rate of post-surgical infections, reduce the use of systemic antibiotics that have proven to be ineffective against certain common resistant strains of bacteria, including methicillin-resistant staphylococcus aureus, or MRSA, and vancomycin-resistant enterococcus, or VRE, reduce the negative side effects associated with the increasingly widespread use of antibiotics, accelerate post-surgical healing which should lead to quicker patient discharge from the hospital, and ultimately reduce hospital readmission rates. We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. The initial phase will be a 30 patient, 21-day skin irritation trial that we expect to complete in August 2014. Following an independent data monitoring committee, or DMC, review of the results from the skin irritation phase, we plan to enroll 20 patients in the Phase 1 part of our Phase 1/2 clinical trial, to evaluate the safety of RUT58-60 within the abdominal cavity, which we refer to as the safety run-in. Subject to review of the safety run-in data by the DMC, we will continue patient enrollment in the Phase 2 part of our Phase 1/2 clinical trial for RUT58-60. Pending the successful completion of that trial and our planned pivotal clinical trials, the first of which we anticipate will be our planned Phase 2B trial and the second of which we anticipate will be our planned Phase 3 trial, we plan to submit our New Drug Application, or NDA, to the FDA in late 2017.

We believe that RUT58-60 will complement the paid for performance paradigm and it is designed to reduce the overall healthcare costs associated with post-surgical infections and improve hospital economics. We believe the benefits of RUT58-60 will be significant:

- RUT58-60 mimics the human body's own infection-fighting mechanism,
- RUT58-60 has not shown evidence of toxicity or other negative side effects in our animal and other preclinical studies,
- preclinical studies of RUT58-60 conducted by us have not produced resistant bacteria, and
- RUT58-60 appears to provide broad spectrum anti-microbial effect.

We believe that RUT58-60 has the potential to be used as a prophylactic therapy to prevent and treat infections, and may accelerate patient discharge from the hospital and ultimately lead to an overall reduction in hospital readmission rates.

The benefits of HOCl in preventing infection have been well-demonstrated in products with lower concentrations of HOCl than RUT58-60. To date, HOCl based products have only been cleared for use as medical devices for topical applications in the United States, Europe and certain other countries. Earlier formulations have not been able to achieve therapeutic indication status, primarily due to their lack of stability and therefore have been limited for use as topical applications. Historically, the lack of stability has posed a vexing problem to companies hoping to pursue HOCl products for therapeutic indications in invasive applications and has prevented these companies from being able to conduct the clinical trials necessary to prove whether HOCl is safe and effective for use as a therapeutic.

HOCl based products have been used successfully to prevent infection in topical applications and have been sold commercially since at least 2005 by other companies, generally as medical devices or for the disinfection of medical devices. Several of these HOCl based products have been commercialized as medical devices by Oculus, our former parent company and the licensor of our technology. Through our license and supply agreement with Oculus, we have obtained exclusive rights to the RUT58-60 technology, as well as a proprietary method of manufacturing and producing HOCl with pharmaceutical potential by incorporating additional small molecules without sodium hypochlorite, the result of which increases the compound's stability and biocompatibility, or the compound' ability to remain in direct contact with internal tissues and organs. We believe our recent enhancements to the stability and biocompatibility of the compound will allow us to expand the use of HOCl so that it may be used in direct contact with internal organs and thus, for invasive applications, including surgical and trauma procedures, as well as additional clinical indications. With these enhancements, we believe our lead product candidate will be able to meet the safety and efficacy standards that the FDA requires for the approval of a new drug. Obtaining approval of new drug by the FDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval.

The FDA review processes can take years to complete and approval is never guaranteed. If we are successful obtaining FDA approval of RUT58-60 as a drug, we plan to commercialize it for invasive applications.

There are approximately 30 million surgical and trauma procedures in the United States per year, approximately 7 million of which are abdominal surgeries. Our initial goal is to obtain FDA approval for RUT58-60 for the prevention of infection associated with abdominal surgery and thereafter we plan to pursue FDA approval for RUT58-60 for use in other types of surgical procedures as well as additional clinical indications.

If we are successful in receiving FDA approval for RUT58-60 for the prevention of infection in abdominal surgery, we plan to pursue other types of surgeries, including cardiac, pulmonary and spinal, among others. Based upon data from preclinical studies conducted by us and data reported in third party publications, we believe that the safety and tolerability profile of RUT58-60, combined with its broad-range antimicrobial potency without specificity, offer a practical and unique approach to stem the high rate of hospital acquired infections and infections resulting from complications in surgeries and the increasing emergence of new antibiotic resistant bacteria that pose a significant risk to public health. We believe that RUT58-60 represents a significant innovation over existing uses of HOCl in topical applications and over systemic antibiotics, which are the current standard of care for the prevention and treatment of infection in surgical and other invasive applications, and has the potential to raise the clinical bar for anti-infective products generally in the face of increasing headwinds.

In addition to the United States, we plan to seek regulatory approval to commercialize RUT58-60 in Canada, Europe and Japan. Under our license and supply agreement with Oculus, we have exclusively licensed the HOCl technology relating to RUT58-60 for commercialization in the United States, Europe, Japan and Canada. Together, these markets represented approximately 71% of the global medicines market in 2011. In parallel with our clinical development activities for RUT58-60, we have commenced discussions with various pharmaceutical companies for potential partnership and collaboration activities for RUT58-60 in the United States, Canada, Europe and Japan. To date, we have not entered into any partnerships or collaborations for RUT58-60 and we cannot guarantee that we will be successful entering into any such arrangements on terms favorable to us, or at all.

Our Strategy

Our goal is to be the first company to market HOCl based drugs for the prevention and treatment of infection in invasive procedures. By doing so, we hope to be able to reduce the number of post-surgical infections, reduce the increasingly widespread use of systemic antibiotics and the negative side effects associated with them, accelerate post-surgical healing which should lead to quicker patient discharge from the hospital, and reduce hospital readmission rates. The key elements of our strategy to achieve this goal are listed below.

- Initiate and complete clinical trials for our lead drug candidate, RUT58-60, for the first indication (abdominal surgery) and obtain regulatory approval to market as a drug in the United States.

  - Establish research and development and manufacturing facilities in compliance with the FDA's Current Good Manufacturing Practices, or cGMP, requirements for manufacturing drugs.

  - Commercialize RUT58-60 in the United States either through a direct sales force or with a partner.

- Engage strategic partners to develop, obtain regulatory approval for, and commercialize RUT58-60 for invasive use in Europe and Japan.

- Expand the use of, and obtain regulatory approval for, RUT58-60 for use in other types of surgeries and traumatic procedures.

- Leverage our proprietary HOCl chemistry technology to develop a pipeline of innovative drugs for the prevention and treatment of infection in surgical and other invasive applications.

Our Solution

We believe that HOCl, the active pharmaceutical ingredient in RUT58-60 and other drug candidates that we plan to develop in the future, has several potential benefits over systemic antibiotics, which are the current standard of care for the prevention of infection associated with surgical and trauma procedures, as described below.

- *Broad Spectrum Activity Including Against Antibiotic Resistant Strains of Bacteria*. HOCl has been shown in non-clinical studies to kill bacteria, viruses, spores, and fungi. We believe this can be achieved through common mechanisms of action, including by denaturation, a process in which the structure of surface proteins on the

microorganism is irreversibly changed or damaged, which results in the destruction of pathogen. RUT58-60 has been shown in non-clinical studies to eradicate MRSA, VRE, and other antibiotic resistant microorganisms. RUT58-60's biologic activity is localized and fast-acting, which results in rapid bacterial destruction; in vitro studies have demonstrated potent 30-second kill times against several commonly found, clinically relevant, aggressive treatment-resistant bacteria.

- *Multi-targeted; Does Not Promote Emergence of Superbugs*. We believe that RUT58-60 has the potential to be used broadly as a prophylactic agent to prevent infections in surgical patients because, in pre-clinical studies, it has not been shown to promote resistance to bacteria and therefore does not increase the emergence of drug-resistant pathogens. RUT58-60 does not target specific strains or receptor targets that the microorganism can then quickly mutate to induce resistance. Further, exposure to HOCl causes irreversible destabilization of protein structures necessary for continued metabolism for bacteria and other microbes.

- *Pro-healing Potential*. HOCl products have demonstrated faster tissue healing in studies published in peer-reviewed journals and other publications. Although the mechanism of action for incision site healing has not been formally established in RUT58-60, we believe that incision sites will heal quicker, resulting in faster patient recovery and discharge from the hospital.

- *Mimics Body's Natural Microbe-Fighting Mechanism*. Human bodies have evolved over thousands of years to produce HOCl naturally to kill infection-causing microbes quickly and without creating the opportunity for microbes to mutate and become resistant. We believe that we have chemically engineered RUT58-60 to mimic the body's natural response to unfamiliar and unwanted organisms, without the undesirable side effects resulting from the proliferation and overuse of antibiotics.

No Change to Surgeon Behavior Required. Sterile saline is currently the most commonly used irrigation solution to prevent infection during and following surgery when lavage is used to wash the surgical site following surgical and trauma procedures, but it does not contain the antiseptic benefits traditionally associated with antibiotics to prevent post-surgical infection. The use of a lavage wash in surgeries is not new and therefore, we believe that the replacement of saline (or other currently used post-operative irrigation solutions) with RUT58-60 in surgical settings will be an easy and logical transition for surgeons and will not require additional training, time, education, ramp up or behavior changes by surgeons.

Prepackaged, Sterilized, Ready to Use. We believe that RUT58-60, if approved by the FDA, will be the only prepackaged, sterilized, ready-to-use HOCl based drug designed to prevent infection following surgery. We intend to package RUT58-60 in convenient, sterile packaging that will not require mixing or solution preparation prior to use, thereby reducing the need for human intervention and further minimizing opportunities to introduce other organisms that may cause infection and the risk of medical error.

Stable Formulation. RUT58-60 is not expected to require special handling precautions or storage requirements beyond those typically required for similar sterile products found in hospital and other indoor settings. Laboratory tests suggest that RUT58-60 may have a shelf life ranging from one to two years depending on the size and type of packaging. We believe that RUT58-60 is a unique, shelf stable form of HOCl that has the potential to meet the FDA's requirements for a drug.

Enhanced Biocompatibility for Internal Use. We believe RUT58-60 is the first and only form of HOCl based drug designed for internal use. We believe RUT58-60 represents an innovative way to improve the potential pharmaceutical properties of HOCl by incorporating additional small molecules without sodium hypochlorite, the result of which enhances the biocompatibility of the compound in a manner that allows the compound to remain in direct contact with internal tissues and organs.

Hospital Cost Savings Potential. We believe that RUT58-60 has the potential to improve surgical outcomes and lower hospital costs by preventing infection, decreasing the time to patient discharge and reducing hospital readmission rates. Post-surgical infections are costly and, under new government regulations and payor policies, these infections are increasingly not covered for reimbursement. High patient costs associated with the treatment of infections may be related to longer hospitalizations and extended care, patient isolation due to the high rates of infection transmission, and the use of expensive systemic antibiotics used to target infection. Post-surgical infection may also undermine the healing process, prolong healing time and increase hospital readmissions after initial discharge. Eventually, we believe that RUT58-60 may also help reduce the use of systemic antibiotics, thereby lowering overall cost of the hospital visit.

Bacteria and Bacterial Resistance to Antibiotics

Bacteria are microscopic, single cell organisms, or microorganisms, that can survive and reproduce in the human body; and in certain situations, may cause infections. These bacterial infections may be caused by a number of types and variations of bacteria and may results in symptoms that range from mild to serious and life threatening. Most

bacteria can be categorized according to a single characteristic, the cell wall. A Gram stain is often performed to differentiate bacteria into Gram-positive Bacteria, which have a permeable thick cell wall, or Gram-negative Bacteria, which have a less permeable cell wall. The Gram stain is a violet or deep blue colored dye that is absorbed into the cell wall of a Gram-positive bacteria, thus a Gram-positive bacterium can be seen with its violet or deep blue hue stain when viewed under a microscope.

Common Gram-positive Bacteria include:

- Staphylococcus, or “Staph,” including methicillin-resistant Staph aureus, or “MRSA,” which was historically a common hospital acquired infection that is now and increasingly found outside of the hospital and in the general community.

- Streptococcus, or “Strep,” including Streptococcus pneumoniae, or “pneumonia,” which may cause infections in the lung, ear, throat, bloodstream, and/or meninges.

- Enterococcus, including vancomycin-resistant enterococcus, or “VRE,” which is a common hospital acquired infection.

Common Gram-negative Bacteria include:

- Escherichia coli, or “E coli,” which is commonly found in the human gastrointestinal tract, and may cause infections in the gastrointestinal or urinary tracts in some patients, or in the bloodstream or skin.

- Acinetobacterbaumannii, which is an antibiotic resistant bacterial strain that has been linked to hospital acquired infections.

- Pseudomonas aeruginosa, which is a naturally occurring antibiotic resistant bacterial strain that produces a biofilm, or extracellular matrix, to adhere individual bacteria together and prevent antibiotic access to the cellular targets.

- Klebsiellapneumoniae, or “Klebsiella,” including KPC, a strain of Klebsiella, which is a bacterial strain that is resistant to the antibiotic drug carbapenem.

Bacteria are thought to be among the earliest living organisms on Earth and have adapted to survive in many harsh and unique environments that tend not to sustain other forms of life. In a similar fashion, bacteria have evolved and formed resistance to several types of antibiotics, sterilizing agents, and environmental conditions. Therefore, in order to survive, bacteria have developed resistance to many of these commonly used chemicals and conditions. Bacteria containing new genetic mutations, which strengthen them to resist the impact of antibiotics that were designed to kill the bacteria, reproduce. This reproduction can lead to formation of new colonies (populations) of bacteria with similar genetic traits. Additionally, many bacteria are capable of sharing genetic information across bacterial species in ways that induce drug resistance from one organism to another and thus extend drug resistance to new types of bacterial pathogens.

There are generally four primary mechanisms of bacterial activity found in microorganisms that cause resistance to antimicrobial drugs, such as antibiotics:

- Bacteria may develop capabilities to alter or inactivate the antimicrobial drug. The enzymatic deactivation of penicillin G in some penicillin-resistant bacteria is an example of this type of bacterial resistance.

- Bacteria can alter the site being targeted by antibiotics. The alteration of the binding site of penicillin and the creation of MRSA and other penicillin-resistant bacteria are examples of this type of mutation.

- Bacteria can alter their specific metabolic pathway to process chemicals in new ways. An example of this type of bacterial resistance is how sulfonamide-resistant bacteria are now using preformed folic acid.

- Bacteria can reduce drug accumulation by decreasing permeability to the drug and/or increasing active efflux (pumping out) of the drugs across the cell surface.

The common practice of using antibiotics to treat patients with a wide range of infections that are known, or presumed to be attributable to bacteria has resulted in the evolution and spread of drug-resistant bacteria in hospital and community settings and in the global food supply. Over time, new antibiotic drugs have been developed by the medical community to address these drug-resistant bacteria; however, the proliferation of new antibiotic drugs has resulted in the further evolution of “Superbug” bacteria that have developed resistance to several commonly prescribed antibacterial drugs. In turn, physicians have modified their use of broad-spectrum (treats a wide range of bacteria including Gram-positive and Gram-negative strains) and narrow-spectrum (treats a select group of bacteria) antibiotics. Broad spectrum antibiotics are commonly used as first-line therapies to treat patients with infections prior to the identification of the type or specific bacterial strain responsible for the infection, until such a time as a more specific, narrow-spectrum antibiotic can be used or added.

The widespread increase in antibiotic-resistant bacteria has been widely recognized as a rapidly emerging threat to public health on a global basis. Reports from several organizations have discussed the growing concern over the spread of antibiotic resistance and that if significant efforts are not effectively made to decrease the proliferation of antibiotic resistant-related infections, infections that were formerly treatable may become untreatable, thereby placing patients at risk for injury or death. The risk that a patient contracts a life-threatening infection, simply while being treated for common medical conditions and procedures, such as surgery, chemotherapy, care of the elderly and infants, and other patients with compromised immune systems, that causes a greater threat to the patient's health than the common medical condition for which they are being treated, seems to invert the treatment paradigm. The toll on patients and the healthcare system is becoming increasingly problematic. In the hospital setting, patients that are infected with antibiotic-resistant bacteria tend to have longer and more expensive hospital stays, and are more likely to experience significant negative health consequences, including death, as a result of these infections. Based on this data and feedback from physicians and other healthcare professionals, we believe that innovative anti-infective drugs that are able to kill antibiotic-resistant bacteria, which do not carry the negative side effects commonly associated with antibiotics, would meet this significant unmet medical need and that RUT58-60 may be one of them.

Limitations of Current Anti-Infective Products

In post-surgical and trauma applications, common methods of controlling infection, include the use of systemic and topical antibiotics and mechanical washes, such as saline, which have proven to be only moderately effective in preventing infections. In addition, certain topical and systemic antibiotics have negative side effects and antibiotics and antiseptic agents also tend to inhibit the healing process due to their toxicity and may require specialized preparation or handling. Antibiotics, both topical and systemic, can lead to the emergence of drug-resistant bacteria, such as MRSA and VRE. As a result, no single treatment is used universally for post-surgical applications; and, we believe that RUT58-60 has the potential to fill that void by preventing or treating infection in surgical and other invasive applications.

Commonly used antiseptics, mechanical washes, such as saline or Ringer's solution, and systemic antibiotics have limitations and negative side effects that may constrain their usage. For example:

- Antibiotics and antiseptics can kill bacteria and cure infection but may promote antibiotic resistance in select microbial strains;

- Many antiseptics, including Betadine, hydrogen peroxide and Dakin's solution, can be toxic when exposed to the body's internal organs. Dilute forms of these antiseptics may not be as effective in eradicating pathogens;

- Advanced care products, such as silver based products, are not cleared by the FDA for internal use; and

- The increase in antibiotic-resistant bacterial strains, such as MRSA, VRE, and C. diff, has compromised the effectiveness of some antibiotics, such as daptomycin and Bacitracin.

Our Lead Drug Candidate, RUT58-60

We are developing our lead drug candidate, RUT58-60, for the prevention of infection in surgical and other invasive applications. The initial indication that we are pursuing is for use in abdominal surgery. The active pharmaceutical ingredient in RUT58-60 is HOCl. It is manufactured without any sodium hypochlorite, and it incorporates additional small molecules, the result of which increases the stability and biocompatibility of the compound so that it may be used in direct contact with internal organs. We believe that we are the first company to have produced a shelf stable and tissue biocompatible form of HOCl that will satisfy FDA's safety and efficacy requirements as a drug for invasive use. To date, despite attempts by several commercial enterprises, we are not aware of any company that has been successful in developing HOCl as a drug for invasive use in the United States. Our plan for RUT58-60 is to conduct the clinical trials that will be necessary to prove its safety and efficacy for use during surgery and our goal is to receive FDA approval initially as a drug for the prevention of infection following abdominal surgery. Subject to FDA approval of RUT58-60, we plan to commercialize RUT58-60 for the prevention of infection in surgical and other invasive applications.

We are rapidly advancing our clinical development program for RUT58-60. We submitted our IND for a Phase 1/2 clinical trial of RUT58-60 in the United States in early May 2014. The IND package also included, among other items, pre-clinical data derived from studies using HOCl based products, as well as a several independent publications and reports using topical formulations of HOCl from various manufacturers. Several topical HOCl based products have been cleared by the FDA as medical devices and marketed in the United States, Europe and certain other countries by various companies and have accumulated an extensive clinical data bank demonstrating the safety and efficacy of HOCl as a topical product used to moisten, debride and clean, and in some instances, be used as an anti-infective.

In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60. We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. The initial phase will be a 30-patient, 21-day skin irritation trial that we expect to complete in August 2014. Following an independent data monitoring committee review of the results from the skin irritation phase, we plan to enroll 20 patients in the Phase 1 part of our Phase 1/2 clinical trial, to evaluate the safety of RUT58-60 within the abdominal cavity, which we refer to as the safety run-in. Subject to review of the safety run-in data by the independent data monitoring committee, we will continue patient enrollment in the Phase 2 part of our Phase 1/2 clinical trial for RUT58-60. The Phase 1/2 trial will be a controlled, double blind, randomized, and multi-centered study to evaluate the safety, tolerability, and efficacy of RUT58-60 as an adjunct therapy to systemic antibiotics for the prevention of infection associated with abdominal surgery.

Improvements in RUT58-60 Over Existing HOCl Formulations

With most classes of anti-infectives containing HOCl, chemists have generally not been able to synthesize a formulation containing HOCl that meets the FDA's requirements applicable to a drug for invasive use, such as sufficient tolerability, biocompatibility, efficacy, stability and sterility; and, only been able to achieve tolerability and efficacy sufficient for use as a topical agent. We believe the proprietary chemical formulation and manufacturing process that formed the basis for RUT58-60 will further optimize the earlier formulations of hydrochlorous acid in a manner that will result in tolerability, biocompatibility, efficacy, stability and sterility to potentially allow for it to be used as a drug in surgical and other invasive procedures where it will be in direct contact with human internal organs.

We believe that the absence of hypochlorite (OCL-) in RUT58-60 and the incorporation of additional small molecules increase the stability and biocompatibility of the compound so that it may be used in direct contact with internal organs. We believe these chemical attributes are substantial improvements over existing HOCl formulations and may cause RUT58-60 to meet the FDA's requirements applicable to a drug for invasive use. Furthermore, the final packaged RUT58-60 will be subject to a standard sterilization process as required for internal use. This final critical step in the manufacturing of RUT58-60 is designed to prevent the potential for introduction of infectious agents related to the packaging material when the drug is used in sterile surgical suites. In preclinical studies for RUT58-60, we have demonstrated that RUT58-60's stability withstands the temperature treatment associated with the sterilization processes. We believe these chemical attributes (tolerability, biocompatibility, efficacy, stability and sterility) have the potential to enable RUT58-60 to become the first HOCl based drug candidate for potential use in surgical and other invasive applications.

Select Pathogen Activity of RUT58-60

In March, 2013, we tested the pathogen activity of RUT58-60 in preclinical studies. Below are the average kill times using RUT58-60 on certain common bacteria that cause infection. The results demonstrate that RUT58-60 is effective in reducing the organism populations by > 7 logs at all intervals shown. Notably, RUT58-60 completely eradicated the

bacteria within the first 30 seconds after application of the drug solution onto the cell cultures.

Bacteria Challenge Populations	Contact Times (Log Reductions*) 30 Sec	1 Min	2 Min	5 Min	10 Min	% Bacterial Reduction**	Incubation*** Times (hrs)
MRSA (Methicillin-resistant S. aureus)	8.5	8.5	8.5	8.5	8.5	99.9999997%	24.5
E. coli	8.4	8.4	8.4	8.4	8.4	99.9999996%	24
P. aeruginosa	8.2	8.2	8.2	8.2	8.2	99.9999993%	25
VRE (E. faecalis)	8.1	8.1	8.1	8.1	8.1	99.9999993%	24
P. mirabilis’	8.3	8.3	8.3	8.3	8.3	99.9999995%	57
S. marcescens	8.8	8.8	8.8	8.8	8.8	99.9999999%	24.5
C. albicans	7.1	7.1	7.1	7.1	7.1	99.9999929%	22.5

* Log Reduction is a mathematical term used to demonstrate a Log, or 10-fold, reduction in live bacteria.

** Calculations show no detectable surviving bacterial presence in the samples tests. Test methods did not use serial dilutions (a series of dilution that reduces the concentration of bacteria by a defined amount per stage).

