

Ruthigen, Inc.  
Form 10-K  
June 10, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended March 31, 2015

**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**  
*(State or other jurisdiction)*

**46-1821392**  
*(I.R.S. Employer Identification No.)*

*of incorporation or organization)*

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

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

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

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  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.

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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

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

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 sold as of September 30, 2014, the last business day of its most recently completed second fiscal quarter, was \$13,572,764.

As of June 5, 2015, the registrant had 4,804,290 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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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,” “project,” “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 were incorporated in January 2013 as a wholly-owned subsidiary of Oculus Innovative Sciences, Inc. (“Oculus”) and operated as such until the completion of our initial public offering in March 2014. We were reincorporated from Nevada to Delaware in September 2013. We currently have no products approved for sale. We have been focusing on the commercialization of our lead drug candidate, RUT58-60, which is a broad spectrum anti-infective drug for the prevention and treatment of infection in surgical and trauma procedures. We have licensed the intellectual property rights underlying the RUT58-60 from Oculus pursuant to a License and Supply Agreement with Oculus.

## Merger

On March 13, 2015, we entered into an agreement and plan of merger (the “Merger Agreement”) with Ruthigen Merger Corp., our wholly owned subsidiary (“Merger Sub”), and Pulmatrix Inc., a Delaware corporation (“Pulmatrix”), which provides for the merger of Merger Sub with and into Pulmatrix, with Pulmatrix surviving as our wholly owned subsidiary, and Merger Sub will cease to exist (the “Merger”). See our Current Report on Form 8-K dated March 13, 2015 for additional details related to the Merger.

We will issue shares of our common stock to the Pulmatrix equity holders in connection with the Merger as merger consideration and shares of common stock to certain lenders of Pulmatrix upon the conversion of bridge loans, such that the former Pulmatrix security holders will hold approximately 83% of Ruthigen’s post-merger shares. Although we are the legal acquirer and will issue shares of its common stock to effect the merger with Pulmatrix, the business combination will be accounted for as a reverse acquisition of Ruthigen by Pulmatrix under GAAP. In addition, at the effective time of the Merger, warrants to purchase shares of Pulmatrix common stock will be converted into and exchangeable for warrants to purchase shares of our common stock pursuant to an exchange ratio described in the Merger Agreement.

If the Merger is completed, Hojabr Alimi, our Chief Executive Officer and Sameer Harish, our Chief Financial Officer will resign from their current positions with the Company and continue to be employed by the combined company and have agreed to terminate equity grants previously made to them and will receive cash and restricted stock units pursuant to the new employment agreements Pulmatrix and Ruthigen entered into with each of Messrs. Alimi and Harish.

Pending the consummation of the Merger, the Merger Agreement permits us to scale down our operations as we deem necessary and requires us to scale back patient enrollment in our clinical trial of RUT58-60, our primary drug candidate, and it is currently anticipated that the combined company would focus its resources on the development of products within the scope of Pulmatrix’s current business plan. As a result, following the Merger, the combined company may seek to sell or assign its rights related to our current drug candidates, including RUT58-60.

## **Sale of Common Stock by Oculus**

On January 8, 2015, we consented to the proposed sale of 2,000,000 shares of common stock held by our former parent, Oculus, to certain accredited investors (the “Oculus Share Purchasers”) at a purchase price of \$2.75 per share subject to the occurrence of the closing of the Merger pursuant to a securities purchase agreement.

On March 13, 2015, Oculus entered into a securities purchase follow-up agreement with the Oculus Share Purchasers pursuant to which it reduced the number of shares of our common stock to be sold to 1,650,000 at a price of \$2.75 per share, provided that 50,000 shares may be sold to one or more investors prior to closing. If the Merger does not close by August 13, 2015 or as may be extended up to 60 calendar days at Oculus’s discretion, there will be no obligation of the Oculus Share Purchasers to purchase the shares. Oculus will retain the voting rights to the 50,000 shares until and through the date of closing of the Merger. In the event that the closing of the Merger does not occur on or prior to September 30, 2015, the 50,000 shares of common stock will become fully tradable and full voting rights will transfer to the buyer(s) of such shares. On March 13, 2015, Oculus entered into a securities purchase agreement with several investors, pursuant to which the investors agreed to purchase the 350,000 shares of our common stock at a price of \$2.75 per share. On March 23, 2015, this sale closed. Oculus retained the voting rights to the 350,000 shares until and through the date of closing of the Merger. In the event that the closing of the Merger does not occur on or prior to September 30, 2015, the 350,000 shares of Ruthigen common stock will become fully tradable and full voting rights will transfer to the purchasers of such shares. Voting restrictions applicable to shares of Ruthigen common stock held by Oculus are not affected and remain in effect until the closing of the Merger.

## **Business**

We are a biopharmaceutical company focused on pioneering new hypochlorous acid (“HOCl”), based therapies designed to improve patient outcomes and reduce healthcare costs associated with infections related to surgical procedures. Our lead drug candidates, including RUT58-60, are broad spectrum anti-infective products that we have been developing for the prevention and treatment of infection in surgical and trauma procedures. We are focusing development of our drug candidates 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 it 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 submitted our Investigational New Drug Application (“IND”), for RUT58-60 to the U.S. Food and Drug Administration (“FDA”), in early May 2014. In June 2014, our IND became effective thereby allowing us to begin human clinical testing of RUT58-60. In July 2014, we began human clinical testing of RUT58-60 in a 21-day skin irritation trial. In August 2014, we completed the skin irritation trial with 36 human subjects participating for 21 consecutive days. In October 2014, we initiated the Phase 1/2 clinical trial, and, in November 2014 we began patient enrollment in the Phase 1 portion of the Phase 1/2 clinical trial to evaluate the safety, tolerability, and potential efficacy of our lead drug candidate, RUT58-60, for use as an adjunct to systemic antibiotics in abdominal surgery and patient screening began at four clinical trial sites in the United States. To date, we have not received any reports of any serious adverse events. Pursuant to the Merger Agreement we may scale down our operations, including scaling back



patient enrollment in our clinical trial to evaluate the safety of RUT58-60 within the abdominal cavity.

We believe that our drug candidates have 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 believe that our drug candidates will complement the paid for performance paradigm and they are designed to reduce the overall healthcare costs associated with post-surgical infections and improve hospital economics. We believe the benefits of its drug candidates will be significant as they:

- mimic the human body's own infection-fighting mechanism,
- have not shown toxicity or serious side effects in its animal and other preclinical studies,
  - do not produce resistant bacteria in vitro, and
- demonstrate broad spectrum anti-microbial effectiveness in vitro.

We believe that our drug candidates have 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, sterility and effectiveness 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 in the United States and Europe and for broader medical claims in certain other countries where approval has been granted. 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's 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. 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.

There are approximately 30 million surgical and trauma procedures in the United States per year, approximately 7 million of which are abdominal surgeries, based upon market research.

If we are successful in receiving FDA approval for our drug candidates 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 our drug candidates, 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 our technology represents a significant innovation over existing uses of HOCl in topical applications and over systemic antibiotics 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.

We have focused much of our research and development efforts for RUT58-60 and other formulations on pre-clinical development and optimization. Our research and development team is working to further optimize the performance of our drug candidates 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 and other formulations may be able to be used in surgical applications.

Under our license and supply agreement with Oculus, we have exclusively licensed the HOCl technology relating to RUT58-60 and other formulations for commercialization in the United States, Europe, Japan and Canada. According to IMS Health, an information technology firm, these markets represented approximately 71% of the global medicines market in 2011. In parallel with our clinical development activities, we have conducted 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 favorable terms, or at all.

## **Strategy**

We were founded with the goal of being the first company to market HOCl based drugs for the prevention and treatment of infection in surgical procedures. We believe our technology may 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. We have agreed to scale back patient enrollment in our clinical trial of RUT58-60 pending completion of our proposed merger with Pulmatrix. In order to move forward with our strategy, the key elements to achieve our goals are:

Initiate and complete clinical trials for its drug candidates, 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 our drug candidates 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 our drug candidates for use in Europe and Japan.

## **HOCl Technology**

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 our technology has the potential to be used broadly as a prophylactic agent to prevent infections in surgical patients. In pre-clinical studies, our drug candidates have not been shown to promote resistance to bacteria and therefore do 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 our drug candidates 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 our drug candidates 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.* If approved by the FDA, we believe our drug candidates will be the only prepackaged, sterilized, ready-to-use HOCl based drugs 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.* 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, and does not require special handling precautions or storage requirements beyond those typically required for similar sterile products found in hospital and other indoor settings.

*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 our drug candidates 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.

## **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.

Acinetobacterbaumanni, 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.

### **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 our candidates have 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.

### **Drug Formulation, RUT58-60**

We have developed our investigational drug, RUT58-60, for the prevention of infection in surgical and other invasive applications. The initial indication that we have been 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 for use in abdominal surgery. 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 has been to conduct the clinical trials that will be necessary to prove its safety and efficacy for use during surgery.

We submitted an 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 it to begin human clinical testing of RUT58-60. In July 2014, we began human clinical testing of RUT58-60 in a 21-day skin irritation trial. In August 2014, we completed

the skin irritation trial with 36 human subjects participating for 21 consecutive days. In October 2014, we initiated the Phase 1/2 clinical trial, and, in November 2014 we began patient enrollment in the Phase 1 portion of its Phase 1/2 clinical trial to evaluate the safety, tolerability, and potential efficacy of our lead drug candidate, RUT58-60, for use as an adjunct to systemic antibiotics in abdominal surgery and patient screening began at four clinical trial sites in the United States. Pursuant to the Merger Agreement, we may scale down our operations, including scaling back patient enrollment in our Phase 1/2 clinical trial to evaluate the safety of RUT58-60 within the abdominal cavity. To date, we have not received any reports of any serious adverse events.

### **Improvements in RUT58-60 Over Existing HOCl Formulations**

With most classes of anti-infective products 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 hypochlorous 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 (ClO) 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. Furthermore, the final packaged RUT58-60 has been 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.

### 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*)					% Bacterial Reduction**	Incubation*** Times (hrs)
	30 Sec	1 Min	2 Min	5 Min	10 Min		
<i>MRSA (Methicillin-resistant S. aureus)</i>	8.5	8.5	8.5	8.5	8.5	99.9999997 %	24.5
<i>E. coli</i>	8.4	8.4	8.4	8.4	8.4	99.9999996 %	24
<i>P. aeruginosa</i>	8.2	8.2	8.2	8.2	8.2	99.9999993 %	25
<i>VRE (E. faecalis)</i>	8.1	8.1	8.1	8.1	8.1	99.9999993 %	24
<i>P. mirabilis'</i>	8.3	8.3	8.3	8.3	8.3	99.9999995 %	57
<i>S. marcescens</i>	8.8	8.8	8.8	8.8	8.8	99.9999999 %	24.5
<i>C. albicans</i>	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.

### 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 11 th 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, showing 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 white 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, Ruthigen has 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 in 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 a report from IMS Health from July 2012, these markets represented approximately 71% of the global medicines market in 2011.

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. We have focused the clinical and regulatory development for RUT58-60 on the prevention of infection in the abdominal surgery market.

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 its drug candidates is 30 million. We believe this represents an addressable market in the United States of approximately \$3.0 billion to \$4.5 billion based upon its market research. Our clinical development focus for RUT58-60 has been on the prevention of infections associated with abdominal surgery in the United States, which, based upon input from its physician consultants, we estimate is approximately a \$700 million market opportunity.

## **Clinical Development**



The overarching goal of our clinical development program has been 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 potential 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. 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. In July 2014, we began human clinical testing of RUT58-60 in a 21-day skin irritation trial. In August 2014, we completed the skin irritation trial with 36 human subjects participating for 21 consecutive days. In October 2014, we initiated the Phase 1/2 clinical trial, and, in November 2014 we began patient enrollment in the Phase 1 portion of our Phase 1/2 clinical trial to evaluate the safety, tolerability, and potential efficacy of our lead drug candidate, RUT58-60, for use as an adjunct to systemic antibiotics in abdominal surgery and patient screening began at four clinical trial sites in the United States. We may scale down our operations, including scaling back patient enrollment in our clinical trial to evaluate the safety of RUT58-60 within the abdominal cavity. To date, we have not received any reports of any serious adverse events. Initiation and completion of clinical trials for our lead drug candidate, for the first indication (abdominal surgery) as a drug in the United States, will be dependent on authorization by our board of directors after the proposed Merger is consummated.

Our clinical trial protocol includes two arms, test (RUT58-60) and control (saline). All patients 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 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 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 consists of a total of 400 ml of RUT58-60 or saline, as applicable. The surgical site during the first lavage are rinsed with RUT58-60 or saline. The surgical site during the second lavage are exposed to RUT58-60 or saline for approximately three minutes. Finally, after the abdominal cavity is closed, patients are 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) are obtained with a swab. The swab samples are 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 informational purposes only and are not clinical endpoints of the trial.

### **Development History of RUT58-60**

In October 2011, Hojabr 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, 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 our company. 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.

### **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*

On May 23, 2013, we entered into license and supply agreement with Oculus pursuant to which Oculus agreed to license certain of its proprietary technology to us to enable our research, development and commercialization of RUT58-60 and any improvements to it and any sterile prescription drug product (the “Product”) in the United States, Canada, the European Union and Japan (collectively, the “Territory”) for use in the surgical irrigation drug product indications set forth in the development and commercialization plan set forth in Schedule 3 of the License and Supply Agreement (the “Field”). Oculus will be prohibited from using the licensed proprietary technology to sell products that compete with our products within the Territory, and we may not 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 license and supply 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 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. Under the license and supply agreement, we are 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, we will be required to make royalty payments to Oculus based on our annual net sales of the Product from the date of the first commercial sale 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 license and supply 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 its development, commercialization or manufacture of the Product in the Field in the Territory with certain exceptions, and each party has agreed to indemnify the other with respect to third party claims arising from its inaccuracies 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.

#### *Terminated Shared Services Agreement*

Our shared services agreement with Oculus was terminated effective April 6, 2015 pursuant to written notice from Oculus received on March 5, 2015. We have constructed our own manufacturing apparatus and have secured a third party contract manufacturing organization to fulfill our manufacturing needs. We do not anticipate the need to produce any additional clinical trial materials through Oculus at this time.

Pursuant to the shared services agreement, Oculus provided us with general accounting, human resources, consulting and technical services at fixed rates.

In addition, Oculus provided us with certain standard activities which included the transfer of protocols, procedures related to methods of manufacturing, for building manufacturing equipment and employee training for test methods, manufacturing and manufacturing transfer. As of the termination of the shared services agreement, our employees will not be permitted access to Oculus facilities without prior consent from Oculus.

Furthermore, Oculus had made available to us their laboratories and laboratory personnel for product development testing. We have secured a third party contract research organization to fulfill our analytical testing requirements.

#### *Separation Agreement*

On August 2, 2013, we entered into a separation agreement with Oculus that contained provisions relating to our ongoing relationship with Oculus. On January 31, 2014, we amended the separation agreement with Oculus. The

separation agreement became effective upon the closing of our initial public offering in March 2014 and has a term of 8.5 years, unless earlier terminated by agreement of the parties

*Voting.* So long as Oculus and its affiliates own 19.9% of our common stock, Oculus will vote all of its shares 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 initial public offering related expenses incurred prior to and in connection with our initial public offering for which it is 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 its initial public offering.

*Marketing and Transfer Restrictions.* In order for the parties to control the flow of shares held by Oculus into the market to attempt to minimize price volatility and instability in the trading market, the separation agreement contains a series of restrictions on Oculus' ability to transfer the shares of common stock owned by Oculus. As a general matter, transfers of shares 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 shares and is required to refer indications of interest from third parties regarding the transfer of shares it owns to us, except during certain prescribed periods set forth in the separation agreement.

*Lockup.* Oculus and its affiliates are restricted from transferring, pledging, or encumbering shares for twelve months from the closing of the initial public offering (the "Oculus Lock Up Period") without the consent of our board of directors and the managing underwriter in our initial public offering.

Following the Oculus Lock Up Period, transfers by Oculus of the shares of our common stock shares that 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. In addition to the prescribed manner for Oculus to conduct transfers described above, if, after 41.5 months following the closing of its initial public offering, Oculus has not consummated transfers of 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 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 shares 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 shares Oculus transfers.

*Distribution.* We believe that a distribution of our 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 our 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 the Oculus Lock Up Period 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 our shares to Oculus stockholders and we have agreed to register any shares that Oculus may distribute in the future.

