Filed Pursuant to Rule 424(b)(4)
Registration Nos.: 333-168224 and 333-171222

PROSPECTUS

2,900,000 Shares of Common Stock

This is an initial public offering of 2,900,000 shares of our common stock.

Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is $6.00. Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol “VTUS.”

Investing in our common stock involves a high degree of risk. Please read our “Risk Factors” beginning on page 14.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$ 6.00	$17,400,000
Underwriting discounts and commissions(1)	$ 0.435	$ 1,261,500
Proceeds, before expenses, to us(2)	$ 5.565	$16,138,500

(1) Does not include a non-accountable expense allowance of $261,000, which is equal to 1.5% of the gross proceeds of this offering, payable to the co-managing lead underwriters. See “Underwriting” for a description of compensation and other items of value payable to the underwriters.

(2) We estimate that the total expenses of this offering will be approximately $1,187,500, consisting of $261,000 for the underwriters’ non-accountable expense allowance and approximately $926,500 for legal, accounting, printing costs and various fees associated with the registration and listing of our shares.

We have granted a 45-day option to the underwriters, to purchase up to 435,000 additional shares of our common stock (15% of the shares sold) solely to cover over-allotments, if any. The shares issuable upon exercise of the underwriters’ over-allotment option are identical to those offered by this prospectus and have been registered under the registration statement of which this prospectus forms a part.

In connection with this offering, we have also agreed to issue to the underwriters a warrant to purchase up to 6.8% of the shares sold in this offering (excluding the over-allotment shares). If the underwriters exercise this warrant, each share of our common stock may be purchased at $7.50 per share (125% of the price of the shares sold in the offering).

We are offering the shares of common stock on a firm commitment basis. The underwriters expect to deliver our shares to purchasers in the offering on or about December 22, 2010.

Rodman & Renshaw, LLC **National Securities Corporation**

The date of this prospectus is December 16, 2010.

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Ventrus Biosciences, Inc. and other trademarks or service marks of Ventrus Biosciences appearing in this prospectus are the property of Ventrus Biosciences. This prospectus may refer to brand names, trademarks, service marks or trade names of other companies and organizations, and those brand names, trademarks, service marks and trade names are the property of their respective holders.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. This prospectus includes all material information relating to this offering. You should carefully read this prospectus and the additional information under the heading "Where You Can Find More Information" before making an investment decision.

You should rely only on the information we have provided in this prospectus and any free writing prospectus we provide you. We have not authorized anyone to provide you with information different from that contained in this prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained herein. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus is accurate only as of the date on the front of the document, regardless of the time of delivery of this prospectus or any sale of a security.

Unless the context otherwise requires, "Ventrus," "the company," "we," "us," "our" and similar names refer to Ventrus Biosciences, Inc.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that is important to you. You should carefully read the more detailed information contained in this prospectus, including the section entitled "Risk Factors" beginning on page 14 and our financial statements for the years ended December 31, 2008 and 2009 and the nine months ended September 30, 2009 and 2010, and related notes, which are included in this prospectus. We refer to Ventrus Biosciences, Inc. as "Ventrus", the "company", "we", "our", and "us".

Company Overview

General

We are a development stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoids, anal fissures and fecal incontinence. To our knowledge, there currently are no prescription or over-the-counter, or OTC, drugs approved by the U.S. Food and Drug Administration, or FDA, currently available in the U.S. for the treatment of these conditions. There are approximately 12.5 million Americans suffering from hemorrhoids, 7 million from fecal incontinence and over 4 million from anal fissures. Our lead product, Inferanserin (VEN 309) is a new chemical entity, or NCE, for the topical treatment of hemorrhoids. In multiple clinical studies in 360 patients, VEN 309 demonstrated good tolerability and no severe adverse events, and statistically significant improvements in bleeding, itchiness and pain. We have filed a special protocol assessment, or SPA, with the FDA to allow us to begin the first of two Phase III clinical trials for VEN 309.

Our additional product candidate portfolio consists of two in-licensed late-stage drugs intended to treat anal fissures (VEN 307) and fecal incontinence (VEN 308). These candidates are two molecules that were previously approved and marketed for other indications and that have been formulated into our proprietary topical treatments for these new gastrointestinal indications. In August 2007, we had a pre-IND meeting with the FDA concerning VEN 307 (diltiazem cream for the treatment of pain from anal fissures) where it was established that next clinical studies needed for approval were two pivotal Phase III trials, preceded (if conducted in the U.S.) by three short-term dermal toxicology studies. In June 2007, we had a pre-IND meeting with the FDA concerning VEN 308 (phenylephrine gel for the treatment of fecal incontinence associated with ileal pouch anal anastomosis) where it was established that the next clinical study in the program should be a Phase II(b) study where multiple doses will be assessed and that existing toxicology data are sufficient to support this study. We have not had further meetings with the FDA on either VEN 307 or VEN 308 since the meetings in 2007. The development of the three products, VEN 307, VEN 308 and VEN 309, was delayed subsequent to the FDA meetings due to a lack of financial resources. We intend to use the proceeds from this offering to advance VEN 309 and VEN 307 through the next stage of development.

Our Products and Development Strategy

Our three late-stage product candidates are:

Iferanserin ointment (VEN 309) for the topical treatment of hemorrhoids. Hemorrhoids, which are characterized by the inflammation and swelling of veins around the anus or lower rectum, can cause bleeding, itching, pain and difficulty defecating. As reported by the National Institute of Diabetes and Digestive Kidney Diseases, hemorrhoids affect approximately 12.5 million adults in the U.S. Despite such a high prevalence, we are not aware of any FDA-approved prescription or OTC drugs for the treatment of hemorrhoids in the U.S. While there are commonly used prescription and over the counter, or OTC, products for hemorrhoids in the U.S., such as Anusol, Preparation H and some herbal preparations, none has been approved by the FDA because they entered the market prior to 1962. The great majority of these treatments provide only temporary relief from the symptoms of hemorrhoids and do not address the cause of hemorrhoids. These treatments' mechanism of action is either general, such as steroids, or unknown, in the case of herbal remedies, and we are not aware of any reports published in medical journals on the efficacy or safety of any product currently marketed in the U.S. for the treatment of hemorrhoids.

Iferanserin (VEN 309), a NCE formulated as an ointment for intra-anal application, has highly selective, antagonistic activity against peripheral 5-HT_{2A} receptors involved in clotting and the

contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. By limiting 5-HT_{2A} receptor activity, VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain. We believe that the potential for side effects will be limited because iferanserin is topically applied and iferanserin does not enter the brain to affect $5HT_2$ CNS receptors at the exposures seen with topical application. In multiple clinical trials, iferanserin ointment significantly reduced bleeding, pain and itchiness compared to placebo with minimal adverse effects. As a result, we believe VEN 309 to be more effective than the currently available conventional hemorrhoid topical therapies and more attractive than surgical procedures, which are the only other currently validated treatment options.

We have licensed Iferanserin ointment (VEN 309) from Sam Amer & Co., Inc., or Amer, who had developed VEN 309 through Phase II studies and up to readiness for Phase III studies in the U.S. and Europe. Our license includes rights to all existing intellectual property and any further improvements on VEN 309 owned by Amer for the topical treatment of anorectal disorders. An investigator IND for iferanserin was filed with the FDA in November 1991 and transferred to Amer as the sponsor in January 1994 and remains open. A total of seven clinical trials with iferanserin have been completed by Amer and its previous licensees between 1993 and 2003. In these studies in 359 individuals, of whom 220 were exposed to iferanserin, the adverse side effects were mostly gastrointestinal (diarrhea, lower abdominal discomfort, residual stools, and anal irritation), which we believe may be related to the intra-anal method of administration. These side effects were considered mild by the investigators, and required no medical treatment. There were no serious adverse events reported in any patient and no mortality in these studies.

The Phase I studies in volunteers and the Phase II studies in patients demonstrated that iferanserin is well tolerated, and minimally absorbed. Phase II studies consistently demonstrate that iferanserin treatment significantly reduces hemorrhoidal symptoms of bleeding, itching and pain, and that the 0.5% concentration that we will be developing was superior to lower concentrations and to higher concentration (1%) in the comprehensive reduction of hemorrhoid symptoms. Iferanserin, as are many drugs in its chemical class, particularly widely used anti-depressants, is metabolized by and inhibits the CYP 2D6 enzyme in the liver.

A Phase IIB/Phase III randomized double blind controlled study for 14 days, in 121 patients, was sponsored by Amer in Germany in 2003, comparing the 0.5% concentration with placebo ointment. In this study, compared with placebo, iferanserin ointment significantly reduced bleeding, itching and pain (P <0.05) by day 3, a reduction maintained to day 14. There were also no clinically significant adverse findings for either iferanserin or the placebo ointment.

We commissioned a *post hoc* analysis of the German study for the end point that the FDA agreed would be the primary efficacy endpoint for the future Phase III pivotal trials. This endpoint is defined as time to cessation of bleeding that lasts for three days or more for which iferanserin 0.5% twice daily will be compared with placebo. In this analysis of the data in the German study, the median time to cessation of bleeding was 10.5 days in the placebo group and 4.5 days in the treatment group which was highly statistically significant (P <0.01).

We had an end-of Phase II meeting with the FDA in February 2008. At that meeting, the FDA advised us that VEN 309 can enter Phase III development, and, as for many chronic or repeat use drugs, our New Drug Application must include a total of 1,500 patients exposed to VEN 309 in clinical trials, which includes two pivotal Phase III studies, a clinical pharmacology program, chronic toxicology, and a 104-week carcinogenicity study in two species for consideration for approval, all of which can be conducted in parallel. The FDA agreed with a primary endpoint for the two pivotal trials as being time to the cessation of bleeding which lasts for at least three days. We originally filed a SPA with the FDA in June 2008 to ensure their explicit agreement with our Phase III clinical plan for VEN 309. Due to lack of funds, we could not follow up or complete the process, but were able to resume with another filing in March 2010 on which we received comments in May 2010 in which the FDA clarified their additional requirements related to the primary and secondary endpoints and recurrence. We filed another submission in July 2010 which could not be

processed because the FDA required us to reformulate the questions set forth in the filing. In August and September 2010, we had a series of emails and telephone calls with the FDA in which we believe that agreement has been reached on the precise definition of the endpoints and how to assess recurrence of hemorrhoids in the study and on October 28, 2010 we filed another submission reflecting these discussions. The FDA has 45 days to respond to this submission and we expect to complete the SPA process by the end of the first quarter of 2011.