*** Incubated on Tryptic Soy Agar (TSA) at 30 – 35°C.

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Proven Utility of HOCl

While we do not have the requisite regulatory approval to market RUT58-60 as a drug with an antimicrobial or healing indication in the United States, Europe, or Japan, we believe several factors including clinical results, laboratory testing, scientific papers authored on and physician-led clinical studies based on other HOCl containing solutions and formulations, suggest that HOCl, the active pharmaceutical ingredient in RUT58-60, may significantly reduce a wide range of infections in surgical and traumatic injuries and potentially accelerate patient discharge. Further, a number of physician-led clinical studies suggest that HOCl is safe, easy to use and may shorten hospital stays, lower aggregate patient care costs and, in certain cases, reduce the need for antibiotics. In one such clinical presentation at the 11th Scientific Conference 2008 in Kota Bharu, Malaysia, Dr. M.G. Khairulasri, et al., reported results from a prospective, randomized clinical trial of 178 patients who underwent elective coronary artery bypass graft, or CABG, surgery. Oculus provided product at no cost for purposes of this study. Results of this study were also published in the Heart Surgery Forum, a cardiothoracic multimedia journal, in August 2010. Patients received either Dermacyn (Group A), a HOCl based formulation manufactured by Oculus, or a 10% povidone-iodine solution (Group B) as an adjunct therapy to the use of systemic antibiotics. All patients also received intravenous prophylaxis (antibiotics) in addition to the lavage solution. After their surgeries, the patients' sternums were closed and in both groups, the wounds were soaked for 15 minutes. Patients were evaluated several times prior to discharge and again following discharge at weeks 2, 4, and 6 for the presence of wound infection and side-effects. The primary outcome was the presence of sternotomy wound infection, which was defined and graded according to the United States Centers for Disease Control and Prevention, or CDC, in their National Nosocomial Infections System (Horan 1992). On average, 5.7% of the patients in Group A and 15.6% of the patients in Group B showed an incidence of sternal wound infection (p=0.033). 100% of the patients in Group A who showed signs of infection exhibited superficial infections. 71% of the patients in Group B who showed signs of infection exhibited superficial infections and 29% exhibited deep (non-superficial) infections.

As demonstrated by Malle E in 2003, the over production and storage of enzymes required by our body to produce HOCl, and its subsequent byproducts can cause potential harm to internal arteries and organs including kidney. By contrast, we believe that RUT58-60 provides the clinical benefits of HOCl without the toxicity resulting from other precursors and byproducts. HOCl is generally understood to be unstable because it carries a weak chlorine bond leading to diffusion of chlorine gas with the passage of time. We believe that RUT58-60 contains HOCl without the presence of toxic precursors, byproducts or sodium hypochlorite. Upon reaction with proteins, amino acids, nucleic acids (deoxyribonucleic acid, or DNA, and ribonucleic acid, or RNA), and lipids, including those associated with bacteria, RUT58-60 loses its chlorine thus forms an aqueous solution and is rendered neutral. Our in vivo toxicity tests have shown animals are capable of tolerating higher doses of RUT58-60 with long-term exposures. Based on our initial research, we believe that RUT58-60 may have a shelf life ranging from one to two years depending on the size and type of packaging.

Mechanism of Action of RUT58-60's Active Pharmaceutical Ingredient, HOCl

HOCl is extremely unstable as it is produced in the body or under laboratory conditions. The short shelf life of HOCl is attributable to its weak chlorine bond that readily reacts with biomolecular sites including general surface proteins on bacterial membranes. Through reactions with biomolecules, the chlorine ion is rapidly lost as it binds to nearby available biomolecules including surface bacterial proteins. After reaction, water remains as the final residue. We believe the tissue absorbs the water. Initial cell surface reactions to HOCl have been reported to occur in as little as 100 milliseconds, as reported by Albrich and Hurst (FEBS Letters, 1982).

HOCl has been described in peer reviewed literature as the most potent antibacterial agent when compared to other anti-infectives. Winter in 2008 reported that HOCl, on the other hand, reacts with free cysteines about seven orders of magnitudes faster than hydrogen peroxide.

HOCl has demonstrated to be potent and fast acting through targeting non-specific biomolecules on bacterial cell membrane. It is widely documented that HOCl readily reacts with a wide range of biomolecules including DNA strands, RNA strands, fatty acid groups, cholesterol and proteins amongst others. It is a highly reactive compound and upon reaction it is completely rendered neutral. Unlike antibiotics, the potency of HOCl and damage is delivered with no specificity as reported by McKenna in 1988. We believe this mechanism of action induced by HOCl drastically reduces the potential for emergence of new superbugs.

Bonvillain RW et al in 2011 demonstrated that HOCl can damage the integrity of the bacterial cell membrane through increasing its permeability. The graph below (Bonvillain RW in 2011) shows the rapid drop in bacterial viability followed by immediate cell membrane integrity damage at concentrations of approximately 0.05mM to 0.1mM of HOCl. By contrast, RUT58-60 contains 2.0mM of HOCl, which represents a 40-fold increase in the minimal concentration of HOCl needed to initiate bacterial cell membrane damage.

According to Bonvillain RW in 2011 and Barrette WC Jr in 1989, HOCl targets and disrupts the energy cycle within bacteria (adenosine triphosphate — ATP). ATP is the central function for production of energy for bacteria. Therefore, HOCl first, induces irreversible damage to bacterial cell membrane proteins thus interrupting the proteins' functionality, then it targets the bacterial cell membrane and finally shuts down the center for production of energy for bacteria. As a direct result of protein damage by HOCl according to Barrette WC Jr, in 1989, cellular metabolism is disrupted causing a principally decreased production of Adenosine-5"-triphosphate, energy production (ATP), a universal, biological energy storage and transfer molecule. Studies show protein instability induced by HOCl is non-reversible.

Other sources for production of HOCl includes our while blood cells. Neutrophils are specific type of white blood cells that are responsible for production of HOCl to fight infection. Our body's immune system has evolved to incorporate the use of HOCl to fight pathogens. The production of HOCl by immune cells requires the involvement of additional biomolecules and transient chemicals. Myeloperoxidase has been reported as the key enzyme to convert hydrogen peroxide into HOCl in our body (Anitra Carr in 1996). Therefore, higher concentrations of myeloperoxidase are required by our body to produce the potent concentrations of HOCl found in RUT58-60. However, the higher presence of myeloperoxidase and its oxidative ability is associated with toxicity and damage found in patients suffering from late stage kidney disease.

The science of HOCl is not well understood in the industry. For example, it has been demonstrated that HOCl reacts with unsaturated bonds in lipids which comprise the bacterial cell membrane, whereas bleach (OCl-) does not participate in this reaction. While topical disinfectants such as bleach may induce necrosis in certain open wounds, we have demonstrated that exposure to HOCl both in vivo and in vitro induces no harm. In contrast to hypochlorite, HOCl is highly tolerated by mammalian cells as demonstrated by Gonzales in 2006. Additionally, as reported by Allison Kutner 2013 as well as Diana Gonzales-Espinosa in 2007, mammalian cells contain cellular amino acids and pumps that assist in neutralizing HOCl and keeping mammalian cells safe. Mammalian cells contain amino acids such as Taurine that help protect the cells from the oxidation process caused by HOCl.

HOCl has also been studied for purposes of evaluating, and has been shown to demonstrate, pro-healing capabilities. Landsman, et al (2011), a clinical trial sponsored by Oculus which used Oculus' HOCl based product (not RUT58-60), showed a statistically significant improvement in clinical success, as determined by the complete resolution of signs and symptoms of disease, in diabetic foot ulcer patients. The HOCl group outperformed a control group of patients that used saline with levofloxacin, an antibiotic commonly used with these patients. The HOCl group showed a 93% success rate at 14 days vs. a 56% success rate in the control group.

Market Opportunity

Under our license and supply agreement with Oculus, we have exclusively licensed certain HOCl technology relating to RUT58-60 for commercialization in the United States, Europe, Japan and Canada. According to an IMS report from July 2012, these markets represented approximately 71% of the global medicines market in 2011. We plan to rapidly advance our clinical development program for RUT58-60 for the prevention of infection following abdominal surgery.

In 2005, $4.7 billion was spent for the treatment of surgical and trauma wounds according to Kalorama Information, a life sciences market research firm. Based on 46 million surgical and trauma procedures annually in the United States and more than 230 million procedures worldwide according to Medtech Insight, we estimate our ultimate addressable market to be in excess of $4 billion in the United States alone. However, initially, we plan to focus the clinical and regulatory prospects for RUT58-60 on the prevention of infection in the abdominal surgery market. Subject to successful completion of our planned clinical trials for RUT58-60 in the abdominal surgery indication, we plan to advance RUT58-60, or derivations of it that we develop, for other types of surgical and invasive indications.

The medical community is facing an increased rate of infection and the traditional use of antibiotics, antiseptics and antimicrobials not only cannot meet the medical need, but also, the ever-increasing overuse of these agents carries side effects, including the emergence of new superbugs, that have created other medical needs. The burden of infection following surgical and trauma procedures imposes significant economic consequences that impact both patients and hospitals. The hospital direct cost of treating healthcare-associated infections ranged from approximately $36 billion to $45 billion in 2007, according to the 2009 CDC report titled “The Direct Medical Cost of Healthcare-Associated Infections in U.S. Hospitals and the benefits of Prevention.”

In a 2008 study funded by the World Health Organization and published in The Lancet, it was estimated that 234 million major surgical procedures are undertaken on an annual basis worldwide. This estimate included 64 million procedures in the United States, 43 million in Europe and 16 million in Japan. For this estimate, major surgery was defined as any intervention occurring in a hospital operating theatre involving the incision, excision, manipulation, or suturing of tissue, and usually requiring regional or general anesthesia or profound sedation to control pain.

The CDC estimates there were 48 million in-patient procedures in the United States in 2009. Further, the CDC estimates there were approximately 53 million ambulatory procedures in 2006. Based on an analysis of data from a variety of industry sources and input from our physician consultants, we estimate that the number of patients undergoing advanced surgical interventions and that may benefit from RUT58-60 is 30 million. We believe this represents an addressable market in the United States of approximately $3.0 billion to $4.5 billion. Our initial clinical development focus for RUT58-60 will be on the prevention of infections associated with abdominal surgery in the United States, which, based upon input from our physician consultants, we estimate is approximately a $700 million market opportunity for RUT58-60. Pending successful completion of our planned clinical trials for RUT58-60 in the abdominal surgery indication, we plan to initiate additional studies to expand the clinical indications for use of

RUT58-60 in pulmonary, cardiac, orthopedic and spinal surgeries, among other invasive applications.

Clinical Development

The overarching goal of our clinical development program is to develop drugs, which use HOCl as the active pharmaceutical ingredient, without sodium hypochlorite, and incorporate additional small molecules for the prevention and treatment of infection in surgical and other invasive applications. We believe the results of our enhanced HOCl formulations will be increased stability and improved biocompatibility for use in direct contact with internal organs. We have designed RUT58-60 to prevent infections associated with surgical and trauma procedures, initially in abdominal surgery. We have conducted pre-clinical testing to support our IND for RUT58-60, and we have received feedback from the FDA to our proposed Phase 1/2 clinical trial protocol. Based on feedback we received from the FDA, we submitted our IND for RUT58-60 to the FDA in early May 2014. In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60. We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. The initial phase will be a 30-patient, 21-day skin irritation trial that we expect to complete in August 2014. Following an independent data monitoring committee review of the results from the skin irritation phase, we plan to enroll 20 patients in the Phase 1 part of our Phase 1/2 clinical trial, to evaluate the safety of RUT58-60 within the abdominal cavity, which we refer to as the safety run-in. We expect the Phase 1 part of the trial to be completed in the fourth quarter of 2014. Subject to review of the safety run-in data by the independent data monitoring committee and confirmation of no significant adverse events, we will continue patient enrollment of an additional 130 patients in the Phase 2 part of our Phase 1/2 clinical trial for RUT58-60, with a goal of enrolling a total of 150 patients. The Phase 1/2 trial will be a controlled, double blind, randomized, and multi-centered study to evaluate the safety, tolerability, and efficacy of RUT58-60 as an adjunct therapy to systemic antibiotics for the prevention of infection associated with abdominal surgery.

We expect to complete the Phase 2 part of our Phase 1/2 clinical trial in the first quarter of 2015. Following completion of our Phase 1/2 clinical trial, we expect to establish a protocol for and conduct our planned Phase 2B pivotal clinical trial. Thereafter, we expect to commence our planned Phase 3 pivotal clinical trial. Assuming successful completion of these clinical trials, we expect to submit our NDA to the FDA in late 2017. Based on these anticipated timelines and the resources we have allocated, we expect the total operating expense to bring RUT58-60 through our goal of FDA approval will be approximately $50 million. In parallel with our clinical development activities, we have commenced discussions with various pharmaceutical companies for potential partnership and collaboration activities for RUT58-60 in the United States, Canada, Europe and Japan. To date, we have not entered into any partnerships or collaborations for RUT58-60 and we cannot guarantee that we will be successful entering into any such arrangements on terms favorable to us, or at all.

Our Phase 1/2 Clinical Trial for RUT58-60

We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. The initial phase of our Phase 1/2 clinical trial will be a 30-patient, 21-day skin irritation trial that we expect to complete in August 2014. We have designed this initial clinical trial as a controlled, double blind, randomized and multi-centered study to evaluate the safety, tolerability and efficacy of RUT58-60 as an adjunct therapy to systemic antibiotics for the prevention of infection associated with abdominal surgery. More specifically, our Phase 1/2 clinical trial is being combined to encompass the primary objective of Phase 1 clinical trials, which is safety, as well as all of the common objectives of Phase 2 clinical trials, including tolerability and efficacy (or the rate of post-surgical infection following the use of RUT58-60). Although the trial will be used to evaluate the safety profile of RUT58-60, we will first test RUT58-60 in a 30 patient, 21-day human skin irritation trial prior to the Phase 1 part of the Phase 1/2 trial. We have designed the Phase 1/2 trial to have a “safety run-in,” which means that we will conduct the initial phase of the trial on a smaller subset of the total number of anticipated trial subjects. Following the collection of the safety data from the smaller subset, we will submit the data to an independent data monitoring committee for interim analysis, rather than needing to submit the safety data to the FDA or amend the IND in a manner that would require additional review and feedback from the FDA and result in delay. Subject to confirmation by the DMC of the absence of safety markers and significant adverse events, we will continue with the Phase 2 portion of the trial. For the FDA’s description of the three phases of human clinical trials, please see “Government Regulation and Product Approval” elsewhere in this “Business” section.

Our goal is to enroll 150 patients in this trial. The patient population for the trial will include patients undergoing non-emergency abdominal surgeries, including, appendectomies, hernias, colorectal surgeries and laparotomies, among others, and will exclude patient populations typically excluded from clinical trials involving abdominal surgery, as well as those abdominal surgery patients who are already receiving a systemic antibiotic for reasons other than the planned abdominal surgery.

Our proposed Phase 1/2 clinical trial protocol includes two arms, test (RUT58-60) and control (saline). All patients will receive the same pre-surgical systemic antibiotic, which is the current standard of care to prevent infections associated with abdominal surgery. Following the surgery, patients in both arms of the trial will receive a total of two

lavage washes in the abdominal cavity and a single rinse above the fascia, a layer of connective tissue that surrounds the abdominal cavity. The first and second lavages will consist of either RUT58-60 for patients in the test arm or saline for patients in the control arm. Saline is the most commonly used irrigation solution when lavage is used to wash the surgical site following abdominal surgery. Each lavage will consist of a total of 400 ml of RUT58-60 or saline, as applicable. The surgical site during the first lavage will be rinsed with RUT58-60 or saline. The surgical site during the second lavage will be exposed to RUT58-60 or saline for approximately three minutes. Finally, after the abdominal cavity is closed, patients will be rinsed once more (no extended exposure time) with 100 ml of RUT58-60 or saline, as applicable. Incisions will be closed after this final rinse.

In addition, in both arms of the trial, prior to each lavage and after the last lavage, a microbiological sample from each patient's peritoneal surface (parietal and visceral) will be obtained with a swab. The swab samples will be evaluated to identify the potential types and population of microorganisms present in the abdominal cavity prior to final closure of the surgical site. The data we obtain from the swabs are for our informational purposes only and are not clinical endpoints of the trial.

Patients in both arms of the trial will be evaluated for signs and symptoms of infection, in accordance with the guidelines published by the CDC on the day of the surgery (day zero), day 1, day 14 and day 28. The CDC guidelines for surgical infection include evaluation of antibiotic prophylaxis, microbiologic culture, clinical signs and symptoms, concomitant therapy and medication and adverse events. We believe the results of our Phase 1/2 clinical trial will demonstrate that RUT58-60 is as safe and tolerable as the saline control arm in reducing and preventing the number of infections contracted by patients following abdominal surgery.

Development History of RUT58-60

In October 2011, Mr. Alimi, Oculus' then-Chief Executive Officer and currently our Chief Executive Officer, authorized and directed Oculus to engage an external drug development consultant to assist an internal working group formed to focus on pursuing new strategies. In February 2012, the Oculus research and development group prepared a series of alternative formulations to Oculus' existing HOCl based formulations, some of which formed the understanding and basis of the potential drug candidate, RUT58-60. In July 2012, a potential conceptual formulation, called RD-4, among three other formulations designed for invasive applications including surgical, was also identified. In November 2012, the Oculus board concluded that the interest in pursuing invasive surgical applications for the then-to-be-formed subsidiary Ruthigen was the most attractive, because it would best leverage the body of knowledge and intellectual property for HOCl based applications that Oculus had accumulated to date. The Oculus board further concluded that the focus on invasive surgical applications would involve significant future research and development and clinical and commercial expenditures, as well as a longer term plan that would require a separate cost center and additional financing, separate and apart from Oculus' existing HOCl business. In December 2012, Oculus disclosed new HOCl based formulations to its intellectual property counsel, which formulations formed the basis for the current RUT58-60 formulation. The formulation, discovery and development activities directed by an Oculus internal working group resulted in the technology for a new class of products, the first of which was ultimately conceived as RUT58-60 in January 2013, at which time the operations of the internal working group were formally separated into Ruthigen. Through the license and supply agreement we entered into with Oculus, we have obtained exclusive rights to the technology that resulted from the efforts of the internal working group, including the RUT58-60 technology, as well as a proprietary method of manufacturing and producing HOCl with pharmaceutical potential by incorporating additional small molecules without sodium hypochlorite, the result of which increases the compound's stability and biocompatibility.

Research and Development Pipeline

Since our inception, we have focused much of our research and development efforts for RUT58-60 on pre-clinical development and optimization. Our research and development team is working to further optimize the performance of RUT58-60 by testing variations in the formulation and chemical components of RUT58-60. We also seek to further optimize the proprietary chemical formulation and manufacturing process that gives us reason to believe that RUT58-60 may be able to be used invasively. Since our inception, we have collaborated with research and development personnel and resources from Oculus to develop RUT58-60. In order to pursue our goal of building a robust pipeline of HOCl based drugs for invasive use, we expect to continue to leverage research and development resources and personnel from Oculus in the near term and engage in limited research and development hiring as we begin testing RUT58-60 in our planned clinical trials. Pending the results of our planned clinical trials, we expect to increase our research and development hiring in order to broaden our pipeline of applications for RUT58-60 beyond its initial use in abdominal surgery and into other types of surgeries and invasive applications.

Since our inception, we have focused our research and development activities primarily in two areas:

First, following the discovery of the proprietary chemical formulation and manufacturing process that formed the basis for RUT58-60, we have focused on identifying additional surgical procedures for RUT58-60, beyond the initial indication for use in the prevention of infection associated with abdominal surgery. We evaluate and prioritize additional surgical procedures based on the likelihood of the patient contracting a post-surgical infection in a certain type of surgery, the length of the post-surgical hospital stay and the potential to shorten the stay with RUT58-60, the likelihood of patient readmission following discharge due to having contracted a post-surgical infection and general feedback from surgeons regarding the anticipated clinical impact of a product such as RUT58-60 being used following other types of surgical procedures. Based on our initial research and development, following abdominal surgery, we are evaluating the use of RUT58-60 to prevent or treat infection following orthopedic knee replacement surgery; coronary artery bypass graft; cardiovascular prosthetic vascular graft; hysterectomy; orthopedic hip replacement surgery; nephrectomy and prostatectomy.

Second, in order to ensure the safety and efficacy of RUT58-60 in additional surgical procedures, we expect that RUT58-60 will require additional formulation optimization and changes depending on each type of surgical procedure. For example, during open heart surgery, RUT58-60 or a derivation of it that we develop for cardiovascular surgery, must show safety when interacting with cardiac electrical impulses, which RUT58-60 was not designed to address in the initial abdominal surgery indication. We expect these surgery-specific derivations of RUT58-60 will give rise to additional intellectual property, may require us to generate additional clinical data in support of their use and will likely result in separately branded products.

One of the many reasons that we have chosen to pursue the use of RUT58-60 initially in abdominal surgery is because of the high-impact opportunity that abdominal surgery offers us in the clinical trial setting to expose multiple internal organs to RUT58-60 at one time. By exposing multiple organs to RUT58-60 at one time, we expect to be able to leverage our findings to drive our selection of additional surgical indications for RUT58-60, or derivations of it that we develop. In addition, as our clinical experience with RUT58-60 for use in the abdominal surgery indication increases through our Phase 1/2 clinical trial, we are hopeful that we will be able to leverage the results and data from our toxicity, animal and other studies performed for the abdominal surgery indication into other additional indications. If we are successful, we believe that we may be able to move directly into pivotal clinical trials for certain of these additional surgical indications and if so, our regulatory timelines may be accelerated. The timing of our research and development activities for indications beyond RUT58-60 in abdominal surgery will depend on the successful completion of our clinical program for RUT58-60, availability of funding and resources for earlier-stage development programs, feedback and guidance from the FDA and other regulatory agencies, market demand, and general market conditions.

Our Collaboration with Oculus

We have licensed the intellectual property rights underlying the newly discovered RUT58-60 from Oculus pursuant to a license and supply agreement with Oculus, the terms of which are described below.

License and Supply Agreement

We have entered into a license and supply agreement with Oculus, pursuant to which Oculus has agreed to exclusively license certain of its proprietary technology to us to enable our research, development and commercialization of newly discovered RUT58-60 and any improvements to it, or the "Product," in the United States, Canada, the European Union and Japan, or collectively, the "Territory," in certain invasive uses in humans, or the "Field," which do not include dermatologic uses or uses for ophthalmic, sinusitis or otic indications. Oculus will be prohibited from using the licensed proprietary technology to sell products that compete with our products within the Territory, and we cannot sell any device or product that competes with Oculus products being sold or developed as of the effective date of the license and supply agreement.

Under the agreement, our right to commercialize the Product in the Field in the Territory is exclusive and shall be performed in accordance with the development and commercialization plan set forth in the agreement (which may be modified by us in our discretion), and Oculus shall manufacture and supply to us, at a purchase price equal to 20% over the cost of goods to Oculus, the Product as and when we request. In addition, under the license and supply agreement, we have the right to purchase from Oculus the manufacturing equipment required to make RUT58-60 at a purchase price equal to Oculus' cost of goods plus 20%.

Under the license and supply agreement, we will be required to make a total of $8 million of milestone payments over the next several years to Oculus for our first Product only, as follows: $1.5 million upon completion of last patient enrollment in our Phase 1/2 clinical trial; $1.5 million upon completion of last patient enrollment in our first pivotal clinical trial; $3 million upon completion of our first meeting with the FDA following completion of our first pivotal clinical trial; and $2 million upon first patient enrollment in our second pivotal clinical trial. In addition, as further consideration under the agreement, we will be required to make royalty payments to Oculus based on our annual net sales of the Product from the date of first commercial sale to the date that we cease to commercialize the Product, which percentage royalty rate will vary between 3% and 20% and will increase based on various net sales thresholds and will differ depending on the country in which the sales are made.

The agreement contains representations and warranties of the parties regarding its enforceability, no conflict with agreements to which the parties are bound, and no violations of law, and representations of Oculus that it has not granted any other license with respect to the Product for use in the Field in the Territory. We have agreed to indemnify Oculus with respect to third party claims arising from our development, commercialization or manufacture of the Product in the Field in the Territory with certain exceptions, and we have each agreed to indemnify the other with respect to third party claims arising from our respective inaccuracy and/or breach of representations and warranties or negligence or willful misconduct. Either party may terminate the agreement for an uncured material breach, but only after undergoing a dispute resolution process. In addition, either party may terminate the agreement if the other party ceases to do business, makes an assignment for the benefit of creditors or voluntarily files, fails to contest an involuntary filing or is adjudicated bankrupt or insolvent under bankruptcy, insolvency, receivership or similar law.