*Registration Rights.* If after the Lock-Up Period, Oculus and its affiliates own greater than 19.9% of our common stock, and we register shares in connection with a public offering for cash, Oculus has "piggy back" registration rights of up to 30% of the value of the securities we register. The agreement also provides for certain demand registration rights. In addition, as described under "Marketing and Transfer Restrictions" above, if, following a minimum of 41.5 months following the closing of the initial public offering, Oculus has not consummated transfers of shares 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 shares transferred by Oculus pursuant to the separation agreement as of the time Oculus elects to exercise its one-time right.

*Standstill.* If Oculus and its affiliates own greater than 19.9% of our common stock, 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 shares Oculus owns or deposit any shares in a voting trust.

*Restrictions Relating to Debt.* Oculus has agreed that, if its affiliates own greater than 19.9% of our common stock, Oculus shall disclose in writing to any creditor holding shares as collateral that such shares are subject to certain transfer restrictions.

*Equity Plan, Oculus Equity and Corporate Governance.* The parties 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 its initial public offering, and the formula for an annual evergreen refresh provision which shall provide for the reservation of additional shares, and other share caps on certain types of awards and future equity plans. The separation agreement also provides that options for common stock of Oculus held by our employees and directors shall continue to vest as long as such persons continue to be employed by or serve as a director of our company. In addition, the separation agreement provides that our restated certificate of incorporation and bylaws shall 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 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 maintain 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 such coverage shall include our directors and officers.

### *Oculus Side Letter Agreement*

In connection with the proposed Merger, on March 13, 2015, Pulmatrix entered into a side letter agreement with Oculus pursuant to which, among other things, Oculus agreed, from the effective date of the Merger, to (i) waive our obligations to use commercially reasonable efforts to develop and commercialize products licensed from Oculus under the License and Supply Agreement until the earlier of one year from the closing of the Merger or August 31, 2016; (ii) provide a general release from claims and liabilities arising under the License and Supply Agreement, the separation agreement and the shared services agreement in favor of us; and (iii) permit us to run a sale process for our pre-merger business, including any products licensed from Oculus, and to assign all of our surviving rights under the License and Supply Agreement, the separation agreement and the shared services agreement, subject to certain consent rights of Oculus with respect to the identity of the proposed purchaser. In the event of a sale of our pre-merger business with a minimum aggregate purchase price of \$1 million, Oculus will have a right of first refusal to acquire such business on exactly the same terms, and in the event that Oculus does not exercise its right of first refusal and the aggregate purchase price exceeds \$10 million, Oculus will receive 10% of the gross consideration from such sale.

### **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 our ability and Oculus' ability 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 its 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.

The intellectual property rights upon which we rely to operate our business derive from our collaboration with Oculus. Through our license and supply agreement with Oculus, we have exclusive rights to certain of Oculus' patents and pending applications (both U.S. and foreign) that cover composition of matter, proprietary manufacturing processes



for HOCl based products, 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 March 31, 2015, 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 licensed from Oculus. These patents and pending applications (if issued) will expire in 2027 – 2034.

## **Manufacturing**

Since our inception, RUT58-60 has been manufactured at Oculus in its Petaluma, California manufacturing facility. We have 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 to a CMO is dependent on our ability to 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.

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 has been manufactured under cGMP conditions and has been subject to the standard sterilization processes required by FDA. 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.

## **Sales and Marketing/Commercialization**

We do not currently have a commercialization organization capable of marketing, selling and distributing our drug candidates. We have conducted discussions with pharmaceutical, biotechnology and other organizations that we believe have existing experience and resources to bring our initial, and potentially future, product candidates to market. 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 favorable terms, or at all.

## **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-infective products 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. The following three companies in the United States and/or Europe produce HOCl products intended for medical applications:

- Oculus, our licensor with which we have a non-competition provision as part of our licensing agreement designed to protect both companies' ability to develop and commercialize products in their 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.

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 colonization 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. Principal companies include:

Cubist Pharmaceuticals, Forest Laboratories, Astra Zeneca, and Tetrphase Pharmaceuticals.

Other notable companies developing antibiotic therapies include: Achaogen, Basilea, Cempra, Durata Therapeutics, GlaxoSmithKline, 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 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 a new drug application (“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, a 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 its 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 NDA, plus the time between the submission date of a 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 its 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 its products. Future FDA and state inspections may identify compliance issues at the facilities of its 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 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 its products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before it 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 its 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 5, 2015, we employed a total of five full-time employees and several part-time consultants and CROs, all of whom are based in the United States. We are not a party to any collective bargaining agreements. We believe our relations with our employees are good.

### **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. We currently 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. In July 2014, we began human clinical testing of RUT58-60 in a 21-day skin irritation trial. In August 2014, we completed the skin irritation trial with 36 human subjects participating for 21 consecutive days. In October 2014, we initiated the Phase 1/2 clinical trial, and, in November 2014, we began patient enrollment in the Phase 1 portion of the Phase 1/2 clinical trial to evaluate the safety, tolerability, and potential efficacy of our lead drug candidate, RUT58-60, for use as an adjunct to systemic antibiotics in abdominal surgery and patient screening began at four clinical trial sites in the United States. Pursuant to the Merger Agreement, we may scale down our operations, including scaling back patient enrollment in our clinical trial to evaluate the safety of RUT58-60 within the abdominal cavity.

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

Our future success depends heavily on our ability to successfully develop, obtain regulatory approval for, and commercialize our drug candidates, 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, 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 alone or in partnership with others. We will not be permitted to market or promote RUT58-60 or other product candidates, before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of its 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 drug candidates, 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 have has licensed RUT58-60 for development and commercialization 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.***

Drug candidates 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 have has conducted a number of pre-clinical tests using RUT58-60 in support of the IND for RUT58-60, which was submitted 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. In July 2014, we began human clinical testing of RUT58-60 in a 21-day skin irritation trial. In August 2014, we completed the skin irritation trial with 36 human subjects participating for 21 consecutive days. In October 2014, we initiated the Phase 1/2 clinical trial, and, in November 2014, we began patient enrollment in the Phase 1 portion of the Phase 1/2 clinical trial to evaluate the safety, tolerability, and potential efficacy of our lead drug candidate, RUT58-60, for use as an adjunct to systemic antibiotics in abdominal surgery and patient screening began at our clinical trial sites in the United States. If and when, 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 anticipate, 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 its 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 or its other drug candidates 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 its 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 drug candidates.***

Currently, we have no products approved for sale. We have not submitted an application 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 its drug candidates. 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 may 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:

- 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 any 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 development activities 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 is at an early stage. 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 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.

***We are dependent on a third party manufacturing organization to fulfill our manufacturing needs, our development of RUT58-60, 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 party manufacturers 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 a third party organization to manufacture RUT58-60 and we have no independent experience in manufacturing and cannot assure you that any clinical-grade product will ever be produced or that we, 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.

Our shared services agreement with Oculus, which covered our manufacturing arrangement with Oculus, was terminated effective April 6, 2015. We previously relied on Oculus to manufacture, and prepare for shipment, RUT58-60, out of its Petaluma, California, facility for its preclinical studies and Phase 1/2 clinical trial. We did not control the manufacturing processes of Oculus and have been 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 the third party manufacturing organization if it:

- does not perform as agreed;
- is not capable of producing or processing sufficient quantities of our drug candidates;
- is not able to manufacture materials that conform to our specifications;
- is not able to hire or retain the necessary employees; and

is unable to comply with cGMP requirements and with FDA, state and foreign regulatory requirements, and does 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.

We have secured 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 to a CMO is dependent on our ability to 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. In the future, we may 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 stock.

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, laws 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 we or our third party manufacturers encounters 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 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 expects 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 may 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 5, 2015, we employed a total of five full-time employees. 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 and two operations specialists.

We may expand our management team to include an operation ramp up of additional technical staff required to achieve our business objectives. We may 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, it 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 any sales and marketing arrangements for our drug candidates. We are developing our drug candidates 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 it. 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 it 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, its 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 drug candidates we develop depends on a number of factors, including:

- our demonstration of the clinical efficacy and safety of such drugs;
- timing of market approval and commercial launch of such drugs;
- the clinical indication(s) for which such drugs are 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. However, our internal research capabilities are limited, and 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 currently 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 our business.

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, 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 may 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 our 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 telephones, 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.

Likewise, we relies 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 results 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.

***If the Merger is consummated, the business operations, strategies and focus of Ruthigen will fundamentally change, and these changes may not result in an improvement in the value of its common stock.***

Pending the consummation of the Merger, the Merger Agreement permits us to scale down our operations as we deem necessary and requires us to scale back patient enrollment in our clinical trial of RUT58-60, our primary drug candidate, and it is currently anticipated that the combined company would focus its resources on the development of products within the scope of Pulmatrix's current business plan. As a result, following the Merger, the combined company may seek to sell or assign its rights related to our current drug candidates, including RUT58-60. If completed, any such sale or assignment may be at a substantial discount, the consideration received may not accurately represent the value of the assets sold or assigned and stockholders may not participate in the future prospects of such drug candidates.

Following the Merger, it is expected that the combined company's primary products will be PUR1900, Pulmatrix's lead anti-infective product candidate, PUR0200, Pulmatrix's bronchodilator therapy candidate and Pulmatrix's other iSPERSE-based product candidates. Consequently, if the Merger is consummated, an investment in Ruthigen's common stock will primarily represent an investment in the business operations, strategies and focus of Pulmatrix. All of Pulmatrix's product candidates are still under development and may never be approved for sale or successfully commercialized. The failure to successfully commercialize one or more of Pulmatrix's current product candidates will significantly diminish the anticipated benefits of the Merger and have a material adverse effect on the business of the combined company. We cannot assure you that Ruthigen's business operations, strategies or focus will be successful following the Merger, and the Merger could depress the value of Ruthigen's common stock.

### **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 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 our 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 it has 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;

• delay 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 our current or future 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 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 our 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 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.

*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, or any other drug candidate, 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 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, or any other drug candidate, 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 on 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, or any other drug candidate, 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 it, 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 our 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.*

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 us. 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 HOCI 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, Tetrphase 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 revenues, if any.

#### **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 subsidiary of Oculus. We reincorporated in Delaware on September 25, 2013. We have a limited operating history on which to evaluate our business. We have incurred net losses since we began operations in October 2011. Through March 31, 2015, we had an accumulated deficit of \$10,360,000. 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 initial public offering, 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. 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 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 stockholders' 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 it adjusts 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 our drug candidates.***

RUT58-60 is currently our only drug candidate in a clinical trial. 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 drug candidates involves a high degree of risk. Many important factors affect its ability to successfully develop and commercialize RUT58-60, and our other drug candidates including our ability to:

- demonstrate safety and efficacy 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 drugs in commercial quantities at reasonable costs;
- obtain reimbursement coverage;
- compete successfully against other products; and
- market RUT58-60, or our other drug candidates, successfully.

We cannot assure you that we will successfully develop and commercialize RUT58-60, or our other drug candidates, or that we will obtain required regulatory approvals for our commercialization. As a result, we may never generate revenues from RUT58-60 sales or sales of our other drug candidates. 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 if and when we advance RUT58-60 into future 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, pursues development of additional innovative HOCl based pharmaceutical formulations and/or pursues 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 initial public offering, will be sufficient to fund our current operations into the quarter ending June 30, 2016. These funds will not be sufficient to enable us to conduct future clinical trials, seek marketing approval for RUT58-60 or commercially launch RUT58-60, or any other drug candidate, in the United States 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 our operations, and such inability would have a material adverse effect on its 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 any planned clinical trials for our drug candidates;
- sustain commercialization of any other product candidate;
  - develop our manufacturing capabilities;
  - increase our sales and marketing efforts;
- 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;
- 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;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our efforts to acquire or license complementary technologies or acquire complementary businesses;
  - changes in product development plans;
  - 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.

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.

***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. 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 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 our license and supply agreement 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 United States 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, 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 its 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 that we may license or own. We can give no assurances that our intellectual property protection will be sufficient to prevent third parties from designing around patents it owns or licenses 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 owns or licenses. If we do not prevail in enforcing its 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 its 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 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 may substantially change the regulations and procedures surrounding patent applications, issuance of patents, and prosecution of patents. We can give no assurances that its patents and those of any licensor 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.



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

A third party may sue us or our licensor or otherwise make a claim, alleging infringement or other violation of the third party's 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 commercial activities relating to the affected products, which could include a recall of the affected products and/or a cessation of sales.

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.

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 its patented products even if we own or license patent rights relating to its 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 it from manufacturing, developing or marketing certain of its 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, any intellectual property litigation could be perceived negatively by securities analysts or investors which could have a material adverse effect on the value of its 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 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 could make it 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 inadvertently disclosed confidential information of third parties.***

We employ individuals and contract with independent consultants and agencies that 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 its 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 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.

***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 its common stock. As of June 5, 2015, Oculus holds approximately 34% of our outstanding common stock and approximately 42% of the voting power of our common stock. Additionally, without a distribution or other liquidity event of our shares of common stock held by Oculus, there will be limited liquidity in the market for our common stock, which will impact our stockholders and stock price. 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 and chairman of the board served as the chief executive officer of Oculus until February 2013 and chairman of the board of Oculus until February 2014. Our chief financial officer since February 2013 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 us and Oculus 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 our separation from Oculus;

- distribution and supply obligations;

- employee retention and recruiting;
- business combinations involving us;
- sales or distributions by Oculus of all or any portion of our 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 are a party to a 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.

*We and our stockholders may not achieve some or all of the expected benefits of our separation from Oculus.*

We are focused on developing HOC1 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 us 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 it 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.

### **Risks Related to Our Common Stock**

#### ***The trading market in our common stock has been extremely limited.***

Since our initial listing on the NASDAQ Capital Market on March 21, 2014, the trading market in our common stock has been extremely limited. 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 March 31, 2015, approximately 50% of our outstanding shares of common stock were controlled 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 March 31, 2015, 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.

#### ***The price of our common stock may fluctuate substantially.***

The market price of our common stock may fluctuate, as a result of, among other factors:

the 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 contractual conditions;

- the sale of our common stock by our stockholders, executives, and directors;
  - the limitations in trading volumes of our shares of common stock;
  - our ability to obtain financing when needed to fund our operations;
  - 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;

- 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;

- 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 related to 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;

analyst research reports, recommendations and changes in recommendations, price targets, and withdrawals of coverage;

- departures and additions of key personnel;
- disputes and litigation related to intellectual property, proprietary rights, and contractual obligations;
- changes in applicable laws;
- 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 fluctuate or 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 that we issued in our initial public offering do not confer any rights of common stock ownership on our 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 initial public offering, 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 initial public offering, we issued an aggregate of 3,047,500 Series A warrants, all of which are outstanding as of March 31, 2015. 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, as of April 1, 2015, we have reserved 1,230,855 shares of our common stock under our 2013 Employee, Director and Consultant Equity Incentive Plan (the “2013 Plan”), and 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 stockholders would experience additional dilution. In addition, subject to the approval of the Company’s stockholders, the pool of available stock available for grant under our 2013 Plan will increase at the beginning of each fiscal year by the lower of: (i) 2,551,500 shares; (ii) 5% of the number of shares of outstanding common stock; and (iii) an amount determined by our board of directors.

On March 12, 2015, in connection with the Merger Agreement, our compensation committee and board of directors unanimously approved the Ruthigen, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan (the “New 2013 Plan”), subject to the approval of our stockholders. The New 2013 Plan will allow for the issuance of up to 6,853,319 shares of our common stock, up from 1,230,855 shares, pursuant to awards to be granted under the New 2013 Plan.

***“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 may 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 reporting company require significant expenditures, 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. Compliance with such requirements also places demands on management’s time and attention.

***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 it has 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 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.

***If we fail to comply with listing requirements, NASDAQ may delist our common stock from our exchange, which could limit investors’ ability to make transactions in our common stock and subject it to additional trading restrictions.***

If we fail to satisfy the continued listing requirements of the NASDAQ Capital Market (“NASDAQ”), such as the corporate governance requirements or the minimum closing bid price requirement, the 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 our 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 our 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; and
- decreased ability to issue additional securities or obtain additional financing in the future.