A composition of matter patent for our version of the compound has been issued in the major markets worldwide, and expires in the U.S. and Europe in 2015, after which VEN 309 will have five years of market exclusivity after approval in the U.S. and 10 years in Europe. Based on the unexpected finding that the 0.5% concentration is more effective in the comprehensive reduction of hemorrhoid symptoms than the 0.1% and the 1.0% concentrations, in August 2010, we filed a patent claiming our specific concentration range for VEN 309 which, we believe, if issued, will block generic substitution for 20 additional years. However the original patent could be challenged by a third party and invalidated, and the concentration patent may never issue and even if issued could be challenged by a third party.

We intend to use the proceeds from this financing to contract with clinical research organizations, or CROs, to conduct the first of the two required Phase III clinical trials with VEN 309 in the treatment of hemorrhoids in the U.S. and Canada, using the FDA-agreed protocol under the SPA, supervised by us, and to contract the initiation of the carcinogenicity study required for the approval of VEN 309 in the U.S. We expect to be able to initiate the first Phase III pivotal trial by the end of the first half of 2011, and anticipate that the clinical trial will be completed and data will be available in the first quarter of 2012. We plan to begin the carcinogenicity studies in 2011 and expect they will take up to 40 months to complete. Assuming successful results from the first pivotal trial, we plan to conduct the required additional Phase III trial and clinical pharmacology program, for which we will need additional capital. Assuming successful completion of those studies and sufficient capital, we expect to be able to file a NDA with the FDA for the approval of VEN 309 for the treatment of hemorrhoids. If all activities are successful, we anticipate FDA approval as early as 2015.

If the efficacy of VEN 309 in our trials is insufficient, if studies are delayed, or if unexpected safety issues arise, or if the FDA or the European authorities raise other concerns, VEN 309 might not be approved for marketing or might take significantly longer to be approved. While we expect the proceeds from this offering should be sufficient to complete the first Phase III study, start the carcinogenicity study and meet our payment obligations to Amer, if the development activities are more costly or take longer than expected, we might not have sufficient funds to complete the study or be able to effect the payments due to Amer on a timely basis, which could result in the loss of our rights to the product.

Diltiazem cream (VEN 307), a topical treatment for the relief of pain associated with anal fissures. Anal fissures, or small tears or cuts in the skin that lines the anus, affect approximately 2% of the U.S. adult population, based on studies conducted in the U.S. between 1990 and 1998 by Dr. Wolfgang Jost and on U.S. Census data. They can be extremely painful, cause bleeding and often require surgery, which itself can have unsatisfactory outcomes. At present, we are not aware of any FDA-approved drugs for the treatment of anal fissures. However, diltiazem cream is currently used as the preferred treatment by many gastroenterologists across the U.S. in a version that must be specially mixed for each patient in the pharmacy. Topical nitroglycerine has also been used in this way but has a higher rate of side effects than topical diltiazem, notably headaches, as found in a study published in 2002 by Dr. Kocher (see Table 1 under “Business — Diltiazem Cream (VEN 307) Development — Investigator-initiated clinical studies”). Custom-mixed diltiazem, however, is not an FDA-approved use nor is the cost reimbursed by Medicare or health insurance plans. When applied topically for the treatment of anal fissures, diltiazem, which has been used for decades for hypertension and angina, dilates the blood vessels supplying the region, reduces anal sphincter tone, and thereby substantially decreases pain. In the majority of multiple clinical trials conducted against placebo or topical nitroglycerine conducted between 1999 and 2002 by various

researchers, diltiazem cream significantly reduced the pain associated with anal fissures. Our product VEN 307 is a proprietary formulation of diltiazem that when applied topically is only minimally absorbed, at one-tenth the amount of the lowest dose used for cardiovascular treatment. We believe this low absorption improves VEN 307's safety profile and lowers the risk of side effects. We expect to capture immediate market share if VEN 307 is approved due to its known efficacy among gastroenterologists, its ease of prescription as a pre-formulated FDA-approved drug with no need for custom mixing necessary at the pharmacy, and the ability for patients to be reimbursed through their health plan or Medicare.

We have licensed the exclusive North American rights to VEN 307 for the topical treatment of anal fissures from S.L.A. Pharma. S.L.A. Pharma has completed early-stage clinical trials, toxicology studies and manufacturing for VEN 307 up to the end of Phase II. During a pre-IND meeting that we had with the FDA in 2007, the FDA agreed on the design of our Phase III clinical program which will include two pivotal Phase III trials with pain as a primary endpoint as well as the other requirements necessary to obtain approval of a NDA 505b(2) application in the U.S. A 505b(2) application allows an applicant to seek approval on the basis of a combination of a prior approval of a similar product or published literature, and some new clinical studies conducted or sponsored by the applicant. Section 505(b)(2) applications are often used for changes in a drug that require clinical investigations and thus cannot be handled through the generic drug process, such as a new indication or change in dosage form. S.L.A. Pharma, as our partner, began one pivotal Phase III trial of VEN 307 for the treatment of anal fissure in the European Union, or E.U., in November 2010. We expect completion of recruitment of patients to occur in the fourth quarter of 2011 and anticipate top-line results in the second quarter of 2012 and the final report from this study in the third quarter of 2012.

S.L.A. Pharma has filed a patent application for the method of use of diltiazem cream in anal fissures which, if issued will expire in 2017. However, this application has not yet issued for reasons of novelty and obviousness (prior art) and this action of the patent office was appealed by S.L.A. Pharma to the U.S. Patent Office Appeal Board. On August 31, 2010, the Appeal Board affirmed S.L.A. Pharma's position on novelty but not inventiveness over prior art. S.L.A. Pharma intends to file a request for continuing examination of the pending patent and we expect Patent Office action within 12 months. If the continued prosecution of this patent is unsuccessful, or, if successful, and the issued patent is invalidated, we would then have three years of market exclusivity after approval under the Hatch-Waxman Act because VEN 307 would be a 505(b)(2) approved drug.

We plan to employ a two-pronged development strategy for VEN 307. While S.L.A. Pharma is conducting the first Phase III clinical trial in the E.U., which is anticipated to be completed in the second quarter of 2012, we intend to initiate development of a superior formulation with new intellectual property. This new intellectual property would be a new extended release formulation of diltiazem. There are several proven methodologies for extended release topical formulations, and we believe that diltiazem is readily drugable in this regard. We intend to assess three to four alternatives preclinically with multiple contractors, and then assess absorption and effect on internal anal sphincter, or IAS, pressure with the most promising one. We expect to file patent applications in North America for the most promising specific technology combined with diltiazem for all formulations that are technically feasible.

If S.L.A. Pharma successfully completes its E.U. trial for VEN 307, we will make the final decision on which formulation to pursue depending on several factors, including whether the new formulation is clinically superior, our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate. If the new U.S. developed formulation is superior and the other factors are met, we plan to initiate two pivotal trials in parallel in order to complete the NDA for an estimated FDA submission in 2013. If the new U.S. formulation is not superior, and/or if we deem the patentability of the existing formulation to be satisfactory, we plan to finish clinical development utilizing the current European formulation, which would require one more pivotal trial in the U.S. We expect to continue to pursue other lifecycle options such as combining diltiazem with other drugs. Both development pathways could result in a NDA

submission in 2013. If all activities are successful and assuming sufficient capital, we anticipate FDA approval as early as 2014. We intend to use a portion of the proceeds of this offering to fund a portion of S.L.A. Pharma's Phase III trial in Europe and to develop the extended release formulation of diltiazem.

If the efficacy of VEN 307 is insufficient in our or in S.L.A. Pharma's Phase III trials, if the studies are delayed, or if unexpected safety issues arise, or if the FDA raises other concerns, VEN 307 might not be approved for marketing or might take significantly longer to be approved. If the development activities of VEN 307 are more costly or take longer than expected we may not have sufficient funds to make our required payments to S.L.A. Pharma on a timely basis which could result in the loss of our rights to the product.

Phenylephrine gel (VEN 308) for the treatment of fecal incontinence associated with ileal pouch anal anastomosis, an FDA orphan indication. Ileal pouch anal anastomosis, or IPAA, is a surgical procedure used as part of a colectomy, which is a treatment for patients with ulcerative colitis. Fecal incontinence resulting from dysfunctional sphincter tone is a common consequence of this procedure. According to a U.S. community based epidemiology study (Nelson et al., JAMA, 1995), 2.2% of U.S. adults suffer from fecal incontinence, which we estimate to be approximately 7 million people, based on 2009 Census Bureau adult population estimates. Currently, there are few options available to treat this problem, consisting of bulk laxatives, fiber diets, Imodium, which is a treatment for diarrhea, and invasive surgical procedures. In addition, Oceana Therapeutics is currently pursuing FDA approval of Solesta™, an injectable inert bulking agent product approved in the European Union for the treatment of fecal incontinence in adult patients who have failed conservative therapy, and Norgine plans to conduct a Phase I trial with NRL001, a suppository formulation of an alpha adrenergic stimulating agent for the treatment of fecal incontinence, which is anticipated to start in Europe in early 2011. We are not aware of any FDA-approved drugs for fecal incontinence. In multiple clinical trials with patients suffering from IPAA-associated fecal incontinence, topical phenylephrine significantly (and in some patients, dramatically) improved patient bowel control. In clinical trials with other forms of incontinence, improvements were also observed following application of topical phenylephrine, depending on the cause of the incontinence. Our product VEN 308 is a gel formulation of phenylephrine. Applied topically, VEN 308 increases anal sphincter tone, thereby improving fecal incontinence in patients where sphincter tone is the major cause of their symptoms, such as post-IPAA surgery. We believe VEN 308 has significant advantages over the limited treatment options currently available for fecal incontinence associated with IPAA including, but not limited to, increased efficacy and/or reduced invasiveness.

We have licensed the exclusive North American rights to VEN 308 from S.L.A. Pharma. SLA has applied for, and a method of use patent has issued in the US for VEN 308 which expires in 2017.

S.L.A. Pharma developed the specific formulation of phenylephrine for the topical use in fecal incontinence and developed the manufacturing method, and their previous partner, Solvay, conducted important pharmacokinetic studies. We had a pre-IND meeting with the FDA in June 2007. The FDA advised us that the next stage in development should be a Phase II (b) study to determine the optimal dose(s) and regimen(s) to be used in Phase III. Based on the results of this study the Phase III program can be designed and agreed on.