Shared Services Agreement

We have entered into a shared services agreement with Oculus, pursuant to which Oculus will provide us with general services, including general accounting and human resources, until the termination of the agreement (as described below). Oculus has also agreed to provide us with consulting and technical services. We shall pay Oculus for such consulting and technical services at the hourly or fixed monthly rate set forth in the shared services agreement, which is subject to change based upon mutual written agreement between Oculus and us. We pay invoices generated by Oculus within thirty days of receipt thereof. All such general, consulting and technical services shall be performed by Oculus' internal staff and such services shall be rendered in a manner generally consistent with Oculus' own business practices.

In addition to the general, consulting and technical services, Oculus has agreed to provide us with certain standard activities on a billable basis at the rates set forth in the shared services agreement through the 180-day period following the completion of our IPO. The standard activities include the transfer of protocols, procedures and standard operating procedures directly or indirectly related to methods of manufacturing, all procedures for building manufacturing equipment and the certain training of our employees including for test methods, manufacturing and manufacturing transfer. Additionally, Oculus will permit us to access its Petaluma, California and Seattle, Washington facilities during normal business hours (subject to certain exceptions) and for the purposes described in the shared services agreement.

Further, Oculus shall make available to us their laboratories and/or cause to make available the laboratory personnel of Micromed Laboratories, Inc., or Micromed, a wholly owned subsidiary of Oculus, for the purpose of stability testing and other testing required for pre-clinical development and development under the license and supply agreement. Oculus shall provide us with an estimated cost similar to the estimate customarily given to other Oculus/Micromed customers in advance of completing the work. The fees for such tests conducted by Micromed shall be the same as those Micromed charges its current clients for the same services and we shall receive the same pricing offered to Micromed's other clients. In addition, if we request services that will require the use of outside resources and/or materials, Oculus shall provide an estimate of costs for such services, without a mark-up or commission. During the period prior to the completion of our IPO, certain fees in accordance with the shared services agreement were charged to an Oculus investment account and will not be payable by us. With our IPO completed, we will pay invoices generated by Oculus within thirty (30) days of receipt thereof. We will not reimburse expenses except where preapproved in writing.

The shared services agreement may be terminated upon the mutual written agreement of the parties or upon thirty days written notice by either party, provided, however, that Oculus may not provide thirty days written notice before the six-month anniversary of the completion of our IPO. In addition, the shared services agreement may be terminated by the non-defaulting party upon or after the occurrence of a material breach by the other party that is uncured within thirty days after receipt of written notification of such breach, subject to a dispute resolution process. If such breach is not correctable within thirty days, the correction must be initiated within thirty days and thereafter diligently pursued thereafter. Lastly, the shared services agreement may be terminated if either we or Oculus go into liquidation and a

receiver or trustee for the property or estate of either us or Oculus is not removed within 120 days.

We shall indemnify, defend and hold Oculus harmless for any third party loss alleged against Oculus as a result of our gross negligence or willful misconduct or our breach of the warranties contained in the shared services agreement, and for any property damage or personal injury to the extent caused by our use of Oculus' facilities. Oculus shall indemnify, defend and hold us harmless for any third party loss incurred by us as a result of Oculus' gross negligence, willful misconduct, or Oculus' breach of its warranties contained in the shared services agreement.

Separation Agreement

Effectiveness and Term — On August 2, 2013, we entered into a separation agreement with Oculus, or the separation agreement, that contains key provisions relating to our ongoing relationship with Oculus and, more specifically governs our relationship with Oculus now that we have completed our IPO. On January 31, 2014, we amended and restated the separation agreement with Oculus. Because Oculus continues to hold a substantial portion of our common stock, at least initially, following our IPO, the separation agreement contains certain limitations on Oculus' ability to control various aspects of our business and operations in order for us to operate as independently as possible from Oculus to unlock the value proposition of RUT58-60, which we expect to result in financial gain to us and Oculus, if we are successful. The separation agreement took effect upon the closing of our IPO and terminates 8.5 years following the closing of our IPO, unless the parties mutually agree to terminate it earlier, and, as a general matter, most of the material restrictions and obligations contained in the separation agreement lapse when Oculus and its subsidiaries (other than Ruthigen) own less than 19.9%, or the ownership threshold for purposes of the agreement, of the outstanding shares of our common stock.

Voting — Oculus has agreed that, subject to the ownership threshold, Oculus shall vote or consent all of the Ruthigen shares Oculus owns in the same manner as the majority of the minority holders of our common stock (non-Oculus holders).

Expense Allocation and Reimbursement — The separation agreement sets forth the methodology for the allocation of the operational and IPO related expenses incurred prior to and in connection with our IPO for which we are required to reimburse Oculus. We will also reimburse Oculus for expenses such as salaries and benefits advanced or paid on our behalf or for our benefit during a transition period which began upon the closing of our IPO.

Marketing and Transfer Restrictions — In order for the parties to control the flow of the Ruthigen shares held by Oculus into the market to attempt to minimize price volatility and instability in the trading market for our shares, the separation agreement contains a series of restrictions on Oculus' ability to transfer the Ruthigen shares Oculus owns. As a general matter, transfers of the Ruthigen shares Oculus owns are primarily expected to be conducted through private marketing efforts in private placement transactions, except in the cases prescribed in the separation agreement. For example, Oculus is restricted from engaging in marketing efforts related to the transfer of the Ruthigen shares it owns and is required to refer indications of interest from third parties regarding the transfer of the Ruthigen shares it owns to us, in each case, except during certain prescribed periods set forth in the separation agreement. With respect to transfer restrictions, Oculus is restricted from transferring any of the Ruthigen shares it owns during the initial one-year lock up period that began immediately following our IPO unless Oculus obtains the consent of our board of directors and the lead underwriter in our IPO. Following the one-year lock up period, transfers by Oculus of the Ruthigen shares it owns must be conducted with the consent of our board of directors or within the prescribed requirements for such transfers set forth in the separation agreement. These prescribed requirements include that the transfers must be in private placement transactions, that the purchase price discount may not exceed 15% or 20% of the prevailing market price depending on the type of transferee, the amount of shares transferred in a given transfer (or series of transfers comprising a single transaction) may not exceed the greater of 5% of our outstanding shares or $1,500,000 in net proceeds to Oculus, as well as certain other requirements set forth in the separation agreement. We have also agreed to assist Oculus in consummating transfers of the Ruthigen shares it owns, because we expect to be well-informed as to where the investor demand for our shares resides and we believe our involvement may be beneficial to Oculus and the trading market for our shares. In addition to the prescribed manner for Oculus to conduct transfers described above, if, following a minimum of 41.5 months following the closing of our IPO, Oculus has not consummated transfers of the Ruthigen shares it owns resulting in at least $3.8 million in net proceeds to Oculus, then Oculus has a one-time transfer and registration right to transfer the Ruthigen shares it owns in an amount equal to the difference between $3.8 million and the net proceeds received by Oculus resulting from transfers of the Ruthigen shares it owns as of the time Oculus elects to exercise its one-time right. Transfers conducted using this one-time right must be conducted with the consent of our board of directors or within the prescribed requirements for such transfers set forth in the separation agreement, including, for example, that the purchase price discount may not exceed 30% of the prevailing market price, the amount of shares transferred may not exceed $3,800,000 in net proceeds to Oculus, as well as certain other requirements set forth in the separation agreement. The separation agreement also provides for certain cooling off periods between marketing attempts and/or successful transfers, the length of which are dependent upon whether and how many Ruthigen shares Oculus transfers.

Distribution — We believe that a distribution of Ruthigen shares by Oculus to Oculus stockholders would be advantageous to the market for our shares by increasing liquidity, would accelerate our ability to become independent from Oculus by decreasing Oculus' ownership of our common stock and would be beneficial for Oculus' stockholders who would have a direct opportunity to participate in the Ruthigen value proposition. The decision to conduct any such distribution is at the sole discretion of Oculus' board of directors and would be subject to the expiration of any applicable lock-up periods and other agreements we have or may have with Oculus. There is no assurance that a distribution will ever occur. However, pursuant to the separation agreement, Oculus has agreed, from time to time, to retain investment bankers and tax advisors to re-evaluate the advisability of conducting a plan of distribution of the Ruthigen shares Oculus owns and we have agreed to register any shares that Oculus may distribute in the future.

Registration Rights — The separation agreement provides Oculus with certain "piggy back" registration rights of up to 30% of the value of the securities we register after the lock-up period, if we propose to register any of our common stock now that our IPO has been completed, subject to certain conditions and limitations. In addition, following transfers by Oculus of the Ruthigen shares, Oculus has certain demand registration rights requiring us to register all of the Ruthigen shares Oculus has transferred. In addition, as described under "*Marketing and Transfer Restrictions*" above, if, following a minimum of 41.5 months following the closing of our recently completed IPO have lapsed under the separation agreement and Oculus has not consummated transfers of the Ruthigen shares it owns resulting in at least $3.8 million in net proceeds to Oculus, then Oculus has a one-time transfer and registration right that requires us, subject to certain conditions and limitations, to register the difference between $3.8 million and the Ruthigen shares transferred by Oculus pursuant to the separation agreement as of the time Oculus elects to exercise its one-time right.

Standstill — Oculus has agreed that, subject to the ownership threshold, Oculus shall not, and shall not act in concert with any person to, make or participate in a solicitation of proxies or powers of attorney or similar rights to vote any of the Ruthigen shares Oculus owns or to deposit the Ruthigen shares Oculus owns in a voting trust.

Restrictions Relating to Debt — Oculus has agreed that, subject to the ownership threshold, Oculus shall disclose in writing the existence of the transfer and other restrictions involving the Ruthigen shares Oculus owns, which are set forth in the separation agreement, to potential lenders in the context of Oculus negotiating to incur debt in the future, where such debt would be collateralized by the Ruthigen shares Oculus owns.

Equity Plan, Oculus Equity and Corporate Governance — We and Oculus agreed on the terms of our equity incentive plan, including the formula for the number of shares reserved under the plan, the vesting schedule of awards under the plan, timing, size and award type of the initial grants which we made following the closing of our IPO, and the formula for the evergreen refresh provision and other share caps on certain types of awards and future equity plans. The separation agreement clarifies that options for common stock of Oculus held by employees and directors of Ruthigen shall continue to vest as long as the individuals continue in service to Ruthigen. In addition, the separation agreement provides that our restated certificate of incorporation and bylaws for purposes of operating as a public company will contain provisions for a staggered board of directors and plurality voting for the election of directors.

Indemnification — The separation agreement provides that each party will indemnify, defend and hold harmless the other party and its affiliates for third party claims asserted against the other party.

Directors' and Officers' Insurance — The separation agreement provides that, so long as Oculus shall as Oculus maintains a directors' and officers' insurance program covering the past and present officers and directors of Oculus, the program shall be standard in Oculus' industry and if there is a change to the program, then Oculus shall provide prior notice. In addition, Oculus has agreed not to exclude any former Oculus director from any insurance policy coverage if such coverage is made available to Oculus' then existing directors and officers.

Miscellaneous — The separation agreement also contains customary provisions regarding confidentiality, access to information, books and records, dispute resolution and the release of claims that pre-date the effective date of the separation agreement.

Intellectual Property

The proprietary nature of, and protection for, our drug candidates and our discovery programs, processes and know-how are important to our business. Oculus has sought patent protection in the United States and internationally for its topical HOCl based inventions and we intend to do the same for our discovery programs, and any other inventions we make, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to our business. We also rely on trade secrets to protect our proprietary discoveries.

Our commercial success will depend in part on the ability of us and Oculus to obtain and maintain patent protection and trade secret protection of our current and future drug candidates and the innovative methods used to develop and manufacture them, as well as to successfully defend these patent and trade secret rights against potential competitors. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of Oculus' pending patent applications or with respect to any patent applications filed by us, Oculus or other licensors in the future, nor can we be sure that any of Oculus' existing patents or any patents that may be granted to us, Oculus or other licensors in the future will be commercially useful in protecting our product candidates, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors — Risks Relating to Our Intellectual Property."

The intellectual property rights upon which we rely to operate our business derive from our collaboration with Oculus and more specifically, through our license and supply agreement with Oculus, the terms of which are described in "Our Collaboration with Oculus" elsewhere in this "Business" section.

Through our license and supply agreement with Oculus, we have exclusive rights to certain of Oculus' patents and know-how to develop and market specified products within the territory and field described in the agreement. Oculus' patent portfolio generally relates to oxidative reductive potential water including, for example, formulations, apparatuses, methods of use and processes for producing. As of June 15, 2014, the patent portfolio owned or licensed by Oculus includes 5 issued U.S. patents, 36 issued foreign patents, 16 pending U.S. patent applications and 77 pending foreign patent applications. In general, the issued U.S. and foreign patents expire in 2020 – 2027. The expiration dates of pending U.S. and foreign patent application will be from 2020 – 2027 in the event that such applications issue. Several of these patents relate to the innovative HOCl formulation and manufacturing process that formed the basis for RUT58-60, which we have licensed from Oculus. These patents and pending applications (if issued) will expire in 2027 – 2034.

Manufacturing

Since our inception, RUT58-60 has been manufactured for us by Oculus in its Petaluma, California manufacturing facility. We expect that Oculus will continue to manufacture RUT58-60 for us through our Phase 1/2 clinical trial. We believe that leveraging Oculus' existing manufacturing facility and capabilities, in the immediate term, is the most efficient and rapid way for us to advance RUT58-60 through the initial Phase 1/2 clinical trial. We believe that we will have access, through Oculus, to a sufficient number of machines to produce an adequate amount of RUT58-60 to meet our anticipated clinical development and clinical trial requirements for our Phase 1/2 clinical trial. Prior to the commencement of our Phase 2B pivotal clinical trial, we plan to secure alternative manufacturing capabilities through a third party contract manufacturing organization, or CMO, that complies with the FDA's cGMP requirements for manufacturing sterile drugs. Our ability to transfer our manufacturing from Oculus to a CMO is dependent on our ability to identify and establish a relationship with a CMO, acquire and transfer technology and know-how, assist the CMO to pass regulatory inspections and gain necessary certifications and clearances, and continue to work with the CMO to maintain a compliant manufacturing facility. We may elect to establish an independent manufacturing facility to conduct our Phase 3 clinical trial and, if the drug is approved, for our initial commercial supplies. In order to establish in-house manufacturing facility, we would be required to transfer manufacturing processes, acquire manufacturing equipment, and transfer know-how as required to satisfy various regulatory requirements. Our license and supply agreement with Oculus provides us with exclusive access to the many issued patents and pending applications (both U.S. and foreign), which are owned by Oculus, that cover proprietary manufacturing processes for HOCl based products.

RUT58-60 is manufactured using a proprietary process in which the creation of HOCl is controlled through uniquely developed chemical processing apparatuses that yield HOCl in a stable form. The resulting formulation can be further sterilized including its final packaging to make it suitable for use in the surgical suite. To date, we are not aware of any sterile forms of HOCl approved for invasive use in the surgical suite in the United States or elsewhere. RUT58-60 will be manufactured under cGMP conditions and will be subject to the standard sterilization processes required by FDA for drugs intended for invasive use. This final critical step in the manufacturing of RUT58-60 is designed to prevent the potential for the introduction of infectious agents related to the packaging material when the drug is used in sterile surgical suites. In laboratory studies for RUT58-60, we have demonstrated that RUT58-60's stability withstands the conditions associated with the sterilization processes.

The quality assurance methods for our production batch of RUT58-60 in accordance with cGMP. The Oculus facility that manufactures RUT58-60 is required to meet and maintain regulatory standards applicable to the manufacture of clinical-grade pharmaceutical products; and is certified and complies with cGMP medical device Quality Systems Regulation or QSR, and International Organization for Standardization, or ISO, guidelines. In addition, the machines used to manufacture RUT58-60 regularly undergo testing as part of a qualification protocol mandated by cGMP, QSR and ISO requirements. This qualification is designed to ensure that the final product is consistently manufactured in accordance with product specifications at all manufacturing sites. Certain of the materials and components used in manufacturing are proprietary and are covered by our license and supply agreement with Oculus.

Sales and Marketing/Commercialization

Our lead drug candidate, RUT58-60, as well as the other product candidates we plan to develop in the future, are primarily intended to address a variety of invasive, anti-infective market segments, some of which are large healthcare markets. We do not currently have a commercialization organization capable of marketing, selling and distributing RUT58-60. We have commenced discussions and may establish partnerships with pharmaceutical, biotechnology and other organizations that have the existing organization experience and resources to bring our initial, and potentially future, product candidates to market. In some cases, we may collaborate with third parties during the development stage of a product candidate to further benefit from their financial support as well as clinical development, regulatory, market research, pre-marketing and other expertise. For commercialization outside of the United States, we may enter into joint ventures, license arrangements or distribution agreements, as appropriate, depending on the particular requirements of the market and the potential partner’s core competencies to assist us with such requirements. Pending FDA approval of our products, we may establish or contract with a specialty sales force with expertise in marketing and selling HOCl based anti-infectives to various healthcare markets. We may also establish or contract for other complementary capabilities related to marketing and selling our potential pharmaceutical products.

Competition

We believe the principal competitive factors in our target market include improved patient outcomes, such as time in the hospital, healing time, adverse events, and safety of products; ease of use; stability; eliminating the emergence of resistant pathogens; and, cost effectiveness. The anti-infective pharmaceutical and biotechnology industries are highly competitive. We compete with a number of large well-established and well-funded companies that sell a broad range of products, including topical anti-infectives and antibiotics; prescription products for the prevention and treatment of infections; advanced technologies, such as skin substitutes, growth factors and sophisticated delayed release silver based dressings; and other anti-infective products used in the hospital settings. We potentially may compete with academic, government and other private and public research institutes and organizations in the discovery and development of innovative anti-infective compounds and solutions. Our competitors may discover, develop, or license technologies that are more effective, have an improved safety or tolerability profile, or a more cost effective than RUT58-60 or any future product candidate we may discover, develop or license. These competitive product candidates may render our product candidates obsolete or non-competitive. Currently, we believe no single anti-infective product dominates the surgical or traumatic injury markets because many of the products: have limitations to product stability and ease of use; are not broad spectrum covering all gram negative and gram positive bacteria; induce resistance in pathogens, specifically bacteria; have known systemic side effects; rely principally on the treatment of already infected patients or may not be cost effective for hospitals.

While many companies are able to produce HOCl based products, we believe these products are not and may not ever be designed to meet the same rigorous product stability targets for RUT58-60, have not made the scientific enhancement and advances to produce formulations to withstand sterilization and are not formulated for use with internal organs and tissue exposure during surgery. We recognize three companies in the United States and/or Europe that produce HOCl products intended for medical applications; these companies are:

- Oculus, our licensor with which we have non-compete and licensing agreements designed to protect both companies' ability to develop and commercialize products in our respective fields and territories;

- PuriCore, a company whose core revenue is focused on developing and selling a form of HOCl for topical use and the other major uses of their products include sterilization of endoscopes; and

- NovaBay, a company which is developing HOCl products for ophthalmology and wound care.

Through our license and supply agreement with Oculus that took effect upon the completion of our IPO, we believe we will control the use of HOCl technologies for invasive applications, including the prevention of infections associated with surgery and traumatic procedures, throughout the territory identified in the agreement.

Notable societies, including IDSA and WHO, have issued public statements expressing concern over the limited number of new antibiotic approvals and drugs under development, specifically in regards to the management of drug-resistant pathogens. Amidst these calls-to-action and additional physician interest in innovative and novel antibiotic therapies, we expect the field of biotechnology and pharmaceutical companies that market or are developing antibiotic therapies to grow. Notably, in July 2012, the Food and Drug Administration Safety and Innovation Act, or FDASIA, was passed, which included the Generating Antibiotics Incentives Now Act, or GAIN Act. The GAIN Act is intended to provide incentives for the development of new, qualified infectious disease products. These incentives may result in more competition in the market for new antibiotics, and may cause pharmaceutical and biotechnology companies to shift their efforts towards the development of products that could be competitive with RUT58-60 and any of our future potential product candidates.

Protocols for the prevention of infection prior to surgery vary from hospital to hospital and to a lesser degree from surgeon to surgeon. Several common techniques described in medical literature include the prophylactic use of systemic broad-spectrum antibiotics, which historically has been considered a standard of care by many physicians, antiseptics used to sterilize an incision site, saline or saline plus active lavage of the surgical site, diagnostic testing to identify bacterial colonizations and to assess an individual’s risk of infection, and general improvements to protocols used by personnel within the surgical suite. Despite these efforts, post-surgical infections remain a significant unmet medical need and many companies have commercialized or are developing antibiotics to address this growing concern. These companies include:

- Cubist Pharmaceuticals is developing CXA-201, which is a broad-spectrum antibiotic cocktail that incorporates cephtolozane/tazobactum/metronidazole for intra-abdominal infections.

- Forest Laboratories & Astra Zeneca are developing CAZ-104, which is a broad-spectrum antibiotic cocktail that incorporates cephtazidine/avibactum/metronidazole for intra-abdominal infections.

- Tetraphase Pharmaceuticals is developing eravacycline, which is a broad-spectrum antibiotic for intra-abdominal infections.

- Other notable companies developing antibiotic therapies include: Achaogen, Basilea, Cempra, Durata Therapeutics, GlakoSmithKline, Merck, Paratek, Rempex, Rib-X, and Trius.

- Select major broad spectrum antibiotic drugs include: Levaquin (JNJ/Generic), Zosyn (generic), Meerem (Astra Zeneca/generic), Primaxin (Merck/generic), Tygacil (Pfizer), Augmentin (generic), Metronidazole in combinations (Forest Laboratories, Astra Seneca, Cubist), Cephalosporin (generic), Doribax (JNJ), Avelox (Bayer), and Invanz (Merck).

Some of our competitors producing antibiotics enjoy several competitive advantages over us, including: significantly greater name recognition; established relationships with healthcare professionals, patients and third party payors; established distribution networks; additional product lines and the ability to offer rebates or bundle products to offer discounts or incentives; greater experience in conducting research and development, manufacturing, obtaining regulatory approval for products and marketing; and greater financial and human resources for product development, sales and marketing and patient support.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the European Medicines Agency, or EMA, through the Marketing Authorization Application, or MAA, process before they may be legally marketed in Europe. Our product candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters;
- product seizures;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement, or civil or criminal penalties.

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

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices, or GLP, or other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCP, and other applicable requirements to establish the safety and efficacy of the proposed drug for its intended use;

- submission to the FDA of an NDA;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and

- FDA review and approval of the NDA.

As part of the IND, an IND sponsor must submit to the FDA the results of preclinical tests, which may include laboratory evaluations and animal studies, together with manufacturing information and analytical data, and the proposed clinical protocol for the first Phase of the clinical trial of the drug. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a "clinical hold" because of safety concerns or perceived procedural deficiencies. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials may begin. A clinical hold may be imposed by the FDA at any time during the life of an IND, and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, must also review and approve each new clinical protocol and patient informed consent form prior to commencement of the corresponding clinical trial at each institution where a trial is to be performed.

Human clinical trials are typically conducted in three sequential Phases that may overlap or be combined:

- *Phase 1*: The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase 2*: Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- *Phase 3*: Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the end-of-Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

If a drug is intended to treat a serious or life threatening condition for which there is an unmet medical need, a company may request that the FDA consider the drug for a fast track development program at the time of submitting its IND or at any time prior to receiving marketing approval. The fast track program is designed to facilitate the development and expedite the review of a new drug for the treatment of specific conditions. If the FDA agrees that the drug meets the criteria for fast track development for treatment of one or more conditions, it will grant fast track status.

United States Drug Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth and substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may seek advice and a recommendation from an external advisory committee as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require submission of additional clinical or other data and information which, upon agency review and interpretation, may or may not be deemed by the FDA to satisfy the criteria for approval. The FDA may also issue a “complete response” letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA.

NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

In the recently enacted FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law requires the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes.