### **Risks Related to the Proposed Merger**

*The issuance of our shares of common stock to Pulmatrix stockholders in the Merger will substantially dilute the voting power of current stockholders. Having a minority share position may reduce the influence that current stockholders have on our management.*

Pursuant to the terms of the Merger Agreement, at the effective time of the Merger, we will issue approximately 27,848,269 shares of our common stock to Pulmatrix equity holders as merger consideration, and immediately following the Merger, we will issue 1,636,364 shares of common stock upon conversion of Pulmatrix bridge loans. Upon completion of the Merger, current stockholders will hold 5,653,618 shares, or approximately 16.1% of the issued and outstanding equity and former Pulmatrix stockholders will own 29,484,633 shares or approximately 83.9% of our issued and outstanding equity, in each case, excluding options and restricted stock units. Accordingly, the issuance of shares of our common stock to Pulmatrix equity holders in the Merger will significantly reduce the ownership stake and relative voting power of each share of common stock held by current stockholders. Consequently, following the Merger, the ability of our current stockholders to influence the management of Ruthigen will be substantially reduced.

***There is no assurance when or if the Merger will be completed. Any delay in completing the Merger may substantially reduce the benefits that we expect to obtain from the Merger.***

Completion of the Merger is subject to the satisfaction or waiver of a number of conditions as set forth in the Merger Agreement. There can be no assurance that we and Pulmatrix will be able to satisfy the closing conditions or that closing conditions beyond their control will be satisfied or waived. If the Merger and the integration of the companies' respective businesses are not completed within the expected timeframe, such delay may materially and adversely affect the synergies and other benefits that we and Pulmatrix expect to achieve as a result of the Merger and could result in additional transaction costs, loss of revenue or other effects associated with uncertainty about the Merger.

***Because the lack of a public market for Pulmatrix's outstanding shares makes it difficult to evaluate the fairness of the Merger, Pulmatrix stockholders may receive consideration in the Merger that is greater than or less than the fair market value of the Pulmatrix shares.***

The outstanding capital stock of Pulmatrix is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Pulmatrix shares. Since the percentage of our common stock to be issued to Pulmatrix equity holders was determined based on negotiations between the parties, it is possible that the value of our common stock to be issued in connection with the Merger will be greater than the fair market value of Pulmatrix shares. Alternatively, it is possible that the value of our shares common stock to be issued in connection with the Merger will be less than the fair market value of Pulmatrix shares.

***Our directors and officers may have interests in the Merger that are different from, or in addition to, those of our stockholders generally that may influence them to support or approve the Merger.***

Our officers and directors may have interests in the Merger that are different from, or are in addition to, those of our stockholders. Effective upon the closing of the Merger, Messrs. Alimi and Harish will be employed by the combined company and receive compensation and other consideration. These interests may have influenced our directors and executive officers of Ruthigen and Pulmatrix to support or recommend the proposals presented to our stockholders.

***The announcement and pendency of the Merger could have an adverse effect on our business, financial condition, results of operations or business prospects.***

The announcement and pendency of the Merger could disrupt our business in the following ways, among others:

our employees may experience uncertainty regarding their future roles in the combined company, which might adversely affect our ability to retain, recruit and motivate key personnel;

the attention of our management may be directed towards the completion of the Merger and other transaction-related considerations and may be diverted from the day-to-day business operations and matters related to the Merger may require commitments of time and resources that could otherwise have been devoted to other opportunities that might have been beneficial to us; and

suppliers and other third parties with business relationships with us may decide not to renew or may decide to seek to terminate, change or renegotiate their relationships with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us or otherwise.

Should they occur, any of these matters could adversely affect our business, financial condition, results of operations or business prospects.

***Covenants in the Merger Agreement place certain restrictions on our conduct of business prior to the closing of the Merger, including entering into a business combination with another party.***

The Merger Agreement restricts us from taking certain specified actions with respect to the conduct of our business without Pulmatrix's consent, including prohibition on soliciting, initiating, encouraging discussions or negotiations with or providing non-public information to any person concerning a merger, reorganization, consolidation, share exchange, business combination, recapitalization, liquidation, dissolution or similar transaction. These restrictions may prevent us from pursuing otherwise attractive business opportunities or other capital structure alternatives and making other changes to our business or executing certain of its business strategies prior to the completion of the Merger, which could be favorable to our stockholders.



***The issuance of our common stock in connection with the Merger could decrease the market price of our common stock.***

In connection with the Merger and as part of the merger consideration, we will issue shares of common stock to Pulmatrix equity holders. The issuance of our common stock in the Merger may result in fluctuations in the market price of our common stock, including a stock price decrease.

***We expect to incur substantial expenses related to the Merger and the integration of Pulmatrix.***

We expect to incur substantial expenses in connection with the Merger and integration of Pulmatrix. We may incur additional costs to maintain employee morale and to retain key employees and will incur significant fees and expenses relating to legal, accounting, financial advisory and other transaction fees and costs associated with the Merger. Specifically, based on estimates as of March 31, 2015, we expect to incur approximately \$3.6 million of transaction costs related to the Merger, including \$2.4 million payable in cash and \$1.2 million payable in stock. Additionally, there are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including purchasing, accounting and finance, sales, billing, payroll, manufacturing, marketing and employee benefits, and we may incur after-tax integration and restructuring costs and other costs incurred to execute the transaction following completion of the Merger.

### **Risks Related to the Combined Company Following the Merger**

***Although we expect that the Merger will result in benefits to the combined company, the combined company may not realize those benefits because of various challenges.***

We may not be able to fully realize the anticipated benefits of the Merger. The integration of a new company is a complex, costly and time-consuming process. This process may disrupt the business of either or both of the companies, and may not result in the full benefits expected by us. Delays in the integration process could adversely affect the combined company's business, financial results, financial condition, and stock price following the Merger. There can be no assurance that the combination will result in the realization of the anticipated benefits from the Merger.

***The market price of the combined company's common stock after the Merger may be subject to significant fluctuations and volatility, and stockholders may be unable to resell their shares at a profit and incur losses.***

There has not been a public market for the combined company's common stock. The market price of the combined company's common stock could be subject to significant fluctuation following the Merger. Our business differs from that of Pulmatrix in important respects and, accordingly, the results of operations of the combined company and the market price of the combined company common stock following the Merger may be affected by factors different from those currently affecting the independent results of operations of our company. Market prices for securities of early-stage pharmaceutical, medical device, biotechnology and other life science companies have historically been particularly volatile. Some of the factors that may cause the market price of the combined company's common stock to fluctuate include:

• the announcement of new products, new developments, services or technological innovations by the combined company or the combined company's competitors;

• actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in the combined company's business, operations or prospects;

• announcements relating to strategic relationships, mergers, acquisitions, partnerships, collaborations, joint ventures, capital commitments, or other events by the combined company or the combined company's competitors;

- conditions or trends in the biotechnology and pharmaceutical industries;

• changes in the economic performance or market valuations of other biotechnology and pharmaceutical companies;

general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to the combined company's performance or financial condition;

- sale of the combined company's common stock by stockholders, including executives and directors;
- volatility and limitations in trading volumes of the combined company's common stock;

the combined company's ability to obtain financings to conduct and complete research and development activities including, but not limited to, its human clinical trials, and other business activities;

ability to secure resources and the necessary personnel to conduct clinical trials on the combined company's desired schedule;

- failures to meet external expectations or management guidance;

changes in the combined company's capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of common stock by stockholders;

- the combined company's cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;

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; and
- other events or factors, many of which may be out of the combined company's control.

***If the Merger is consummated, our business operations, strategies and focus will fundamentally change, and these changes may not result in an improvement in the value of our common stock.***

Pending the consummation of the Merger, the Merger Agreement permits us to scale down our operations as we deem necessary and requires us to scale back patient enrollment in our clinical trial of RUT58-60, our primary drug candidate, and it is currently anticipated that the combined company would focus its resources on the development of products within the scope of Pulmatrix's current business plan. As a result, following the Merger, the combined company may seek to sell or assign its rights related to our current drug candidates, including RUT58-60. If completed, any such sale or assignment may be at a substantial discount, the consideration received may not accurately represent the value of the assets sold or assigned and our stockholders may not participate in the future prospects of such drug candidates.

Following the Merger, it is expected that the combined company's primary products will be PUR1900, Pulmatrix's lead anti-infective product candidate, PUR0200, Pulmatrix's bronchodilator therapy candidate and Pulmatrix's other iSPERSE-based product candidates. Consequently, if the Merger is consummated, an investment in Ruthigen's common stock will primarily represent an investment in the business operations, strategies and focus of Pulmatrix. All of Pulmatrix's product candidates are still under development and may never be approved for sale or successfully commercialized. The failure to successfully commercialize one or more of Pulmatrix's current product candidates will significantly diminish the anticipated benefits of the Merger and have a material adverse effect on the business of the combined company. We cannot assure you that Ruthigen's business operations, strategies or focus will be successful following the Merger, and the Merger could depress the value of Ruthigen's common stock.

***We may issue additional equity securities in the future, which may result in dilution to existing investors.***

To the extent we raise additional capital by issuing equity securities, including in a debt financing where we issue convertible notes or notes with warrants our stockholders may experience substantial dilution. We may, from time to time, sell additional equity securities in one or more transactions at prices and in a manner we determine. If we sell additional equity securities, existing stockholders may be materially diluted. In addition, new investors could gain rights superior to existing stockholders, such as liquidation and other preferences. In addition, the number of shares available for future grant under our equity compensation plans may be increased in the future. In addition, the exercise or conversion of outstanding options or warrants to purchase shares of capital stock may result in dilution to our stockholders upon any such exercise or conversion.

All of our outstanding shares of common stock are, and any shares of common stock that are issued in the Merger will be, freely tradable without restrictions or further registration under the Securities Act of 1933, as amended (the “Securities Act”) except for the restricted stock units that will be issued to certain employees and consultants, shares of common stock issued to certain advisors, and any shares held by affiliates, as defined in Rule 144 under the Securities Act.

***The concentration of the capital stock ownership with insiders of the combined company after the Merger will likely limit the ability of the stockholders of the combined company to influence corporate matters.***

Following the Merger, the executive officers, directors, 5% percent or greater stockholders, and their respective affiliated entities of the combined company will in the aggregate beneficially own approximately 57% of the combined company’s outstanding common stock. As a result, these stockholders, acting together, have control over matters that require approval by the combined company’s stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other stockholders may view as beneficial.

***In the event that the combined company fails to satisfy any of the listing requirements of The NASDAQ Capital Market, its common stock may be delisted, which could affect its market price and liquidity.***

Following the Merger, the combined company’s common stock is expected to be listed on The NASDAQ Capital Market. For continued listing on The NASDAQ Capital Market, the combined company will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. In the event that the combined company fails to satisfy any of the listing requirements of The NASDAQ Capital Market, its common stock may be delisted. If the combined company is unable to list on The NASDAQ Stock Market, it would likely be more difficult to trade in or obtain accurate quotations as to the market price of the combined company’s common stock. If the combined company’s securities are delisted from trading on The NASDAQ Stock Market, and the combined company is not able to list its securities on another exchange or to have them quoted on NASDAQ, the combined company’s securities could be quoted on the OTC Bulletin Board or on the “pink sheets.” As a result, the combined company could face significant adverse consequences including:

- a limited availability of market quotations for its securities;

a determination that its common stock is a “penny stock” which will require brokers trading in its common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for its securities;

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 June 2015 and our monthly rent is approximately \$1,700. We also maintain an office located in Walnut Creek, California, where we lease and occupy approximately 400 square feet of executive office space under a lease which expires in September 2015 and has a monthly rent of approximately \$700.

Item 3. LEGAL PROCEEDINGS.

There are no pending legal proceedings to which we are a party. Our property is not the subject of any pending legal proceedings.

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 the high and low sales prices per share of our common stock as reported on The NASDAQ Capital Market for the periods shown:

The following table sets forth the high and low trading prices per share of Ruthigen common stock as reported on The NASDAQ Capital Market for the periods shown:

	Common Stock	
	High	Low
Year Ended March 31, 2015		
First Quarter	\$7.15	\$5.75
Second Quarter	\$6.49	\$4.05
Third Quarter	\$5.70	\$3.31
Fourth Quarter	\$4.64	\$3.25
	High	Low
Year Ended March 31, 2014		
Fourth Quarter (beginning March 21, 2014)	\$8.47	\$6.65

**Stockholders**

As of June 5, 2015, there were 9 stockholders of record of the 4,804,290 outstanding shares of Common Stock, one of which represents stock held by multiple investors.

## **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**

As March 31, 2015, approximately \$6.7 million of the \$17.0 million of net proceeds from our IPO had been used. There has been no material change in our 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) under the Securities Act on March 21, 2014. We have broad discretion in the use of the net proceeds from our IPO. We may find it necessary or advisable to use the net proceeds from our IPO for other purposes than those described in our final prospectus.

## **Item 6. SELECTED FINANCIAL DATA.**

Not required for smaller reporting companies.



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 pioneering new hypochlorous acid, or HOCl, based therapies designed to improve patient outcomes and reduce healthcare costs associated with infections related to post-operative invasive procedures. 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. In July 2014, we began human clinical testing of RUT58-60 in a 21-day skin irritation trial. In August 2014, we completed the skin irritation trial with 36 human subjects participating for 21 consecutive days. In October 2014, we initiated the Phase 1/2 clinical trial, and, in November 2014 we began patient enrollment in the Phase 1/2 clinical trial to evaluate the safety, tolerability, and potential efficacy of our lead drug candidate, RUT58-60, for use as an adjunct to systemic antibiotics in abdominal surgery and patient screening began at four clinical trial sites in the United States. We are in the process of enrolling the first 20 patients in the Phase 1 part of our exploratory Phase 1/2 clinical trial to evaluate the safety of RUT58-60 within the abdominal cavity. To date, the company has not received any reports of any serious adverse events. The study is being conducted at seven clinical sites in the U.S. The company has identified a number of additional clinical sites for the potential Phase 2 part of our Phase 1/2 clinical trial for RUT58-60. Following a review of the safety run-in data, we plan to pursue our Phase 2 and Phase 3 clinical trial strategy.

We believe that our drug candidates have 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 believe that our drug candidates will complement the paid for performance paradigm and they are designed to reduce the overall healthcare costs associated with post-surgical infections and improve hospital economics. We believe the benefits of its drug candidates will be significant as they:

- mimic the human body's own infection-fighting mechanism,
- have not shown toxicity or serious side effects in its animal and other preclinical studies,
  - do not produce resistant bacteria in vitro, and
- demonstrate broad spectrum anti-microbial effectiveness in vitro.

We believe that our drug candidates have 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's 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.

There are approximately 30 million surgical and trauma procedures in the United States per year, approximately 7 million of which are abdominal surgeries, based upon its market research.

If we are successful in receiving FDA approval for our drug candidates 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 our drug candidates, 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 our technology represents a significant innovation over existing uses of HOCl in topical applications and over systemic antibiotics 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.

We have focused much of our research and development efforts for RUT58-60 and other formulations on pre-clinical development and optimization. Our research and development team is working to further optimize the performance of our drug candidates 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 and other formulations may be able to be used in surgical applications.

Under our license and supply agreement with Oculus, we have exclusively licensed the HOCl technology relating to RUT58-60 and other formulations for commercialization in the United States, Europe, Japan and Canada. According to IMS Health, an information technology firm, these markets represented approximately 71% of the global medicines market in 2011. In parallel with our clinical development activities, we have conducted 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 favorable terms, or at all.

## **Merger**

On March 13, 2015, we entered into the Merger Agreement with Merger Sub and Pulmatrix which provides for the merger of Merger Sub with and into Pulmatrix, with Pulmatrix surviving as our wholly owned subsidiary, and Merger Sub will cease to exist. See our Current Report on Form 8-K dated March 13, 2015 for additional details related to the Merger.

If the Merger is consummated, we will issue shares of our common stock to the Pulmatrix equity holders in connection with the Merger as merger consideration and shares of common stock to certain lenders of Pulmatrix upon the conversion of bridge loans, such that the former Pulmatrix security holders will hold approximately 83% of Ruthigen's post-merger shares. Although we are the legal acquirer and will issue shares of its common stock to effect the merger with Pulmatrix, the business combination will be accounted for as a reverse acquisition of Ruthigen by Pulmatrix under GAAP. In addition, at the effective time of the Merger, warrants to purchase shares of Pulmatrix common stock will be converted into and exchangeable for warrants to purchase shares of our common stock pursuant to an exchange ratio described in the Merger Agreement.

If the Merger is completed, Hojabr Alimi, our Chief Executive Officer and Sameer Harish, our Chief Financial Officer will step down in their current roles and continue to be employed by the combined company and have agreed to terminate equity grants previously made to them and will receive cash and restricted stock units pursuant to the new employment agreements Pulmatrix and Ruthigen entered into with each of Messrs. Alimi and Harish.