We do not plan to use the proceeds from this offering to develop VEN 308. If we raise sufficient capital in future financings, we plan to submit an IND to the FDA for VEN 308 as a treatment for fecal incontinence associated with IPAA and to initiate a U.S. Phase IIb dose-ranging study in 2012. IPAA-related fecal incontinence has been designated by the FDA as an orphan indication, which means that VEN 308, if approved by the FDA, would enjoy seven years of market exclusivity in the U.S. after approval. If the FDA approves VEN 308 for the treatment of fecal incontinence associated with IPAA, we intend to investigate additional fecal incontinence indications.

Our License Agreements

We do not own and did not develop any of our product candidates. We have licensed our three product candidates from third parties. All clinical trials to date have been conducted either by the licensor, the

licensor's previous partners or by independent investigators, as have the preclinical studies and product formulation activities. Since we licensed these products, we have focused our efforts on establishing and clarifying the regulatory pathway for late phase clinical trials and regulatory approval, and on establishing the contract manufacturing capacity and methods necessary to allow late phase clinical trials to proceed, all of which will be conducted by contracted third parties under our direction. We are dependent on the availability and competency of these third parties for the continued development of our product candidates.

We license VEN 307 and VEN 308 from S.L.A. Pharma. We owe substantial amounts of money to S.L.A. Pharma and have obligations related to VEN 308 and to fund S.L.A. Pharma's development efforts for VEN 307 in the E.U. and to pay license fees. These payments are summarized in the chart below.

Amount Due	Date Due	Fee Description
$41,500	Monthly beginning October 1, 2010, and continuing until S.L.A. Pharma is no longer managing the development program for VEN 307.	Project management fees for VEN 307.
$600,000	December 31, 2010	Development costs for VEN 307.
$800,000	Upon the completion of enrollment into the Phase III clinical trial that S.L.A. Pharma is conducting in Europe, anticipated at the end of 2011.	Development costs for VEN 307.
Up to $400,000	If contingencies are met, payable monthly as invoiced by S.L.A. Pharma.	Development expenses for VEN 307. Contingent upon (i) receipt of a final study report from the S.L.A. Pharma Phase III VEN 307 trial in Europe (anticipated in the third quarter of 2012), and (ii) if we have raised net proceeds of at least $20.0 million from sales of securities and/or licensing of rights to our products by that time.

If we commercialize a product candidate, we must pay S.L.A. Pharma annual royalties ranging from the mid to upper single digit percentages, based upon net sales of the product. We also are required to make future milestone payments totaling up to $20 million upon the achievement of various milestones related to regulatory events. In the event we breach these obligations, we could lose our rights to VEN 307, which would have a material adverse effect on our business and prospects.

In addition, pursuant to an August 30, 2010 amendment to the license agreement between us, in the event we do not complete this offering or another financing by December 31, 2010 with net proceeds of at least $10.0 million, S.L.A. Pharma may terminate the license agreement for VEN 307 immediately. Further, S.L.A. Pharma may terminate the license agreement at any time, even during or after the successful completion of this offering, with one month notice in the event that a third party wishes to enter into a license agreement for VEN 307 and VEN 308 and has entered into an agreement to that effect, provided that the termination will not be effective if within that one-month period we pay all then required development payments under the agreement, which could total $1.4 million in the aggregate depending on when this occurs. If the license agreement were terminated, our business would be materially harmed.

We license VEN 309 from Amer, who had developed VEN 309 through Phase II studies and up to readiness for Phase III studies in the U.S. and Europe. Our license includes rights to all existing intellectual property and any future improvements on VEN 309 owned by Amer. We are required to make future milestone payments totaling up to $20 million upon the achievement of various milestones related to regulatory or commercial events. If we commercialize iferanserin, we will be obligated to pay to Amer annual royalties ranging from the upper single to lower double digit percentages for sales in the U.S. and ranging from the low to mid single digit percentages for sales outside of the U.S., based upon sales of the product. In the event we breach these obligations, we could lose rights to VEN 309, which would have a material adverse effect on our business and prospects.

Our Financial Condition

Because our drug candidates have only reached, or are only approaching, Phase III studies, we have not yet filed a new drug application, or NDA, for approval with any regulatory authority. Approval is necessary before any of our products could generate revenue. Assuming approval of our most advanced product, VEN 307, we do not expect to have any revenues from our products until 2014 at the earliest. Our only sources of capital until then will be from additional sales of securities, the licensing or sale of our rights to our products to other companies or other financing sources such as loans. If the results from a clinical trial for any of our products are negative or if unexpected safety issues arise or if capital markets are constrained, we might not be able to raise capital or out-license our products and might not have access to capital on a timely basis, in which event we might not be able to continue as a going concern.

We have incurred losses since we began operations and, as of September 30, 2010, we had a deficit accumulated during the development stage of $23,818,110. We expect to incur substantial additional losses over the next several years as our research, development, pre-clinical testing, and clinical trial activities increase. As a result of our continued losses, our independent auditors have included an explanatory paragraph in their report on our financial statements for the fiscal years ended December 31, 2009 and 2008, expressing substantial doubt as to our ability to continue as a going concern.

Our Management

Although incorporated in 2005, we began active operations in the spring of 2007 upon the licensing of VEN 307 and VEN 308 by Paramount BioSciences from S.L.A. Pharma. Shortly thereafter, we hired Thomas Rowland as our chief executive officer (who was then and remains one of our directors), Dr. Terrance Coyne as our chief medical officer, and Dr. John Dietrich as our vice president of clinical operations, as well as other employees. Due to our lack of capital, Drs. Coyne and Dietrich resigned in February 2009. Mr. Rowland resigned as our chief executive officer in February 2009, but he continued to act as our president from the date of his resignation in February 2009 until May 2010. Simultaneously with the resignation of Dr. Dietrich, we entered into a consulting agreement with him whereby he provides consultation on manufacturing, preclinical and clinical aspects of our drug programs on an as-needed basis. These arrangements with Mr. Rowland and Dr. Dietrich allowed us to continue minimal operations following their resignations until June 2010. Between February 2009 and June 2010, our only business activities consisted of maintaining our licenses with S.L.A. Pharma and Amer and financing and business development activities.

Upon the successful completion of our convertible promissory note offering in May 2010, our Board of Directors determined to proceed with this offering to raise capital to finance the partial development of VEN 309 and VEN 307. To conserve our resources, and recognizing that permanent employment would be dependent on our raising capital in this offering, in June 2010, we entered into consulting agreements with Dr. Russell Ellison, our Chief Executive Officer and Chief Medical Officer, and David Barrett, our Chief Financial Officer. Since June 2010, our only business activities have consisted of maintaining our licenses with S.L.A. Pharma and Amer and activities connected with this offering.

We also have entered into employment agreements with Dr. Ellison and Mr. Barrett that will automatically become effective on the closing of this offering. Assuming the successful completion of this offering, we expect to retain Dr. Dietrich as our Vice President of Clinical Operations pursuant to either a consulting or an employment agreement, and we also plan to add a clinician, two clinical project managers, a business development and marketing professional and an executive assistant, some or all of whom may work on a contract or permanent employment basis.

One of our current directors, Mr. Rowland, has served on our Board since we began active operations in the spring of 2007 and Dr. Joseph Felder has served since May 2008. From June 2009 until June 2010, when we did not have employees and were not actively conducting operations, Dr. Felder and Mr. Rowland were our only directors. We had other directors during this time, but they resigned, although their resignations were not related to any disagreement with management. When Dr. Ellison began consulting in June 2010 he also joined the Board. Dr. Ellison and our Chief Financial Officer, who began consulting in June 2010, have been instrumental in building the Board since that time. See “Management — Overview.”

Reverse Stock Split

On November 10, 2010, we effected a 1-for-12.4 reverse stock split of all of our common stock. The ratio for the reverse stock split was determined by our Board of Directors. The purpose of the reverse stock split was to ensure that the price per share of our common stock offered in this offering would be within the $6.00 to $7.00 price range set forth on the cover page of this prospectus. The reverse stock split was also approved by our stockholders. All share amounts referred to herein have been adjusted to reflect the effect of our 1-for-12.4 reverse stock split.

Corporate Information

We were incorporated in Delaware in October 2005 under the name South Island Biosciences, Inc. and changed our name to Ventrus Biosciences, Inc. in April 2007. Our executive offices are located at 787 7th Avenue, 48th Floor, New York, New York 10019. Our telephone number is (212) 554-4300. Our website address is *www.ventrusbio.com*. Information contained in, or accessible through, our website does not constitute part of this prospectus.

Risk Factors

Investing in our common stock involves substantial risks, which are described under “Risk Factors” beginning on page 14.

Conflicts of Interest

One of our principal stockholder’s beneficial ownership in both our stock and National Holdings Corporation, the parent corporation of National Securities Corporation, one of the co-managing underwriters in this offering, results in us being deemed to be in “common control” with National Securities Corporation pursuant to FINRA rules. Consequently, this offering is being conducted in accordance with the applicable provisions of FINRA Rule 2720. See “Conflicts of Interest” on page 115.

THE OFFERING

Common stock offered	2,900,000 shares of common stock
Common stock to be outstanding after this offering	6,746,365 shares of common stock(1)
Use of proceeds	We expect to use the net proceeds from this offering, which will be approximately $15.0 million, to increase our liquidity, conduct clinical trials for our product candidates and pay our licensing obligations for our product candidates. If this offering is not completed by December 31, 2010, convertible notes in the principal amount of $11,923,586 will be due and payable on that date. In that event, we would expect to either seek a further extension of the December 31, 2010 maturity date or use a portion of the net proceeds to repay these notes. See "Use of Proceeds" beginning on page 37.
Nasdaq Capital Market symbol	"VTUS"

(1) The number of shares of common stock to be outstanding after this offering is based on 447,347 shares outstanding as of November 30, 2010 and excludes:

- 162,016 shares of common stock issuable upon the exercise of options granted to our directors with an exercise price equal to the initial public offering price of $6.00 per share;
- shares of common stock issuable upon the exercise of options we are committed to issue to our Chief Executive Officer and Chief Financial Officer at the closing of this offering and a warrant we have issued to a consultant that will be adjusted at the closing of this offering, which, based on the sale of 2,900,000 shares in this offering at the initial public offering price of $6.00, will result in 879,519 shares issuable under the options and 76,480 shares issuable under the warrant (the options and the warrant will have an exercise price equal to the initial public offering price of $6.00 per share);
- 11,290 shares of common stock issuable upon the exercise of warrants at an exercise price of $7.69 per share;
- 42,782 shares of common stock issuable upon the exercise of warrants with a weighted average exercise price of $12.40 per share;
- 9,947 shares of common stock issuable upon the exercise of warrants with a weighted average exercise price of $66.46 per share;
- 104,867 shares of common stock, based on the initial public offering price of $6.00 per share, issuable upon the exercise of warrants with an exercise price equal to $6.60 (110% of the initial public offering price);
- 13,605 shares of common stock issuable upon the exercise of a warrant at an exercise price of $1.24 per share issued on August 30, 2010 to S.L.A. Pharma;
- shares of common stock issuable upon the exercise of warrants issued to our 2010 noteholders and placement agent, which, based on the initial public offering price of $6.00 per share, will result in an aggregate of 557,119 shares issuable under the warrants (the noteholder warrants will have an exercise price equal to 110% of the initial public offering price of $6.00 per share and the placement agent warrants will have an exercise price equal to 125% of the initial public offering price of $6.00 per share);

- 2,307,200 shares of our common stock reserved for issuance under our 2010 Equity Incentive Plan (less the shares to be covered by the option to be granted to our Chief Executive Officer and Chief Financial Officer described above); and
- 197,200 shares of our common stock, representing 6.8% of the shares to be sold in this offering, that will be reserved for issuance under the warrant we will grant to the underwriters upon completion of this offering with an exercise price of 125% of the initial public offering price of $6.00 per share.