If approved by the FDA, the product's use may be limited to specific diseases, dosages or indications. In addition, the FDA may require us to conduct additional testing post-approval, which may involve further nonclinical studies or clinical trials designed to further assess the drug's safety and effectiveness and may require additional testing and surveillance programs to monitor the safety of the drug in the marketplace.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our product candidates, a U.S. patent we own or license from Oculus may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active pharmaceutical ingredient. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, or BPCA, certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA, or a Written Request, relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA’s filing requirements.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, Biologics License Applications, or BLA, and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe

and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

As part of the FDASIA, Congress made a few revisions to BPCA and PREA, which were slated to expire on September 30, 2012, and made both laws permanent.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and obtaining its approval of specified manufacturing or labeling changes; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Reimbursement

Sales of our product candidates, if approved, will depend, in part, on the extent to which surgeons believe that the use of our products will lead to fewer post-surgical infections and hospitals and other institutions at which surgical procedures are performed believe that the use of our products will result in cost savings to them. The costs of most drugs used during surgical procedures are typically included in the cost of the procedure and are not reimbursed as separate expenses by third-party payors, such as government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The containment of healthcare costs has become a priority for federal and state governments, and decreasing infections following surgery, accelerating patient discharge from hospitals following surgery and reducing hospital readmissions have been primary targets in this effort.

We expect that there will continue to be a number of federal and state proposals to limit the growth of healthcare costs, including the cost of surgical procedures and hospital stays. The adoption of other legislative or regulatory proposals could have a material adverse effect on our business, financial condition and profitability.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Other United States Regulations

Pharmaceutical companies also are subject to various federal and state laws pertaining to healthcare "fraud and abuse," including anti-kickback laws and false claims laws, and the reporting of payments to physicians and teaching hospitals.

Anti-Kickback Laws

U.S. federal laws prohibit fraud and abuse involving state and federal healthcare programs, such as Medicare and Medicaid. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including the Centers for Medicare & Medicaid Services, or CMS, the Department of Justice, the Office of Inspector General for the Department of Health and Human Services and various state agencies. These anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by a federal healthcare program. Remuneration is broadly defined to include anything of value, such as, cash payments, gifts or gift certificates, discounts, or the furnishing of services, supplies or equipment. The anti-kickback laws are broad and prohibit many arrangements and practices that are lawful in businesses outside of the healthcare industry.

The penalties for violating the anti-kickback laws can be severe. The sanctions include criminal and civil penalties, and possible exclusion from the federal healthcare programs. Many states have adopted laws similar to the federal anti-kickback laws, and some apply to items and services reimbursable by any payor, including third-party payors.

State and Federal Prohibitions on False Claims

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. Under the False Claims Act, a person acts knowingly if he has actual knowledge of the information or acts in deliberate ignorance or in reckless disregard of the truth or falsity of the information. Specific intent to defraud is not required. Provisions of the False Claims Act allow a private individual to bring an action on behalf of the federal government and to share in any amounts paid by the defendant to the government in connection with the action. The number of filings under these provisions has increased significantly in recent years. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each false claim. Conduct that violates the False Claims Act may also lead to exclusion from the federal healthcare programs. Given the number of claims likely to be at issue, potential damages under the False Claims Act for even a single inappropriate arrangement could be significant. In addition, various states have enacted similar laws modeled after the False Claims Act that apply to items and services reimbursed under Medicaid and other state healthcare programs, and, in several states, such laws apply to claims submitted to all payors.

Federal Prohibitions on Healthcare Fraud and False Statements Related to Healthcare Matters

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and state laws there are numerous regulations for protecting the privacy and security of protected health information. Additional administrative simplification provisions created the following new federal crimes: healthcare fraud, false statements relating to healthcare matters, theft or embezzlement in connection with a health benefit program and obstruction of criminal investigation of healthcare offenses. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including a private insurer. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. The theft or embezzlement statute prohibits knowingly and willfully embezzling, stealing or otherwise converting or misapplying the money or property of a healthcare benefit program. The obstruction of criminal investigations of healthcare offenses statute prohibits willfully preventing, obstructing, misleading or delaying the communication of information and records relating to a violation of a federal healthcare offense to a criminal investigator. A violation of any of these laws is a felony and may result in fines, or exclusion from the federal healthcare programs.

The Physician Payment Sunshine Act

The Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Patient Protection and Affordable Care Act, or ACA, requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Program, to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made by that entity, or by a third party as directed by that entity, to physicians and teaching hospitals, or to third parties on behalf of physicians or teaching hospitals, during the course of the preceding calendar year. The Final Rule implementing the Sunshine Act, published on February 8, 2013, requires data collection on payments to begin on August 1, 2013. The first annual report, comprised of data collected from August 1, 2013 to December 31, 2013, is due March 31, 2014. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1 million). We will be required to collect data on and report these payments.

Employees

As of June 15, 2014, we employed a total of six full-time employees and several part-time consultants and CROs, all of whom are based in the United States. In addition, we have access to certain of Oculus' employees and resources through the various agreements we have entered into with Oculus. We are not a party to any collective bargaining agreements. We believe our relations with our employees are good.

Company History and Available Information

We incorporated under the laws of the State of Nevada on January 18, 2013 as a wholly-owned subsidiary of Oculus Innovative Sciences, Inc. and we reincorporated from Nevada to Delaware on September 25, 2013. Our fiscal year end is March 31. Our principal executive offices are located at 2455 Bennett Valley Rd., Suite C116, Santa Rosa, California 95404. Our telephone number is (707) 525-9900. Our website address is *www.ruthigen.com*. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on the SEC's website at www.sec.gov and through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have

total annual gross revenues of $1 billion or more; (ii) March 31, 2019; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. References herein to “emerging growth company” shall have the meaning associated with it in the JOBS Act.

Item 1A. RISK FACTORS.

You should consider carefully the following risk factors, together with all of the other information included or incorporated in this report. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business

We are a development stage company with no commercial products.

We are developing RUT58-60, our lead drug candidate, initially for the prevention of infection associated with abdominal surgery. Currently, we have no product candidates in our clinical development pipeline other than RUT58-60 and have no products approved for sale. We submitted our IND for RUT58-60 to the FDA in early May 2014. In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60. We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. We have not yet begun human clinical trials, and therefore, we are still many years from beginning to commercialize and market RUT58-60 or any other product candidate, if ever. We expect the clinical development of RUT58-60 will require significant additional effort, resources, time, and expenses prior to seeking FDA approval. RUT58-60 is not expected to be commercially available in the United States or outside the United States for several years, if ever.

We are heavily dependent on the success of our lead drug candidate, RUT58-60, and we cannot provide any assurance that our lead drug candidate or other product candidates we may have in the future will be commercialized.

We intend to invest the vast majority of our time and financial resources in the development and commercialization of our lead drug candidate, RUT58-60, which is currently in clinical development. We submitted our IND for RUT58-60 to the FDA in early May 2014. In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60. We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. Our future success depends heavily on our ability to successfully develop, obtain regulatory approval for, and commercialize our lead drug candidate, which may never occur. We currently generate no revenues and incur substantial losses, and we may never be able to develop or commercialize a marketable drug.

Before we generate any revenues from product sales, we must complete preclinical studies and clinical trials for RUT58-60, establish manufacturing capabilities that comply with the FDA's cGMP requirements for manufacturing sterile drugs, receive approval from the FDA in the United States and other regulatory agencies in foreign jurisdictions, build a commercial organization, make substantial investments and undertake significant marketing efforts ourselves or in partnership with others. We will not be permitted to market or promote RUT58-60 or any other product candidates we may have in the future, before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our other product candidates.

We have not previously submitted a BLA or a NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate. We cannot be certain that our lead drug candidate or any other product candidate will be successful in clinical trials or receive regulatory approval. Further, our lead drug candidate or any other product candidate may not receive regulatory approval even if our clinical trials are successful. If we do not receive regulatory approvals for our lead drug candidate or any other product candidate, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our lead drug candidate or any other product candidate, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize RUT58-60 in the United States, Canada, Europe and Japan. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy, clinical trials and commercial sales, pricing and distribution of our lead drug candidate or any other product candidate, and we cannot predict success in these jurisdictions.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

RUT58-60 and any future product candidate that we pursue will be subject to extensive regulation by the FDA in the United States and other regulatory agencies in foreign jurisdictions, including activities related to preclinical studies, human clinical trials, manufacturing, labeling, packaging and sterilization, storage, recordkeeping, advertising, promotion, export, import, marketing and distribution and other possible activities.

Our lead drug candidate, RUT58-60, is a proprietary formulation of HOCl, and, we believe, it has unique features and properties that will differentiate it from other HOCl formulations that are marketed as topical products and regulated by the FDA as medical devices under 510(k) clearances. We expect to pursue FDA drug approval for RUT58-60 as a new chemical entity. There may be other HOCl drug candidates in development by other companies and these candidates may gain FDA drug approval prior to RUT58-60. We are conducting pre-clinical testing to support our IND for RUT58-60, and we have received feedback from the FDA to our proposed Phase 1/2 clinical trial protocol. Based on the feedback we received from the FDA, we submitted the IND for RUT58-60 to the FDA in early May 2014. In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60. We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. As we move through the regulatory process, the FDA may make other suggestions that may impact our ability to complete our clinical trials within the timeframe or budget that we are anticipating, which could impact investors' interest in our business and our stock price.

The results of preclinical studies and clinical trials of previously published HOCl based products may not necessarily be indicative of the results of our future clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of HOCl used historically in the industry and if those assumptions are incorrect, the trials may not produce statistically significant results. Preliminary results may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical trials. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if, or when, we may have an approved product for commercialization or whether we will ever achieve sales or profits of RUT58-60 or other product candidates we may pursue in the future.

We may be subject to extensive regulations and may not obtain marketing approvals for products in Europe and other jurisdictions.

In addition to regulations in the United States, should we or our collaborators pursue marketing approvals for RUT58-60 internationally, we and our collaborators will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or

not we, or our collaborators, obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country.

We expect to pursue marketing approvals for RUT58-60 in Europe and other jurisdictions outside the United States with collaborative partners. The time and process required to obtain regulatory approvals and reimbursement in Europe and other jurisdictions may be different from those in the United States regulatory and approval in one jurisdiction does not ensure approvals in any other jurisdiction; however, negative regulatory decisions in any jurisdiction may have a negative impact on the regulatory process in other jurisdictions.

If we, or our collaborators, fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

We have limited knowledge and experience with NDA studies and product applications and we may not be successful in obtaining FDA approvals for our lead drug candidate, RUT58-60.

Currently, we have no products approved for sale. We submitted our IND for RUT58-60 to the FDA in early May 2014. In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60. We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. Subject to successful completion of our Phase 1/2 clinical trial, we plan to conduct the pivotal clinical trials necessary to support an NDA filing with the FDA. However, we have not submitted an application for, or obtained any FDA approval for, any product through the NDA process. This lack of previous experience with NDA processes and requirements may impede our ability to obtain FDA approval in a timeframe consistent with our expectations and plans, or at all, for RUT58-60. Failure to comply with FDA and other applicable regulatory requirements, either before or after product approval, may subject us to sanctions, including: warning letters, deficiency notifications, application denials, approval denials, requirements for additional pre-clinical and/or clinical studies, civil and/or criminal penalties, injunctions or suspensions of production, black box warnings and other product label requirements, loss of product approvals, product seizures, or recalls.

If our products do not gain market acceptance, our business will suffer because we might not be able to fund future operations.

A number of factors may affect the market acceptance of our products 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 fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts.

If our products do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new product candidates and expanding our sales and marketing efforts for our approved products, which would cause our business to suffer.

Our research and development program for drug candidates other than RUT58-60 is at an early stage, and we cannot be certain our program will result in the commercialization of any drug.

Except for our development program for RUT58-60, our research and development program targeting non-infectious open surgery indications are at an early stage and, to date, we have not developed any other product candidates generated in our research program. Any product candidates we develop will require significant additional research and development efforts prior to commercial sale, including extensive pre-clinical and clinical testing and regulatory approval. This may require increases in spending on internal projects, the acquisition of third party technologies or products, and other types of investments. We cannot be sure that our approach to drug discovery, acting independently or with partners, will be effective or will result in the development of any drug. We cannot expect that any drug candidates that do result from our research and development efforts will be commercially available for many years.

We have limited experience in conducting pre-clinical testing and clinical trials. Even if we receive initially positive clinical trial results, those results will not mean that similar results will be obtained in the later stages of drug development. Our current lead drug candidate and all of our potential drug candidates are prone to the risks of failure

inherent in pharmaceutical product development, including the possibility that none of our drug candidates will be:

- safe, non-toxic and effective;
- approved by regulatory authorities;
- developed into a commercially viable drug;
- manufactured or produced economically;
- successfully marketed; or
- accepted widely by customers.

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We depend on Oculus to manufacture RUT58-60, and our development of RUT58-60 could be stopped or delayed, and our commercialization of RUT58-60, if and when RUT58-60 receives regulatory approval, could be stopped or delayed or made less profitable if third parties manufacturing RUT58-60 fail to provide us with sufficient quantities at acceptable prices.

The manufacture of biotechnology and pharmaceutical products is complex and requires significant expertise, capital investment, process controls and know-how. Common difficulties in biotechnology and pharmaceutical manufacturing may include: sourcing and producing raw materials, transferring technology from chemistry and development activities to production activities, validating initial production designs, scaling manufacturing techniques, improving costs and yields, establishing and maintaining quality controls and stability requirements, eliminating contaminations and operator errors, and maintaining compliance with regulatory requirements. We currently rely on Oculus to manufacture RUT58-60 for testing purposes and we have no independent experience in manufacturing and cannot assure you that any clinical-grade product will ever be produced or that we, Oculus or our other third party manufacturers on which we may rely in the future will maintain operations necessary to continue to produce clinical-grade product for us. We lack the facilities and personnel to manufacture products in accordance with cGMP prescribed by the FDA or to produce an adequate supply of compounds to meet future requirements for clinical trials and commercialization of RUT58-60. Drug manufacturing facilities are subject to inspection before the FDA will issue an approval to market a new drug product, and all of the manufacturers that we intend to use must adhere to the cGMP regulations prescribed by the FDA.

We have entered into a shared services agreement with Oculus that covers our manufacturing arrangement with Oculus. We are currently dependent on Oculus to manufacture RUT58-60, out of its Petaluma, California, facility for our preclinical studies and planned clinical trials and to prepare our products for shipping. If Oculus is unable to fulfill its obligations under the shared services agreement, we may not be able to develop and conduct the planned clinical trials for RUT58-60. We do not control the manufacturing processes of Oculus and are currently dependent on Oculus for the production of RUT58-60 in accordance with cGMP, which include, among other things, quality control, quality assurance and the maintenance of records and documentation.

We may choose, or be forced, to terminate our manufacturing arrangement with Oculus for the following reasons in an effort to gain direct control over manufacturing processes, or to manage costs associated with manufacturing:

- Oculus may not perform as agreed;
- Oculus may not be capable of producing or processing quantities of the drug candidate;
- Oculus may not be able to manufacture materials that conform to our specifications;

- Oculus may not be able to hire or retain the necessary employees; and

- Oculus may be unable to comply with these cGMP requirements and with FDA, state and foreign regulatory requirements, and may not pass regulatory inspections.

Manufacturers are periodically subject to inspections by various regulatory agencies, some of which may be unannounced. The FDA and other regulatory agencies have the ability to issue warning letters and sanctions against manufacturers based upon deficiencies noted during inspections of facilities or based upon material defects in the product label, design, production, or distribution. In addition, we have no control over the ability or willingness of our third party manufacturer to comply with regulatory requirements, maintain adequate quality controls and processes, or maintain qualified personnel. Loss of our third party manufacturer may adversely affect our ability to meet our requirements to conduct clinical trials, secure and maintain regulatory approvals, and meet commercialization targets that we may establish in the future.

Since our inception, RUT58-60 has been manufactured for us by Oculus in its Petaluma, California manufacturing facility. We expect that Oculus will continue to manufacture RUT58-60 for us through our Phase 1/2 clinical trial. We believe that leveraging Oculus' existing manufacturing facility and capabilities, in the immediate term, is the most efficient and rapid way for us to advance RUT58-60 through the initial Phase 1/2 clinical trial. We believe that we will have access, through Oculus, to a sufficient number of machines to produce an adequate amount of RUT58-60 to meet our anticipated clinical development and clinical trial requirements for our Phase 1/2 clinical trial. Prior to the commencement of our Phase 2B pivotal clinical trial, we plan to secure alternative manufacturing capabilities through a third party contract manufacturing organization (CMO) that complies with the FDA's cGMP requirements for manufacturing sterile drugs. Our ability to transfer our manufacturing from Oculus to a CMO is dependent on our ability to identify and establish a relationship with a CMO, acquire and transfer technology and know-how, assist the CMO to pass regulatory inspections and gain necessary certifications and clearances, and continue to work with the CMO to maintain a compliant manufacturing facility. We may elect to establish an independent manufacturing facility to conduct our Phase 3 clinical trial and, if the drug is approved, for our initial commercial supplies; however, we can give no assurances that we will be able to do so or to maintain a self-directed manufacturing facility. In order to establish an in-house manufacturing facility, we would be required to transfer manufacturing processes, acquire manufacturing equipment, and transfer know-how as required to satisfy various regulatory requirements. We can offer no assurances that we would be able to enter into any definitive agreements on acceptable terms for the expanded development and commercial scale manufacturing of RUT58-60 with any other third party manufacturers or establish an independent manufacturing facility. Any supply disruptions may cause significant delays in clinical trials and negatively impact commercial efforts, which may have an adverse effect on the value of our securities.

Oculus, we and/or our third party manufacturers may be adversely affected by developments outside of our control, and these developments may delay or prevent further manufacturing of our products. Adverse developments may include labor disputes, resource constraints, shipment delays, inventory shortages, lot failures, unexpected sources of contamination, lawsuits related to our manufacturing techniques, equipment used during manufacturing, or composition of matter, unstable political environments, acts of terrorism, war, natural disasters, and other natural and man-made disasters. If Oculus, we or our third party manufacturers were to encounter any of the above difficulties, or otherwise fail to comply with contractual obligations, our ability to provide any product for clinical trial or commercial purposes would be jeopardized. This may increase the costs associated with completing our clinical trials and commercial production. Further, production disruptions may cause us to terminate ongoing clinical trials and/or commence new clinical trials at additional expense. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications or pass safety inspections. If production difficulties cannot be solved with acceptable costs, expenses, and timeframes, we may be forced to abandon our clinical development and commercialization plans, which could have a material adverse effect on our business, prospects, financial condition, and the value of our securities.

We may be unable to obtain sufficient clinical trial liability insurance.

Our inability to obtain and retain sufficient clinical trial liability insurance at an acceptable cost to protect against potential liability claims could prevent or inhibit our ability to conduct clinical trials for product candidates we develop. We expect to obtain clinical trial liability insurance; however, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. We expect we will supplement our clinical trial coverage with product liability coverage in connection with the commercial launch of RUT58-60 or other product candidates we develop in the future; however, we may be unable to obtain such increased coverage on acceptable terms or at all. If we are found liable in a clinical trial lawsuit or a product liability lawsuit in the future, we will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing growth.

As of June 15, 2014, we employed a total of six full-time employees and several part-time consultants and CROs, and we have access to certain of Oculus' employees and resources through the various agreements we have entered into with Oculus. Our current internal departments include finance, research and development and administration. We are led by a team that includes two executives, a Director of Regulatory and Quality Assurance, a Director of Medical Affairs and two operations specialists. We intend to expand our management team to include an operation ramp up of additional technical staff required to achieve our business objectives. In addition, we periodically engage individuals employed by Oculus, on a part-time basis, to assist us with establishing and maintaining accounting systems, managing vendors and CROs, project management, research and development, chemistry and toxicology, manufacturing, human resources, and other general and administrative activities. We will need to expand our

managerial, operational, technical and scientific, financial and other resources in order to manage our operations and clinical trials, establish independent manufacturing, continue our research and development activities, and commercialize our product candidate. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth.

Our need to effectively manage our operations, growth and various projects requires that we:

- manage our clinical trials effectively, including our planned Phase 1/2 clinical trial of RUT58-60;

- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;

- continue to improve our operational, financial and management controls and reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may utilize the services of third party vendors to perform tasks including pre-clinical and clinical trial management, statistics and analysis, regulatory affairs, medical advisory, market research, formulation development, Chemistry, Manufacturing and Controls, or CMC, activities, other drug development functions, legal, auditing, financial advisory, and investor relations. Our growth strategy may also entail expanding our group of contractors or consultants to implement these and other tasks going forward. Because we rely on numerous consultants, to outsource many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidate or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidate and, accordingly, may not achieve our research, development and commercialization goals.

If we are unable to develop satisfactory sales and marketing capabilities, we may not succeed in commercializing RUT58-60 or any other product candidate.

We have no experience in marketing and selling drug products. We have not entered into arrangements for the sale and marketing of RUT58-60 or any other product. We are developing RUT58-60 for large patient populations served by surgeons. These patient populations may number in the millions. Typically, pharmaceutical companies would employ groups of sales representatives and associated sales and marketing staff numbering in the hundreds to thousands of individuals to call on this large number of physicians and hospitals. We may seek to collaborate with a third party to market our drugs or may seek to market and sell our drugs by ourselves. If we seek to collaborate with a third party, we cannot be sure that a collaborative agreement can be reached on terms acceptable to us. If we seek to market and sell our drugs directly, we will need to hire additional personnel skilled in marketing and sales. We cannot be sure that we will be able to acquire, or establish third party relationships to provide, any or all of these marketing and sales capabilities. The establishment of a direct sales force or a contract sales force or a combination direct and contract sales force to market our products will be expensive and time-consuming and could delay any product launch. Further, we can give no assurances that we may be able to maintain a direct and/or contract sales force for any period of time or that our sales efforts will be sufficient to grow our revenues or that our sales efforts will ever lead to profits.

Even if we obtain regulatory approvals to commercialize RUT58-60 or any other drug, our drug candidates may not be accepted by physicians or the medical community in general.

There can be no assurance that RUT58-60 or any other product candidate successfully developed by us, independently or with partners, will be accepted by physicians, hospitals and other health care facilities. RUT58-60 and any future product candidates we develop will compete with a number of anti-infective drugs and antiseptic and cleansing products manufactured and marketed by major pharmaceutical and medical technology companies. The degree of market acceptance of any drugs we develop depends on a number of factors, including:

- our demonstration of the clinical efficacy and safety of RUT58-60;
- timing of market approval and commercial launch of RUT58-60;
- the clinical indication(s) for which RUT58-60 is approved;
- product label and package insert requirements;
- advantages and disadvantages of our product candidates compared to existing therapies;
- continued interest in and growth of the market for anti-infective drugs;
- strength of sales, marketing, and distribution support;
- product pricing in absolute terms and relative to alternative treatments;

- future changes in health care laws, regulations, and medical policies; and
- availability of reimbursement codes and coverage in select jurisdictions, and future changes to reimbursement policies of government and third party payors.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations.

Our failure to successfully acquire, develop and market additional drug candidates or approved drug products could impair our ability to grow.

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market additional product candidates and technologies. These investments will not constitute a significant portion of our business. However, our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management’s and technical personnel’s time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;

- higher than expected acquisition and integration costs;

- increased amortization expenses;

- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to retain key employees of any acquired businesses.

Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

We may not be able to attract, retain, or manage highly qualified personnel, which could adversely impact our business.

Our future success and ability to compete in the biopharmaceutical industry is substantially dependent on our ability to identify, attract, and retain highly qualified key managerial, scientific, medical, and operations personnel. The market for key employees in the pharmaceutical and biotechnology industries can be competitive. The loss of the services of any of our key employees without an adequate replacement or our inability to hire new employees as needed could delay our product development efforts, harm our ability to sell our products or otherwise negatively impact our business.

The scientific, research and development personnel upon which we rely to operate our business have expertise in certain aspects of drug discovery, clinical development and regulatory affairs, and it may be difficult to retain or replace these individuals. We conduct our operations at our facilities in Santa Rosa, California, within the greater San Francisco Bay Area, and this region is headquarters to many other biotechnology, pharmaceutical, and medical technology companies, as well as many academic and research institutions, and, therefore, we face increased competition for technical and managerial personnel in this region.