Pending the consummation of the merger, the Merger Agreement permits us to scale down our operations as we deem necessary and requires us to scale back patient enrollment in our clinical trial of RUT58-60, our primary drug candidate, and it is currently anticipated that the combined company would focus its resources on the development of products within the scope of Pulmatrix's current business plan. As a result, following the Merger, the combined company may seek to sell or assign its rights related to our current drug candidates, including RUT58-60.

## Results of Operations

### *Year Ended March 31, 2015 Compared with Year Ended March 31, 2014*

The following table presents selected items in our statements of operations for the years ended March 31, 2015 and 2014, respectively:

	For The Years Ended	
	March 31,	
	2015	2014
Revenues	\$-	\$-
Operating Expenses		
Research and development	2,178,000	1,382,000
Selling, general and administrative	4,530,000	1,736,000
Total Operating Expenses	6,708,000	3,118,000
Loss From Operations	(6,708,000)	(3,118,000)
Other Income		
Interest income	17,000	-
Total Other Income	17,000	-
Net Loss	\$(6,691,000)	\$(3,118,000)

### *Revenue*

We did not recognize product sales for the years ended March 31, 2015 or 2014. 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 \$2,178,000 and \$1,382,000 for the years ended March 31, 2015 and 2014, respectively, representing an increase of \$796,000, or 58%. The increase in research and development expense is primarily a result of the increases in activity directly related to RUT58-60 and the Company's preparations and initiation of clinical trial activities. 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 clinical trials, which are designed to obtain FDA drug approvals for RUT58-60. Research and development expense is charged as incurred. The expansion of our research and development staff was due to our increased focus on medical education, preclinical studies, 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 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. If the Merger is consummated, it is currently anticipated that the combined company would focus its resources on the development of products within the scope of Pulmatrix's current business plan. As a result, following the Merger, the combined company may seek to sell or assign its rights related to our current drug candidates, including RUT58-60.

*Selling, General and Administrative Expense*

Selling, general and administrative expense was \$4,530,000 and \$1,736,000 for the years ended March 31, 2015 and 2014, respectively, representing an increase of \$2,794,000, or 161%. The increase in selling, general and administrative expense is primarily a result of higher legal, accounting, and insurance expenses associated with being a public company of \$1,154,000, the Company's preparations for its initiation of clinical trials and the inclusion of non-cash stock compensation expenses of \$1,079,000, which were not incurred for the fiscal year ended March 31, 2014.

**Liquidity and Capital Resources**

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

	March 31, 2015	2014
Cash	\$10,357,000	\$15,571,000
Working capital	\$9,888,000	\$14,627,000

We reported net losses of \$6,691,000 and \$3,118,000 for the years ended March 31, 2015 and 2014, respectively. At March 31, 2015 and 2014, our accumulated deficit was \$10,360,000 and \$3,669,000, 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.

During the year ended March 31, 2015, we received an additional \$865,000 of net proceeds from the underwriter's exercise of the IPO over-allotment option. At March 31, 2015, we had a cash balance of \$10,357,000. We believe that our existing cash, which includes the proceeds from our IPO, will be sufficient to fund our current business operations through the quarter ending June 30, 2016.

***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.

The obligation of Pulmatrix to complete the Merger is subject to the Company having unrestricted cash on hand, net of outstanding liabilities, at closing of at least (a) \$9,000,000, if the Merger closing date is no later than July 31, 2015, or (b) \$8,850,000, if the Merger closing date is after July 31, 2015 but no later than August 13, 2015. Accordingly, the Merger Agreement permits us to scale down our pre-merger operations as we deem necessary and requires us to scale back patient enrollment in our clinical trial of RUT58-60, our primary drug candidate.

In order to comply with the applicable required amount of unrestricted cash at hand at the closing of the merger, we may enter into a binding stock purchase agreement obligating one or more investors to purchase up to 948,555 shares of our common stock at a price not less than \$2.75 per share, prior to the closing. There can be no assurance that we will be successful in raising the funds needed to meet such cash requirement. If we are unable to meet this cash requirement, Pulmatrix may not complete the Merger.

***Cash Flows During the Years Ended March 31, 2015 and 2014***

During the years ended March 31, 2015 and 2014, our sources and uses of cash were as follows:

*Net Cash Used in Operating Activities*

Net cash used in operating activities was \$5,386,000 and \$2,969,000 for the years ended March 31, 2015 and 2014, respectively. The net cash used in operating activities for the year ended March 31, 2015 was primarily due to cash used to fund a net loss of \$6,691,000, adjusted for non-cash expenses of \$1,080,000, partially offset by \$225,000 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, 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.

*Net Cash Used in Investing Activities*

Net cash used in investing activities was \$156,000 and \$0 for the years ended March 31, 2015 and 2014, respectively. The net cash used during the year ended March 31, 2015 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, 2015 and 2014 was \$328,000 and \$18,444,000, respectively. The net cash provided by financing activities during the year ended March 31, 2015 was attributable to \$865,000 of net proceeds from the underwriter's exercise of the IPO over-allotment option (gross proceeds of \$1,117,000 less \$252,000 of offering costs paid during the year ended March 31, 2015), partially offset by \$537,000 of cash used in the repayment of advances to Oculus, our former parent. 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 Oculus and \$537,000 of net proceeds from advances from Oculus.

### **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 consolidated 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 consolidated 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 consolidated 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 consolidated 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 stock-based compensation, the valuation allowance related to our deferred tax assets and the expense allocations relating to our operations prior to our deconsolidation from Oculus on March 26, 2014.

### *Stock-Based Compensation*

We account for share-based awards exchanged for employee and director services at the estimated grant date fair value of the award. We estimate the fair value of stock options using the Black-Scholes option pricing model. We estimate the fair value of restricted stock and restricted stock units (“RSUs”) based upon the closing market price of our common stock on the date the award is granted. We amortize the fair value of employee awards on a straight-line basis over the requisite service period of the awards. Stock-based compensation expense includes the impact of an estimate for forfeitures for all stock awards. We recognize stock-based compensation expense for awards with performance conditions if and when we conclude that it is probable that the performance condition will be achieved. We reassess the probability of vesting at each reporting period for awards with performance conditions and adjust stock-based compensation expense based on our probability assessment.

We account 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.

### *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. 2014-12, "Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period," ("ASU 2014-12"). The amendments in ASU 2014-12 require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Accounting Standards Codification Topic No. 718, "Compensation - Stock Compensation" as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. We do not anticipate that the adoption of this standard will have a material impact on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The guidance, which is effective for annual reporting periods ending after December 15, 2016, extends the responsibility for performing the going-concern assessment to management and contains guidance on how to perform a going-concern assessment and

when going-concern disclosures would be required under U.S. GAAP. We do not believe adoption of this ASU will have a material effect on our consolidated financial statements.

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.

**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.

**Internal Control over Financial Reporting**

*Management's Annual Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Principal Executive and Financial Officer, and effected by the Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP including those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the disposition of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP and that receipts and expenditures are being made only in accordance with authorizations of our management and Board of Directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 1992 framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of March 31, 2015.

*Changes in Internal Controls*

There were no changes in our internal control over financial reporting that occurred during our last fiscal quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION.

None.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

**Executive Officers and Directors**

Set forth below is certain information with respect to our directors and executive officers.

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
Hojabr Alimi	53	Chief Executive Officer, Chief Science Officer and Chairman of the Board of Directors
Sameer Harish	39	Chief Financial Officer
Richard Conley (1)(2)(3)	64	Director
Gregory French (1)(2)(3)	54	Director
Akihisa Akao (1)	61	Director

(1) Member of our audit committee.

(2) Member of our compensation committee.

(3) Member of our nominating and governance committee.

**Executive Officers**

*Hojabr Alimi* has served as our Chief Executive Officer and Chief Science Officer since February 4, 2013. Mr. Alimi was also appointed Chairman of our board of directors on that same date. From 1999 to February 2013, Mr. Alimi

held the position of President and Chief Executive Officer at our former parent company, Oculus, a public company which he co-founded with his spouse. Mr. Alimi served as Chairman of the Board of Oculus, from 1999 until February 2014. Upon completion of our initial public offering, Mr. Alimi resigned from Oculus' board of directors. Prior to founding Oculus, Mr. Alimi was a corporate microbiologist for Arterial Vascular Engineering. Mr. Alimi received a B.A. in biology from Sonoma State University.

Our board of directors has determined that Mr. Alimi possesses specific attributes that qualify him to serve as a member of our board of directors, including his depth of scientific, operating, strategic, transactional, and senior management experience in our industry, his longevity in the industry, and his intimate knowledge of our company, as he is the founder of Ruthigen and Oculus.

**Sameer Harish** has served as our Chief Financial Officer since February 1, 2013. Prior thereto, from December 2011, Mr. Harish served as the principal of Harish Life Science Advisors, an independent consulting firm, which he founded that provided financial, strategic, and market research advisory services to life science companies. From 2005 to 2011, Mr. Harish held the position of senior equity research analyst covering the medical devices and diagnostics sectors at ThinkEquity LLC and Needham & Co. From 2002 to 2005, Mr. Harish was a research analyst at Symmetry Capital, a health care focused hedge fund, where he guided investments in medical device, biotech, and diagnostic companies. Mr. Harish also held research and laboratory positions at Guidant (now part of Abbott Laboratories) and Synteni (acquired by Incyte Corporation). He received a B.A. from the University of California, Berkeley, where he studied molecular and cell biology with an emphasis in immunology.

#### **Non-Employee Directors**

**Richard Conley** has served as a director since February 2013. From 1999 until March 2014, Mr. Conley served as a member of the board of directors of Oculus. Upon completion of our IPO, Mr. Conley resigned from Oculus' board of directors. Since 2012, Mr. Conley has served as a volunteer member of the Finance Committee and Citizens Bond Oversight Committee of the Sonoma Valley Health Care District. Mr. Conley held the position of Chief Operating Officer at Kautz Family Vineyards, a wine production and marketing and hospitality company, from 2009 to 2011. From 2001 to 2009, Mr. Conley served as Executive Vice President and Chief Operating Officer at Don Sebastiani & Sons International Wine Negotiants, a branded wine marketing company. From 1994 to 2001, he served as Vice President and Chief Operating Officer at Sebastiani Vineyards, a California wine producer, where he was originally hired as Chief Financial Officer in 1994. Mr. Conley received a B.S. in finance and accounting from Western Carolina University and an M.B.A. from St. Mary's College of California.

Our board of directors has determined that Mr. Conley possesses specific attributes that qualify him to serve as a member of our board of directors, including the depth of his financial, accounting, operating and transactional experience.

**Gregory French** has served as a director since February 2013. Mr. French is the co-owner of G&C Enterprises LLC, a real estate and investment company, which he founded in 1999. Mr. French has held various engineering and senior management positions at several medical device companies, including Advanced Cardiovascular Systems, Peripheral Systems Group and Arterial Vascular Engineering. He received a B.S.I.E. from the California Polytechnic State University, San Luis Obispo. Mr. French was a director of Oculus from 2000 until his resignation effective as of February 21, 2014.

Our board of directors has determined that Mr. French possesses specific attributes that qualify him to serve as a member of our board of directors, including extensive experience in the healthcare industry and a depth of operating and senior management experience.

**Akihisa Akao** has served as a director since February 27, 2015. Mr. Akao has been the Chief Executive Officer of White Moon Medical, Inc. since he founded such company in 1999. The company provides consulting services as well as capital to early-stage healthcare companies which are expanding into Asian markets. Mr. Akao served as a director of Oculus from April 1999 until May 2008. Mr. Akao has 38 years of experience in the healthcare industry and development therapies in areas of pulmonology, wound care, general surgery, cardiovascular and anesthesiology. Mr. Akao has served on the board of directors at MedTech Heart K.K., a medical technology company, since August 2011. Mr. Akao has served as the general manager in Japan at Power Medical Interventions Inc., a medical device company, from January 2001 to September 2005 and as President from December 2006 to December 2009 until its merger with Covidien. Mr. Akao received a B.A. in electronic engineering from Doshisha University, Kyoto Japan.

Our board of directors has determined that Mr. Akao possesses specific attributes that qualify him to serve as a member of our board of directors, including extensive experience in the healthcare industry and of his financial, operating and transactional experience.

If the Merger is completed all of our current officers and directors will resign immediately prior to the Merger.

#### **Other Involvement in Certain Legal Proceedings**

There are no legal proceedings that have occurred within the past ten years concerning our directors, or control persons which involved a criminal conviction, a criminal proceeding, an administrative or civil proceeding limiting one's participation in the securities or banking industries, or a finding of securities or commodities law violations.

### **Board Composition and Election of Directors**

Our board of directors currently consists of four directors. Our board of directors is divided into three classes, class I, class II and class III, with members of each class serving staggered terms where the term of each class of directors expires at each successive annual meeting of the stockholders. The members of the classes are divided as follows:

- the class I director is Hojabr Alimi, and his term will expire at the 2018 annual meeting of stockholders

the class II directors are Richard Conley and Akihisa Akao, and their terms will expire at the 2016 annual meeting of stockholders; and

- the class III director is Gregory French, and his term will expire at the 2017 annual meeting of stockholders.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new term at the annual meeting of stockholders in that year.

### **Board Committees and Independence**

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which operates under a charter that has been approved by our board of directors.

Our board of directors has determined that all of the members of the audit committee, the compensation committee and the nominating and corporate governance committee are independent, as defined under The NASDAQ Marketplace Rules, including, in the case of all of the members of our audit committee, the independence requirements contemplated by Rule 10A-3 under the Securities Exchange Act of 1934. In making such determination, the board of directors considered the relationships that each director has with our company and all other facts and circumstances that the board of directors deemed relevant in determining director independence, including the beneficial ownership of our capital stock by each director.

There are no family relationships among any of our directors or executive officers.

None of our directors or officers is a director in any other reporting companies. None of our directors or officers has been affiliated with any company that has filed for bankruptcy within the last ten years. The Company is not aware of any proceedings to which any of the Company's officers or directors, or any associate of any such officer or director, is a party adverse to the Company or has a material interest adverse to it.

*Audit Committee.* Our audit committee is comprised of Richard Conley, Gregory French and Akihisa Akao. Our board of directors has determined that Richard Conley is an audit committee financial expert, as defined by the rules of the Securities and Exchange Commission, and satisfies the financial sophistication requirements of applicable NASDAQ rules.

Under the applicable NASDAQ rules, we are permitted to phase in our compliance with the independent audit committee requirements set forth in NASDAQ Marketplace Rule 5605(c)(2)(A)(ii) on the same schedule as we are permitted to phase in our compliance with the independent audit committee requirement pursuant to Rule 10A-3(b)(1)(iv)(A) under the Exchange Act, which require (1) one independent member at the time of listing; (2) a majority of independent members within 90 days of listing; and (3) all independent members within one year of listing.

Our board of directors has determined that each of Messrs. Conley, French and Akao is an independent director under the NASDAQ Marketplace Rules and Rule 10A-3 of the Exchange Act. Mr. Alimi resigned from our audit committee on February 27, 2015 and was replaced with Mr. Akao on such date who is independent under NASDAQ Marketplace Rule 5605(c)(2)(A)(ii) and Rule 10A-3.

Our audit committee is authorized to:

- review the proposed scope and results of the audit;
- review and pre-approve audit and non-audit fees and services;
- review accounting and financial controls with the independent auditors and our financial and accounting staff;
- review and approve transactions between us and our directors, officers and affiliates;
  - recognize and prevent prohibited non-audit services;
- establish procedures for complaints received by us regarding accounting matters;
- oversee internal audit functions, if any; and
- prepare the report of the audit committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement .

*Compensation Committee.* Our compensation committee is comprised of Gregory French and Richard Conley.

Our compensation committee is authorized to:

- review and recommend the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;

- administer our stock incentive plans;

- prepare the report of the compensation committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement; and

- have the sole authority to retain or obtain the advice of any compensation consultant, independent legal counsel or other adviser after taking into account certain factors which address the independence of that consultant, counsel or adviser.

*Nominating and Governance Committee.* Our nominating and governance committee is comprised of Richard Conley and Gregory French.

Our nominating and governance committee is authorized to:

- identify and nominate members of the board of directors;

- develop and recommend to the board of directors a set of corporate governance principles applicable to our company; and

- oversee the evaluation of our board of directors.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our common stock and other of our equity securities. Officers, directors and greater than ten percent stockholders are required by regulations of the Securities and Exchange Commission to furnish us with copies of all Section 16(a) forms they file.

Our records reflect that all reports required to be filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, by our executive officers and directors have been filed on a timely basis.