Except as otherwise indicated, all information in this prospectus assumes:

- the conversion of all outstanding convertible notes with a principal balance of $11,923,586 and accrued interest thereon of $2,079,572 (as of December 22, 2010, the expected closing date of this offering), into 3,334,085 shares of common stock upon the closing of this offering, based on the initial public offering price of $6.00; and
- the issuance of 64,933 shares to S.L.A. Pharma at the close of this offering, as required under the terms of the license agreement between us and S.L.A. Pharma as a result of this offering, based on the initial public offering price of $6.00.

Except as otherwise indicated, all information contained in this prospectus excludes the possible issuance of up to 435,000 additional shares of our common stock to cover over-allotments.

Except as otherwise indicated, all share amounts and prices in this prospectus gives effect to the 1-for- 12.4 reverse stock split that we effected on November 10, 2010.

Summary Financial Data

The following table presents summary financial data for the fiscal years ended December 31, 2009 and 2008 and the period October 7, 2005 (inception) to September 30, 2010, after giving effect to the 1-for-12.4 reverse stock split that we effected on November 10, 2010. We derived the summary statement of operations data for the years ended December 31, 2009 and 2008 from our audited financial statements included elsewhere in this prospectus. We derived the summary statement of operations data for the nine months ended September 30, 2010 and 2009 and the period from October 7, 2005 (inception) to September 30, 2010 from our unaudited financial statements included elsewhere in this prospectus. We have prepared this unaudited information on the same basis as the audited financial statements. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The historical results are not necessarily indicative of the results to be expected for any future periods.

Statement of Operations Data:

	Nine Months Ended September 30,		Year Ended December 31,		Period from October 7, 2005 (inception) to September 30, 2010
	2010	2009	2009	2008	
Operating expenses:					
Research and development	$ 1,128,113	$ 2,073,529	$ 2,942,992	$ 5,978,723	$ 13,529,007
General and administrative	492,418	211,667	397,238	1,185,587	3,097,506
Loss from operations	(1,620,531)	(2,285,196)	(3,340,230)	(7,164,310)	(16,626,513)
Interest income	1,705	139	140	13,091	15,694
Interest expense, including amortization of debt discount and deferred financing costs and charge related to conversion of related party notes	(4,305,555)	(638,040)	(1,199,315)	(1,635,211)	(7,207,291)
Net loss	$ (5,924,381)	$ (2,923,097)	$ (4,539,405)	$ (8,786,430)	$ (23,818,110)
Basic and diluted net loss per common share[(1)]	$ (13.24)	$ (6.57)	$ (10.20)	$ (20.83)	
Weighted average number of common shares outstanding[(1)]	447,347	444,928	445,040	421,721	

(1) The impact of the 1-for-12.4 reverse stock split effected on November 10, 2010 has been applied retroactively.

The following table presents a summary of our unaudited balance sheet data at September 30, 2010:

- on an actual basis;
- on an unaudited pro forma basis to reflect (i) the conversion of all outstanding convertible notes with a principal balance of $11,923,586, plus accrued interest of $2,079,572 as of December 22, 2010, the expected closing date of this offering, into 3,334,085 shares of common stock upon the closing of this offering, and (ii) the issuance of 64,933 shares to S.L.A. Pharma at the close of this offering, as required under the terms of the license agreement between us and S.L.A. Pharma as a result of this offering, based on the initial public offering price of $6.00 per share; and
- on an unaudited pro forma, as adjusted basis to reflect the pro forma adjustments described above and our receipt of an estimated $15.0 million net proceeds from our sale of 2,900,000 shares of our common stock in this offering at the initial public offering price of $6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	At September 30, 2010		
	Actual	Pro Forma	Pro Forma, as Adjusted
Balance Sheet Data:			
Cash and cash equivalents	$ 271,075	$ 271,075	$ 15,222,075
Working capital (deficiency)	(16,014,957)	(2,275,242)	12,675,758
Total assets	579,272	283,924	15,234,924
Total liabilities	17,536,219	4,123,343	4,123,343
Deficit accumulated during the development stage	(23,818,110)	(32,392,344)	(32,392,344)
Total stockholders' equity (deficiency)	(16,956,947)	(3,512,580)	11,438,420

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information in this prospectus, before you decide whether to buy our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition and results of operations. In that case, the trading price of our common stock could decline, and you might lose all or part of your investment.

Risks Related to Our Financial Condition

We have had negative cash flows from operations and might not be able to generate sufficient cash to service our existing indebtedness under notes payable and a bank line of credit, the level of which indebtedness could have a material adverse effect on our financial health.

Our ability to make payments on our indebtedness depends on our ability to generate cash in the future. We expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. Assuming conversion of $11,923,586 of principal amount of convertible notes into shares of our common stock upon the closing of this offering, we will be obligated to pay the following indebtedness (as of September 30, 2010):

- an aggregate of $1,573,000 in principal under promissory notes issued to Paramount Credit Partners, an affiliate of Paramount BioSciences, of which Dr. Linday A. Rosenwald, our largest stockholder, is the sole member, which are due on the earlier of December 31, 2013 or the completion by us of a transaction, or series of related transactions, including an equity offering after this initial public offering, sale of assets, licensing or strategic partnership, in which we raise at least $5,000,000 in gross cash proceeds;
- $800,000 in principal under a promissory note issued to Israel Discount Bank of New York, which is guaranteed by Lindsay A. Rosenwald, the sole member of Paramount BioSciences, which is due on September 22, 2011; and
- $420,000 in principal under a promissory note issued to Israel Discount Bank of New York, which is guaranteed by Lindsay A. Rosenwald, which is due on demand or on November 4, 2011.

There can be no assurance that we will be in a position to pay any of this indebtedness when due or obtain extensions of the maturity dates. We anticipate that we will need to secure additional funding in order for us to be able to pay our obligations when due.

Moreover, this level of debt could have important consequences to you as an investor in our securities. For example, it could:

- make it more difficult for us to satisfy our obligations with respect to our outstanding notes and our other indebtedness and obligations, including payments owed to our licensors;
- limit our flexibility in planning for the development, clinical testing, approval and marketing of our products;
- place us at a competitive disadvantage compared to any of our competitors that are less leveraged than we are;
- increase our vulnerability to both general and industry-specific adverse economic conditions; and
- limit our ability to obtain additional funds.

The addition of further debt to our current debt levels could make it more difficult for us to repay our indebtedness and meet our other obligations and would intensify the leverage-related risks that we now face.

We have issued convertible notes that have a maturity date of December 31, 2010.

As of the date of this prospectus, we had outstanding convertible notes in the principal amount of $11,923,586, which have a maturity date of December 31, 2010. The entire principal amount of these notes, plus accrued interest, will convert into shares of our common stock upon the completion of this offering. However, if the offering is not completed by December 31, 2010, the notes will be due and payable on that date. We do not expect to be able to repay all of the notes if they mature on December 31, 2010, given our current cash position. Further, if the offering is not completed by December 31, 2010, investors might not want the proceeds of the offering to be used to repay these notes. As a result, it is not certain that we could complete the offering at all unless the maturity date of the notes was extended. If the offering were to close after December 31, 2010 and we immediately used the proceeds to repay these notes, we would deplete our cash reserves significantly and not be able to pursue our business plan without additional capital. This would have an adverse impact on our financial condition, which would in turn have an adverse affect on the price of our stock that you purchase in this offering. Finally, the failure to repay these notes on December 31, 2010 in the absence of an extension could subject us to lawsuits, which could further deplete our cash reserves, which would further adversely affect our stock price.

Our failure to meet our substantial obligations to our licensors could result in the termination of our licenses or put substantial burdens on our financial position.

We have in-licensed all of our product candidates. Our licenses require us to make substantial up-front, milestone, and royalty payments. If we fail to make these payments, the licensors might terminate the licenses on relatively short notice, in which event we would not be able to commercialize drug candidates that were covered by the licenses.

We owe substantial amounts of money to S.L.A. Pharma, a Swiss corporation, from which we licensed two of our product candidates, VEN 307 and VEN 308, and have obligations related to VEN 308 and to fund S.L.A. Pharma's development efforts for VEN 307 in the E.U., all of which are set forth in the chart below.

Amount Due	Date Due	Fee Description
$41,500	Monthly beginning October 1, 2010, and continuing until S.L.A. Pharma is no longer managing the development program for VEN 307.	Project management fees for VEN 307.
$600,000	December 31, 2010	Development costs for VEN 307.
$800,000	Upon the completion of enrollment into the Phase III clinical trial that S.L.A. Pharma is conducting in Europe, anticipated at the end of 2011.	Development costs for VEN 307.
Up to $400,000	If contingencies are met, payable monthly as invoiced by S.L.A. Pharma.	Development expenses for VEN 307. Contingent upon (i) receipt of a final study report from the S.L.A. Pharma Phase III VEN 307 trial in Europe (anticipated in the third quarter of 2012), and (ii) if we have raised net proceeds of at least $20.0 million from sales of securities and/or licensing of rights to our products by that time.