In addition, we have scientific, medical and clinical advisors who assist us in designing and formulating our products and with development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

Despite our efforts to retain valuable employees, members of our management and scientific and development teams may terminate their employment with us on short notice. Although we have written employment agreements with our executive officers, these employment agreements provide for at-will employment, which means that our executive officers can leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or our other key employees, including our regulatory affairs director and our head of manufacturing, the latter of whom is an employee of Oculus to whom we have access through the Shared Services Agreement, and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with any regulations applicable to us, to provide accurate information to regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, or to report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risk.

Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our costs and expenses.

Our operations, and those of our directors, advisors, contractors, consultants, CROs, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics and other natural and man-made disaster or business interruptions. Our phones, electronic devices and computer systems and those of our directors, advisors, contractors, consultants, CROs, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man-made disasters. Our headquarters are in Santa Rosa, California and may be subject to risks particularly those that are characteristic of the region such as earthquakes, wildfires, shipping and port delays and closures, flooding, fog, and other natural and man-made events that may adversely affect our results of operations and financial condition. Operating as a virtual company, our employees conduct business outside of our headquarters and leased or owned facilities. These locations may be subject to additional security and other risk factors due to the limited control of our employees. If such an event as described above were to occur in the future, it may cause interruptions in our operations, delay research and development programs, clinical trials, regulatory activities, manufacturing and quality assurance activities, sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Likewise, we rely on third parties to manufacture RUT58-60 and conduct clinical trials, and similar events as those described in the prior paragraph relating to their business systems, equipment and facilities could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed or altogether terminated.

Risks Related to Development and Regulatory Approval of RUT58-60 and Our Product Candidates

We cannot be certain that RUT58-60 or any of our future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

Our business currently depends entirely on the successful development and commercialization of RUT58-60. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of RUT58-60 for the prevention of infection associated with abdominal surgery and other indications and our future product candidates.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA. We have not submitted any marketing applications for any of our product candidates.

NDA’s must include extensive preclinical and clinical data and supporting information to establish the product candidate’s safety and effectiveness for each desired indication. NDA’s must also include significant information regarding the CMC for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA.

Regulators of other jurisdictions have their own procedures for approval of product candidates. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a

product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

We cannot predict whether our future trials and studies will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date. If we are unable to obtain approval from the FDA or other regulatory agencies for RUT58-60 and our other product candidates, or if, subsequent to approval, we are unable to successfully commercialize RUT58-60 or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

Clinical trials for our product candidates are expensive, time-consuming, uncertain and susceptible to change, delay or termination.

Clinical trials are very expensive, time-consuming and difficult to design and implement. Even if the results of our clinical trials are favorable, clinical trials usually continue for several years and may take significantly longer to complete. In addition, we, the FDA, an Institutional Review Board, or other regulatory authorities, including state and local, may suspend, delay or terminate our clinical trials at any time for various reasons, including:

- lack of effectiveness of our lead drug candidate or any other product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;

- inadequacy of or changes in our manufacturing process or product formulation;

- delays in obtaining regulatory authorization to commence a study, including "clinical holds" or delays requiring suspension or termination of a study by a regulatory agency, such as the FDA, before or after a study is commenced;

- changes in applicable regulatory policies and regulations;

- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;

- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;

- unfavorable results from ongoing clinical trials and pre-clinical studies;

- failure of our contract research organizations, or CROs, or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;

- failure by us, our employees, our CROs or their employees to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for controlled substances;

- scheduling conflicts with participating clinicians and clinical institutions; and

- failure to design appropriate clinical trial protocols.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

There is a high rate of failure for drug candidates proceeding through clinical trials.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our

interpretation of the data. In the event that we obtain negative results from the RUT58-60 planned clinical trials or receive poor clinical results for other product candidates, or the FDA chooses to block progress of the trials due to potential CMC issues or other hurdles or does not approve our NDA for RUT58-60, we may not be able to generate sufficient revenue or obtain financing to continue our operations, our ability to execute on our current business plan will be materially impaired, our reputation in the industry and in the investment community would likely be significantly damaged and the price of our stock would likely decrease significantly.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our product candidates, or limit the scope of any approved label or market acceptance.

If RUT58-60 or any of our product candidates, prior to or after any approval for commercial sale, cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may interrupt, delay or halt clinical trials;
- regulatory authorities may deny regulatory approval of our product candidates;
- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy, or REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or limitations on the indications for use;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

We may voluntarily suspend or terminate our planned clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our product candidates are unlikely to receive regulatory approval or unlikely to be successfully commercialized. In addition, regulatory agencies, institutional review boards or data safety monitoring boards may at any time order the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate any planned clinical trial of RUT58-60 or any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our strategic alliance partners.

Any failure by us to comply with existing regulations could harm our reputation and operating results.

We will be subject to extensive regulation by U.S. federal and state and foreign governments in each of the markets where we intend to sell RUT58-60 if and after it is approved. For example, we will have to adhere to all regulatory requirements including the FDA's current GCP, GLP and cGMP requirements. If we or Oculus fail to comply with applicable regulations, including FDA pre-or post-approval cGMP requirements, then the FDA or other foreign regulatory authorities could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies.

If RUT58-60 is approved in the United States, it will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information, including both federal and state requirements in the United States. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of the product, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory

requirements, a regulatory agency or enforcement authority may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from RUT58-60 and our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenue from sales of RUT58-60, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. We expend significant resources on compliance efforts and such expenses are unpredictable and might adversely affect our results. Changing laws, regulations and standards might also create uncertainty, higher expenses and increase insurance costs.

If we are found in violation of federal or state "fraud and abuse" laws, we may be required to pay a penalty and/or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition and results of operations.

In the United States, we will be subject to various federal and state health care "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in federal and state health care programs, which could affect us, particularly upon successful commercialization of our products in the United States. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a federal health care program, such as Medicare or Medicaid. Under federal government regulations, some arrangements, known as safe harbors, are deemed not to violate the federal Anti-Kickback Statute. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental health care programs. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal anti-kickback statute, some of which apply to the referral of patients for health care services reimbursed by any source, not just governmental payers. Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and if we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in federal or state health care programs, and our business, results of operations and financial condition may be adversely affected.

We expect to face competition, often from companies with greater resources and experience than us.

The pharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than we do. Some of these competitors and potential competitors have more experience than we do in the development of pharmaceutical products, including validation procedures and regulatory matters. We are aware of three companies in the United States and/or Europe that produce HOCl based products intended for medical applications, including Novabay, Oculus and Puricore, which we consider our potential competitors in this regard. In addition, many other companies have commercialized or are developing antibiotics that aim to address the increasingly growing concern of post-surgical infections, including Achaogen, Basilea, Cempra, Cubist Pharmaceuticals, Durata Therapeutics, Forest Laboratories & Astra Zeneca, GlaxoSmithKline, Merck, Paratek, Rempex, Rib-X, Tetraphase Pharmaceuticals, and Trius. If we are unable to compete successfully with these and other potential future competitors, we may be unable to grow and sustain our revenue.

Risks Relating to Our Financial Position and Need for Additional Capital

Our limited operating history makes evaluating our business and future prospects difficult, and may increase the risk of any investment in our securities.

We were incorporated in Nevada in January 2013 as a wholly-owned U.S. subsidiary of Oculus, a Delaware corporation, which was incorporated in California in 1999 as Micromed Laboratories, Inc., and in August 2001, changed its name to Oculus Innovative Sciences, Inc. We reincorporated from Nevada to Delaware on September 25, 2013. We have a limited operating history and have incurred net losses since we began operations in October 2011. Through March 31, 2014, we had an accumulated deficit of $3,669,000. These losses have resulted principally from costs incurred in connection with our research and development activities, pre-clinical tests and other regulatory activities, preparations for our IPO, other general and administrative costs associated with our operations, and carve-out financial information from Oculus prior to our incorporation on January 18, 2013. We face considerable risks and difficulties as a company with limited operating history, particularly as an entity with a former parent company that has incurred losses since inception. If we do not successfully address these risks, our business, prospects, operating results and financial condition may be materially and adversely harmed.

We expect to incur significant additional operating losses over the next several years as we expand our research and development efforts, pre-clinical testing and clinical trials, and we implement manufacturing, marketing and sales programs. In addition, as our development testing activities continue, our operating losses may increase. Further, this may result in negative cash flow in future periods as we fund operating losses and capital expenditures, and, therefore, will result in decreases in our working capital, total assets and stockholder's equity, which may not be offset by future financings. Our limited operating history makes it particularly difficult for us to predict our future operating results and appropriately budget for our expenses. In the event that actual results differ from our estimates or we adjust our estimates in future periods, our operating results and financial position could be materially affected.

Moreover, we do not have a product approved for commercial sale. We have limited experience as a newly formed research and development stage entity in the biopharmaceutical field, and our prospects must be considered in light of the fact that we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical or biotechnology areas. These risks include, but are not limited to, unforeseen capital requirements, delays in obtaining regulatory approvals, failure to gain market acceptance and competition from foreseen and unforeseen sources. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties encountered by companies in the early stage of development.

Our operating results for the foreseeable future will depend significantly on our ability to fund our research and development programs for, obtain regulatory approval of, and to successfully commercialize RUT58-60.

RUT58-60 is currently our only drug candidate. We may not receive revenues or royalties from commercial sales of RUT58-60 or any other drug in the foreseeable future, if at all.

Our development of RUT58-60 involves a high degree of risk. Many important factors affect our ability to successfully develop and commercialize RUT58-60, including our ability to:

- demonstrate safety and efficacy of RUT58-60 at each stage of the clinical trial process;
- meet applicable regulatory standards and receive required regulatory approvals;
- obtain and maintain necessary patents and/or licenses;
- produce RUT58-60 in commercial quantities at reasonable costs;
- obtain reimbursement coverage for RUT58-60;
- compete successfully against other products; and
- market RUT58-60 successfully.

We cannot assure you that we will successfully develop and commercialize RUT58-60 or that we will obtain required regulatory approvals for its commercialization. As a result, we may never generate revenues from RUT58-60 sales. To date, we have not generated any revenue from RUT58-60 or any other product and we do not know when, or if, we will generate any revenue in the future. We may never be able to successfully develop or commercialize RUT58-60 or any other product. Even if we do commercialize RUT58-60 or other product candidates in the future, we may incur significant sales, marketing, manufacturing and other general and administrative expenses, as well as continued research and development expenses. As a result, we cannot predict when we will become profitable, if at all, and if we do, we may not remain profitable for any substantial period of time. If we fail to achieve profitability within the timeframe expected by investors, the market price of the common stock may decline, and, therefore, may negatively impact our ability to raise capital, invest in or expand our business, acquire additional products or licenses, commercialize our products, or continue our operations.

We will need additional funding to advance our clinical trial programs, launch and commercialize our lead drug candidate or any other product candidate.

Pharmaceutical product development, which includes research and development, pre-clinical and clinical studies and human clinical trials, is a time-consuming and expensive process that takes years to complete. We expect that our expenses will increase substantially as we move RUT58-60 into human clinical trials, seek regulatory approval for RUT58-60 for the abdominal surgery indication, seek regulatory approval for RUT58-60 in additional surgical and traumatic injury indications, pursue development of additional innovative HOCl based pharmaceutical formulations and/or pursue development of HOCl based pharmaceuticals in additional indications. If we obtain marketing approval for RUT58-60 or any other product candidate that we develop, license, or acquire, we expect to incur significant commercialization expenses related to pre-launch activities, regulatory compliance requirements, sales and marketing, manufacturing and distribution. Additionally, we may incur expenses directly related to license and product acquisitions.

We believe that our existing cash, which includes the proceeds from our IPO, will be sufficient to fund our operations into the quarter ending December 31, 2015, including our capital expenditure requirements and financial obligations to complete our planned Phase 1/2 clinical trial of RUT58-60, to conduct research and development activities for additional indications, to establish an independent research facility and to pay certain milestone payments to Oculus. These funds will not be sufficient to enable us to conduct our planned Phase 2B pivotal trial or Phase 3 pivotal clinical trial, seek marketing approval for RUT58-60 or commercially launch RUT58-60 in the U.S. or any other country or geographic area.

Our inability to raise capital on acceptable terms in the future may cause us to delay, diminish, or curtail certain operational activities, including research and development activities, clinical trials, sales and marketing, and other operations, in order to reduce costs and sustain the business, and such inability would have a material adverse effect on our business and financial condition.

We expect capital outlays and operating expenditures to increase over the next several years as we work to conduct clinical trials, establish independent manufacturing operations, commercialize our products and expand our infrastructure. We may need to raise additional capital to, among other things:

- fund our planned Phase 2B pivotal clinical trial for RUT58-60;
- fund our planned Phase 3 pivotal clinical trial for RUT58-60;
- fund additional clinical trials and preclinical trials for RUT58-60 as requested or required by regulatory agencies;
- fund clinical trials and preclinical trials for RUT58-60 in new indications;
- sustain commercialization of RUT58-60 or any other new product candidate;
- develop our manufacturing capabilities, if any;
- increase our sales and marketing efforts to drive market adoption and address competitive developments;
- acquire, license or in-license other product candidates;
- finance capital expenditures and our general and administrative expenses;
- develop new products;
- maintain, expand and protect our intellectual property portfolio, if any;
- add operational, financial and management information systems; and

- hire additional clinical, quality control, scientific, and general and administrative personnel.

Our present and future funding requirements will depend on many factors, including but not limited to:

- the progress and timing of our clinical trials;
- the level of research and development investment required to maintain and improve our technology position;
- cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, if any;
- our efforts to acquire or license complementary technologies or acquire complementary businesses;
- changes in product development plans needed to address any difficulties in commercialization;
- competing technological and market developments;
- changes in regulatory policies or laws that may affect our operations; and
- changes in physician acceptance or medical society recommendations that may affect commercial efforts.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current and future service providers, manufacturers, suppliers, hospitals and other medical facilities, our third party payors, and other partners could be negatively affected by these difficult economic times, which could adversely affect our ability to attain our operating

goals on schedule and on budget or meet our business and financial objectives.

Risks Related to Intellectual Property

If we and Oculus do not obtain protection for our respective intellectual property rights, our competitors may be able to take advantage of our research and development efforts to develop competing drugs.

Our success, competitive position and future revenues will depend in part on our ability and the ability of Oculus, the licensor of intellectual property rights relating to RUT58-60, to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. Under the license and supply agreement that we have entered into with Oculus, we hold certain exclusive patent rights for a specified field and territory, including licensed rights under U.S. patents and U.S. patent applications as well as licensed rights under foreign patents and patent applications owned by Oculus.

We may file additional patent applications both in the U.S. and in other countries, as appropriate. However, the patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include but are not limited to the following:

- Patents may not be granted from patent applications submitted by us or our licensor Oculus to the U.S. Patent and Trademark Office or foreign patent applications.

- Patents that have issued or will issue, where our own or in-licensed patents and patent applications from Oculus or another entity, may be challenged, invalidated, or circumvented, or otherwise may not provide any competitive advantage.

- Countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

- Our competitors, many of which have substantially greater resources than us and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets.

- There may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns.

In addition, the U.S. Patent and Trademark Office and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or Oculus are able to obtain patents, the patents may be substantially narrower than anticipated.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we take measures to protect this information by entering into confidentiality and inventions agreements with our employees, scientific advisors, consultants, and collaborators, we cannot provide any assurances that these agreements will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are breached, or that our trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

Patent protection and other intellectual property protection are important to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

Our intellectual property may not be sufficient to protect our products from competition and may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third

parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from Oculus. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our products; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own; and, the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to RUT58-60 or other drug candidates in the future. There can be no assurance that we will be able to successfully defend patents we own or license from Oculus in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights and enforcement may be less extensive in jurisdictions outside of the United States; thus, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Changes to patent law, including the Leahy-Smith America Invests Act (AIA or Leahy-Smith Act) of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents, and prosecution of patents. We can give no assurances that our patents and those of our licensor, Oculus, can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the U.S. Patent and Trademark Office, courts and foreign government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The actual or purported intellectual property rights of third parties may negatively affect our business.

A third party may sue us or Oculus, the licensor of RUT58-60, or otherwise make a claim, alleging infringement or other violation of the third party's patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights. If we do not prevail in successfully defending this type of litigation, we may be required to:

- pay monetary damages;
- obtain a license in order to continue manufacturing or marketing the affected products, which may not be available on commercially reasonable terms, or at all; or
- stop activities, including any commercial activities, relating to the affected products, which could include a recall of the affected products and/or a cessation of sales in the future.

The costs of defending an intellectual property claim could be substantial and could materially adversely affect our operating results and financial condition, even if we successfully defend such claims. We cannot offer assurances that we will be able to defend ourselves against claims by third parties due to the high costs associated with intellectual property litigation, amongst other factors.

The intellectual property rights in the field of surgical medicine frequently involve complex legal and factual questions. We are not guaranteed the right to practice our patented technology or develop, manufacture or commercialize our patented products even if we own or license patent rights relating to our products. We cannot be certain that a competitor or other third party does not have or will not obtain rights to intellectual property that may prevent us from manufacturing, developing or marketing certain of our products, regardless of whether we believe such intellectual property rights are valid and enforceable or we believe we would be otherwise able to develop a more commercially successful product, which may harm our operating results and financial condition.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the value of our securities.

If we materially breach or default under our license and supply agreement with Oculus, Oculus will have the right to terminate the agreement and we could lose critical license rights, which would materially harm our business.

We do not currently own any patents, trademarks, or copyrights; however, our business is substantially dependent upon certain intellectual property rights that we license from Oculus. Therefore, our commercial success will depend to a large extent on our ability to maintain and comply with our obligations under our license and supply agreement with Oculus. Our license and supply agreement with Oculus provides Oculus with the right to terminate the license and supply agreement for an uncured breach by us, or if we are insolvent or the subject of a bankruptcy proceeding, or potentially other reasons. In addition, under the license and supply agreement, we are required to use commercially reasonable efforts to satisfy certain development milestones and other obligations with regard to the development and commercialization of RUT58-60 in order for us to maintain the license. We expect that other technology in-licenses that we may enter into in the future will contain similar provisions and impose similar obligations on us. If we fail to comply with any such obligations to Oculus or future licensors, such licensor will likely terminate their out-licenses to us, in which case we would not be able to market products covered by these licenses, including the RUT58-60 technology. The loss of our license with Oculus with respect to the RUT58-60 technology, and potentially other licenses that we enter into in the future, would have a material adverse effect on our business. In addition, our failure to comply with obligations under our material in-licenses may cause us to become subject to litigation or other potential disputes under any such license agreements.

In addition, our license and supply agreement with Oculus requires us to make certain payments, including license fees, milestone payments royalties, and other such terms typically required under licensing agreements and these types of technology in-licenses generally could make it difficult for us to find corporate partners and less profitable for us to develop product candidates utilizing these existing product candidates and technologies.

We may be subject to claims that our employees, independent consultants or agencies have wrongfully used or disclosed confidential information of third parties.

We employ individuals and contract with independent consultants and agencies who may have previously worked at or conducted business with third parties; and, we may be subject to claims that we or our employees, consultants or agencies have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to our Relationship with Oculus

Approval of commercial terms between us and Oculus does not preclude the possibility of stockholder litigation, including but not limited to derivative litigation nominally against Oculus and against its directors and officers and also against us and our directors and officers.

The commercial terms of the license and supply agreement, shared services agreement and separation agreement that we have entered into with Oculus have been negotiated on behalf of Oculus by a Special Transaction Committee consisting solely of disinterested Oculus directors. We believe such negotiations have been at arms' length. We have no basis for believing that the terms of these agreements will not be in the best interests of both Oculus and its stockholders and also us and our stockholders. Nonetheless, no assurance can be given that any stockholder of Oculus will not claim in a lawsuit that such terms in fact are not in the best interests of Oculus and its stockholders, that the directors and officers of Oculus breached their fiduciary duties in connection with such agreements and that any disclosures by Oculus to its stockholders regarding these agreements and the relationship between Oculus and us did not satisfy applicable requirements. In any such instance, we and our directors and officers may also be named as defendants and we would have to defend ourselves and our directors and officers. While we will seek indemnification from Oculus under the terms of these agreements against any damages or other costs, which could be substantial, no such indemnification has yet been agreed to or may be agreed to and be in effect. Further, any such litigation would be time-consuming and would divert focus and resources from the development of our product candidates and our business, including but not limited to possibly delaying our clinical trials due to our management having to spend time and attention on such litigation.

Your investment in our securities may be adversely affected due to Oculus' ownership of our common stock.

The liquidity of the market for our common stock may be constrained for as long as Oculus continues to hold a significant position in our common stock. As of the date of this filing, Oculus holds approximately 42% of our outstanding common stock. Additionally, without a distribution or other liquidity event of the shares of Ruthigen common stock held by Oculus, there will be limited liquidity in the market for our common stock, which will impact our stockholders and our stock price. We believe that a distribution of the shares of Ruthigen common stock held by Oculus to Oculus stockholders would be advantageous to the market for our shares of common stock by increasing liquidity, would accelerate our ability to become independent from Oculus by decreasing Oculus' ownership of our common stock. A lack of liquidity in the market for our common stock may adversely affect our stock price and therefore, our ability to raise additional funds in the public markets, which may have a material adverse effect on our ability to grow our business.

The ownership by our executive officers and our directors of shares of Oculus common stock and rights to purchase Oculus common stock may create, or may create the appearance of, conflicts of interest.

The ownership by our executive officers and our directors of shares of Oculus common stock, options to purchase shares of Oculus common stock, or other equity awards of Oculus may create, or may create the appearance of, conflicts of interest. Our chief executive officer served as the chief executive officer of Oculus until February 2013, when he stepped down to run Ruthigen. Our chief financial officer served as the chief financial officer of Ruthigen since February 2013 and has been granted options in Oculus. Two of our three directors formerly served on the board of directors of Oculus. Because of the current and former positions of our executive officers and our directors with Oculus, they own shares of Oculus common stock, options to purchase shares of Oculus common stock or other equity awards of Oculus. Ownership by our executive officers and directors of common stock or options to purchase common stock of Oculus, or any other equity awards, may create the appearance of, conflicts of interest when these individuals are faced with decisions that could have different implications for Oculus than the decisions have for us. Any perceived conflicts of interest resulting from investors questioning the independence of our management or the integrity of corporate governance procedures may materially affect our stock price.

Any disputes that arise between us and Oculus with respect to our past and ongoing relationships could harm our business operations.

Disputes may arise between Oculus and us in a number of areas relating to our past and ongoing relationships, including:

- intellectual property, technology and business matters, including failure to make required technology transfers and failure to comply with non-compete provisions applicable to Oculus and us;
- labor, tax, employee benefit, indemnification and other matters arising from the Separation;
- distribution and supply obligations;
- employee retention and recruiting;
- business combinations involving us;
- sales or distributions by Oculus of all or any portion of its ownership interest in us;

- the nature, quality and pricing of services Oculus has agreed to provide us; and

- business opportunities that may be attractive to both Oculus and us.

We have entered into the separation agreement with Oculus related to the separation of our business operations from those of Oculus that contains certain limitations on Oculus' ability to control various aspects of our business and operations, notwithstanding Oculus' substantial ownership position in our common stock. This agreement may be amended upon agreement between us and Oculus.

We and our stockholders may not achieve some or all of the expected benefits of the Separation.

We are focused on developing HOCl based drugs to prevent and treat infection in invasive applications. Drug development is an expensive and time-consuming process, but we believe the knowledge we have gained while operating as a subsidiary of Oculus has helped expedite this process. However, in order to realize the value proposition of Ruthigen as a drug development company, we intend to target early stage healthcare and pharmaceutical focused investors, who are interested in investing in drug development companies and who appreciate the risks, rewards and typically longer investment timelines associated with such investments. In order to successfully attract this type of new investment, we believe it is critical that we separate from Oculus, because we believe that doing so will provide us with some or all of the following benefits:

- improving strategic and operational flexibility, increasing management focus and streamlining decision-making by providing the flexibility to implement our strategic plan and to respond more effectively to different customer needs and the changing economic environment;

- allowing us to adopt the capital structure, investment policy and dividend policy best suited to our financial profile and business needs, without competing for capital with Oculus' other businesses;

- creating an independent equity structure that will facilitate our ability to affect future acquisitions utilizing our common stock; and

- facilitating incentive compensation arrangements for employees more directly tied to the performance of our business, and enhancing employee hiring and retention by, among other things, improving the alignment of management and employee incentives with performance and growth objectives of our business.