**Code of Conduct and Ethics**

Our board of directors has adopted a written Corporate Code of Conduct and Ethics and Whistleblower Policy (the “Corporate Code”) applicable to our employees, officers and directors, including those officers responsible for financial reporting. The Corporate Code is available on our website at [www.ruthigen.com](http://www.ruthigen.com). We expect that any amendments to the code, or any waivers of its requirements, will be disclosed.

**Item 11. EXECUTIVE COMPENSATION.****Summary Compensation Table**

The following table sets forth the compensation paid to, accrued or earned during the fiscal years ended March 31, 2015 and March 31, 2014 by our chief executive officer and our only other executive officer as of March 31, 2015 and March 31, 2014. We refer to these officers as our named executive officers.

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus (\$)</b>	<b>Stock Awards (\$) (1)</b>	<b>Option Awards (\$) (1)</b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Hojabr Alimi	2015	\$ 375,000	\$-	\$ 939,047	\$ 764,005	\$ 50,856 (3)	\$ 2,128,908
Chief Executive Officer and Chief Science Officer	2014	\$ 375,000	\$ 158,000 (2)	\$-	\$-	\$ 51,856 (4)	\$ 584,856
Sameer Harish	2015	\$ 225,000	\$-	\$ 563,850	\$ 95,800	\$ 7,961 (5)	\$ 892,611
Chief Financial Officer	2014	\$ 225,000	\$-	\$-	\$-	\$-	\$ 225,000

The amounts reported in these columns represent the grant date fair value of the stock and option awards granted during the fiscal year ended March 31, 2015 as calculated in accordance with FASB ASC Topic 718. For a detailed (1) discussion of the assumptions used in estimating fair values, see Note 7. Stockholders’ Equity in the notes that accompany our consolidated financial statements.



(2) Represents a one-time cash bonus of \$158,000 related to the preparation and filing of our registration statement on Form S-1 for our initial public offering.

(3) Includes Company matching 401(k) contributions in the amount of \$8,654 and Company paid vacation of \$42,202.

Includes the reimbursement of tax preparation services of \$25,884, the reimbursement of legal fees of \$18,744,  
(4) Company matching 401(k) contributions of \$3,750, personal use of our company car in the amount of \$3,462, and payment by the Company of life insurance premiums in the amount of \$16.

(5) Represents Company matching 401(k) contributions in the amount of \$7,961.

## **Narrative to Summary Compensation Table**

### *Employment Agreements with Our Named Executive Officers*

#### ***Hojabr Alimi***

On March 21, 2013, we entered into an employment agreement with an effective date of February 4, 2013 (the “Alimi Employment Agreement”) with Hojabr Alimi to reflect his role and responsibilities as President and Chief Executive Officer. The Alimi Employment Agreement provided for an annual base salary of \$375,000, subject to increase (but not decrease), as determined by our board of directors. Mr. Alimi may also receive stock options and/or other stock-based awards as determined by us in our sole discretion. Additionally, Mr. Alimi is eligible to participate in our bonus plans and incentive plans as established from time to time by us. The Alimi Employment Agreement also provides for payments to Mr. Alimi in the event of termination without cause or resignation by Mr. Alimi for Good Reason, as such terms are defined in the Alimi Employment Agreement. In the event Mr. Alimi is terminated without cause or resigns for Good Reason, he is entitled to (i) a lump severance payment equal to 24 times the average monthly base salary paid to Mr. Alimi over the preceding 12 months (or for the term of Mr. Alimi’s employment with us if less than 12 months); (ii) automatic vesting of all unvested options and other equity awards; (iii) the extension of exercisability of all options and other equity awards to at least 12 months following the date Mr. Alimi terminates employment or, if earlier, until the option expires; (iv) up to one year (the lesser of one year following the date of termination or until Mr. Alimi becomes eligible for medical insurance coverage provided by another employer) reimbursement for health care premiums under COBRA; and (v) a full gross up of any excise taxes payable by Mr. Alimi under Section 4999 of the Internal Revenue Code because of the foregoing payments and acceleration (including the reimbursement of any additional federal, state and local taxes payable as a result of the gross up), subject to the restrictions of Section 409A of the Internal Revenue Code.

Under the Alimi Employment Agreement, “Good Reason” is defined as the occurrence of one or more of the following without Mr. Alimi’s consent: (i) the assignment of Mr. Alimi to duties materially inconsistent with Mr. Alimi’s authorities, responsibilities, and status (including titles and reporting requirements) as Chief Executive Officer, or a material reduction or alteration in the nature or status of Mr. Alimi’s authorities, duties or responsibilities, other than an insubstantial and inadvertent act that is remedied by the company promptly after receipt of notice thereof given by Mr. Alimi; (ii) a reduction by us in Mr. Alimi’s base salary as in effect on the effective date or as the same shall be increased from time to time, or we otherwise fail to satisfy our compensation obligations to Mr. Alimi under the Alimi Employment Agreement, after notice by Mr. Alimi and a reasonable opportunity to cure; or (iii) the failure by us to obtain a satisfactory agreement from any successor of our company to assume and agree to perform the Alimi Employment Agreement. Mr. Alimi 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. Alimi’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 affiliates, including but not limited to the board of directors of Oculus; and his return to us and our affiliates (the “Company Group”) of all property belonging to the Company Group, received from or on account of us, any other entity in the Company Group, or any of the Company Group’s respective affiliates by Mr. Alimi. In addition, Mr. Alimi is not entitled to such benefits if he does not comply with the non-competition and invention assignment provisions of the Alimi Employment Agreement during the term of his employment, or the confidentiality provisions of the Alimi 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. Alimi does not comply with the non-solicitation provisions of the Alimi Employment Agreement, which prohibit Mr. Alimi 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.

In addition, on August 12, 2013, the Compensation Committee of Oculus approved the grant of a one-time cash bonus of \$158,000 to Mr. Alimi in order to recognize his efforts related to the filing of our registration statement for our IPO.

On January 31, 2014, in connection with our entry into various amendments to our commercial agreements with Oculus, Oculus guaranteed the payment of Mr. Alimi's severance in an amount not to exceed \$385,000, under certain circumstances.

On November 28, 2014, the compensation committee of the board of directors approved an amended and restated employment agreement for Mr. Alimi which supersedes the employment agreement previously in effect between us and Mr. Alimi. The prior employment agreement went into effect when we were a wholly-owned subsidiary of Oculus and Mr. Alimi was the Chairman of the board of directors of Oculus. The amended and restated employment agreement primarily removes all references to Oculus and other legacy references related to us being a subsidiary of Oculus.

The amended and restated employment agreement continues to provide for an annual base salary of \$375,000, subject to increase, as determined by our board of directors. The amended and restated employment agreement further provides for payments to Mr. Alimi in the event of termination without cause or resignation by Mr. Alimi for good reason, as such terms are defined in the amended and restated employment agreement. In the event that Mr. Alimi is terminated without cause or resigns for good reason, he is entitled to: (i) a lump severance payment equal to 24 times the average monthly base salary paid to Mr. Alimi over the preceding 12 months; (ii) up to one year (the lesser of one year following the date of termination or until Mr. Alimi 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. 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. Alimi 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). Furthermore, we will reimburse Mr. Alimi for relocation expenses if our principal executive offices are moved or he is required to relocate, subject to certain conditions. Mr. Alimi 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. Alimi'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 (as such term is defined in the employment agreement), 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. Alimi. In addition, Mr. Alimi 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. Alimi does not comply with the non-solicitation provisions of the employment agreement, which prohibit Mr. Alimi 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.

***Sameer Harish***

On February 1, 2013, and as amended on May 23, 2013, Oculus entered into an employment letter with Sameer Harish to reflect his roles and responsibilities as Chief Financial Officer of our company (the “Harish Employment Letter”). Mr. Harish’s employment was contingent upon, in addition to proof of identity, his signing of a Proprietary Information and Inventions Agreement and a Confidentiality Agreement with Oculus. Pursuant to the terms of the Harish Employment Letter, Mr. Harish was entitled to receive an annual base salary of \$225,000.

On June 24, 2014, our compensation committee approved an employment agreement for Mr. Harish (the “Harish Employment Agreement”), which replaced the offer letter previously in effect between us and Mr. Harish. The Harish Employment Agreement continues to provide for an annual base salary of \$225,000, subject to increase, as determined by our board of directors. Mr. Harish may also receive stock options and/or other stock-based awards as determined by us in our sole discretion. In addition, Mr. Harish is eligible to participate in our bonus plans and incentive plans that we establish from time to time, as well as all employee pension and welfare benefit plans and programs made available by us to our senior-level employees generally. The Harish 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 Harish 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 (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 Harish Employment Agreement during the term of his employment, or the confidentiality provisions of the Harish 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 Harish 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.

If the Merger is completed, Messrs. Alimi and Harish will be employed by the combined company and have agreed to terminate equity grants previously made to them and will receive cash and restricted stock units pursuant to new employment agreements Pulmatrix and Ruthigen entered into with each of Messrs. Alimi and Harish, effective upon the closing of the Merger.

*Outstanding Equity Awards*

The table below reflects all outstanding equity awards made to any named executive officer that were outstanding at March 31, 2015.

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END**

**Option Awards**

**Stock Awards**

<b>Number of</b>	<b>Equity incentive plan awards:</b>	<b>Market</b>	<b>Equity incentive plan awards: Number of unearned</b>	<b>Equity incentive Plan awards : Market or payout value of unearned shares,</b>
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Name	Number of securities			Number of securities			Number of shares or units of stock that have not vested	value of shares, units or other rights that have not vested	shares, units or other rights that have not vested	units or other rights that have not vested
	underlying unexercised options exercisable	underlying unexercised options unexercisable	(1)	underlying unexercised options	Option price	Option expiration date				
Hojabr Alimi	39,906	119,594	(1)	-	\$ 6.37	5/12/2024	-	-	-	\$ -
	-	-		-	\$ -		93,725	322,414	-	\$ -
	-	-		-	\$ -		-	-	24,055	(2) \$ 82,749
Sameer Harish	26,271	78,729	(3)	-	\$ 6.37	5/12/2024	-	-	-	\$ -
	-	-		-	\$ -		55,937	192,423	-	\$ -
	-	-		-	\$ -		14,900	51,256	14,900	(2) \$ 51,256

- (1) Option is exercisable to the extent of 13,302 shares quarterly between May 12, 2015 to February 12, 2016, and 13,178 shares on May 12, 2016.
  
- (2) Represents restricted stock units that vest based upon the completion of certain performance conditions.
  
- (3) Option is exercisable to the extent of 8,757 shares quarterly between May 12, 2015 to February 12, 2016, and 8,673 shares on May 12, 2016.

**Director Compensation**

The following table summarizes the compensation awarded during the fiscal year ended March 31, 2015 to our directors who are not named executive officers in the Summary Compensation Table above:

Name	Fees Earned or Paid in			Total (\$)
	Cash (\$)	Stock Awards (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(1)</sup>	
Gregory French	\$ 38,000	\$ 441,000	\$ 47,900	<sup>(2)</sup> \$526,900
Richard Conley	\$ 43,000	\$ 441,000	\$ 47,900	<sup>(2)</sup> \$531,900
Akihisa Akao <sup>(3)</sup>	\$ 2,712	\$ -	\$ -	\$2,712

The amounts reported in this column represent the grant date fair value of the stock and option awards granted during the year ended March 31, 2015, calculated in accordance with FASB ASC Topic 718. For a detailed <sup>(1)</sup> discussion of the assumptions used in estimating fair values, see Note 10 – Stockholders’ Deficiency in the notes that accompany our consolidated financial statements.

<sup>(2)</sup> Represents options to purchase 10,000 shares of common stock at an exercise price of \$6.37 per share. The shares vest ratably over three years on a quarterly basis.

<sup>(3)</sup> Mr. Akao was appointed as a director effective February 27, 2015.

On September 30, 2013, our board of directors approved a director compensation policy that took effect upon the completion of our IPO that provides cash compensation of \$40,000 per year to our chairman, if such person is not an employee, \$25,000 per year to each non-employee, non-chairman director, plus \$10,000 per year to the chairman of our audit committee, \$5,000 per year to each other member of our audit committee, \$5,000 per year to the chairman of our compensation committee and our nominating and governance committee and \$3,000 per year to each other member of our compensation committee and our nominating and governance committee. Members of our board of directors who are also our employees, such as Mr. Alimi, do not receive any fees for their service on our board of directors, as a chairman or committee member. The policy also provides that directors may elect, in lieu of annual cash payments, to receive, in part or in full, fully-vested stock options or fully-vested shares of common stock, or a combination thereof, equal to the dollar-value of the non-cash portion of their annual compensation, calculated in accordance with FASB Accounting Standards Codification ASC 718, “Share-Based Payment” on the payment date.

Under the policy, upon initial election or appointment to the board of directors, new non-employee directors receive a non-qualified stock option to purchase 5,000 shares of our common stock at an exercise price equal to the fair market value on the date of grant that vests one year from the date of grant. Each year of a non-employee director’s tenure, the director will receive a non-qualified stock option to purchase 5,000 shares of our common stock at an exercise price



equal to the fair market value on the date of grant that vests three years from the date of grant. The options become fully vested and exercisable upon a change of control.

In addition, equity awards may be granted under the 2013 Plan to our non-employee directors from time to time as may be determined by our compensation committee.

All directors are eligible to receive reimbursement for reasonable out-of-pocket expenses incurred in connection with attendance at meetings of our board of directors, and our non-employee directors are also eligible to receive reimbursement, upon approval of the board of directors or a committee thereof, for reasonable out-of-pocket expenses incurred in connection with attendance at various conferences or meetings with our management.

**Equity Compensation Plan Information**

The following table provides information as of March 31, 2015:

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders [1]	895,691	\$ 6.37	102,664
Equity compensation plans not approved by security holders	-	\$ -	-
Total	895,691	\$ 6.37	102,664

[1] – Shares represent grants under the 2013 Plan.

**2013 Employee, Director and Consultant Equity Incentive Plan**

Our 2013 Plan became effective on the closing of our initial public offering in March 2014 and will expire on September 30, 2023. Under the 2013 Plan, we may grant incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards. When the 2013 Plan took effect in March 2014, 998,355 shares of our common stock were authorized for issuance thereunder.

In addition, the 2013 Plan contains an “evergreen” provision, which allows for an annual increase in the number of shares of our common stock available for issuance under the plan on the first day of each fiscal year equal to the lowest of: (i) 232,500 shares of our common stock; (ii) 5% of the number of shares of our common stock outstanding as of such date; and (iii) an amount determined by our board of directors or compensation committee. As of April 1, 2015, there were 1,230,855 shares of common stock authorized for issuance under the 2013 Plan and there were 335,164 shares available for issuance under the 2013 Plan.

The board of directors has authorized our compensation committee to administer the 2013 Plan. In accordance with the provisions of the plan, the compensation committee will determine the terms of options and other awards. The compensation committee or the independent members of our board of directors will determine:

- which employees, directors and consultants shall be granted options and other awards;
- the number of shares of our common stock subject to options and other awards;
- the exercise price of each option, which generally shall not be less than fair market value on the date of grant;
- the schedule upon which options become exercisable;
- the termination or cancellation provisions applicable to options;
- the terms and conditions of other awards, including conditions for repurchase, termination or cancellation, issue price and repurchase price; and
- all other terms and conditions upon which each award may be granted in accordance with the 2013 Plan.

Upon a merger, consolidation or sale of all or substantially all of our assets, the administrator of the 2013 Plan, or the board of directors of any corporation assuming our obligations, may, in its sole discretion, take any one or more of the following actions pursuant to our plan, as to some or all outstanding awards:

· provide that outstanding options will be substituted for shares of the successor corporation or consideration payable with respect to our outstanding stock in connection with the corporate transaction;

· provide that the outstanding options must be exercised within a certain number of days, either to the extent the options are then exercisable, or at our board of directors' discretion, any such options being made partially or fully exercisable;

terminate outstanding options in exchange for payment of an amount equal to the difference between (a) the consideration payable upon consummation of the corporate transaction to a holder of the number of shares into which such option would have been exercisable to the extent then exercisable (or, in our board of directors' discretion, any such options being made partially or fully exercisable) and (b) the aggregate exercise price of those options;

provide that outstanding stock grants will be substituted for shares of the successor corporation or consideration payable with respect to our outstanding stock in connection with the corporate transaction;

the terms and conditions of other awards, including conditions for repurchase, termination or cancellation, issue price and repurchase price; and

terminate outstanding stock grants in exchange for payment of any amount equal to the consideration payable upon consummation of the corporate transaction to a holder of the same number of shares comprising the stock grant, to the extent the stock grant is no longer subject to any forfeiture or repurchase rights (or, at our board of directors' discretion, all forfeiture and repurchase rights being waived upon the corporate transaction).