In addition, if we commercialize a product candidate, we must pay S.L.A. Pharma annual royalties based upon net sales of the product. If we commercialize a product candidate, we must pay S.L.A. Pharma annual royalties ranging from the mid to upper single digit percentages, based upon net sales of the product. We also are required to make future milestone payments totaling up to $20 million upon the achievement of various milestones related to regulatory events for both VEN 307 and VEN 308, the earliest of which is not

anticipated until 2015. In the event we breach these obligations, we could lose our rights to VEN 307 or VEN 308, or both, depending on the breach, which would have a material adverse effect on our business and prospects.

In the event we do not complete this offering or another financing by December 31, 2010 with net proceeds of at least $10 million, S.L.A. Pharma may terminate the license agreement immediately.

We have also entered into a license agreement with Amer, a California company, whereby we acquired patent rights to iferanserin, VEN 309, for the topical treatment of anorectal disorders. We are required to make future milestone payments totaling up to $20 million upon the achievement of various milestones related to regulatory or commercial events. If we commercialize iferanserin, we will be obligated to pay to Amer annual royalties ranging from the upper single to lower double digit percentages for sales in the U.S. and ranging from the low to mid single digit percentages for sales outside of the U.S., based upon sales of the product. In the event we breach these obligations, we could lose rights to VEN 309, which would have a material adverse effect on our business and prospects.

Our independent registered public accounting firm, in their audit report related to our financial statements for the years ended December 31, 2009 and 2008, expressed substantial doubt about our ability to continue as a going concern.

As a result of our continued losses, our independent auditors have included an explanatory paragraph in their report on our financial statements for the fiscal years ended December 31, 2009 and 2008, expressing substantial doubt as to our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in the report of our independent auditors will make it more difficult for us to secure additional financing or enter into strategic relationships on terms acceptable to us, if at all, and likely will materially and adversely affect the terms of any financing that we might obtain. If revenues grow slower than we anticipate, assuming we begin to generate revenue at some future time, or if operating expenses exceed our expectations or cannot be adjusted accordingly, the value of your investment could decline significantly.

Risks Related to Our Business

We have a limited operating history and a history of operating losses, and expect to incur significant additional operating losses.

We were established in October 2005, began active operations in the spring of 2007 and have only a limited operating history. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have generated losses since we began operations and, as of September 30, 2010, we had a deficit accumulated during the development stage of $23,818,110. We expect to incur substantial additional losses over the next several years as our research, development, pre-clinical testing, and clinical trial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products unless and until our product candidates are approved by the FDA for sale, and might never generate revenues from the sale of products.

We are not currently profitable and might never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we might never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more product candidates, we expect to incur substantial losses for the foreseeable future. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake development and clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

Our ability to generate revenue and achieve profitability will depend on, among other things:

- successful completion of animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials, for our product candidates;
- obtaining necessary regulatory approvals from the FDA and international regulatory agencies;
- establishing manufacturing, sales, and marketing arrangements with third parties; and
- raising sufficient funds to finance our activities.

We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations might be materially adversely affected.

We expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We might not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would negatively impact the value of our common stock.

We have no approved products.

To date, we have no approved product on the market and have generated no product revenues. Unless and until we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of this offering, cash on hand, licensing fees and grants and future securities offerings.

We are a development-stage company and might not be able to commercialize any product candidates.

We are a development-stage company and have not demonstrated our ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- continuing to undertake preclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales, marketing and distribution activities.

Our development of current and future product candidates is subject to the risks of failure and delay inherent in the development of new pharmaceutical products and products based on new technologies, including:

- delays in product development, clinical testing, or manufacturing;
- unplanned expenditures in product development, clinical testing, or manufacturing;
- failure of a product candidate to demonstrate acceptable safety and efficacy;
- failure to receive regulatory approvals;
- emergence of superior or equivalent products;
- inability to manufacture on our own, or through any others, product candidates on a commercial scale or at a financially viable cost; and
- failure to achieve market acceptance.

Because of these risks, our research and development efforts might not result in any commercially viable products. If we do not successfully complete a significant portion of these development efforts, obtain required regulatory approvals, or have commercial success with any approved products, our business, financial condition and results of operations will be materially harmed.

We will need additional financing to fund our activities in the future.

We anticipate that we will incur operating losses for the foreseeable future. Based on the estimated $15 million in net proceeds raised in this offering, we expect that the net proceeds of this offering will provide us with sufficient capital to fund our operations through the third quarter of 2012. However, we might consume our available capital before that time if, for example, we are not efficient in developing our product candidates and conducting clinical trials or if regulatory requirements change.

Moreover, we believe we will require substantial funds in addition to the proceeds from this offering to support our operations. We anticipate that to complete the clinical trial process to obtain the approval of our product candidates will cost approximately $15 million for VEN 307, $20 million for VEN 308 and $20 million for VEN 309. We might seek equity or debt financings in the future to fund our operations. However, there is no assurance that we will be successful in raising the additional capital we need to fund our business plan on terms that are acceptable to us, or at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to initiate or complete clinical trials or obtain approval of any product candidate from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, forego sales and marketing efforts, sacrifice attractive business opportunities, cease operations entirely and sell or otherwise transfer all or substantially all of our remaining assets.

We are dependent on license relationships.

We have acquired by license technology that is critical to our business, and we might enter into additional licenses in the future. Licenses to which we are a party contain, and we expect that any future licenses will contain, provisions requiring up-front, milestone, and royalty payments to licensors. If we fail to comply with these obligations to a licensor, that licensor might have the right to terminate the license on relatively short notice, in which event we would not be able to commercialize drug candidates or technologies that were covered by the license. Also, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates.

Our independent registered public accounting firm has identified material weaknesses in our financial reporting process.

Our independent registered public accounting firm has identified material weaknesses in our financial reporting process with respect to lack of accounting expertise, segregation of duties and lack of independent review over financial reporting. Our independent registered public accounting firm also identified numerous errors in the accounting for routine transactions and non-routine, complex transactions, including with respect to the valuation of common stock and derivative securities, the recording of debt discount and related amortization for warrants issued in connection with debt financings and calculation of deferred tax assets. The material weaknesses identified with respect to lack of accounting expertise and segregation of duties relate to the policies and procedures that:

- pertain to the procedures to ensure that information required to be disclosed is properly gathered and reported;
- pertain to the maintenance of records that accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- 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 financial statements.

We intend to take the following measures to address the material weaknesses identified by our independent registered public accounting firm and improve our periodic financial statement reporting process:

- hire a permanent Chief Financial Officer (our current Chief Financial Officer is serving part-time pursuant to a six-month consulting agreement, but will become full-time upon the completion of this offering) to strengthen our internal staffing and technical expertise in financial accounting and reporting;

- limit access to the accounting and information systems and related data to strengthen segregation of duties;
- upgrade our accounting software system; and
- implement procedures and controls in the financial statement close process to improve the accuracy and timeliness of the preparation of quarterly and annual financial statements.

There can be no assurance that we will be able to successfully implement our plans to remediate the material weaknesses in our financial reporting process. Our failure to successfully implement our plans to remediate these material weaknesses could cause us to fail to meet our reporting obligations, to produce timely and reliable financial information, and to effectively prevent fraud. Additionally, such failure could cause investors to lose confidence in our reported financial information, which could have a negative impact on our financial condition and stock price.

Corporate and academic collaborators might take actions to delay, prevent, or undermine the success of our products.

Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of drug candidates heavily depends on collaborating with corporations, academic institutions, licensors, licensees, and other parties. However, there can be no assurance that we will successfully establish these collaborations. In addition, should a collaboration be terminated, replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and might not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from these collaborations, or that any collaborator will not compete with us. If any collaboration is not successful, we might require substantially greater capital to undertake development and marketing of our proposed products and might not be able to develop and market these products effectively, if at all. In addition, a lack of development and marketing collaborations might lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

We rely on data provided by our collaborators and others that has not been independently verified and could prove to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and our business. If these third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

We rely exclusively on third parties to formulate and manufacture our product candidates.

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates, which are currently being manufactured entirely by commercial third parties. If any product candidate we might develop or acquire in the future receives FDA approval, we will rely on one or more third-party contractors to manufacture our products. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We might be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would generally require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our future contract manufacturers might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with the FDA's Current Good Manufacturing Practices, or cGMP, and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors.
- We might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than us.

Each of these risks could delay our clinical trials or the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates and could result in higher costs or deprive us of potential product revenues. As a result, our business, financial condition, and results of operations might be materially harmed.

If we or our collaborators are unable to manufacture our products in sufficient quantities or are unable to obtain regulatory approvals for the manufacturing facility, we might be unable to meet demand for our product, and we might lose potential revenues.

We require access to, or development of, facilities to manufacture a sufficient supply of our product candidates in order to complete our clinical trials and commercialize our product candidates. We currently contract with an outside source to manufacture our compounds for our clinical needs. If, for any reason, we become unable to rely on our current source or any future source to manufacture our product candidates, either for clinical trials or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for preclinical, clinical and commercial purposes. We might not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. Such third-party manufacturers must receive FDA approval before they can produce clinical material or commercial product, and any that we identify might not receive such approval. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance might be materially affected.

Before we can begin to commercially manufacture our product candidates, we must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with cGMPs and applicable non-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. We, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection might significantly delay FDA approval of our products. If we fail to comply with these requirements, we would be subject to possible regulatory action and might be limited in the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition, and results of operations might be materially harmed.

Preclinical and clinical trials required for our product candidates are expensive and time-consuming, and their outcome is uncertain.

In order to obtain FDA approval to market a new drug product, we must demonstrate safety and effectiveness in humans. To meet these requirements, we must conduct extensive preclinical testing and adequate and well-controlled clinical trials. Conducting clinical trials is a lengthy, time consuming, and expensive process. The length of time might vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting preclinical or clinical trials might cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials might be delayed by many factors, including, for example:

- inability to manufacture sufficient quantities of qualified materials under cGMP for use in clinical trials;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients;
- modification of clinical trial protocols;
- changes in regulatory requirements for clinical trials;
- the lack of effectiveness during clinical trials;
- the emergence of unforeseen safety issues;
- delays, suspension, or termination of clinical trials by the institutional review board responsible for overseeing the study at a particular study site; and
- government, institutional review board or other regulatory delays or clinical holds requiring suspension or termination of the trials.

The results from preclinical testing and early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain or have obtained positive results from preclinical or early clinical trials, we might not achieve the same success in future clinical trials. Clinical trials might not provide statistically significant data supporting a product candidate's safety and effectiveness to meet the requisite regulatory approvals.

The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay the filing of our New Drug Applications, or NDAs, with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operation.

Existing and unforeseen safety issues could hinder the development of our product candidates and their adoption, if approved.