If we are not successful implementing the Separation, we may not be able to achieve the full strategic and financial benefits we expect to receive, or the benefits may be delayed or not occur at all. Even if we are able to achieve stand-alone, independent status as a drug development company, there can be no assurance that investors and analysts will place a greater value on us as a stand-alone drug development company than as a wholly- or substantially-owned subsidiary of Oculus.

The assets and resources that we acquire from Oculus in the Separation may not be sufficient for us to operate as a stand-alone company, and we may experience difficulty in separating our assets and resources from Oculus.

Because we have not operated as a stand-alone company in the past, we may have difficulty doing so. We may need to acquire assets and resources in addition to those provided by Oculus to us, and in connection with the Separation, may also face difficulty in separating our resources from Oculus' and integrating newly acquired assets into our business. For example, we expect to secure the use of an independent research and development and manufacturing facility, manufacturing and packaging equipment. Further, we may need to hire additional personnel to assist with administrative and technical functions, and acquire other office and laboratory equipment for use in the ordinary course operations of our business. If we have difficulty operating as a stand-alone company, fail to acquire assets that we need to run our operations, or incur unexpected costs in separating our business from Oculus' business or in integrating newly acquired assets into our business, our business, financial condition and results of operations will be adversely affected.

Risks Related to Our Common Stock

The trading market in our common stock has been extremely limited and substantially less liquid than the average trading market for a stock quoted on the NASDAQ Capital Market.

Since our initial listing on the NASDAQ Capital Market on March 21, 2014, the trading market in our common stock has been extremely limited and substantially less liquid than the average trading market for companies quoted on the NASDAQ Capital Market. The quotation of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether a more active market for our common stock will develop in the future. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of June 15, 2014, approximately 50% of our outstanding shares

of common stock was held by our officers, directors, beneficial owners of 5% or more of our securities and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price. In addition, as of June 15, 2014, 2,000,000 shares of common stock, or 42% of our outstanding shares, were restricted from resale under securities laws or as a result of lock-up agreements, further limiting the liquidity of our common stock; however, such lock-up agreements will expire at the close of business on March 21, 2015.

The price of our common stock may fluctuate substantially.

Prior to our IPO in March 2014 there was no public market for our common stock and it is too early to determine whether an active trading market will develop and continue, which may make the price of our common stock fluctuate substantially. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this “Risk Factors” section and elsewhere in this Annual Report on Form 10-K, are:

- sale of our common stock by Oculus, our former parent and largest stockholder at potentially significant discounts to the prevailing market price, subject to certain conditions, in accordance with the terms of the separation agreement;
- sale of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our human clinical trials, and other business activities;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;

- commencement, enrollment or results of our clinical trials of RUT58-60 or any future clinical trials we may conduct;
- changes in the development status of RUT58-60;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned pre-clinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for RUT58-60;
- our announcements or our competitors' announcements regarding new products or services, enhancements, significant contracts, acquisitions or strategic investments;
- unanticipated safety concerns related to the use of RUT58-60;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of common stock by our stockholders, including Oculus;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
-

changes in general economic, political and market conditions in or any of the regions in which we conduct our business;

- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics;
- announcements or actions taken by Oculus as our principal stockholder;
- open-market transactions that may occur prior to or immediately after any distribution of shares by Oculus; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights.

We may seek the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaborative and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders ownership interests will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or grant licenses on terms that are not favorable to us.

Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for holders of the warrants to exercise the warrants.

The Series A Warrants we issued in our IPO do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a formulaic price that is subject to adjustment for a limited period of time. The holders of our Series A Warrants may exercise their right to acquire additional shares of our common stock and Series B Warrants to purchase additional shares of our common stock. In order to do so, they must pay an exercise price of $7.25 per Series A Warrant within the two years following the date of issuance, after which date any unexercised Series A Warrants will expire and have no further value. There can be no assurance that the market price of our common stock will equal or exceed the exercise price of the Series A Warrants, and consequently, whether it will ever be profitable for holders of the Series A Warrants to exercise the Series A Warrants. This same analysis applies with equal effect to our Series B Warrants that are issuable upon exercise of the Series A Warrants, however the exercise of the Series B Warrants is $9.0625 per share and the expiration date is five years following the date of issuance.

There is no public market for our warrants and we do not expect one to develop.

We sold units in our IPO, each of which contained one share of common stock and one Series A Warrant. The Series A Warrants are exercisable for additional shares of common stock and Series B Warrants. The Series B Warrants are issuable for additional shares of common stock. There is no public trading market for our Series A Warrants or our Series B Warrants that are issuable upon exercise of the Series A Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any securities exchange. Without an active market, the liquidity of our warrants will be limited.

The exercise of outstanding options and warrants to acquire shares of our common stock will cause additional dilution which could cause the price of our common stock to fall.

In our IPO, we issued an aggregate of 3,047,500 Series A Warrants, all of which are outstanding as of June 15, 2014. Each of our Series A Warrants is exercisable for one share of common stock and one Series B Warrant to purchase one share of common stock. Accordingly, we have reserved 6,095,000 shares of our common stock for issuance upon exercise of our Series A Warrants and Series B Warrants. If the holders of our Series A Warrants exercise their warrants, you will experience dilution at the time they exercise their Series A Warrants. Similarly, if those who exercised their Series A Warrants also exercise the Series B Warrants they receive upon exercise of the Series A Warrants, you will experience further dilution at the time they exercise their Series B Warrants. The Series A Warrants and Series B Warrants contains price adjustment provisions, which may cause the exercise prices to be reduced relative to the initial exercise prices of 100% and 125% of the initial public offering price per unit, respectively, if we complete future equity sales at discounts to the then-market price and below the initial exercise price of the warrants.

In addition, we have reserved 998,355 shares of our common stock reserved for future issuance under our 2013 Employee, Director and Consultant Equity Incentive Plan, and as of June 15, 2014, a majority of these shares are subject to outstanding stock options and restricted stock units. Furthermore, we may issue additional options, warrants and other types of equity in the future as part of stock-based compensation, capital raising transactions, technology licenses, financings, strategic licenses or other strategic transactions. To the extent these options are exercised, existing common stockholders would experience additional dilution which would cause their percentage ownership to decline and may cause the price of our common stock to decline.

"Penny stock" rules may make buying or selling our securities difficult which may make our stock less liquid and make it harder for investors to buy and sell our securities.

If our shares of common stock are delisted by NASDAQ and begin to trade on an over-the-counter market such as the Over-the-Counter Bulletin Board or any quotation system maintained by OTC Markets, Inc., trading in our securities will be subject to the SEC's "penny stock" rules and it is anticipated that trading in our securities will continue to be subject to the penny stock rules for the foreseeable future. The SEC has adopted regulations that generally define a penny stock to be any equity security that has a market price of less than $5.00 per share, subject to certain exceptions. These rules require that any broker-dealer who recommends our securities to persons other than prior customers and accredited investors must, prior to the sale, make a special written suitability determination for the purchaser and receive the purchaser's written agreement to execute the transaction. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated with trading in the penny stock market. In addition, broker-dealers must disclose commissions payable to both the broker-dealer and the registered representative and current quotations for the securities they offer. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities.

Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management is be required to devote substantial time to compliance matters.

As a publicly traded company, we incur significant additional legal, accounting and other expenses that we did not incur as a privately held, wholly-owned subsidiary of Oculus. The obligations of being a public company in the United States require significant expenditures place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage that we had through Oculus. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

We are an "emerging growth company" and our election to delay adoption of new or revised accounting standards applicable to public companies may result in our financial statements not being comparable to those of other public companies. As a result of this and other reduced disclosure requirements applicable to emerging growth companies, our securities may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards.

In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to delay such adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result of such election, our financial statements may not be comparable to the financial statements of other public companies. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We could remain an “emerging growth company” until the earliest to occur of earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) March 31, 2019; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of RUT58-60. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business and results in a decline in the market price of our common stock.

NASDAQ may delist our common stock from its exchange, which could limit investors’ ability to make transactions in our common stock and subject us to additional trading restrictions.

If we fail to satisfy the continued listing requirements of the NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, the NASDAQ Stock Market (or NASDAQ) may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

If the NASDAQ Capital Market does not maintain the listing of our securities for trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;

- reduced liquidity with respect to our securities;

- a determination that our shares of common stock are "penny stock" which will require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;

- a limited amount of news and analyst coverage for our company; and

- decreased ability to issue additional securities or obtain additional financing in the future.

Item 1B. UNRESOLVED STAFF COMMENTS.

None.

Item 2. PROPERTIES.

Our corporate headquarters are located in Santa Rosa, California, where we lease and occupy approximately 995 square feet of executive office space. The term of our lease expires in October 2014 and our monthly rent is approximately $1,700.

Item 3. LEGAL PROCEEDINGS.

The Company is not a party to any litigation in any court, and management is not aware of any contemplated proceeding by any governmental authority against the Company.

Item 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

Our Common Stock began trading on the NASDAQ Capital Market on March 21, 2014 under the symbol "RTGN." The following table sets forth, for the periods indicated, the high and low sales prices for the Common Stock, as reported by NASDAQ, since the Common Stock commenced public trading:

Year Ended March 31, 2014	High	Low
Fourth Quarter (beginning March 21, 2014)	$8.47	$6.65

Stockholders

As of June 15, 2014, there were two stockholders of record, one of which represents stock held by multiple investors that is held in street name and the other is Oculus, of the 4,804,290 outstanding shares of Common Stock.

Dividends

The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future. The Company currently intends to retain earnings, if any, to finance the growth of the Company.

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

None.

Use of Proceeds from the Sale of Registered Securities

We registered units, with each unit consisting of one share of common stock and one Series A Warrant, or the Units, in connection with our IPO under the Securities Act. The registration statement on Form S-1 (File No. 333-190376), or the Registration Statement, filed in connection with our IPO was declared effective by the SEC on March 21, 2014. The IPO commenced on March 21, 2014 and did not terminate until after the sale of all of the shares registered on the Registration Statement. Through March 31, 2014, 2,650,000 Units, sold at a price of $7.25 per Unit, with such Units including 2,650,000 shares of common stock and 2,650,000 Series A Warrants, and 397,500 Series A Warrants, sold at a price of $0.0092 per Series A Warrant, were registered and sold in our IPO. As of the date of this filing, the IPO has terminated.

Dawson James Securities, Inc. acted as the sole book-running manager for the IPO. The net IPO proceeds received by us, after deducting underwriting discounts and commissions and expenses incurred in connection with the IPO, were approximately $16.0 million. No IPO expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

We intend to invest the net proceeds from our IPO in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus dated March 21, 2014, filed with the SEC pursuant to Rule 424(b)(4).

Item 6. SELECTED FINANCIAL DATA.

The following table sets forth our selected financial data for the periods and as of the dates indicated. Expenses of the Company for the year ending March 31, 2013 contain carve-out financial statements, including expense allocations related to salaries and consulting activities, which benefited the Company, from the Former Parent from April 1, 2012 through January 18, 2013, prior to the incorporation of Ruthigen. The financial information included herein may not necessarily reflect expenses and cash flows of the Company if operated on a stand-alone basis.

You should read the following selected financial data in conjunction with our audited financial statements and the related notes thereto included elsewhere in this Annual Report and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report.

Our historical results are not necessarily indicative of the results that may be expected in the future.

	For The Years Ended March 31,	
	2014	2013
Statement of Operations Data:		
Revenues	$-	$-
Operating Expenses		
Research and development	1,382,000	258,000
Selling, general and administrative	1,736,000	265,000
Total Operating Expenses	3,118,000	523,000
Net loss	$(3,118,000)	$(523,000)
Net Loss Per Share - Basic and Diluted	$(1.53)	$(0.26)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	2,036,301	2,000,000

	March 31,	
	2014	2013
Balance Sheet Data:		
Cash	$15,571,000	$96,000
Working capital (deficit)	14,627,000	(1,000)
Total assets	15,576,000	148,000

Total liabilities	947,000	101,000
Total stockholders' equity	14,629,000	47,000

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk Factors" and under "Forward-Looking Statements" in this Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company focused on the discovery, development, and commercialization of pharmaceutical-grade hypochlorous acid, or HOCl, based therapeutics designed to prevent and treat infection in invasive applications. Our lead drug candidate, RUT58-60, is a broad spectrum anti-infective that we are developing for the prevention and treatment of infection in surgical and trauma procedures. We are focusing RUT58-60 for use initially to prevent infections in abdominal surgery due to the large addressable market, high rate of post-surgical infection associated with abdominal surgery, the high-impact opportunity that abdominal surgery offers us in the clinical trial setting to expose multiple internal organs to RUT58-60 at one time, and feedback from surgeons identifying post-surgical infection in abdominal surgery (relative to other surgeries) as a significant unmet medical need. We were incorporated in January 2013 as a wholly-owned subsidiary of Oculus Innovative Sciences, Inc., or Oculus or the Former Parent, and we were operated as a wholly-owned subsidiary of Oculus until the completion of our initial public offering, or IPO, in March 2014. We currently have no products approved for sale. We submitted our Investigational New Drug Application, or IND, for RUT58-60 to the United States Food and Drug Administration, or FDA, in early May 2014. In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60.

Our goal is to become the first company to market RUT58-60 as a drug containing HOCl for the prevention and treatment of infection in invasive surgeries in the United States. We believe that RUT58-60 has the potential to significantly reduce the rate of post-surgical infections, reduce the use of systemic antibiotics that have proven to be ineffective against certain common resistant strains of bacteria, including methicillin-resistant staphylococcus aureus, or MRSA, and vancomycin-resistant enterococcus, or VRE, reduce the negative side effects associated with the increasingly widespread use of antibiotics, accelerate post-surgical healing which should lead to quicker patient discharge from the hospital, and ultimately reduce hospital readmission rates. We expect to commence patient enrollment in the initial phase of our first human clinical trial in July 2014. The initial phase will be a 30 patient, 21-day skin irritation trial that we expect to complete in August 2014. Following an independent data monitoring committee, or DMC, review of the results from the skin irritation phase, we plan to enroll 20 patients in the Phase 1 part of our Phase 1/2 clinical trial, to evaluate the safety of RUT58-60 within the abdominal cavity, which we refer to as the safety run-in. Subject to review of the safety run-in data by the DMC, we will continue patient enrollment in the Phase 2 part of our Phase 1/2 clinical trial for RUT58-60. Pending the successful completion of that trial and our

planned pivotal clinical trials, the first of which we anticipate will be our planned Phase 2B trial and the second of which we anticipate will be our planned Phase 3 trial, we plan to submit our New Drug Application, or NDA, to the FDA in late 2017.

We believe that RUT58-60 will complement the paid for performance paradigm and it is designed to reduce the overall healthcare costs associated with post-surgical infections and improve hospital economics. We believe the benefits of RUT58-60 will be significant:

- RUT58-60 mimics the human body's own infection-fighting mechanism,
- RUT58-60 has not shown evidence of toxicity or other negative side effects in our animal and other preclinical studies,
- preclinical studies of RUT58-60 conducted by us have not produced resistant bacteria, and
- RUT58-60 appears to provide broad spectrum anti-microbial effect.

We believe that RUT58-60 has the potential to be used as a prophylactic therapy to prevent and treat infections, and may accelerate patient discharge from the hospital and ultimately lead to an overall reduction in hospital readmission rates.

The benefits of HOCl in preventing infection have been well-demonstrated in products with lower concentrations of HOCl than RUT58-60. To date, HOCl based products have only been cleared for use as medical devices for topical applications in the United States, Europe and certain other countries. Earlier formulations have not been able to achieve therapeutic indication status, primarily due to their lack of stability and therefore have been limited for use as topical applications. Historically, the lack of stability has posed a vexing problem to companies hoping to pursue HOCl products for therapeutic indications in invasive applications and has prevented these companies from being able to conduct the clinical trials necessary to prove whether HOCl is safe and effective for use as a therapeutic.

HOCl based products have been used successfully to prevent infection in topical applications and have been sold commercially since at least 2005 by other companies, generally as medical devices or for the disinfection of medical devices. Several of these HOCl based products have been commercialized as medical devices by Oculus, our former parent company and the licensor of our technology. Through our license and supply agreement with Oculus, we have obtained exclusive rights to the RUT58-60 technology, as well as a proprietary method of manufacturing and producing HOCl with pharmaceutical potential by incorporating additional small molecules without sodium hypochlorite, the result of which increases the compound's stability and biocompatibility, or the compound' ability to remain in direct contact with internal tissues and organs. We believe our recent enhancements to the stability and biocompatibility of the compound will allow us to expand the use of HOCl so that it may be used in direct contact with internal organs and thus, for invasive applications, including surgical and trauma procedures, as well as additional clinical indications. With these enhancements, we believe our lead product candidate will be able to meet the safety and efficacy standards that the FDA requires for the approval of a new drug. Obtaining approval of new drug by the FDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. If we are successful obtaining FDA approval of RUT58-60 as a drug, we plan to commercialize it for invasive applications.

There are approximately 30 million surgical and trauma procedures in the United States per year, approximately 7 million of which are abdominal surgeries. Our initial goal is to obtain FDA approval for RUT58-60 for the prevention of infection associated with abdominal surgery and thereafter we plan to pursue FDA approval for RUT58-60 for use in other types of surgical procedures as well as additional clinical indications.

If we are successful in receiving FDA approval for RUT58-60 for the prevention of infection in abdominal surgery, we plan to pursue other types of surgeries, including cardiac, pulmonary and spinal, among others. Based upon data from preclinical studies conducted by us and data reported in third party publications, we believe that the safety and tolerability profile of RUT58-60, combined with its broad-range antimicrobial potency without specificity, offer a practical and unique approach to stem the high rate of hospital acquired infections and infections resulting from complications in surgeries and the increasing emergence of new antibiotic resistant bacteria that pose a significant risk to public health. We believe that RUT58-60 represents a significant innovation over existing uses of HOCl in topical applications and over systemic antibiotics, which are the current standard of care for the prevention and treatment of infection in surgical and other invasive applications, and has the potential to raise the clinical bar for anti-infective products generally in the face of increasing headwinds.

In addition to the United States, we plan to seek regulatory approval to commercialize RUT58-60 in Canada, Europe and Japan. Under our license and supply agreement with Oculus, we have exclusively licensed the HOCl technology relating to RUT58-60 for commercialization in the United States, Europe, Japan and Canada. Together, these markets represented approximately 71% of the global medicines market in 2011. In parallel with our clinical development activities for RUT58-60, we have commenced discussions with various pharmaceutical companies for potential partnership and collaboration activities for RUT58-60 in the United States, Canada, Europe and Japan. To date, we have not entered into any partnerships or collaborations for RUT58-60 and we cannot guarantee that we will be successful entering into any such arrangements on terms favorable to us, or at all.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) March 31, 2019; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Results of Operations

Year Ended March 31, 2014 Compared with Year Ended March 31, 2013

Expenses of the Company for the year ending March 31, 2013 contain carve-out financial statements, including expense allocations related to salaries and consulting activities, which benefited the Company, from the Former Parent from April 1, 2012 through January 18, 2013, prior to the incorporation of Ruthigen. The financial information included herein may not necessarily reflect expenses and cash flows of the Company if operated on a stand-alone basis.

The following table presents selected items in our statements of operations for the years ended March 31, 2014 and 2013, respectively:

	For The Years Ended March 31,	
	2014	2013
Revenues	$-	$-
Operating Expenses		
Research and development	1,382,000	258,000
Selling, general and administrative	1,736,000	265,000
Total Operating Expenses	3,118,000	523,000
Net loss	$(3,118,000)	$(523,000)

Revenue

We did not recognize product sales for the years ended March 31, 2014 or 2013. Our ability to generate product revenues in the future will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize RUT58-60 in the United States. In the event we choose to pursue a partnering arrangement to commercialize RUT58-60 or other products outside the United States, we would expect to initiate additional research and development and clinical trial activities in the future.

Research and Development Expense

Research and development expense was $1,382,000 and $258,000 for the years ended March 31, 2014 and 2013, respectively, an increase of $1,124,000, or 436%. The increase in research and development expense is primarily a result of the commencement of Ruthigen's operations directly related to RUT58-60 in January 2013. Research and development expense consists of costs related to the research and development of RUT58-60 and our manufacturing process; the development and testing of new drug formulations; preclinical studies; consulting fees; personnel related costs, including salaries, and benefits; and in the preparations for clinical trials, which are designed to obtain FDA drug approvals for RUT58-60. Research and development expense is charged as incurred. These expenses were attributable to salary, other personnel related expenses, and consulting expenses in the research and development, clinical, and regulatory departments. The expansion of our clinical and regulatory team was due to our increased focus on medical education, clinical trials and the management of regulatory trials.

We expect that research and development expense will continue to increase substantially in future years as we seek to begin our clinical trial enrollment and pursue regulatory approvals for RUT58-60. Based on the anticipated timelines and the resources we have allocated, we expect the total operating expense to bring RUT58-60 through our goal of FDA approval will be approximately $50 million. In addition, we expect to expand the scope of our new product development, which may also result in substantial increases in research and development expense.

Selling, General and Administrative Expense

Selling, general and administrative expense was $1,736,000 and $265,000 for the years ended March 31, 2014 and 2013, respectively, an increase of $1,471,000, or 555%. The increase in selling, general and administrative expense is primarily a result of the commencement of Ruthigen's operations directly related to RUT58-60 in January 2013. Selling, general and administrative expense consists of personnel related costs, including salaries, bonuses, and benefits; and development expenses associated with RUT58-60 marketing preparations; costs related to administrative personnel and senior management; costs related to the completion of the license and supply agreement, shared services agreement and separation agreement with Oculus. These expenses also include the costs of conducting market research, attending and/or participating in industry conferences and seminars, business development activities, and other general business and outside consulting activities. Selling, general and administrative expense also includes travel costs, for employees and third-party consultants, legal and accounting fees and other professional and administrative costs.

We expect that selling, general and administrative expense will increase in the future as we grow our operations, increase our personnel and expand our infrastructure to support the requirements of being a public company.

Liquidity and Capital Resources

We measure our liquidity in a number of ways, including the following:

	March 31, 2014	2013
Cash	$15,571,000	$96,000
Working Capital (Deficiency)	$14,627,000	$(1,000)

We reported net losses of $3,118,000 and $523,000 for the years ended March 31, 2014 and 2013, respectively. At March 31, 2014 and 2013, our accumulated deficit was $3,669,000 and $551,000, respectively. We have not yet achieved profitability. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will eventually need to generate significant product revenues to achieve profitability. We may never achieve profitability.

On March 26, 2014, we closed our IPO and received $16,184,000 of net proceeds (including repayment of $798,000 of IPO costs to our Former Parent). Subsequent to March 31, 2014, we received an additional $865,000 of net proceeds from our IPO. We believe that our existing cash, which includes the proceeds from our IPO, will be sufficient to fund our operations into the quarter ending December 31, 2015. We intend to use our existing cash as follows:

- approximately $8,000,000 to fund our planned Phase 1/2 clinical trial of RUT58-60, to conduct research and development activities for additional indications, and to establish an independent research facility;

- approximately $1,500,000 in milestone payments to our Former Parent, payable upon completion of last patient enrollment in our Phase 1/2 clinical trial; and

- approximately $6,500,000 for general corporate purposes and working capital (including repayment of $653,000 of non-IPO costs to our Former Parent).

This expected use of net proceeds from the IPO represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the status of and results from clinical trials of RUT58-60. As a result, our management will retain broad discretion over the allocation of the net proceeds from the IPO. We may find it necessary or advisable to use the net proceeds from the IPO for other purposes, and we will have broad discretion in the application of net proceeds from the IPO.

Future Capital Requirements and Availability of Funds

We expect to continue to incur substantial operating losses in the future and to make capital expenditures to support the expansion of our research and development programs, establishment of a research and development and manufacturing facility and to initiate commercial operations. We anticipate using a portion of the net proceeds from the IPO to finance these activities. It may take several years to obtain the necessary regulatory approvals to commercialize RUT58-60 as a drug in the United States. There is no assurance that such approvals will be obtained.