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

The following table lists, as of June 5, 2015, the number of shares of common stock of our Company that are beneficially owned by (i) each person or entity known to our Company to be the beneficial owner of more than 5% of the outstanding common stock; (ii) each executive officer and director of our Company; and (iii) all officers and directors as a group. Information relating to beneficial ownership of common stock by our principal shareholders and management is based upon information furnished by each person using "beneficial ownership" concepts under the rules of the Securities and Exchange Commission. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or direct the voting of the security, or investment power, which includes the power to vote or direct the voting of the security. The person is also deemed to be a beneficial owner of any security of which that person has a right to acquire beneficial ownership within 60 days. Under the Securities and Exchange Commission rules, more than one person may be deemed to be a beneficial owner of the same securities, and a person may be deemed to be a beneficial owner of securities as to which he or she may not have any pecuniary beneficial interest. Except as noted below, each person has sole voting and investment power.

The percentages below are calculated based on 4,804,290 shares of our common stock issued and outstanding as of June 5, 2015. Unless otherwise indicated, the address of each person listed is c/o Ruthigen, Inc., 2455 Bennett Valley Rd., Suite C116, Santa Rosa, California 95404.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
<b>Directors and Executive Officers</b>		
Hojabr Alimi	53,208	(1) 1.10 %
Sameer Harish	35,028	(1) *
Richard Conley	8,336	(1) *
Gregory French	8,336	(1) *
Akihisa Akao	5,000	(1) *
All current executive officers and directors as a group (5 persons)	109,908	(1) 2.24 %
<b>5% Stockholders</b>		
Oculus Inovative Sciences, Inc. 1129 N. McDowell Blvd. Petaluma, CA 94954	2,000,000	(2) 41.63 %
Marlin Capital Investments LLC 555 South Federal Highway #450 Boca Raton, FL 33432	369,773	(3) 7.70 %
Barry Honig 555 South Federal Highway #450 Boca Raton, FL 33432	384,052	(4) 7.99 %

\*Represents beneficial ownership of less than 1%.

(1) Represents shares issuable upon the exercise of stock options.

Based on a Schedule 13D filed on March 23, 2015 and includes (i) 350,000 shares of common stock that Oculus sold on March 23, 2015 and for which Oculus retained voting power but has no dispositive power and (ii) (2) 1,650,000 shares of common stock that Oculus has agreed to sell upon the closing of the Merger and for which Oculus has retained voting power but has no dispositive power. Jim Schutz, chief executive officer of Oculus, may be deemed to beneficially own the shares held by Oculus.

(3) Based on a Schedule 13G filed on February 13, 2015. Barry Honig, the manager of Marlin Capital Investments LLC ("Marlin Capital"), has voting and dispositive power over such securities held by Marlin Capital. Does not include 14,279 shares held by Mr. Honig in his own name. Excludes Series A warrants to purchase an aggregate of 383,793 shares of our common stock exercisable at an initial exercise price of \$7.25 per share, and (ii) Series B warrants to purchase one share of our common stock at an initial exercise price of \$9.0625 per share. The Series A warrant and the Series B warrant are governed by certain beneficial ownership blockers preventing the holder from

exercising such securities to the extent such conversion or exercise would cause the holder to beneficially hold in excess of 4.99% of our issued and outstanding common stock, which may be waived upon 61 days' prior notice. Mr. Honig's and Marlin Capital's beneficial ownership has been limited accordingly.

Includes (i) 14,279 shares of common stock and (ii) 369,773 shares of common stock which are held by Marlin Capital and are also reported on this table as being beneficially owned by Marlin Capital. Barry Honig, manager of Marlin Capital holds voting and dispositive power over such securities. Excludes Series A warrants to purchase an aggregate of 383,793 shares of our common stock exercisable at an initial exercise price of \$7.25 per share and (ii) (4) Series B warrants to purchase one share of our common stock at an initial exercise price of \$9.0625 per share. The Series A warrant and the Series B warrant are governed by certain beneficial ownership blockers preventing the holder from exercising such securities to the extent such conversion or exercise would cause the holder to beneficially hold in excess of 4.99% of Ruthigen's issued and outstanding common stock, which may be waived upon 61 days' prior notice. Mr. Honig's and Marlin Capital's beneficial ownership has been limited accordingly.

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

**Certain Relationships and Related Person Transactions**

*Relationship with Oculus*

We have a license and supply agreement, a shared services agreement and a separation agreement with Oculus, the holder of 2,000,000 shares or approximately 42% of our outstanding shares of common stock. These agreements, which took effect upon the completion of our initial public offering in March 2014, govern our relationship with Oculus. In addition, we entered into a funding agreement with Oculus that governed certain aspects of our operations, financing and governance until the completion of our initial public offering. The license and supply agreement covers our exclusive rights to the license, development and manufacturing of our lead drug candidate, RUT58-60. The shared services agreement covers certain transitional services to be provided by Oculus following the completion of our offering. We entered into the separation agreement with Oculus in order to maximize our ability to operate as independently as possible from Oculus in order to unlock the value proposition of RUT58-60, notwithstanding Oculus' substantial ownership of us, and therefore the separation agreement contains certain limitations on Oculus' ability to control various aspects of our business and operations. In addition, the members of our Board of Directors who were also members of Oculus' board of directors stepped down from Oculus' board and continued their service on our Board following our initial public offering. The shared services agreement was terminated on April 6, 2015.

Pursuant to the terms of the separation agreement with Oculus, so long as Oculus and its affiliates own 19.9% of our common stock, Oculus shall vote all of its shares in the same manner as the majority of the minority holders of our common stock.

*Equity Awards and Compensation*

Following the closing of our initial public offering and during the year ended March 31, 2015, we granted Hojabr Alimi, our Chief Executive Officer, Chief Science Officer and Chairman of the Board of Directors, 159,500 stock options, 125,000 restricted stock units and 24,055 performance-based restricted stock units. At that same time, we also granted Sameer Harish, our Chief Financial Officer, 105,000 stock options, 74,600 restricted stock units and 14,900 performance-based restricted stock units.

During the fiscal year ended March 31, 2014, our non-employee directors did not receive any compensation for their service on our Board, other than Gregory French for whom we reimbursed certain legal expenses of \$51,975 incurred in connection with our separation from Oculus. During the fiscal year ended March 31, 2015, we granted our

non-employee directors restricted stock units for 140,000 shares of our common stock under our 2013 Plan and options to purchase 20,000 shares of our common stock under our 2013 Plan.

*Directors and Officers*

Prior to February 21, 2014, all of our then directors also served as directors of Oculus. Gregory French resigned from the board of directors of Oculus effective as of February 21, 2014, and he continues to serve on our Board of Directors. Hojabr Alimi, our Chief Executive Officer, Chief Science Officer and Chairman of our Board of Directors, previously served as the Chairman of the board of directors of Oculus. Richard Conley previously served as a director of Oculus. Upon completion of our initial public offering in March 2014, Messrs. Alimi and Conley stepped down from Oculus' board and continue their service on our Board of Directors.

*Indemnification Agreements*

We have entered into indemnification agreements with each of our directors and officers. The indemnification agreements and our restated certificate of incorporation and restated by-laws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.



*Director Independence*

Our Board of Directors has determined that Richard Conley, Gregory French and Akihisa Akao qualify as independent directors under the definition promulgated by The NASDAQ Stock Market LLC.

Item 14. **PRINCIPAL ACCOUNTING FEES AND SERVICES.**

The following table presents fees for professional audit services rendered by Marcum LLP for the audit of the Company's annual consolidated financial statements for the years ended March 31, 2015 and 2014, and fees billed for other services rendered by Marcum LLP during those periods.

	For the Years Ended March 31,	
	2015	2014
Audit fees <sup>(1)</sup>	\$ 143,639	\$ 276,762
Audit related fees <sup>(2)</sup>	-	-
Tax Fees <sup>(3)</sup>	14,790	-
All other fees <sup>(4)</sup>	-	-
	\$ 158,429	\$ 276,762

<sup>(1)</sup> Audit fees consisted of fees for professional services rendered by Marcum LLP for the audit of the Company's annual financial statements and reviews of interim financial statements and services that are normally provided by Marcum LLP in connection with statutory and regulatory filings or engagement.

<sup>(2)</sup> No audit related fees were incurred by the Company in fiscal 2014 or 2015.

<sup>(3)</sup> Tax fees consisted of fees for professional services rendered by Marcum LLP for the preparation of the Company's tax return.

<sup>(4)</sup> No other fees were incurred by the Company in fiscal 2014 or 2015.

## **Policy on Audit Committee Pre-Approval of Audit and Permissible Non-audit Services of Independent Public Accountant**

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. **Audit** services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits, and attest services and consultation regarding financial accounting and/or reporting standards.

2. **Audit-Related** services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. **Tax** services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning, and tax advice.

4. **Other Fees** are those associated with services not captured in the other categories. The Company generally does not request such services from our independent registered public accounting firm.

## 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)** 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:

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Included with this Report</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date</b>	<b>SEC File/Reg. Number</b>
2.1	Agreement and Plan of Merger dated March 13, 2015, by and among the Company, Pulmatrix and Ruthigen Merger Corp.		Form 8-K (Exhibit 2.1)	3/13/15	001-36199
3.1	Restated Certificate of Incorporation		Form 8-K (Exhibit 3.1)	03/31/14	001-36199
3.2	Restated Bylaws		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	02/24/14	333-190476

		(Exhibit 4.3)	
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 the Company and VStock Transfer, LLC	Form S-1 (Exhibit 4.5)	02/24/14 333-190476
<b>Agreements with Executive Officers and Directors</b>			
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 the Company and Sameer Harish, dated June 24, 2014	Form 10-K (Exhibit 10.1.2)	6/30/14 001-36199
10.2*	Employment Agreement by and between the Company 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
10.5.1*	Amended and Restated Employment Agreement dated November 29, 2014 between the Company and Hojabr Alimi	Form 8-K (Exhibit 10.1)	11/28/14	001—36199
10.5.2*	Employment Agreement dated March 13, 2015, between the Company, Pulmatrix and Hojabr Alimi	Form S-4 (Exhibit 10.4.1)	4/15/15	333-203417
10.5.3*	Employment Agreement dated March 13, 2015, between the Company, Pulmatrix and Sameer Harish	Form S-4 (Exhibit 10.3.1)	4/15//15	333-203417
10.15	Cancellation Agreement dated March 13, 2015 between the Company and Sameer Harish	Form S-4 (Exhibit 10.3.2)	4/15/15	333-203417
10.16	Lock-Up Agreement dated March 13, 2015 between the Company and Sameer Harish	Form S-4 (Exhibit 10.3.3)	4/15/15	333-203417
10.17	Cancellation Agreement dated March 13, 2015 between the Company and Hojabr Alimi	Form S-4 (Exhibit 10.4.2)	4/15/15	333-203417
10.18	Lock-Up Agreement dated March 13, 2015 between the Company and Hojabr Alimi	Form S-4 (Exhibit 10.4.3)	4/15/15	333-203417

**Lease Agreements**

10.6.1	Assignment and Assumption of Lease Agreement by and between Gladiator Capital Funds, LLC, the Company., 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
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10.6.2	Third Amendment to Office Lease by and between the Company and SR Office Properties LLC, dated October 3, 2013.	Form S-1  (Exhibit 10.3.1)	10/16/13 333-190476
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**Agreements with Respect to Collaborations, Licenses, Research and Development**

10.7.1**	License and Supply Agreement by and between the Company and Oculus Innovative Sciences, Inc., dated May 23, 2013.	Form S-1  (Exhibit 10.4)	10/16/13 333-190476
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10.7.2	Amendment No. 1 to License and Supply Agreement by and between the Company and Oculus Innovative Sciences, Inc., dated October 9, 2013.	Form S-1  (Exhibit 10.4.1)	10/16/13 333-190476
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10.7.3	Amendment No. 2 to License and Supply Agreement by and between We, Inc. and Oculus Innovative Sciences, Inc., dated November 6, 2013.	Form S-1  (Exhibit 10.4.2)	11/07/13 333-190476
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10.7.4	Amendment No. 3 to License and Supply Agreement by and between the Company and Oculus Innovative Sciences, Inc., dated January 31, 2014.	Form S-1  (Exhibit 10.4.3)	02/24/14 333-190476
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10.8.1	Shared Services Agreement by and between the Company 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 the Company 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 the Company 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	2013 Employee, Director and Consultant Equity Incentive Plan	Form 10-K (Exhibit 10.11)	6/30/14	001-36199
10.12	Form of option agreement under the 2013 Incentive Plan.	Form 10-K (Exhibit 10.12)	6/30/14	001-36199
10.13	Form of restricted stock unit agreement under the 2013 Incentive Plan.	Form 10-K (Exhibit 10.13)	6/30/14	001-36199
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	Form 10-K (Exhibit 10.14)	6/30/14	001-36199
10.19	Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan	Form S-4/A (Exhibit 10.14)	5/1/15	333-203417

**Other Exhibits**

10.20	Securities Purchase Agreement dated January 8, 2015 between Michael Brauser, Barry Honig, Oculus and the Company	Form 8-K (Exhibit 10.1)	1/13/15	001-36199
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10.21	Securities Purchase Follow-Up Agreement dated March 12, 2015 between Michael Brauser, Barry Honig, Oculus, the Company and Dawson James Securities, Inc.	Form 8-K (Exhibit 10.1)	3/13/15	001-36199
10.22	Securities Purchase Agreement dated March 12, 2015 between, Oculus, the Company, Dawson James Securities, Inc. and the listed investors	Form 8-K (Exhibit 10.2)	3/13/15	001-36199
10.23	Consulting Agreement dated March 3, 2015 between Dawson James Securities, Inc. and the Company	X		
10.24	Consulting Agreement dated March 10, 2015 between Robert B. Prag and the Company	X		
10.25	Engagement Letter dated May 7, 2015 between the Company and Dawson James Securities, Inc.	X		
10.26	Amendment No. 1 to Securities Purchase Follow-Up Agreement, dated March 12, 2015 between Michael Brauser, Barry Honig, Oculus, the Company and Dawson James Securities, Inc.	X		



21	Subsidiaries	X
23.1	Consent of Marcum LLP, independent registered public accounting firm.	X
31.1	Certification 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
101	The following materials from the Registrant’s Annual Report on Form 10-K for the year ended March 31, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of March 31, 2015 and 2014, (ii) Consolidated Statements of Operations for the years ended March 31, 2015 and 2014, (iii) Consolidated Statements of Changes in Stockholders’ Equity for the years ended March 31, 2015 and 2014, (iv) Consolidated Statements of Cash Flows for the years ended March 31, 2015 and 2014, and (v) Notes to Consolidated Financial Statements.	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.

\*\*\*Furnished herewith.

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 9, 2015 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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Hojabr Alimi Hojabr Alimi	Chief Executive Officer, Chief Science Officer and Chairman of the Board of Directors (Principal Executive Officer)	June 9, 2015
/s/ Sameer Harish Sameer Harish	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	June 9, 2015
/s/ Richard Conley Richard Conley	Director	June 9, 2015
/s/ Gregory French Gregory French	Director	June 9, 2015
/s/ Akihisa Akao Akihisa Akao	Director	June 9, 2015

**RUTHIGEN, INC. & SUBSIDIARY**

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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**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 consolidated balance sheets of Ruthigen, Inc. and Subsidiary (the “Company”) as of March 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders’ equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Ruthigen, Inc. and Subsidiary as of March 31, 2015 and 2014, and the consolidated 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.