Iferanserin (VEN 309), like numerous other drugs, is dependent on the CYP2D6 enzyme for its metabolism. An important property of CYP2D6 is that its activity is affected by genetic variability in individuals, including individuals who are CYP2D6 deficient and that its activity can be reduced by certain drugs. If this enzyme is inhibited by other medications being taken by a patient or the patient has a genetically reduced amount or a deficiency of the enzyme, and the patient takes iferanserin, the patient might have a higher level of iferanserin in his or her blood and might experience side effects although we are unaware of what the side effects might be. One patient in one of our Phase I studies had a genetic reduction of this enzyme and did experience substantially higher levels of iferanserin in his blood. However, no side effects were observed in this patient. There are several well known drugs that also are dependent on CYP 2D6, including several antidepressants as well as tamoxifen. We might restrict the use of iferaserin in patients taking medications that inhibit or are dependent on the CYP2D6 enzyme, depending on the outcome of clinical drug-drug interaction clinical studies that we intend to undertake subsequent to the completion of the first Phase III clinical trial with this product. Iferanserin (VEN 309) has demonstrated arrythmogenic potential in in vitro (hERG channel) studies at exposures 60-100 times the dose expected in humans when using the 0.5% concentration applied topically twice daily. We expect to conduct an arrhythmia clinical study ("thorough QT study") as part of our Phase III clinical pharmacology program, which studies are routinely required by the FDA. Even though VEN 309 has a wide safety margin in this area, we cannot be certain of the outcome of this study, and demonstration of clinically meaningful arrhythmia risks could compromise or prevent the approvability of the product in major markets.

Both diltiazem and phenylephrine have been safely used extensively for decades when given orally at much higher exposures (blood levels) than currently under study in the topical application of VEN 307 and VEN 308.

Despite these safety records, other safety issues could arise during testing of our products, which might delay testing or prevent further development entirely. If a product is approved, any limitation on use that might be necessary could hinder its adoption in the marketplace. In addition, if any product is approved, it could be used against any instructions that we publish that limit its use, which could subject us to litigation.

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

If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing drugs might provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or might offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we might not achieve sufficient product revenues and our business will suffer.

We might compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

We might not obtain the same resources and experience as our competitors. If we are unable to perform these tasks effectively and efficiently, our results of operations might be materially adversely affected.

Developments by competitors might render our products or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries are intensely competitive. We might compete with organizations that are developing treatments for the indications that our products target.

To our knowledge, there are currently no approved drugs for treatment of anal fissures, though ProStrakan Group plc is currently developing a topical nitroglycerin for such treatment. For the treatment of fecal incontinence, to our knowledge there are currently no products approved or in development although there are two non-drug products in development. For the treatment of hemorrhoids, some physicians are known to prescribe topical steroids, although such treatment has not been approved by the FDA for this indication. Further, many hemorrhoid sufferers use Wyeth’s Preparation H® or similar products for symptomatic relief (active ingredients can vary by country but generally include glycerin, phenylephrine HCl, pramoxine HCl, and white petrolatum). No data is publicly available regarding the clinical efficacy of this or other over-the-counter symptomatic treatments for hemorrhoids. Finally, there are surgical devices being studied for the treatment of hemorrhoids. If our competitors develop effective treatments for anal fissure, fecal incontinence or hemorrhoids and successfully commercialize those treatments, our business and prospects might be materially harmed.

If we are not able to develop collaborative marketing relationships with licensees or partners, or create an effective internal sales, marketing, and distribution capability, we might be unable to market our products successfully.

To market our products, we will have to establish our own marketing and sales force or out-license our product candidates to, or collaborate with, larger firms with experience in marketing and selling pharmaceutical products. There can be no assurance that we will be able to successfully establish our own marketing capabilities or establish marketing, sales, or distribution relationships with third parties; that such relationships, if established, will be successful; or that we will be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, sales, or distribution arrangements with third

parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third parties. If we are unable to establish such third-party sales and marketing relationships, or choose not to do so, we will have to establish our own in-house capabilities. We, as a company, have no experience in marketing or selling pharmaceutical products and currently have no sales, marketing, or distribution infrastructure. To market any of our products directly, we would need to develop a marketing, sales, and distribution force that both has technical expertise and the ability to support a distribution capability. To establish our own marketing, sales, and distribution capacity would significantly increase our costs, and require substantial additional capital. In addition, there is intense competition for proficient sales and marketing personnel, and we might not be able to attract individuals who have the qualifications necessary to market, sell, and distribute our products. There can be no assurance that we will be able to establish internal marketing, sales, or distribution capabilities.

Physicians and patients might not accept and use our drugs.

Even if the FDA approves one of our product candidates, physicians and patients might not accept and use it. Acceptance and use of our products will depend upon a number of factors, including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our product;
- cost-effectiveness of our product relative to competing product or therapies;
- availability of reimbursement for our product from government or other healthcare payors; and
- effective marketing and distribution efforts by us and our licensees and distributors, if any.

If our current product candidates are approved, we expect sales to generate substantially all of our revenues for the foreseeable future, and as a result, the failure of these products to find market acceptance would harm our business and would require us to seek additional financing.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payors.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage might not be available, and reimbursement levels might be inadequate, to cover our products. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for our products, once approved, market acceptance of such products could be reduced.

Proposals to modify the current health care system in the United States to improve access to health care and control its costs are continually being considered by the federal and state governments. In March 2010, the U.S. Congress passed landmark healthcare legislation. We cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically. We anticipate that the U.S. Congress and state legislatures will continue to review and assess this legislation and possibly alternative health care reform proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

Health administration authorities in countries other than the United States may not provide reimbursement for our products at rates sufficient for us to achieve profitability, or at all. Like the United States, these countries have considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates.

Any reduction in reimbursement rates under Medicare or foreign health care programs could negatively affect the pricing of our products. If we are not able to charge a sufficient amount for our products, then our margins and our profitability will be adversely affected.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other significant personnel or experience increases in our compensation costs, our business might materially suffer.

We are highly dependent on the services of our Chief Executive Officer and Chief Medical Officer, Dr. Russell H. Ellison. The employment agreement with Dr. Ellison, which will become effective upon the completion of this offering, will not ensure the retention of Dr. Ellison. This will also be true for the future management team members, all of whom we will need to hire. Furthermore, our future success also depends, in part, on our ability to identify, hire, and retain those additional management team members. We expect to experience intense competition for qualified personnel and might be unable to attract and retain the personnel necessary for the development of our business. Finally, we do not currently maintain, nor do we intend to obtain in the future, “key man” life insurance that would compensate us in the event of the death or disability of any of the members of our management team.

If we cannot enforce non-compete and confidentiality provisions applicable to our employees and consultants, our business might materially suffer.

We include a non-compete provision in any employment agreement we enter into with an employee. The non-compete provision included in employment agreements with our former chief executive officer, chief medical officer and chief scientific officer were in effect during the term of those agreements and for a period of six months after termination. All of those provisions have lapsed. We are not currently a party to any employment agreement although there is a non-compete provision in the employment agreement we have entered into with our Chief Executive Officer, Russell Ellison that will become effective immediately after the successful completion of this offering. That non-compete runs during the term of the agreement and for a period of six months after termination.

We include a confidentiality provision in any employment or consulting agreement we enter into with an employee or a consultant. The confidentiality provision runs during the term of the agreement and thereafter without limit. As a result, the confidentiality provisions contained in the employment agreements with our former chief executive officer, chief medical officer and chief scientific officer remain in effect and are in effect under all of our current consulting agreements.

All of our employees or consultants to date have been subject to an employment or a consulting agreement. For future employees with whom we do not enter into an employment agreement, we will enter into a confidentiality agreement with the same provisions described above.

To be able to enforce these non-compete and confidentiality provisions we would need to know of any breach and have sufficient funds to enforce the provisions. We cannot assure you that we would know of or be able to afford enforcement of any breach. In addition, such provisions are subject to state law and interpretation by courts, which could limit the scope and duration of these provisions. Any limitation on or non-enforcement of these non-compete and confidentiality provisions could have an adverse effect on our business.

If we are unable to hire additional qualified personnel, our ability to grow our business might be harmed.

At November 30, 2010, we had only four consultants to carry out our business plan. We will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

We might not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our current and future management and other administrative

and operational resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

We might seek to develop our business through acquisitions of or investment in new or complementary businesses, products or technologies, and the failure to manage these acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

We might consider opportunities to acquire or invest in other technologies, products and businesses that might enhance our capabilities or complement our current product candidates. Potential and completed acquisitions and strategic investments involve numerous risks, including potential problems or issues associated with the following:

- assimilating the purchased technologies, products or business operations;
- maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with the acquisition or investment;
- diversion of our management's attention from our preexisting business;
- maintaining or obtaining the necessary regulatory approvals or complying with regulatory standards; and
- adverse effects on existing business operations.

We have no current commitments with respect to any acquisition or investment. We do not know if we will identify suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business or retain key personnel, suppliers or collaborators.

Our ability to successfully develop our business through acquisitions would depend on our ability to identify, negotiate, complete and integrate suitable target businesses or technologies and obtain any necessary financing. These efforts could be expensive and time consuming and might disrupt our ongoing operations. If we are unable to integrate efficiently any acquired business, technology or product into our business, our business and financial condition might be adversely affected.

Risks Related to Our Regulatory and Legal Environment

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products. The FDA regulates small molecule chemical entities, whether administered orally, topically or by injection, as drugs, subject to an NDA, under the Federal Food, Drug, and Cosmetic Act. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation might be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical trials and approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires submitting extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy for each intended use. The development and approval process might take many years, requires substantial resources, and might never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval might limit the indicated medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, might require further regulatory review and approval. Once obtained, any approvals might be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators, or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

We might not obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate.

We cannot assure you that we will receive the approvals necessary to commercialize for sale any of our product candidates, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research, pre-clinical studies, and clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for their indicated uses. The FDA has substantial discretion in the drug approval process and might require us to conduct additional pre-clinical and clinical testing, perform post-marketing studies, or otherwise limit or impose conditions on any approval we obtain. The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed or obtained. There is no guarantee that we will ever be able to develop or acquire another product candidate.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any drugs. The risks associated with foreign regulatory approval processes are similar to the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidates for sale outside the U.S.

Even if approved, our products will be subject to extensive post-approval regulation.

Once a product is approved, numerous post-approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other FDA monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain FDA approval for changes to the approved product, product labeling, or manufacturing process. Application holders also must submit advertising and other promotional material to the FDA and report on ongoing clinical trials. The FDA also has the authority to require changes in the labeling of approved drug products and to require post-marketing studies.