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

- the scope, rate of progress and cost of our 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 and delays in product development as a result of any changes in regulatory oversight applicable to our products;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- 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.

We may seek to raise additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations or other means. We may seek to raise additional capital due to favorable market conditions or strategic considerations even if we have sufficient funds for planned operations. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. Debt financing could require us to

pledge certain assets and enter into covenants that could restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that are not favorable to us. We do not know whether additional funding will be available on acceptable terms, or at all. A failure to secure additional funding when needed may require us to curtail certain operational activities, including regulatory trials, sales and marketing, and international operations and would have a material adverse effect on our future business and financial condition.

Cash Flows During the Years Ended March 31, 2014 and 2013

During the years ended March 31, 2014 and 2013, our sources and uses of cash were as follows:

Net Cash Used in Operating Activities

Net cash used in operating activities was $2,969,000 and $426,000 for the years ended March 31, 2014 and 2013, respectively. The net cash used in operating activities for the year ended March 31, 2014 was primarily due to cash used to fund a net loss of $3,118,000, adjusted for non-cash expenses of $2,000, partially offset by $147,000 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accounts payable and accrued expenses, due to an expansion of operating activities. The net cash used in operating activities for the year ended March 31, 2013 was primarily due to cash used to fund a net loss of $523,000 partially offset by $97,000 of cash provided by changes in the levels of operating assets and liabilities, primarily as a result of increases in accounts payable and accrued expenses, due to an expansion of operating activities.

Net Cash Used in Investing Activities

Net cash used in investing activities was $0 and $4,000 for the years ended March 31, 2014 and 2013, respectively. The net cash used in during the year ended March 31, 2013 was related to purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the years ended March 31, 2014 and 2013 was $18,444,000 and $526,000, respectively. The net cash provided by financing activities during the year ended March 31, 2014 was primarily attributable to $16,228,000 of net proceeds from our IPO (gross proceeds of $19,216,000 less $2,988,000 of offering costs paid during the year ended March 31, 2014), $1,679,000 of investment from our Former Parent and $537,000 of net proceeds from our Former Parent. The net cash provided by financing activities during the year ended March 31, 2013 was primarily attributable to $570,000 of investment from our Former Parent partially offset by $44,000 of costs related to our IPO.

Contractual Obligations

As of March 31, 2014, our most significant long-term contractual obligations were to our Former Parent pursuant to the License and Supply Agreement for (a) up to $8,000,000 of milestone payments; and (b) royalty payments that increase from 3 to 20% of specified revenues based on meeting certain sales thresholds. In addition, we lease approximately 995 square feet of executive office space in Santa Rosa, California, and our monthly rent is approximately $1,700. This lease expires on October 31, 2014.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Critical Accounting Policies

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to exercise its judgment. We exercise considerable judgment with respect to establishing sound accounting policies and in making estimates and assumptions that affect the reported amounts of our assets and liabilities, our recognition of revenues and expenses, and disclosure of commitments and contingencies at the date of the financial statements.

On an ongoing basis, we evaluate our estimates and judgments. We base our estimates and judgments on a variety of factors including our historical experience, knowledge of our business and industry, current and expected economic conditions, the attributes of our products, the regulatory environment, and in certain cases, the results of outside appraisals. We periodically re-evaluate our estimates and assumptions with respect to these judgments and modify our approach when circumstances indicate that modifications are necessary.

While we believe that the factors we evaluate provide us with a meaningful basis for establishing and applying sound accounting policies, we cannot guarantee that the results will always be accurate. Since the determination of these estimates requires the exercise of judgment, actual results could differ from such estimates.

A description of significant accounting policies that require us to make estimates and assumptions in the preparation of our financial statements is as follows:

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include the expense allocations from our Former Parent and the valuation allowance related to our deferred tax assets.

Stock-Based Compensation

We account for share-based awards exchanged for employee and director services based on the estimated fair value of the award on the grant date. We estimate the fair value of employee stock awards using the Black-Scholes valuation model. We amortize the fair value of employee stock awards on a straight-line basis over the requisite service period of the awards. Compensation expense includes the impact of an estimate for forfeitures for all stock awards.

We account for equity instruments issued to non-employees based on the estimated fair value of the instrument on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests or becomes non-forfeitable. Non-employee stock-based compensation charges are amortized over the requisite service period.

Income Taxes

We account for income taxes under Accounting Standards Codification, or ASC, 740 Income Taxes, or ASC 740. Under ASC 740, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Tax benefits claimed or expected to be claimed on a tax return are recorded in our financial statements. A tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. Uncertain tax positions have had no impact our financial condition, results of operations or cash flows.

Research and Development

Research and development expense is charged to operations as incurred and consists primarily of personnel expenses, clinical and regulatory services and supplies.

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-10, “Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation." This ASU removes the definition of a development stage entity from the ASC, thereby removing the financial reporting distinction between development stage entities and other reporting entities from GAAP. In addition, the ASU eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of operations, cash flows, and stockholders’ equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. This ASU is effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early adoption is permitted. We have elected to adopt this ASU early effective with this Annual Report on Form 10-K and its adoption resulted in the removal of all development stage disclosures.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not required for smaller reporting companies.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The information required by this Item 8 is included at the end of this Annual Report on Form 10-K beginning on page F-1.

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

Not applicable.

Item 9A. CONTROLS AND PROCEDURES.

(a) *Evaluation of Disclosure Controls and Procedures*. Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls*. There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the fourth quarter of our last fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Item 9B. OTHER INFORMATION.

Sameer Harish Employment Agreement -- On June 24, 2014, the compensation committee of our board of directors approved an employment agreement for our Chief Financial Officer, Sameer Harish, or the employment agreement, which replaced the offer letter previously in effect between us and Mr. Harish. The employment agreement continues to provide for an annual base salary of $225,000, subject to increase, as determined by our board of directors. The employment agreement further provides for payments to Mr. Harish in the event of termination without cause or resignation by Mr. Harish for good reason, as such terms are defined in the employment agreement. In the event that Mr. Harish is terminated without cause or resigns for good reason, he is entitled to: (i) a lump severance payment equal to 18 times the average monthly base salary paid to Mr. Harish over the preceding 12 months; (ii) up to one year (the lesser of one year following the date of termination or until Mr. Harish becomes eligible for medical insurance coverage provided by another employer) reimbursement for health care premiums under COBRA; and (iii) automatic vesting of all unvested options and other equity awards; provided that in the event Mr. Harish resigns for good reason prior to a change of control, only the vesting of the restricted stock units granted by us on May 12, 2014 shall be accelerated. In addition, if we consummate a change of control all equity awards granted by us that are then-outstanding and unvested shall become fully vested and exercisable immediately prior to and subject to the consummation of the change of control. In addition, we will reimburse Mr. Harish for any excise taxes owed by him under Section 280G and Section 4999 of the Internal Revenue Code because of any acceleration of the equity awards (including a gross up of any additional federal, state and local taxes payable as a result of the reimbursement of the tax payments). Mr. Harish may terminate his employment for any reason upon at least 60 days prior written notice to us.

Receipt of the termination benefits described above is contingent on Mr. Harish's execution of a general release of claims against us, our subsidiaries and our affiliates; his resignation from any and all directorships and every other position held by him with us and each of our subsidiaries; and his return to us and our affiliates or the Company Group, of all property belonging to the Company Group, received from or on account of the Company Group, or any other entity of the Company Group, or any of the Company Group's respective affiliates by Mr. Harish. In addition, Mr. Harish is not entitled to such benefits if he does not comply with the non-competition and invention assignment provisions of the employment agreement during the term of his employment, or the confidentiality provisions of the employment agreement, whether during or after the term of his employment. Furthermore, we are under no obligation to pay the above-mentioned benefits if Mr. Harish does not comply with the non-solicitation provisions of the employment agreement, which prohibit Mr. Harish from interfering with our business relations or those of any other entity in the Company Group, and from soliciting employees of any entity in the Company Group, which provisions apply during the term of employment and for two years following termination.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Management and Corporate Governance Matters," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Code of Conduct and Ethics" in the Company's Proxy Statement for the 2014 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION.

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Executive Officer and Director Compensation" and "Management and Corporate Governance Matters" in the Company's Proxy Statement for the 2014 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Company's Proxy Statement for the 2014 Annual Meeting of Stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Transactions" and "Management and Corporate Governance Matters" in the Company's Proxy Statement for the 2014 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The response to this item is incorporated by reference from the discussion responsive thereto under the caption "Independent Public Accountants" in the Company's Proxy Statement for the 2014 Annual Meeting of Stockholders.

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PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

Item 15(a). The following documents are filed as part of this annual report on Form 10-K:

Item 15(a)(1) and(2) See "Index to Consolidated Financial Statements and Financial Statement Schedules" at Item 8 to this Annual Report on Form 10-K. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

Item 15(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit Number	**Exhibit Description**	**Filed with this Report**	**Incorporated by Reference herein from Form or Schedule**	**Filing Date**	**SEC File/Reg. Number**
3.1	Restated Certificate of Incorporation of Ruthigen, Inc.		Form 8-K (Exhibit 3.1)	03/31/14	001-36199
3.2	Restated Bylaws of Ruthigen, Inc.		Form 8-K (Exhibit 3.2)	03/31/14	001-36199
4.1	Specimen certificate evidencing shares of common stock.		Form S-1 (Exhibit 4.1)	10/16/13	333-190476
4.2	Form of Representative's Warrant Agreement.		Form S-1 (Exhibit 4.2)	02/24/14	333-190476
4.3	Form of Series A Warrant.		Form S-1 (Exhibit 4.3)	02/24/14	333-190476
4.4	Form of Series B Warrant.		Form S-1 (Exhibit 4.4)	02/24/14	333-190476
4.5	Form of Warrant Agreement between Ruthigen, Inc. and VStock Transfer, LLC		Form S-1 (Exhibit 4.5)	02/24/14	333-190476

	Agreements with Executive Officers and Directors				
10.1.1*	Offer of Employment Letter between Oculus Innovative Sciences, Inc. and Sameer Harish, dated January 31, 2013; Amendment to the Offer of Employment as Chief Financial Officer, dated May 23, 2013.		Form S-1 (Exhibit 10.1)	08/08/13	333-190476
10.1.2*	Employment Agreement by and between Ruthigen, Inc. and Sameer Harish, dated June 24, 2014	X			
10.2*	Employment Agreement by and between Ruthigen, Inc. and Hojabr Alimi, dated March 21, 2013.		Form S-1 (Exhibit 10.2)	08/08/13	333-190476
10.3*	Letter Agreement dated January 31, 2014 to Employment Agreement by and between Oculus Innovative Sciences, Inc. and Hojabr Alimi.		Form S-1 (Exhibit 10.2.1)	02/24/14	333-190476
10.4*	Non-Employee Director Compensation Policy		Form S-1 (Exhibit 10.7)	10/16/13	333-190476
10.5*	Form of Indemnification Agreement by and between the Company and its directors and officers.		Form S-1 (Exhibit 10.8)	10/16/13	333-190476

	Lease Agreements			
10.6.1	Assignment and Assumption of Lease Agreement by and between Gladiator Capital Funds, LLC, Ruthigen, Inc., SR Office Properties LLC, and Hojabr Alimi, dated March 5, 2013; Office Lease by and between CA-Waterfall Towers Limited Partnership and Gladiator Capital Funds LLC, dated June 29, 2010; First Amendment to Office Lease by and between CA-Waterfall Towers Limited Partnership and Gladiator Capital Funds LLC, dated August 18, 2011; Second Amendment to Office Lease by and between CA-Waterfall Towers Limited Partnership and Gladiator Capital Funds LLC, dated September 1, 2012.	Form S-1 (Exhibit 10.3)	08/08/13	333-190476
10.6.2	Third Amendment to Office Lease by and between Ruthigen, Inc. and SR Office Properties LLC, dated October 3, 2013.	Form S-1 (Exhibit 10.3.1)	10/16/13	333-190476
	Agreements with Respect to Collaborations, Licenses, Research and Development			
10.7.1**	License and Supply Agreement by and between Ruthigen, Inc. and Oculus Innovative Sciences, Inc., dated May 23, 2013.	Form S-1 (Exhibit 10.4)	10/16/13	333-190476
10.7.2	Amendment No. 1 to License and Supply Agreement by and between Ruthigen, Inc. and Oculus Innovative Sciences, Inc., dated October 9, 2013.	Form S-1 (Exhibit 10.4.1)	10/16/13	333-190476
10.7.3	Amendment No. 2 to License and Supply Agreement by and between Ruthigen, Inc. and Oculus Innovative Sciences, Inc., dated November 6, 2013.	Form S-1 (Exhibit 10.4.2)	11/07/13	333-190476
10.7.4	Amendment No. 3 to License and Supply Agreement by and between Ruthigen, Inc. and Oculus Innovative Sciences, Inc., dated January 31, 2014.	Form S-1 (Exhibit 10.4.3)	02/24/14	333-190476
10.8.1	Shared Services Agreement by and between Ruthigen, Inc. and Oculus Innovative Sciences, Inc., dated May 23, 2013.	Form S-1 (Exhibit 10.5)	08/08/13	333-190476
10.8.2	Amendment No. 1 to Shared Services Agreement by and between Ruthigen, Inc. and Oculus Innovative Sciences, Inc., dated January 31, 2014.	Form S-1 (Exhibit 10.5.1)	02/24/14	333-190476
10.9	Amended Separation Agreement by and between Ruthigen, Inc. and Oculus Innovative Sciences, Inc., dated January 31, 2014.	Form S-1 (Exhibit 10.9)	02/24/14	333-190476

	Equity Compensation Plans	
10.11	Ruthigen, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan, or the 2013 Incentive Plan.	X
10.12	Form of option agreement under the 2013 Incentive Plan.	X

10.13	Form of restricted stock unit agreement under the 2013 Incentive Plan.	X
10.14	Form of performance-based restricted stock unit agreement for grants made under the 2013 Incentive Plan on May 11, 2014 to the executive officers and directors of Ruthigen, Inc.	X
	Other Exhibits	
23.1	Consent of Marcum LLP, independent registered public accounting firm.	X
31.1	Certificate of the Chief Executive Officer	X
31.2	Certification of the Chief Financial Officer	X
32	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X

* Management contract or compensatory plan or arrangement.

** Confidential treatment has been granted with respect to certain portions of this Exhibit, which portions have been omitted and filed separately with the SEC as part of an application for confidential treatment pursuant to the Securities Act of 1933, as amended.

SIGNATURES

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

RUTHIGEN, INC.

Date: June 30, 2014 By: /s/ Hojabr Alimi
Hojabr Alimi
Chief Executive Officer, Chief Science Officer and Chairman of the Board of Directors

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

Signature	**Title**	**Date**
/s/ Hojabr Alimi Hojabr Alimi	Chief Executive Officer, Chief Science Officer and Chairman of the Board of Directors (Principal Executive Officer)	June 30, 2014
/s/ Sameer Harish Sameer Harish	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	June 30, 2014
/s/ Richard Conley Richard Conley	Director	June 30, 2014
/s/ Gregory French Gregory French	Director	June 30, 2014

FINANCIAL STATEMENTS

RUTHIGEN, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Audit Committee of the Board of Directors

and Stockholders of Ruthigen, Inc.

We have audited the accompanying balance sheets of Ruthigen, Inc. (the "Company") as of March 31, 2014 and 2013, and the related statements of operations, changes in stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Ruthigen, Inc. as of March 31, 2014 and 2013, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

As disclosed in Note 2 to the financial statements, management has elected to early-adopt Accounting Standards Update 2014-10, which eliminates the previous disclosure requirements for development stage entities. Our opinion is not modified with respect to this matter.

/s/ Marcum LLP

Marcum LLP
New York, NY
June 30, 2014

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RUTHIGEN, INC.

BALANCE SHEETS

	March 31, 2014	2013
Assets		
Current Assets:		
Cash	$15,571,000	$96,000
Prepaid expenses and other current assets	3,000	4,000
Total Current Assets	15,574,000	100,000
Property and equipment, net	2,000	4,000
Deferred offering costs	-	44,000
Total Assets	$15,576,000	$148,000
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$410,000	$101,000
Payable to Former Parent	537,000	-
Total Current Liabilities	947,000	101,000
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 500,000 shares authorized; no shares issued and outstanding at March 31, 2014 and 2013, respectively	-	-
Common stock, $0.0001 par value; 100,000,000 shares authorized; 4,650,000 and 2,000,000 shares issued and outstanding at March 31, 2014 and 2013, respectively	465	200
Additional paid-in capital	18,297,535	597,800
Accumulated deficit	(3,669,000)	(551,000)
Total Stockholders' Equity	14,629,000	47,000
Total Liabilities and Stockholders' Equity	$15,576,000	$148,000

The accompanying footnotes are an integral part of these financial statements.

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RUTHIGEN, INC.

STATEMENTS OF OPERATIONS

	For The Years Ended March 31,	
	2014	2013
Revenues	$-	$-
Operating Expenses		
Research and development	1,382,000	258,000
Selling, general and administrative	1,736,000	265,000
Total Operating Expenses	3,118,000	523,000
Net Loss	$(3,118,000)	$(523,000)
Net Loss Per Share - Basic and Diluted	$(1.53)	$(0.26)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	2,036,301	2,000,000

The accompanying footnotes are an integral part of these financial statements.

RUTHIGEN, INC.

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

FOR THE YEARS ENDED MARCH 31, 2014 AND 2013

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance - March 31, 2012	-	$ -	$28,000	$(28,000)	$-
Investment from Former Parent	-	-	570,000	-	570,000
Shares issued to Former Parent	2,000,000	200	(200)	-	-
Net loss	-	-	-	(523,000)	(523,000)
Balance - March 31, 2013	2,000,000	200	597,800	(551,000)	47,000
Investment from Former Parent	-	-	1,679,000	-	1,679,000
Shares and warrants issued for cash in connection with initial public offering	2,650,000	265	16,020,735	-	16,021,000
Net loss	-	-	-	(3,118,000)	(3,118,000)
Balance - March 31, 2014	4,650,000	$ 465	$18,297,535	$(3,669,000)	$14,629,000

The accompanying footnotes are an integral part of these financial statements.

RUTHIGEN, INC.

STATEMENTS OF CASH FLOWS

	For The Years Ended March 31,	
	2014	2013
Cash Flows From Operating Activities		
Net loss	$(3,118,000)	$(523,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,000	-
Changes in operating assets and liabilities:		
Prepaid expenses	1,000	(4,000)
Accounts payable and accrued expenses	146,000	101,000
Net Cash Used in Operating Activities	(2,969,000)	(426,000)
Cash Flows From Investing Activities		
Purchases of property and equipment	-	(4,000)
Net Cash Used in Investing Activities	-	(4,000)
Cash Flows From Financing Activities		
Advances from Former Parent	1,453,000	-
Repayment of Former Parent advances	(916,000)	-
Proceeds from issuance of common stock and warrants less issuance costs [1]	16,228,000	(44,000)
Investment from Former Parent	1,679,000	570,000
Net Cash Provided by Financing Activities	18,444,000	526,000
Net Increase In Cash	15,475,000	96,000
Cash - Beginning	96,000	-
Cash - Ending	$15,571,000	$96,000
Supplemental Disclosures of Cash Flow Information:		
Non-cash operating and financing activities:		
Accrued offering costs	$163,000	$-

[1] Gross proceeds of initial public offering of $19,216,000 less $3,195,000 of offering costs, of which $2,826,000 was withheld from the proceeds, $206,000 was paid in cash (including $44,000 paid during the fiscal year ended March 31, 2013) and $163,000 was accrued as of March 31, 2014.

The accompanying footnotes are an integral part of these financial statements.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 1. Organization

Organization

Ruthigen, Inc. (the "Company" or "Ruthigen") was incorporated under the laws of the State of Nevada on January 18, 2013. The Company was reincorporated from Nevada to Delaware on September 25, 2013. The Company's principal office is located in Santa Rosa, California. Ruthigen is a biopharmaceutical company focused on the discovery, development, and commercialization of pharmaceutical-grade hypochlorous acid, or HOCl, based therapeutics designed to prevent and treat infection in invasive applications.

The Company closed its initial public offering ("IPO") on March 26, 2014, pursuant to which an aggregate of 2,650,000 units were sold at a price of $7.25 per unit. Prior to the IPO, the Company was a wholly-owned subsidiary of Oculus Innovative Sciences, Inc. ("Oculus" or "Former Parent"). See Note 6 Stockholders' Equity – Initial Public Offering and Note 9 Subsequent Events for additional details.

Expenses of the Company include those specifically identifiable to the Company, and in periods prior to the year ended March 31, 2014, expenses specifically identifiable to the Company and allocations of salaries and consulting expenses from Oculus. The allocated expenses were primarily based on the use of estimates. Expenses allocated from the Former Parent were costs which benefited the Company and were required for its operations. Certain general corporate expenses of the Former Parent were not allocated because they did not provide a direct or material benefit to the business. In addition, if the Company had been part of its Former Parent during the periods presented, such general corporate expenses incurred by the Former Parent would not have significantly changed as a result of not having to operate the business. In the opinion of management, the methods of allocating costs were reasonable; however such costs did not necessarily equal costs that the Company would have incurred on a stand-alone basis. Therefore, the financial information included herein may not necessarily reflect assets and liabilities and expenses and cash flows of the Company if operated on a stand-alone basis. To date, the Company has not generated any revenues from its operations.

Reverse Stock Split

On September 25, 2013, the board of directors and the stockholders of the Company approved a 1-for-2.5 reverse stock split of the Company's outstanding common stock, $0.0001 par value, which was effected on September 25, 2013. In connection with the reverse stock split, every 2.5 shares of common stock were reclassified and combined into one share of common stock. The reverse stock split reduced the number of shares of common stock outstanding from 5,000,000 to 2,000,000. The total number of authorized common stock that the Company shall have the authority to issue as set forth in the Company's Restated Certificate of Incorporation, as amended, was not proportionally decreased in connection with the reverse stock split.

All common shares and per share amounts contained in the Company's accompanying financial statements have been retroactively adjusted to reflect a 1-for-2.5 reverse stock split, effective as of September 25, 2013.

Note 2. Summary of Significant Accounting Policies

Liquidity and Financial Condition

The Company incurred a net loss of $3,118,000 and $523,000 for the years ended March 31, 2014 and 2013, respectively. At March 31, 2014, the Company's working capital and accumulated deficit were $14,627,000 and $3,669,000, respectively. The Company has not yet achieved profitability and it is expected that research and development and general and administrative expenses will continue to increase and, as a result, the Company will eventually need to generate significant product revenues to achieve profitability.

Subsequent to March 31, 2014, in connection with the exercise of the Over-Allotment Option (as defined in Note 6) by the lead underwriter in the Company's IPO, 154,290 shares of common stock were sold for $1,028,000 of aggregate gross proceeds to the Company. The Company believes that its existing cash, which includes the proceeds from its IPO, will be sufficient to fund its operations into the quarter ending December 31, 2015. However, in order for the Company to execute its research and development strategy and to obtain the necessary regulatory approvals to commercialize RUT58-60 as a drug in the United States, the Company will need to raise additional funds through public or private equity offerings, debt financings, corporate collaborations or other means.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 2. Summary of Significant Accounting Policies - Continued

Liquidity and Financial Condition – Continued

The Company has not secured any commitment for new financing at this time, nor can it provide any assurance that new financing will be available on commercially acceptable terms, if at all. If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives and take additional measures to reduce costs in order to conserve its cash.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include the expense allocations from the Former Parent and the valuation allowance related to the Company's deferred tax assets.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk include amounts held as cash. Cash is maintained in financial institutions located in the United States. The Company is exposed to credit risk in the event of default by these financial institutions for amounts in excess of the Federal Deposit Insurance Corporation insured limits.

Fair Value of Financial Assets and Liabilities

Financial instruments, including cash, accounts payable and accrued expenses are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments.