/s/ Marcum LLP

Marcum LLP  
New York, NY  
June 9, 2015

**RUTHIGEN, INC. & SUBSIDIARY****CONSOLIDATED BALANCE SHEETS**

	March 31, 2015	2014
Assets		
Current Assets:		
Cash	\$ 10,357,000	\$ 15,571,000
Prepaid expenses and other current assets	166,000	3,000
Total Current Assets	10,523,000	15,574,000
Property and equipment, net	157,000	2,000
Total Assets	\$ 10,680,000	\$ 15,576,000
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 635,000	\$ 410,000
Payable to Former Parent	-	537,000
Total Current Liabilities	635,000	947,000
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.0001 par value; 500,000 shares authorized; no shares issued and outstanding at March 31, 2015 and 2014, respectively	-	-
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 4,804,290 and 4,650,000 shares issued and outstanding at March 31, 2015 and 2014, respectively	480	465
Additional paid-in capital	20,404,520	18,297,535
Accumulated deficit	(10,360,000)	(3,669,000 )
Total Stockholders' Equity	10,045,000	14,629,000
Total Liabilities and Stockholders' Equity	\$ 10,680,000	\$ 15,576,000

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



**RUTHIGEN, INC. & SUBSIDIARY****CONSOLIDATED STATEMENTS OF OPERATIONS**

	For The Years Ended March 31,	
	2015	2014
Revenues	\$-	\$-
Operating Expenses		
Research and development	2,178,000	1,382,000
Selling, general and administrative	4,530,000	1,736,000
Total Operating Expenses	6,708,000	3,118,000
Loss From Operations	(6,708,000)	(3,118,000)
Other Income		
Interest income	17,000	-
Total Other Income	17,000	-
Net Loss	\$(6,691,000)	\$(3,118,000)
Net Loss Per Share		
- Basic and Diluted	\$(1.39 )	\$(1.53 )
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	4,823,907	2,036,301

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

**RUTHIGEN, INC. & SUBSIDIARY****CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY****FOR THE YEARS ENDED MARCH 31, 2015 AND 2014**

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total
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
Shares issued for cash in connection with underwriter's exercise of overallotment, net	154,290	15	1,027,985	-	1,028,000
Stock-based compensation	-	-	1,079,000	-	1,079,000
Net loss	-	-	-	(6,691,000 )	(6,691,000 )
Balance - March 31, 2015	4,804,290	\$ 480	\$20,404,520	\$(10,360,000)	\$10,045,000

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



**RUTHIGEN, INC. & SUBSIDIARY****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For The Years Ended March 31,	
	2015	2014
Cash Flows From Operating Activities		
Net loss	\$(6,691,000 )	\$(3,118,000 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,000	2,000
Stock-based compensation	1,079,000	-
Changes in operating assets and liabilities:		
Prepaid expenses	(163,000 )	1,000
Accounts payable and accrued expenses	388,000	146,000
Net Cash Used in Operating Activities	(5,386,000 )	(2,969,000 )
Cash Flows From Investing Activities		
Purchases of property and equipment	(156,000 )	-
Net Cash Used in Investing Activities	(156,000 )	-
Cash Flows From Financing Activities		
Advances from Former Parent	-	1,453,000
Repayment of Former Parent advances	(537,000 )	(916,000 )
Proceeds from issuance of common stock and warrants less issuance costs [1]	865,000	16,228,000
Investment from Former Parent	-	1,679,000
Net Cash Provided by Financing Activities	328,000	18,444,000
Net (Decrease) Increase In Cash	(5,214,000 )	15,475,000
Cash - Beginning	15,571,000	96,000
Cash - Ending	\$10,357,000	\$15,571,000

During the year ended March 31, 2015, gross proceeds from the initial public offering of \$1,117,000 less \$252,000 of offering costs, of which \$89,000 was withheld from the proceeds and \$163,000 was paid in cash that was previously accrued at March 31, 2014. During the year ended March 31, 2014, gross proceeds from the 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 consolidated financial statements.

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## **RUTHIGEN, INC. & SUBSIDIARY**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

#### Note 1. Organization and Plan of Merger

##### *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 pioneering new hypochlorous acid, or HOCl, based therapies designed to improve patient outcomes and reduce healthcare costs associated with infections related to post-operative invasive procedures.

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 7 – Stockholders’ Equity – Initial Public Offering for additional details.

##### *Agreement and Plan of Merger*

On March 13, 2015, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Pulmatrix Inc. (“Pulmatrix”), a privately held biopharmaceutical company focused on the discovery, development, and commercialization of inhalable therapeutics and enabling technologies that treat and control respiratory infectious diseases. The Merger Agreement provides for the merger of Pulmatrix with and into Ruthigen Merger Corp., with Pulmatrix continuing after the merger as the surviving corporation and a wholly owned subsidiary of Ruthigen (the “Merger”). See Note 6 – Commitments and Contingencies – Agreement and Plan of Merger for additional details.

#### Note 2. Summary of Significant Accounting Policies

### ***Liquidity and Financial Condition***

The Company incurred net losses of \$6,691,000 and \$3,118,000 for the years ended March 31, 2015 and 2014, respectively. At March 31, 2015, the Company's working capital and accumulated deficit were \$9,888,000 and \$10,360,000, respectively. The Company has not yet achieved profitability and it is expected that its 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.

The Company believes that its existing cash, which includes the proceeds from its IPO, will be sufficient to fund its stand-alone operations through the quarter ending June 30, 2016. 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. 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. See Note 6 – Commitments and Contingencies – Agreement and Plan of Merger.

### ***Principles of Consolidation***

The consolidated financial statements of the Company include the accounts of its wholly-owned subsidiary, Ruthigen Merger Corp., which was incorporated in the state of Delaware on March 2, 2015. All significant intercompany transactions have been eliminated in the consolidation. See Note 6 – Commitments and Contingencies – Agreement and Plan of Merger.

### ***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U. S. 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 consolidated 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 stock-based compensation, the valuation allowance related to the Company's deferred tax assets and the expense allocations relating to the Company's operations prior to its deconsolidation from its Former Parent on March 26, 2014.

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2. Summary of Significant Accounting Policies - Continued**

*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, net of accumulated depreciation and amortization which is recorded commencing at the in-service date. 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:

	<b>Years</b>
Office equipment	3
Medical 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.

### *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;
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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.

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**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2. Summary of Significant Accounting Policies - Continued**

*Impairment of Long-Lived Assets – Continued*

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 stock options using the Black-Scholes option pricing model. The Company estimates the fair value of restricted stock and restricted stock units (“RSUs”) based upon the closing market price of the Company’s common stock on the date the award is granted. The Company amortizes the fair value of employee awards on the straight-line basis over the requisite service period of the awards. Stock-based compensation expense includes the impact of an estimate for forfeitures for all stock awards. The Company recognizes stock-based compensation expense for awards with performance conditions if and when the Company concludes that it is probable that the performance condition will be achieved. The Company reassesses the probability of vesting at each reporting period for awards with performance conditions and adjusts stock-based compensation expense based on its probability assessment.

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.

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	March 31,	
	2015	2014
Options	315,836	-
Warrants	3,145,650	3,140,250
Restricted stock units	324,047	-
Total	3,785,533	3,140,250

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 2. Summary of 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 consolidated 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 consolidated 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 consolidated 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. 2014-12, "Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period," ("ASU 2014-12"). The amendments in ASU 2014-12 require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply

existing guidance in Accounting Standards Codification Topic No. 718, "Compensation - Stock Compensation" as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments in ASU 2014-12 are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. Entities may apply the amendments in ASU 2014-12 either: (a) prospectively to all awards granted or modified after the effective date; or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The Company does not anticipate that the adoption of this standard will have a material impact on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The guidance, which is effective for annual reporting periods ending after December 15, 2016, extends the responsibility for performing the going-concern assessment to management and contains guidance on how to perform a going-concern assessment and when going-concern disclosures would be required under U.S. GAAP. The Company does not believe adoption of this ASU will have a material effect on its consolidated financial statements.

### ***Subsequent Events***

Management has evaluated subsequent events or transactions occurring through the date these consolidated financial statements were issued. See Note 10 – Subsequent Events.

**RUTHIGEN, INC. & SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## Note 3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consists of the following:

	March 31,	
	2015	2014
Prepaid insurance	\$ 12,000	\$-
Clinical testing and other deposits	114,000	1,000
Prepaid rent	2,000	2,000
Other prepaid expenses and current assets	38,000	-
Total	\$ 166,000	\$ 3,000

## Note 4. Property and Equipment

Property and equipment consists of the following:

	March 31,	
	2015	2014
Office equipment	\$4,000	\$4,000
Medical equipment	156,000	-
	160,000	4,000
Less: accumulated depreciation and amortization	(3,000 )	(2,000)
Property and equipment, net	\$ 157,000	\$ 2,000

Depreciation expense amounted to \$1,000 and \$2,000 for the years ended March 31, 2015 and 2014, respectively. Depreciation expense is reflected in selling, general and administrative expenses in the consolidated statements of operations. As of March 31, 2015, the Company's medical equipment had not been placed into service and, as a result, the Company had not begun depreciating the assets.

## Note 5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31,	
	2015	2014
Accrued employee compensation	\$92,000	\$109,000
Accrued director compensation	43,000	50,000
Accrued legal fees	144,000	183,000
Accrued other professional fees	50,000	45,000
Accrued research and development fees	128,000	9,000
Accrued franchise taxes	146,000	-
Other accrued expenses	32,000	14,000
Total	\$635,000	\$410,000

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## RUTHIGEN, INC. & SUBSIDIARY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### Note 6. Commitments and Contingencies

##### *Agreement and Plan of Merger*

On March 13, 2015, the Company entered into the Merger Agreement with Pulmatrix, a privately held biopharmaceutical company focused on the discovery, development, and commercialization of inhalable therapeutics and enabling technologies that treat and control respiratory infectious diseases, which provides for the merger of Pulmatrix with and into Ruthigen Merger Corp., with Pulmatrix continuing after the merger as the surviving corporation and a wholly owned subsidiary of Ruthigen (the “Merger”).

Subject to the terms and conditions of the Merger Agreement, on a pro forma basis, based upon the number of shares of Ruthigen common stock to be issued in the Merger, following the closing of the Merger, current Pulmatrix stockholders and their designees will own approximately 83% of the combined company and current Ruthigen stockholders and their designees will own approximately 17% of the combined company.

The Company’s and Pulmatrix’s obligations to consummate the Merger are subject to the satisfaction or waiver of customary closing conditions, including, among others, obtaining the requisite approvals of the stockholders of Ruthigen and Pulmatrix, including the approval of the issuance of the shares of common stock of Ruthigen to be issued in connection with the Merger and the charter amendments by the stockholders of Ruthigen, and the effectiveness of a registration statement on Form S-4 relating to the shares of Ruthigen common stock to be issued to Pulmatrix stockholders pursuant to the Merger Agreement. Ruthigen is required to have unrestricted cash on hand, net of outstanding liabilities, at closing of at least (a) \$9,000,000, if the Merger closing date is no later than July 31, 2015 or (b) \$8,850,000, if the Merger closing date is after July 31, 2015 but no later than August 13, 2015. In order to meet the cash minimum requirements, the Company engaged a placement agent in anticipation of an offering prior to the closing of the Merger, although no assurance can be provided that an offering will be completed. See Note 6 – Commitments and Contingencies – New Consulting Agreements. On May 4, 2015, the registration statement on Form S-4 became effective.

Although Ruthigen is the legal acquirer and will issue shares of its common stock to effect the merger with Pulmatrix, the business combination will be accounted for as a reverse acquisition of Ruthigen by Pulmatrix under GAAP. Under

the “acquisition” method of accounting, the assets and liabilities of Ruthigen will be recorded, as of the completion of the merger, at their respective fair values in the financial statements of Pulmatrix. The financial statements of Pulmatrix issued after the completion of the merger will reflect these values, but will not be restated retroactively to reflect the historical financial position or results of operations of Ruthigen.

As a result of the Merger, certain RSUs and stock options will become fully-vested as a result of change of control provisions in the original award agreements. In addition, pursuant to the Merger Agreement, the Company will issue an aggregate of 90,000 shares of common stock to an employee and a director of the Company.

The following other merger-related agreements have been disclosed in: (i) Note 6 – Commitments and Contingencies – New Employment Agreements, (ii) Note 6 – Commitments and Contingencies – New Consulting Agreements, (iii) Note 6 – Commitments and Contingencies – Oculus Side Letter Agreement, (iv) Note 7 – Stockholders’ Equity – New 2013 Plan.

### *Employment Agreements*

On August 12, 2013, the compensation committee of Oculus approved the grant of a one-time cash bonus of \$158,000 to the Company’s Chief Executive Officer (“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.

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 6. Commitments and Contingencies - Continued**

*Employment Agreements – Continued*

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. In addition, if the Company consummates a change of control, all equity awards granted by the Company 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, the Company will reimburse the CFO for any excise taxes owed by the CFO 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).

On November 28, 2014, the compensation committee of the Company's board of directors approved an amended and restated employment agreement for its CEO, which supersedes the employment agreement previously in effect between the Company and the CEO. The prior employment agreement went into effect when the Company was a wholly-owned subsidiary of Oculus, and the CEO was the Chairman of the board of directors of Oculus. The employment agreement primarily removes all references to Oculus and other legacy references related to Ruthigen being a subsidiary of Oculus.

The employment agreement continues to provide for an annual base salary of \$375,000 to the CEO, subject to increase, as determined by the Company's board of directors. The employment agreement further provides for



payments to the CEO in the event of termination without cause or resignation by the CEO for good reason, as such terms are defined in the employment agreement. In the event that the CEO is terminated without cause or resigns for good reason, the CEO is entitled to: (i) a lump severance payment equal to 24 times the average monthly base salary paid to the CEO over the preceding 12 months; (ii) up to one year (the lesser of one year following the date of termination or until the CEO 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. In addition, if the Company consummates a change of control, all equity awards granted by the Company 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, the Company will reimburse the CEO for any excise taxes owed by the CEO 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). Furthermore, the Company will reimburse the CEO for relocation expenses if the Company's principal executive offices are moved or the CEO is required to relocate, subject to certain conditions.

Receipt of the termination benefits described above is contingent on the CEO's execution of a general release of claims against the Company, its subsidiaries and its affiliates; the CEO's resignation from any and all directorships and every other position held by the CEO with the Company and each of its subsidiaries; and the CEO's return to the Company and its affiliates or the Company Group (as such term is defined in the employment agreement), 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 the CEO. In addition, the CEO is not entitled to such benefits if the CEO does not comply with the non-competition, invention assignment, confidentiality, non-solicitation provisions of the employment agreement.

As of March 31, 2015, the potential cash severance payment related to the Company's employment agreements currently in effect with its CEO and CFO amounted to \$1,144,000.

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 6. Commitments and Contingencies - Continued**

*New Employment Agreements*

On March 12, 2015, in connection with the Merger Agreement, the Ruthigen board of directors approved that, as of the effective time of the merger, each of the CEO and the CFO will receive cash and restricted stock units, further discussed below, from Ruthigen as consideration for the termination of outstanding stock options and restricted stock units held by them and for their continued provision of services after the merger and for the one-year non-competition provisions in their new employment agreement.

If the Merger is approved by the respective stockholders, the CEO and CFO will terminate their current employment agreements with Ruthigen dated November 28, 2014 and June 24, 2014, respectively. At such time, the New Employment Agreement with the CEO and the New Employment Agreement with the CFO will each become effective. Additionally, lock-up agreements and cancellation agreements between Ruthigen and the CEO and CFO with respect to the cancellation of outstanding stock options and restricted stock units immediately prior to the merger will become effective. If the Merger is not approved by the respective stockholders, the current employment agreements with each of the CEO and CFO will remain in effect and the lock-up agreements and cancellation agreements will not become effective.

At the effective time of the merger, any and all outstanding stock options and restricted stock units previously granted to the CEO will be terminated in exchange for (i) a lump-sum payment in the amount of \$547,600, less taxes and other withholdings and (ii) a lump-sum equivalent to the CEO's premiums under COBRA for one year, in the same amounts for the same medical coverage as in effect as of the effective time of the merger.

The CEO shall also receive a grant of restricted stock units, pursuant to Ruthigen's 2013 Employee, Director and Consultant Equity Incentive Plan, equal to the lesser of (i) 930,000 and (ii) the quotient of \$3,125,000 divided by the fair market value of the common stock of the combined company as of the effective time of the merger, with such restricted stock units vesting as follows: (i) a number of restricted stock units equal to the lesser of (a) 930,000 and (b) such number of restricted stock units with an aggregate value equal to \$1,400,000 shall be fully vested at the effective time of the merger and (ii) an amount equal to 25% of the restricted stock units unvested as of the effective time of the

merger will vest on a quarterly basis over the following twelve months. The shares of Ruthigen common stock underlying the vested restricted stock units at the effective time of the merger will be delivered to the CEO on the first trading day following the first anniversary of the effective time of the merger, and the shares of Ruthigen common stock underlying the restricted stock units that will vest on a quarterly basis thereafter will be delivered on the first trading day following the 15, 18, 21 and 24 month anniversary of the effective time of the merger, respectively. The shares are subject to lock-up and leak out provisions that limit sales of these shares during the six month period following the delivery of any shares associated with vested restricted stock units, except to the extent necessary to cover tax liabilities associated with receipt of these shares.