Advertising and promotional materials must comply with FDA rules in addition to other applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's cGMP requirements. Application holders must obtain FDA approval for product, manufacturing, and labeling changes, depending on the nature of the change. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veteran's Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

We face the risk of product liability claims and might not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs. If the use of one or more of our or our collaborators' drugs harms people, we might be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We currently do not carry clinical trial insurance or product liability insurance. We intend to obtain such insurance in the future. We cannot predict all of the possible harms or side effects that might result and, therefore, the amount of insurance coverage we hold now or in the future might not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our drug candidates in development, but we might be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which might materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products, our liability could exceed our total assets and our ability to pay the liability. A successful product liability claim or series of claims brought against us would decrease our cash and could cause the value of our common stock to decrease.

We might be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors might involve the controlled use of hazardous materials and chemicals. Although we will strive to have our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any

liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products might require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations. We currently do not carry hazardous materials liability insurance. We intend to obtain such insurance in the future.

Risks Related to Our Intellectual Property

Our license agreement with S.L.A. Pharma is subject to termination if this offering is not completed by December 31, 2010 or if a third party wishes to license VEN 307 and VEN 308 in certain events.

We have in-licensed the rights to VEN 307 and VEN 308 from S.L.A. Pharma. Pursuant to an August 30, 2010 amendment to the license agreement between us, in the event we do not complete this offering or another financing by December 31, 2010 with net proceeds of at least $10.0 million, S.L.A. Pharma may terminate the license agreement immediately. In addition, S.L.A. Pharma may terminate the license agreement at any time, even during or after the successful completion of this offering, with one month's notice in the event that a third party wishes to enter into a license agreement for VEN 307 and VEN 308 and has entered into an agreement to that effect, provided that within that the termination will not be effective if within that one-month period we pay all then required development payments related to VEN 307 under the agreement, which could total an aggregate of $1.4 million depending on when this event occurs. If the license agreement were terminated, our business would be materially harmed.

A patent has not been issued for VEN 307 and might never be issued.

No patent has been issued for VEN 307. S.L.A. Pharma has a pending application in the United States that includes claims that cover topical treatment for the relief of pain associated with anal fissures. This patent has not yet issued for reasons related to the U.S Patent and Trademark Office, or PTO, examiner's concerns about novelty and lack of inventiveness over prior art. S.L.A. Pharma filed an appeal of the examiner's findings to the PTO Board of Appeal. The appeal of US Patent Application No. 09/355,928 was addressed on August 31, 2010 wherein the Appeal Board affirmed the novelty of the topical use of diltiazem while maintaining the lack of inventive step rejection over the prior art, with the proviso that additional data were necessary to show unexpected results. As a result, on October 25, 2010, S.L.A. Pharma filed a Request for Continued Examination, or RCE, with the PTO to continue prosecution of the pending application and to provide the additional data requested by the Appeal Board. S.L.A. Pharma also introduced additional arguments to the PTO to address recent legal decisions by the U.S. Federal Circuit Courts, relevant to the inventive step for the topical use of diltiazem, which decisions have not been previously considered by the PTO examiner. We expect the first PTO action to be made within 12 months. However these additional arguments may not be persuasive and the patent may never issue, or, if issued, may be invalidated.

If the patent does not issue, we will not have the exclusive rights to the intellectual property behind VEN 307, although we will have market exclusivity in the U.S. for three years after FDA approval, if granted. After that, competitors would be able to use and sell the technology without having to pay us to do so, which would greatly diminish the value of the technology to us. In such event, our business will be materially harmed.

Our business depends on protecting our intellectual property.

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

Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors 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. To date, we hold some exclusive patent rights, including rights under U.S. patents and patent applications as well as rights under foreign patents and patent applications. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, the patent process is subject to numerous risks and uncertainties, and there

can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

- Our patent rights might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;
- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful; and
- Countries other than the U.S. might have less restrictive patent laws than those upheld by U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

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 our licensors are able to obtain patents, the patents might 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 and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate. Our business and prospects will be harmed if these protections prove insufficient.

We rely on trade secret protections through confidentiality agreements with our employees, customers and other parties, and the breach of these agreements could adversely affect our business and prospects.

We rely on trade secrets, which we seek to protect, in part, through confidentiality and non-disclosure agreements with our employees, collaborators, supplies, and other parties. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known to or independently developed by our competitors. We might be involved from time to time in litigation to determine the enforceability, scope and validity of our proprietary rights. Any such litigation could result in substantial cost and divert management’s attention from our operations.

If we infringe the rights of third parties we might have to forgo selling our future products, pay damages, or defend against litigation.

If our product candidates, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we might have to:

- obtain licenses, which might not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; and/or

- defend litigation or administrative proceedings which might be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Any of these events could substantially harm our earnings, financial condition and operations.

Risks Related to this Offering

The purchase price of our common stock might not reflect the value of the common stock, and purchasers of our common stock will experience dilution as a result of this offering and future equity issuances.

Based on the initial public offering price of $6.00 per share, purchasers of our common stock in this offering will experience an immediate dilution in the net tangible book value per share of common stock of $4.30 from the offering price. Investors purchasing common stock in this offering will contribute approximately 48.4% of the total amount invested by stockholders since inception (gross of estimated expenses of this offering), but will only own approximately 43.0% of the shares of common stock outstanding. Additionally, the exercise of outstanding options or warrants and future equity issuances, including future public offerings or future private placements of equity securities, any additional shares issued in connection with acquisitions and the conversion of outstanding promissory notes into equity will result in further dilution to investors. See “Dilution” beginning on page 41.

There are interlocking relationships among us and certain affiliates of Paramount BioSciences, LLC, which might present potential conflicts of interest.

Dr. Lindsay Rosenwald is the Chairman, Chief Executive Officer and sole stockholder of Paramount BioCapital, Inc., or Paramount, and is the sole member of Paramount BioSciences, LLC. We acquired the rights to VEN 307 and VEN 308 from Paramount BioSciences who had licensed them from S.L.A. Pharma. Dr. Rosenwald individually and through entities he controls and trusts established for his family beneficially owned as of November 30, 2010 approximately 47.0% of our issued and outstanding common stock, excluding any shares issuable upon the exercise of warrants and the conversion of convertible promissory notes. Dr. Rosenwald will beneficially own approximately 7.6% of our common stock issued and outstanding immediately after this offering, based on the sale of 2,900,000 shares and assuming the exercise and conversion of all warrants and promissory notes beneficially owned by him (based on the initial offering price of $6.00 per share). Dr. Rosenwald’s beneficial ownership after this offering would include shares issuable upon the automatic conversion of promissory notes held by affiliates of Paramount BioSciences and Capretti Grandi, LLC and shares issuable upon the conversion of warrants held by affiliates of Paramount Credit Partners, LLC. Moreover, Dr. Rosenwald has the right to purchase additional shares of our common stock pursuant to purchase right agreements with certain employees of Paramount BioSciences or its affiliates. All share amounts and ownership percentages give effect to the 1-for-12.4 reverse stock split that we effected on November 10, 2010.

In consideration of his guaranteeing the $800,000 promissory note we issued to Israel Discount Bank of New York in September 2010, we entered into a letter agreement with Dr. Rosenwald whereby Dr. Rosenwald has the right to attend our Board meetings and to appoint two directors to our Board. Dr. Rosenwald has not exercised his right to appoint those directors. If and when appointed, these directors would be subject to stockholder approval at the expiration of their terms. This board representation, coupled with his expected beneficial ownership of 7.6% of the common stock of our company after the completion of this offering, increases Dr. Rosenwald’s ability to influence our board of directors and the management of our company.

As of September 30, 2010, we have borrowed from Paramount BioSciences, its affiliates and trusts established for the benefit of Dr. Rosenwald’s family members an aggregate principal amount of $1,001,153. At September 30, 2010, we also have borrowed from Paramount Credit Partners, an entity whose managing member is Dr. Rosenwald, an aggregate principal amount of $1,573,000. As of September 30, 2010, Dr. Rosenwald has guaranteed the promissory note we issued to Israel Discount Bank of New York described above as well as the $420,000 promissory note we issued to Israel Discount Bank of New York in November 2010. Finally, as of September 30, 2010, we owe Paramount Corporate Development, LLC, an affiliate of Dr. Rosenwald’s, $100,000 for services previously rendered and for which there is no due date.

Generally, Delaware corporate law, under which we are governed, requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable from a person who is not an affiliate in an arms-length transaction. We believe that the terms of our relationships with Paramount BioSciences and its affiliates satisfy the requirement of Delaware law, but in the event that one or more parties challenges the fairness of such terms, we might have to expend substantial resources in resolving the challenge, and we can make no guarantees as to the result.

None of our affiliates, Paramount BioSciences, its affiliates or Dr. Rosenwald is obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and we do not expect and purchasers of our common stock should not expect, that any biomedical or pharmaceutical product or technology identified by such affiliates, Paramount BioSciences, its affiliates or Dr. Rosenwald in the future will be made available to us. In addition, certain of our current officers and directors or certain of any officers or directors hereafter appointed or elected might from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. There can be no assurance that such other companies will not have interests in conflict with our own.

We are under common control with National Securities Corporation, a co-managing underwriter in this offering, which presents a conflict of interest under FINRA Rule 2720.

As a result of a recent transaction whereby Lindsay A. Rosenwald, a beneficial owner of approximately 31.9% of our issued and outstanding capital stock, indirectly acquired control (as such term is defined by FINRA Rule 2720) of National Holdings Corporation, the 100% owner and parent of National Securities Corporation, a co-managing underwriter in this offering, National Securities Corporation is presumed to have a “conflict of interest” with us under FINRA Rule 2720. In particular, there may be a conflict of interest between Dr. Rosenwald’s interests as our largest stockholder, and Dr. Rosenwald’s respective interest in National Holdings Corporation as an indirect owner deemed to have “control” of both entities for purposes of FINRA Rule 2720. Because of the conflict of interest under FINRA Rule 2720, this offering is being conducted in accordance with the applicable provisions of that rule. FINRA Rule 2720 requires that the “qualified independent underwriter” (as such term is defined by FINRA Rule 2720) participates in the preparation of the registration statement and prospectus and conducts due diligence. Accordingly, Rodman & Renshaw, LLC, a co-managing underwriter in this offering, is assuming the responsibilities of acting as the qualified independent underwriter in this offering. Although the qualified independent underwriter has participated in the preparation of the registration statement and prospectus and conducted due diligence, we cannot assure you that this will adequately address any potential conflicts of interest related to us and National Securities Corporation. We have agreed to indemnify Rodman & Renshaw, LLC for acting as qualified independent underwriter against certain liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments that Rodman & Renshaw, LLC may be required to make for these liabilities.