The Company measures the fair value of financial assets and liabilities based on 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. The Company maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. The Company uses 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 of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets. Depreciation of leasehold improvements is computed using the straight-line method over the lesser of the estimated useful life of the improvement or the remaining term of the lease. Estimated useful asset life by classification is as follows:

	Years
Office Equipment	3
Manufacturing, lab and other equipment	5
Furniture and fixtures	7

Upon retirement or sale, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

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RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 2. Summary of Significant Accounting Policies - Continued

Impairment of Long-Lived Assets

The Company periodically reviews the carrying values of its long-lived assets when events or changes in circumstances would indicate that it is more likely than not that their carrying values may exceed their realizable values, and records impairment charges when considered necessary. Specific potential indicators of impairment include, but are not necessarily limited to:

- a significant decrease in the fair value of an asset;
- a significant change in the extent or manner in which an asset is used or a significant physical change in an asset;
- a significant adverse change in legal factors or in the business climate that affects the value of an asset;
- an adverse action or assessment by the U.S. Food and Drug Administration or another regulator;
- an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset; and
- operating or cash flow losses combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with an income-producing asset.

When circumstances indicate that an impairment may have occurred, the Company tests such assets for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of such assets and their eventual disposition to their carrying amounts. In estimating these future cash flows, assets and liabilities are grouped at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows generated by other such groups. If the undiscounted future cash flows are less than the carrying amount of the asset, an impairment loss, measured as the excess of the carrying value of the asset over its estimated fair value, will be recognized. The cash flow estimates used in such calculations are based on estimates and assumptions, using all available information that management believes is reasonable.

Stock-Based Compensation

The Company accounts for share-based awards exchanged for employee and director services at the estimated grant date fair value of the award. The Company estimates the fair value of employee stock awards using the Black-Scholes valuation model. The Company amortizes the fair value of employee stock awards on a straight-line basis over the requisite service period of the awards. Compensation expense includes the impact of an estimate for forfeitures for all stock awards.

The Company accounts for equity instruments issued to non-employees at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests or becomes non-forfeitable. Non-employee stock-based compensation charges are amortized over the requisite service period.

Research and Development

Research and development expense is charged to operations as incurred and consists primarily of personnel expenses, clinical and regulatory services and supplies.

Net Loss per Share

The Company computes basic net loss per share by dividing net loss per share available to common stockholders by the weighted average number of common shares outstanding for the period and excludes the effects of any potentially dilutive securities. Diluted earnings per share, if presented, would include the dilution that would occur upon the exercise or conversion of all potentially dilutive securities into common stock using the “treasury stock” and/or “if converted” methods as applicable.

As of March 31, 2014, outstanding stock warrants to purchase 3,140,250 shares of common stock were excluded from the calculation of diluted net loss per common share because their impact would have been anti-dilutive. As of March 31, 2013, the Company did not have any potentially dilutive securities outstanding.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 2. Significant Accounting Policies - Continued

Income Taxes

The Company accounts for income taxes under Accounting Standards Codification (“ASC”) 740 Income Taxes (“ASC 740”). Under ASC 740, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Tax benefits claimed or expected to be claimed on a tax return are recorded in the Company’s financial statements. A tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. Uncertain tax positions have had no impact on the Company’s financial condition, results of operations or cash flows.

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-10, “Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation." This ASU removes the definition of a development stage entity from the ASC, thereby removing the financial reporting distinction between

development stage entities and other reporting entities from GAAP. In addition, the ASU eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of operations, cash flows, and stockholders' equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. This ASU is effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early adoption is permitted. The Company has elected to adopt this ASU effective with this Annual Report on Form 10-K and its adoption resulted in the removal of previously required development stage disclosures.

Subsequent Events

Management has evaluated subsequent events or transactions occurring through the date these financial statements were issued (See Note 9 Subsequent Events).

Note 3. Property and Equipment

Property and equipment consists of the following:

	March 31,	
	2014	2013
Office Equipment	$4,000	$4,000
Less: accumulated depreciation and amortization	(2,000)	-
Total	$2,000	$4,000

Depreciation expense amounted to $2,000 and $0 for the years ended March 31, 2014 and 2013, respectively. Depreciation expense is reflected in selling, general and administrative expenses in the statements of operations.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2014	2013
Accrued employee compensation	$109,000	$40,000
Accrued director compensation	50,000	-
Accrued legal fees	183,000	18,000
Other accrued expenses	68,000	43,000
Total	$410,000	$101,000

Note 5. Commitments and Contingencies

Employment Commitments

The Company has an employment agreement in place with its Chief Executive Officer (“CEO”) that provides for, among other things, the payment of a lump sum severance benefit equal to twenty-four times the CEO’s average monthly base salary paid to the CEO during the twelve months preceding the date of termination. As of March 31, 2014, the CEO’s base salary was $375,000 per annum.

On August 12, 2013, Oculus’ Compensation Committee approved the grant of a one-time cash bonus of $158,000 to the Company’s CEO in order to recognize the CEO’s efforts related to the preparation and filing of the Company’s registration statement on Form S-1 for its IPO.

License and Supply Agreement

The Company entered into a license and supply agreement with Oculus which was effective upon the completion of the IPO, pursuant to which Oculus has agreed to exclusively license certain of its proprietary technology to the Company to enable the Company's research, development and commercialization of newly discovered RUT58-60 and any improvements to it (the "Product") in the United States, Canada, the European Union and Japan (collectively, the "Territory") in certain invasive uses in humans (the "Field") which do not include dermatologic uses or uses for ophthalmic, sinusitis or otic indications.

In order to pay for the costs of development of the Product, Ruthigen obtained financing from Oculus until the IPO was completed. Under the agreement, the Company's right to commercialize the Product in the Field in the Territory is exclusive and shall be performed in accordance with the development and commercialization plan set forth in the agreement (which may be modified by the Company's discretion), and Oculus shall manufacture and supply, at a purchase price equal to 20% over the cost of goods to Oculus, the Product as and when the Company requests. In addition, the Company has the right to purchase certain manufacturing equipment from Oculus at a purchase price equal to a fixed percentage over the cost of the equipment to Oculus, so that the Company may manufacture the Product independently.

Under the license and supply agreement, the Company will be required to make a total of $8 million of milestone payments to Oculus over the next several years for the first Product only, as follows: $1.5 million upon the completion of last patient enrollment in the Phase 1/2 clinical trial, $1.5 million upon the completion of last patient enrollment of the Company's first pivotal trial, $3 million upon completion of the first meeting with the FDA following completion of the Company's first pivotal clinical trial, and $2 million upon first patient enrollment in the second pivotal clinical trial. In addition, as further consideration under the agreement, the Company will be required to make royalty payments to Oculus based on its annual net sales of the Product from the date of first commercial sale to the date that the Company ceases to commercialize the Product, which percentage royalty rate will vary between 3% and 20% and will increase based on various net sales thresholds and will differ depending on the country in which the sales are made.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 5. Commitments and Contingencies - Continued

License and Supply Agreement – Continued

The agreement contains representations and warranties of the parties regarding its enforceability, no conflict with agreements to which the parties are bound, and no violations of law, and representations of Oculus that it has not granted any other license with respect to the Product for use in the Field in the Territory. The Company has agreed to indemnify Oculus with respect to third party claims arising from the Company's development, commercialization or manufacture of the Product in the Field in the Territory with certain exceptions, and the Company and Oculus have each agreed to indemnify the other with respect to third party claims arising from their respective inaccuracy and/or breach of representations and warranties or negligence or willful misconduct. Either party may terminate the agreement for an uncured material breach, but only after undergoing a dispute resolution process. In addition, either party may terminate the agreement if the other party ceases to do business, makes an assignment for the benefit of creditors or voluntarily files, fails to contest an involuntary filing or is adjudicated bankrupt or insolvent under bankruptcy, insolvency, receivership or similar law.

Shared Services Agreement

The Company entered into a shared services agreement with Oculus which was effective upon the completion of the IPO, pursuant to which Oculus will provide Ruthigen with general services, including general accounting and human resources, until the termination of agreement. Additionally, Oculus will permit the Company to access its Petaluma, California and Seattle, Washington facilities during normal business hours (subject to certain exceptions) and for the purposes described in the shared services agreement.

Oculus shall also provide the Company with consulting and technical services. Such services shall be billable at the hourly or fixed monthly rate as set forth in the shared services agreement, which is subject to change based upon mutual written agreement between Oculus and Ruthigen. After the completion of the IPO, the Company agreed to pay invoices generated by Oculus within thirty days of receipt thereof.

Separation Agreement

The Company has entered into a separation agreement with Oculus that contains key provisions relating to the ongoing relationship with Oculus following the completion of the IPO. The separation agreement became effective upon the completion of the IPO and terminates on the earlier of 8.5 years following the closing of the IPO or when the parties mutually agree to terminate it. The separation agreement also contains a series of restrictions on Oculus' ability to transfer the Ruthigen shares that Oculus owns. Oculus is restricted from transferring any of the Ruthigen shares it owns during the first year (the "Lock-Up Period") immediately following the IPO unless it receives consent to do so from the Company's Board of Directors and the lead underwriter in the Company's IPO.

Following the Lock-Up Period, transfers by Oculus of the Ruthigen shares it owns must be conducted with the consent of the board of directors or within the prescribed requirements for such transfers set forth in the separation agreement. These prescribed requirements include that the transfers must be in private placement transactions, the purchase price discount may not exceed certain percentages depending on the transferee, the amount of shares transferred in a given transfer (or series of transfers comprising a single transaction) may not exceed the greater of 5% of the Company's outstanding shares or $1,500,000 in net proceeds to Oculus, as well as certain other requirements set forth in the separation agreement. In addition to the manner described above, if, following a minimum of 41.5 months following the closing of the IPO have lapsed and Oculus has not consummated transfers of the Ruthigen shares it owns resulting in at least $3.8 million in net proceeds to Oculus, then Oculus has a one-time transfer and registration right to transfer the Ruthigen shares it owns in an amount equal to the difference between $3.8 million and the proceeds received by Oculus from prior transfers as of the time Oculus elects to exercise its one-time right. Transfers conducted using this one-time right must be conducted with the consent of the Company's board of directors or within the prescribed requirements for such transfers set forth in the separation agreement, including, for example, that the purchase price discount may not exceed certain percentages, the amount of shares transferred may not exceed $3,800,000 in net proceeds to Oculus, as well as certain other requirements set forth in the separation agreement. The separation agreement provides Oculus with certain "piggy back" registration rights of up to 30% of the value of the securities the Company registers after the lock-up period, if the Company proposes to register any of its common stock following the completion of the IPO, subject to certain conditions and limitations.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 5. Commitments and Contingencies - Continued

Separation Agreement - Continued

The separation agreement also provides for certain cooling off periods between market attempts and/or successful transfers, the length of which are dependent upon whether and the quantity of the Ruthigen shares that Oculus transfers. The majority of the material restrictions and obligations contained in the separation agreement lapse if and when Oculus own less than 19.9% of the outstanding shares of the Company's common stock.

The separation agreement also defined the methodology for the allocation of the operational and IPO related expenses incurred prior to and in connection with the IPO for which the Company was required to reimburse Oculus. The Company will also reimburse Oculus for expenses such as salaries and benefits advanced or paid on the Company's behalf or for the Company's benefit during a transition period following the closing of the IPO. During the year ended March 31, 2014, the Company incurred $1,450,000 of IPO and other costs which were reimbursed to Oculus at the closing of the IPO or shortly thereafter.

The separation agreement provides that each party will indemnify, defend and hold harmless the other party and its affiliates for third party claims asserted against the other party. The separation agreement also provides that, so long as Oculus maintains a directors' and officers' insurance program covering the past and present officers and directors of Oculus, the program shall be standard in Oculus' industry and Oculus shall not exclude any former Oculus director from any insurance policy coverage.

Funding Agreement

On January 31, 2014, the Company entered into a funding agreement with Oculus, pursuant to which Oculus agreed to fund the Company in the additional amount of up to $760,000 to pay certain accounts payables outstanding at December 31, 2013 and to fund certain future expenditures through the closing of the IPO. Through the closing of the

IPO, Oculus funded the Company in the additional amount of $534,000, which was repaid to Oculus on April 1, 2014.

Operating Lease

The Company leases a facility in Santa Rosa, California under a non-cancelable operating lease for approximately 995 square feet of executive office space. The lease expires in October 2014 and monthly rent is approximately $1,700. The aggregate base rent payable over the lease term is being recognized on a straight-line basis. Rent expense amounted to approximately $20,000 and $17,000 for the years ended March 31, 2014 and 2013, respectively. Rent expense is reflected in selling, general and administrative expenses in the statements of operations.

Future minimum payments under the operating lease agreement are as follows:

For the Years Ending March 31,	Amount
2015	$11,813

Note 6. Stockholders' Equity

Authorized Capital

The Company is authorized to issue up to 100,000,000 shares of common stock with a par value of $0.0001 per share and 500,000 shares of preferred stock with a par value of $0.0001 per share.

Description of Common Stock

Each share of common stock has the right to one vote. The holders of common stock are entitled to dividends when funds are legally available and when declared by the board of directors.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 6. Stockholder's Equity - Continued

2013 Plan

In September and October 2013, respectively, the Company's board of directors and stockholders approved the 2013 Employee, Director and Consultant Equity Incentive Plan (the "2013 Plan"), which became effective upon the closing of the IPO. The 2013 Plan will expire on September 30, 2023. Under the 2013 Plan, the Company may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards. There are 998,355 shares of the Company's common stock authorized for issuance under the 2013 Plan. The Company intends to issue new shares of common stock to satisfy 2013 Plan obligations.

In addition, the 2013 Plan contains an "evergreen" provision, which allows for an annual increase in the number of shares of the Company's common stock available for issuance under the 2013 Plan on the first day of each calendar year beginning with calendar year 2015. The annual increase in the number of shares shall be equal to the lowest of: (a) 232,500 shares of the Company's common stock; (b) 5% of the number of shares of the Company's common stock outstanding as of such date; and (c) an amount determined by the Company's board of directors or compensation committee.

Initial Public Offering

On March 21, 2014, the Company announced that it had priced its IPO of 2,650,000 units (the "IPO"), with each unit consisting of (i) one share of common stock and (ii) one Series A warrant (the "Series A Warrant"), at an IPO price of $7.25 per unit (each a "Unit"), less underwriting discounts and commissions and IPO expenses. In addition, the Company granted to the underwriters a 45-day option (the "Over-Allotment Option") to purchase up to (i) 397,500 additional shares of common stock at price of $6.6608 per share, which price reflects underwriting discounts and commissions, and/or (ii) 397,500 additional Series A Warrants at a price of $0.0092 per Series A Warrant, which price reflects underwriting discounts and commissions.

On March 26, 2014, the Company closed on the sale of 2,650,000 Units and the underwriters exercised a portion of the Over-Allotment Option by purchasing Series A Warrants from the Company to purchase 397,500 shares of common stock for nominal value, all of which resulted in $16,021,000 of aggregate net proceeds to the Company ($19,216,000 of gross proceeds less $3,195,000 of issuance costs). As a result, an aggregate of 2,650,000 shares of common stock and Series A Warrants to purchase an aggregate of 3,047,500 shares of common stock were issued in the IPO.

The Series A Warrant is exercisable at a price of $7.25 per warrant for (x) one share of common stock and (y) one Series B warrant (the "Series B Warrant") to purchase one share of common stock at an exercise price of $9.0625 per share. The Series A Warrants are exercisable on the date of issuance and terminate on the second anniversary of the date of issuance. The exercise price and the number of shares for which each Series A Warrant may be exercised is subject to adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Company's common stock. In addition, subject to certain exceptions, the exercise price of the Series A Warrants is subject to a weighted average reduction if the Company issues shares of common stock (or securities convertible into common stock) in the future at a price below both (a) the current exercise price of the Series A Warrant; and (b) the current market price of the Company's common stock. The Series A Warrants may be called by the Company, for consideration equal to $0.0001 per Series A Warrant, on not less than 10 business days' notice if the closing price of the common stock is above 150% of the $7.25 IPO price per unit for any period of 20 consecutive business days ending not more than three business days prior to the call notice date. The Series B Warrants will be exercisable on the date that the warrants are issued and will terminate on the fifth anniversary of the date the warrants are first exercisable. The Company agrees that, during the period the Series A Warrants are outstanding, it will maintain the effectiveness of the registration statement such that the holder may exercise the Series A Warrants to receive registered shares of common stock and registered Series B Warrants (and the shares of common stock underlying the Series B Warrants). The Company determined that the Series A and Series B Warrants are equity instruments because the warrants are (a) freestanding financial instruments; (b) indexed to the Company's own stock; (c) not permitted to be settled for cash; and (d) exercisable into common stock for which the Company has sufficient authorized and unissued shares.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 6. Stockholder's Equity - Continued

Initial Public Offering - Continued

The Company issued to the representative of the underwriters warrants to purchase 92,750 shares of the Company's common stock at an exercise price of $9.0625 per share (the "Representative's Warrants"). The Representative's Warrants are exercisable commencing on March 21, 2015 and expiring on March 21, 2019. The Representative's Warrants and the shares of common stock underlying the warrants have been deemed compensation by Financial Industry Regulatory Authority, Inc. ("FINRA") and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA.

The Company, its officers and directors and its Former Parent have entered into lock-up agreements with the underwriters. Under these agreements, the Company and the other parties have agreed, subject to specified exceptions, not to sell or transfer any common stock or securities convertible into, or exchangeable or exercisable for, common stock, during a period ending 180 days after the date of its prospectus (one year for the shares of common stock owned by the Company's Former Parent), without first obtaining the written consent of representative of the underwriters. The lock up period for the Company, its officers and directors is subject to extension for up to an additional 18 days upon the occurrence of certain specified events.

Investment from Former Parent

During the years ended March 31, 2014 and 2013, the Company's Former Parent made capital contributions to the Company in the amount of $1,679,000 and $570,000, respectively, which were recorded as additional paid-in capital in the statement of changes in stockholders' equity. See Note 7 Related Party Transactions for details associated with the Former Parent's ownership interest in the Company.

Stock Warrants

A summary of the warrant activity during the years ended March 31, 2014 and 2013 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, March 31, 2012	-	$ -		
Granted	-	-		
Exercised	-	-		
Forfeited	-	-		
Outstanding, March 31, 2013	-	-		
Granted	3,140,250	7.30		
Exercised	-	-		
Forfeited	-	-		
Outstanding, March 31, 2014	3,140,250	$ 7.30	2.1	$ -
Exercisable, March 31, 2014	3,047,500	$ 7.25	2.0	$ -

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 6. Stockholder's Equity - Continued

Stock Warrants - Continued

The following table presents information related to stock warrants at March 31, 2014:

Warrants Outstanding			Warrants Exercisable
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$7.2500	3,047,500	2.0	3,047,500
$9.0625	92,750	-	-
	3,140,250	2.0	3,047,500

Note 7. Income Taxes

The Company is included in the U.S. federal and state (California) tax returns with its Former Parent through the March 26, 2014 closing date of the IPO. However, this footnote has been presented as if the Company was filing tax returns on a separate, stand-alone basis during the pre-IPO periods. Post-IPO, the Company will file separate, stand-alone tax returns.

The following summarizes the income tax provision (benefit):

	For The Years Ended March 31,	
	2014	2013
Federal		
Current	$-	$-
Deferred	(1,031,000)	(177,000)
State and local		
Current	-	-
Deferred	(182,000)	(26,000)
	(1,213,000)	(203,000)
Change in valuation allowance	1,213,000	203,000
Income tax provision (benefit)	$-	$-

The Company has the following net deferred tax assets:

	For The Years Ended March 31,			
	2014		2013	
Expected federal statutory rate	(34.0)	%	(34.0)	%
State tax rate, net of federal benefit	(6.0)	%	(4.8)	%
Change in effective state tax rate	(0.3)	%	0.0	%
Other permanent	1.3	%	0.0	%
Change in valuation allowance	39.0	%	38.8	%
Income tax provision (benefit)	0.0	%	0.0	%

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 7. Income Taxes - Continued

A reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	March 31, 2014	2013
Net operating loss carryforwards	$1,427,000	$214,000
Valuation allowance	(1,427,000)	(214,000)
Net deferred tax assets	$-	$-

For the years ended March 31, 2014 and 2013, the Company had approximately $3,567,000 and $551,000 of federal and state net operating loss carryovers ("NOLs"), respectively, which begin to expire if not utilized in 2033. These net operating loss carryovers are subject to annual limitations under Internal Revenue Code Section 382 because there was a greater than 50% ownership change in connection with the March 26, 2014 closing of the IPO.

The Company, after considering all available evidence, fully reserved its deferred tax assets since it is more likely than not that such benefits will not be realized in future periods. The Company has incurred losses for both financial reporting and income tax purposes for the years ended March 31, 2014 and 2013. The Company will continue to evaluate its deferred tax assets to determine whether any changes in circumstances could affect the realization of their future benefit. If it is determined in future periods that portions of the Company's deferred tax assets satisfy the realization standards, the valuation allowance will be reduced accordingly.

The Company does not have any tax positions for which it is reasonably possible that the total amount of gross unrecognized tax benefits will increase or decrease within 12 months of March 31, 2014. The unrecognized tax benefits may increase or change during the next year for items that arise in the ordinary course of business. The earliest Former Parent tax returns that include the Company's carryforward NOLs, which remain subject to examination by tax authorities are those for the fiscal period ended March 31, 2013. The Company has elected to

reflect interest and penalties attributable to income taxes, to the extent they arise, as a component of its income tax provision or benefit.

Note 8. Related Party Transactions

Upon completion of the IPO, on March 26, 2014, the Former Parent owned approximately 43% of the Company's common stock.

During the year ended March 31, 2013, the Company contracted with a direct member of the Chief Executive Officer's family to provide marketing services, including but not limited to brand management of the Company's website, name and logo development. The family member was paid $6,000 for services completed.

Beginning in March 2013, the Company employed an immediate family member of the Chief Executive Officer as an operations technician at an annualized salary of approximately $36,000.

Note 9. Subsequent Events

Initial Public Offering

Subsequent to March 31, 2014, in connection with the IPO, the underwriters exercised a portion of the Over-Allotment Option pursuant to which the Company sold an additional 154,290 shares of common stock, which resulted in $1,028,000 of aggregate gross proceeds to the Company. As of the date of this filing, the IPO has terminated.

RUTHIGEN, INC.

NOTES TO FINANCIAL STATEMENTS

Note 9. Subsequent Events – Continued

Stock-Based Compensation

On May 11, 2014, the Company granted restricted stock units exercisable for an aggregate of 409,355 shares ("RSUs") to employees and directors, pursuant to the 2013 Plan. RSUs for 341,000 shares of common stock vest ratably over three years on a quarterly basis and RSUs for 68,355 shares vest in equal installments based on achievement of the following: (1) enrollment of the first patient in the first pivotal clinical trial for RUT58-60 on or prior to May 11, 2017; (2) enrollment of the first patient in the second pivotal clinical trial for RUT58-60 on or prior to May 11, 2018; and (3) completion of the clinical study report containing the results of the second pivotal clinical trial for RUT58-60 on or prior to May 11, 2019.

On May 12, 2014, the Company granted options to employees and directors to purchase an aggregate of 332,500 shares of common stock at an exercise price of $6.37 per share, pursuant to the 2013 Plan. The shares vest ratably over three years on a quarterly basis.

Employment Agreement

On June 24, 2014, the compensation committee of the Company's board of directors approved an employment agreement for its Chief Financial Officer ("CFO"), which replaced the offer letter previously in effect between the Company and the CFO. The employment agreement continues to provide for an annual base salary of $225,000, subject to increase, as determined by the Company's board of directors. The employment agreement further provides for payments to the CFO in the event of termination without cause or resignation by the CFO for good reason, as such terms are defined in the employment agreement. In the event that the CFO is terminated without cause or resigns for good reason, the CFO is entitled to: (i) a lump severance payment equal to 18 times the average monthly base salary paid to the CFO over the preceding 12 months; (ii) up to one year (the lesser of one year following the date of termination or until the CFO becomes eligible for medical insurance coverage provided by another employer) reimbursement for health care premiums under COBRA; and (iii) automatic vesting of all unvested options and other equity awards; provided that in the event the CFO resigns for good reason prior to a change of control, only the vesting of the restricted stock units granted by the Company on May 12, 2014 shall be accelerated.

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