At the effective time of the merger, any and all outstanding stock options and restricted stock units previously granted to the CFO will be terminated in exchange for (i) a lump-sum payment in the amount of \$337,500, less taxes and other withholdings and (ii) a lump-sum equivalent to the CFO's premiums under COBRA for one year, in the same amounts for the same medical coverage as in effect as of the effective time of the merger.

The CFO shall also receive a grant of restricted stock units, pursuant to Ruthigen's 2013 Employee, Director and Consultant Equity Incentive Plan, equal to the lesser of (i) 355,000 and (ii) the quotient of \$1,037,500 divided by the fair market value of the common stock of the combined company as of the effective time, with such restricted stock units vesting as follows: (i) a number of restricted stock units equal to the lesser of (a) 355,000 and (b) such number of restricted stock units with an aggregate value equal to \$250,000 shall be fully vested at the effective time of the merger and (ii) an amount equal to 25% of the restricted stock units unvested as of the effective time of the merger will vest on a quarterly basis over the following twelve months. The shares of Ruthigen common stock underlying the vested restricted stock units at the effective time of the merger will be delivered to the CFO on the first trading day following the first anniversary of the effective time of the merger, and the shares of Ruthigen common stock underlying the restricted stock units that will vest on a quarterly basis thereafter will be delivered on the first trading day following the 15, 18, 21 and 24 month anniversary of the effective time of the merger, respectively. The shares are subject to lock-up and leak out provisions that limit sales of these shares during the six month period following the delivery of any shares associated with vested restricted stock units, except to the extent necessary to cover tax liabilities associated with receipt of these shares.

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 6. Commitments and Contingencies - Continued**

*New Consulting Agreements*

On March 3, 2015, the Company executed an agreement with an investment banking firm to provide pre-merger strategic services, in exchange for the issuance of 340,000 shares of common stock upon effectiveness of the merger, as a success fee.

On March 10, 2015, the Company executed an agreement with an individual to provide post-merger investor relations services for one year, in exchange for the issuance of 250,000 shares of common stock upon effectiveness of the Merger.

The Company will account for the common stock upon issuance of the shares.

*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. The Company will accrue for the milestone payment liability if and when the Company determines that the achievement of such conditions is probable. As of March 31, 2015, the Company has not accrued for any portion of the milestone payments.

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.

See Note 6 – Commitments and Contingencies – Oculus Side Letter Agreement for additional details.

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 6. Commitments and Contingencies - Continued**

*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. The costs incurred by the Company in connection with the shared services agreement were not material.

On March 5, 2015, the Company received a written notice from Oculus of termination of the shared services agreement, effective on April 6, 2015.

See Note 6 – Commitments and Contingencies – Oculus Side Letter Agreement for additional details.

*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.

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.

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 6. Commitments and Contingencies - Continued**

*Separation Agreement – Continued*

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.

See Note 6 – Commitments and Contingencies – Oculus Side Letter Agreement for additional details.

*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.



*Oculus Side Letter Agreement*

In connection with the Merger, on March 13, 2015, Pulmatrix entered into an agreement (the “Oculus Side Letter Agreement”), pursuant to which, among other things, Oculus agreed, from the effective date of the merger, to (i) waive Ruthigen’s obligations to use commercially reasonable efforts to develop and commercialize products licensed from Oculus under the outstanding License and Supply Agreement between Oculus and Ruthigen, for a period lasting until the earlier of one year from the closing of the merger or August 31, 2016; (ii) provide a general release from claims and liabilities arising under the License and Supply Agreement, the separation agreement and the shared services agreement, each between Oculus and Ruthigen, in favor of Ruthigen; and (iii) to run a sale process for the pre-merger Ruthigen business, including any products licensed from Oculus, and to assign or delegate all of Ruthigen’s surviving rights under the License and Supply Agreement, the separation agreement and the shared services agreement, subject to Oculus’s consent with respect to the identity of the proposed purchaser.

Ruthigen is under no obligation to achieve any milestone event during the waiver period, and no payments will accrue or become due and payable by Ruthigen to Oculus under the License and Supply Agreement, the separation agreement and the shared services agreement, other than the liabilities not exceeding \$5,000 due and payable on the effective date of the merger. After the expiration of the waiver period, Ruthigen may unilaterally terminate the License and Supply Agreement.

Pursuant to the right of first refusal that was granted to Oculus, prior to a sale of the pre-merger business of Ruthigen with a minimum aggregate purchase price of \$1.0 million, Ruthigen must first notify Oculus of the pending transaction and Oculus will have five (5) business days after receipt of such notice to notify Ruthigen whether it intends to acquire the pre-merger business of Ruthigen on exactly the same terms, including the amount and kind of consideration, unless securities of the proposed acquirer will be offered as consideration, in which case Oculus will instead pay cash equal to the fair market value of such securities. If Oculus does not exercise its right of first refusal, Ruthigen may consummate the transaction pursuant to the agreed upon terms. Additionally, if such a transaction is consummated and the transaction generates aggregate proceeds in excess of \$10.0 million, Ruthigen will be obligated to pay ten percent (10%) of the aggregate gross proceeds to Oculus within ten (10) calendar days.

In addition, the Oculus Side Letter Agreement provides that, as of the effective date of the merger, certain provisions in the separation agreement regarding marketing and stock transfer restrictions, lock-up, registration rights, voting, management, compensation and equity incentive plan, will be terminated.

The Oculus Side Letter Agreement is conditioned upon the receipt of payment by Oculus for Oculus’s shares of Ruthigen common stock sold in certain specified transactions.

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 6. Commitments and Contingencies - Continued**

*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. On February 11, 2015, the Company and the landlord agreed to amend the lease such that the lease now expires on June 30, 2015 and the monthly base rent is approximately \$1,700. The aggregate base rent payable over the lease term is being recognized on a straight-line basis. Rent expense related to the lease amounted to approximately \$20,000 and \$20,000 for the years ended March 31, 2015 and 2014, respectively. Rent expense is reflected in selling, general and administrative expenses in the consolidated statements of operations. Future minimum rentals through the lease expiration date of June 30, 2015 are \$5,075.

Note 7. Stockholders' Equity

*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.

### ***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.

### ***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.

## RUTHIGEN, INC. & SUBSIDIARY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### Note 7. Stockholders' Equity - Continued

##### *New 2013 Plan*

On March 12, 2015, in connection with the Merger Agreement, Ruthigen's compensation committee and Ruthigen's board of directors unanimously approved the Ruthigen, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan (the "New 2013 Plan"), subject to the approval of Ruthigen's stockholders. The New 2013 Plan will allow for the issuance of up to 6,853,319 shares of Ruthigen's common stock, up from 1,230,855 shares, pursuant to awards to be granted under the New 2013 Plan. In addition, the New 2013 Plan contains an "evergreen" provision, which allows for an annual increase in the number of shares of Ruthigen's common stock available for issuance under the plan on the first day of each fiscal year beginning in calendar year 2016. The annual increase in the number of shares shall be equal to the lowest of: (i) 2,551,500 shares of Ruthigen's common stock; (ii) five percent (5%) of the number of shares of Ruthigen's common stock outstanding as of such date; and (iii) an amount determined by Ruthigen's board of directors.

##### *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.

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.

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**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Note 7. Stockholders' Equity - Continued**

*Initial Public Offering – Continued*

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.

*Underwriter's Exercise of IPO Over-Allotment Option*

Following the closing of the IPO, during the year ended March 31, 2015 and in connection with its 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 at \$6.6608 per share, which resulted in approximately \$1,028,000 of aggregate net proceeds to the Company. In connection with the underwriters' partial exercise of the over-allotment option, the Company issued to the representative of the underwriters a five-year warrant to purchase an additional 5,400 shares of the Company's common stock at an exercise price of \$9.0625 per share. The warrant is exercisable commencing one year from the date of issuance. The warrant and the shares of common stock underlying the warrant have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA.

*Investment from Former Parent*

During the year ended March 31, 2014, the Company's Former Parent made capital contributions to the Company in the amount of \$1,679,000, which were recorded as additional paid-in capital in the consolidated statement of changes in stockholders' equity. See Note 9 – 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, 2015 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, March 31, 2014	3,140,250	\$ 7.30		
Granted	5,400	9.06		
Exercised	-	-		
Forfeited	-	-		
Outstanding, March 31, 2015	3,145,650	\$ 7.31	1.1	\$ -
Exercisable, March 31, 2015	3,140,250	\$ 7.30	1.1	\$ -

**RUTHIGEN, INC. & SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 7. Stockholders' Equity - Continued***Stock Warrants – Continued*

The following table presents information related to stock warrants at March 31, 2015:

Warrants Outstanding Exercise Price	Outstanding Number of Warrants	Warrants Exercisable	
		Weighted Average Remaining Life In Years	Exercisable Number of Warrants
\$7.2500	3,047,500	1.0	3,047,500
\$9.0625	98,150	4.0	92,750
	3,145,650	1.1	3,140,250

*Stock Options*

The Company has computed the fair value of options granted using the Black-Scholes option pricing model. Option forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate will be adjusted periodically based on the extent to which actual option forfeitures differ, or are expected to differ, from the previous estimate, when it is material. The Company estimated forfeitures related to option grants at an annual rate of 0% for options unvested during the year ended March 31, 2015. The expected term used for options issued to non-employees is the contractual life and the expected term used for options issued to employees and directors is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the “simplified” method to develop an estimate of the expected term of “plain vanilla” employee option grants. Since the Company’s stock has not been publicly traded for a sufficiently long period of time, the Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate



was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following weighted average assumptions:

	For the Year Ended		
	March 31,		
	2015		2014
Risk free interest rate	1.67	%	n/a
Expected term (years)	5.61		n/a
Expected volatility	95	%	n/a
Expected dividends	0.00	%	n/a

The weighted average estimated fair value of the options granted during the year ended March 31, 2015 was \$4.79 per share. There were no options granted during the year ended March 31, 2014.

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. The aggregate grant date value of \$1,593,000 will be recognized proportionate to the vesting period.

The Company recorded stock-based compensation expense related to stock options of \$452,000 and \$0 during the years ended March 31, 2015 and 2014, respectively. As of March 31, 2015, there was \$1,060,000 of unrecognized stock-based compensation expense related to stock options that will be amortized over a weighted average period of 2.1 years.

**RUTHIGEN, INC. & SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 7. Stockholders' Equity - Continued***Stock Options - Continued*

A summary of the stock option activity during the year ended March 31, 2015 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, March 31, 2014	-	\$ -		
Granted	332,500	6.37		
Exercised	-	-		
Forfeited	(16,664 )	6.37		
Outstanding, March 31, 2015	315,836	\$ 6.37	9.0	\$ -
Exercisable, March 31, 2015	81,522	\$ 6.37	8.7	\$ -

The following table presents information related to stock options at March 31, 2015:

Options Outstanding	Options Exercisable
Outstanding	Weighted
Exercise Price	Average Exercise Price
Number of Options	Remaining Life In Years
Number of Options	Number of Options
\$ 6.37	8.7
315,836	81,522

315,836      8.7      81,522

***Restricted Stock Units***

On May 11, 2014, the Company granted RSUs issuable for an aggregate of 409,355 shares 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 had an aggregate grant date value of \$2,148,000. RSUs for 68,355 shares had an aggregate grant date value of \$431,000 and 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.

The Company recorded stock-based compensation expense related to RSUs of \$627,000 and \$0 during the years ended March 31, 2015 and 2014, respectively. As of March 31, 2015, there was \$1,522,000 of unrecognized stock-based compensation expense related to RSUs that will be amortized over a weighted average period of 2.1 years. The Company recognizes stock-based compensation expense for RSUs with performance conditions if and when the Company concludes that it is probable that the performance condition will be achieved. As of March 31, 2015, the Company has not recognized any expense related to RSUs with performance conditions. As of March 31, 2015, there was \$431,000 of unrecognized stock-based compensation expense related to RSUs with performance conditions.

**RUTHIGEN, INC. & SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 7. Stockholders' Equity - Continued***Restricted Stock Units - Continued*

A summary of RSU activity for the years ended March 31, 2015 and 2014 is presented below:

	Number of Units	Weighted Average Grant Date Fair Value	Total Grant Date Fair Value
Non-vested, March 31, 2013	-	\$ -	-
Granted	-	-	-
Vested	-	-	-
Forfeited	-	-	-
Non-vested, March 31, 2014	-	\$ -	\$-
Granted	409,355	6.30	2,579,000
Vested	(85,308 )	6.30	(537,000 )
Forfeited	-	-	-
Non-vested, March 31, 2015	324,047	\$ 6.30	\$2,042,000

**Note 8. 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. Post-IPO, the Company filed separate, stand-alone tax returns. During the year ended March 31, 2015, following the deconsolidation, the Company adjusted its net operating loss ("NOL") carry forward to reflect the value of the NOL available to the Company in future periods.

The following summarizes the income tax provision (benefit):

	For The Years Ended	
	March 31,	
	2015	2014
Federal		
Current	\$-	\$-
Deferred	(1,754,000)	(1,031,000)
State and local		
Current	-	-
Deferred	(309,000 )	(182,000 )
	(2,063,000)	(1,213,000)
Change in valuation allowance	2,063,000	1,213,000
Income tax provision (benefit)	\$-	\$-

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**RUTHIGEN, INC. & SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****Note 8. Income Taxes - Continued**

The Company has the following net deferred tax assets:

	March 31,	
	2015	2014
Net operating loss carryforwards	\$3,224,000	\$1,427,000
Stock-based compensation	262,000	-
Charitable donation carryforwards	4,000	-
Gross deferred tax assets	3,490,000	1,427,000
Valuation allowance	(3,490,000)	(1,427,000)
Net deferred tax assets	\$-	\$-

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

	For The Years Ended			
	March 31,			
	2015		2014	
Expected federal statutory rate	(34.0	)%	(34.0	)%
State tax rate, net of federal benefit	(6.0	)%	(6.0	)%
Change in effective state tax rate	0.0	)%	(0.3	)%
Permanent items - stock-based compensation	2.5	)%	0.0	)%
Permanent items - non-deductible merger expenses	0.4	)%	0.0	)%
Permanent items - other	0.1	)%	1.3	)%
Adjustment of NOL due to deconsolidation	6.2	)%	0.0	)%
Change in valuation allowance	30.8	)%	39.0	)%
Income tax provision (benefit)	0.0	)%	0.0	)%

For the years ended March 31, 2015 and 2014, the Company had approximately \$8,059,000 and \$2,539,000 of federal and state net operating loss carryovers (“NOLs”), respectively, which begin to expire in 2033. These net operating loss carryovers are subject to annual limitations under Internal Revenue Code Section 382 because there has been a greater than 50% ownership change following 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, 2015 and 2014. 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, 2015. The unrecognized tax benefits may increase or change during the next year for items that arise in the ordinary course of business. 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.

**RUTHIGEN, INC. & SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Note 9. Related Party Transactions

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

Upon completion of the IPO, on March 26, 2014, Oculus owned 2,000,000 shares of the Company's common stock or approximately 43% of the then outstanding common stock.

On March 13, 2015, Oculus entered into a securities purchase agreement with several investors, pursuant to which the investors agreed to purchase 350,000 shares of the Company's common stock at a price of \$2.75 per share. On March 23, 2015, this sale closed. Oculus retained the voting rights to the 350,000 shares until and through the date of closing of the Merger. In the event that the closing of the Merger does not occur on or prior to September 30, 2015, the 350,000 shares of the Company's common stock will become fully tradable and full voting rights will transfer to the purchasers of such shares.

On March 13, 2015, Oculus entered into a securities purchase follow-up agreement with several investors pursuant to which Oculus agreed to sell 1,650,000 shares of the Company's common stock at a price of \$2.75 per share to the investors upon completion of the Merger, provided that 50,000 shares may be sold to one or more investors prior to closing. If the Merger does not close by August 13, 2015 or as may be extended up to 60 calendar days at Oculus's discretion, there will be no obligation of the investors to purchase the shares. Oculus will retain the voting rights to the 50,000 shares until and through the date of closing of the Merger. In the event that the closing of the Merger does not occur on or prior to September 30, 2015, the 50,000 shares of common stock will become fully tradable and full voting rights will transfer to the investors.

Note 10. Subsequent Events

*Stock-Based Compensation*



On April 30, 2015, the Company granted to its directors fully-vested, ten-year options to purchase an aggregate of 15,000 shares of common stock at an exercise price of \$3.35 per share, pursuant to the 2013 Plan.

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