We are controlled by our current officers, directors and principal stockholders.

As of November 30, 2010, our directors, officers, principal stockholders and their affiliates beneficially owned approximately 59.5% of our issued and outstanding capital stock, excluding any shares issuable upon the exercise of options or warrants or the conversion of convertible promissory notes. Our directors, officers, principal stockholders and their affiliates will beneficially own approximately 15.1% of our capital stock issued and outstanding immediately after this offering, based on the sale of 2,900,000 shares and assuming the exercise and conversion of all warrants and promissory notes beneficially owned by those persons and entities (based on the initial offering price of $6.00 per share). Following this offering, our directors, officers, principal stockholders and their affiliates will still hold a significant portion of our stock. Accordingly, our officers, directors, principal stockholders and their affiliates control the election of our Board of Directors and the outcome of issues submitted to our stockholders, including any merger, consolidation, or sale of all or substantially all of our assets. The interests of our executive officers, directors and principal stockholders and their affiliates might not coincide with the interests of other holders of our capital stock. This concentration of ownership may harm the value of our common stock by, among other things:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or

- causing us to enter into transaction or agreements that are not in the best interests of all stockholders.

As of November 30, 2010, Dr. Lindsay Rosenwald, our largest stockholder and the sole member of Paramount BioSciences LLC, beneficially owned approximately 31.9% of our issued and outstanding capital stock, excluding any shares issuable upon the exercise of warrants or the conversion of convertible promissory notes. Dr. Rosenwald will beneficially own approximately 7.6% of our capital stock issued and outstanding immediately after this offering, based on the sale of 2,900,000 shares and assuming the exercise and conversion of all warrants and promissory notes beneficially owned by those persons and entities (based on the initial offering price of $6.00 per share).

In consideration of his guaranteeing the $800,000 promissory note we issued to Israel Discount Bank of New York in September 2010, we entered into a letter agreement with Dr. Rosenwald whereby Dr. Rosenwald has the right to attend our Board meetings and to appoint two directors to our Board. Dr. Rosenwald has not exercised his right to appoint a director. If and when appointed, these directors would be subject to stockholder approval at the expiration of their terms. This board representation, coupled with his expected beneficial ownership of 7.5% of the common stock of our company after the completion of this offering, increases Dr. Rosenwald's ability to influence our board of directors and the management of our company.

All share amounts and ownership percentages give effect to the 1-for-12.4 reverse stock split that we effected on November 10, 2010.

We have broad discretion on how we use any proceeds we receive from this offering.

Our management has broad discretion on how to use and spend any proceeds we receive from this offering and may use the proceeds in ways that differ from the proposed uses discussed in this prospectus. Investors in this offering will need to rely upon the judgment of our management with respect to the use of proceeds with only limited information concerning management's specific intentions. It is possible that we may decide in the future not to use the proceeds of this offering in the manner in which we currently expect. Our stockholders may not agree with our decision on how to use such proceeds and our actual uses may not increase the value of your investment. If we fail to spend the proceeds effectively, our business and financial condition would be harmed and we would need to seek additional financing sooner than expected.

There is not now, and there may not ever be, an active market for our common stock.

There is no active market for our common stock, and there is a possibility that no active market for our common stock will develop. Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol "VTUS." Even if this offering is successful and our common stock is listed on the Nasdaq Capital Market, we might not be able to maintain the listing standards of that exchange. If we fail to maintain the listing requirements, our common stock might trade on the OTC Bulletin Board or in the "pink sheets" maintained by Pink OTC Markets, Inc. These alternative markets are generally considered to be markets that are less efficient and less broad than the Nasdaq Capital Market. Accordingly, investors must be prepared to bear the economic risk of an investment in our common stock for an indefinite period of time.

The price of our common stock might fluctuate significantly, and you could lose all or part of your investment.

Volatility in the market price of our common stock might prevent you from being able to sell your shares of our common stock at or above the price you paid for such shares. The trading price of our common stock might be volatile and subject to wide price fluctuations in response to various factors, including:

- success or failure of our product candidates;
- results of our clinical trials and other studies;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- the overall performance of the equity markets;
- changes in interest rates;

- introduction of new products or announcements of significant contracts, acquisitions or capital commitments by us or our competitors;
- legislative, political or regulatory developments;
- issuance of new or changed securities analysts' reports or recommendations, or the announcement of any changes to our credit rating;
- additions or departures of key personnel;
- availability of capital;
- changes in accounting standards, policies, guidance, interpretations or principles;
- threatened or actual litigation and government investigations;
- future sales of our common stock;
- investor perceptions of us and the pharmaceutical industry;
- sale of shares of our common stock by our significant stockholders or members of our management; and
- general economic conditions.

These and other factors might cause the market price of our common stock to fluctuate substantially, which might limit or prevent investors from readily selling their shares of our common stock and might otherwise negatively affect the liquidity of our common stock. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce our share price.

The requirements of being a public company will increase our costs and might strain our resources and distract our management.

We have historically operated our business as a private company. As a public company, we will face increased legal, accounting, administrative and other costs and expenses that we do not incur as a private company. After the consummation of this offering, we will be subject to the following: the reporting requirements of the Securities Exchange Act of 1934, which requires that we file annual, quarterly and current reports with respect to our business and financial condition, the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act of 2002, and the Nasdaq Capital Market, each of which imposes additional reporting and other obligations on public companies. As a public company, we will be required to:

- prepare and distribute periodic public reports and other stockholder communications in compliance with federal securities laws and the Nasdaq Capital Market rules;
- expand the roles and duties of our board of directors and committees thereof;
- institute more comprehensive financial reporting and disclosure compliance functions;
- involve and retain to a greater degree outside counsel and accountants in the activities listed above;
- enhance our investor relations function;
- establish new internal policies, including those relating to trading in our securities and disclosure controls and procedures; and
- comply with the Sarbanes-Oxley Act of 2002, in particular Section 404 and Section 302.

We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. A number of those requirements will require us to carry out activities we have not

done previously and complying with these requirements might divert management's attention from other business concerns, which could have a material adverse effect on our prospects, business, and financial condition.

Additionally, the expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. These increased costs will require us to divert a significant amount of money that we could otherwise use to develop our product candidates or otherwise expand our business. If we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Our internal control over financial reporting does not currently meet the standards required by Section 404 of the Sarbanes-Oxley Act of 2002, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

As a privately held company, we have not maintained internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404 of the Sarbanes-Oxley Act of 2002. We anticipate being required to meet these standards in the course of preparing our financial statements as of and for the year ending December 31, 2011, and our management will be required to report on the effectiveness of our internal control over financial reporting as of December 31, 2011. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. We expect to begin the process of reviewing, documenting and testing our internal control over financial reporting after completion of this offering. We might encounter problems or delays in completing the implementation of any changes necessary to make a favorable assessment of our internal control over financial reporting. If we cannot favorably assess the effectiveness of our internal control over financial reporting, investors could lose confidence in our financial information and the price of our common stock could decline.

We do not intend to pay dividends for the foreseeable future and our stock may not appreciate in value.

We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in shares of our common stock will depend upon any future appreciation in its value. There is no guarantee that shares of our common stock will appreciate in value or that the price at which our stockholders have purchased their shares will be able to be maintained.

Shares eligible for future sale may adversely affect the market price of our common stock, as the future market sale of a substantial amount of outstanding stock in the public marketplace could reduce the price of our common stock.

Holders of a significant number of our shares and/or their designees may be eligible to sell our shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, a non-affiliate stockholder (or stockholders whose shares are aggregated) who has satisfied a six-month holding period, and provided that there is current public information available, may sell all of its securities. Rule 144 also permits the sale of securities, without any limitations, by a non-affiliate that has satisfied a one-year holding period. In addition, lock-up agreements that our executive officers and directors and certain of our stockholders entered into in connection with this offering will expire 180 days after the close of this offering, which will allow those shares to be sold. Any substantial sale of common stock after this offering may have an adverse effect on the market price of our common stock.

Several provisions of the Delaware General Corporation Law and our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our common stock.

Several provisions of the Delaware General Corporation Law and our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger or acquisition that stockholders may

consider favorable, and the market price of our common stock could be reduced as a result. These provisions include:

- "blank check" preferred stock;
- prohibiting us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;
- prohibiting cumulative voting in the election of directors;
- limiting the persons who may call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains estimates and forward-looking statements, principally in "Prospectus Summary," "Risk Factors," "Use of Proceeds," "Dividend Policy," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business." Our estimates and forward-looking statements are mainly based on our current expectations and estimates of future events and trends, which affect or might affect our businesses and operations. Although we believe that these estimates and forward-looking statements are based upon reasonable assumptions, they are subject to several risks and uncertainties and are made in light of information currently available to us. Many important factors, in addition to the factors described in this prospectus, might adversely affect our results as indicated in forward-looking statements. You should read this prospectus and the documents that we have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results might be materially different from what we expect.

Our estimates and forward-looking statements may be influenced by the following factors, among others:

- our expectations regarding our revenues, expenses, effective tax rates and other results of operations;
- our ability to obtain FDA approval of our product candidates;
- our anticipated capital expenditures and our estimates regarding our capital requirements;
- our liquidity and working capital requirements;
- our need to obtain additional funding and our ability to obtain future funding on acceptable terms;
- our product candidates and plans to promote them;
- anticipated trends and challenges in our business and in the markets in which we operate;
- our ability to retain and hire necessary employees and to staff our operations appropriately;
- our ability to find future acquisition opportunities on favorable terms or at all and to manage any acquisitions;
- our ability to compete in our industry and innovation by our competitors;
- our ability to stay abreast of new or modified laws and regulations that currently apply or become applicable to our business;
- estimates and estimate methodologies used in preparing our financial statements; and
- the future trading prices of our common stock and the impact of securities analysts' reports on these prices.

The words "believe," "may," "might," "will," "aim," "estimate," "continue," "would," "anticipate," "intend," "expect," "plan" and similar words are intended to identify estimates and forward-looking statements.

Estimates and forward-looking statements speak only as of the date they were made, and, except to the extent required by law, we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors. Estimates and forward-looking statements involve risks and uncertainties and are not guarantees of future performance. As a result of known and unknown risks and uncertainties, including those described above, the estimates and forward-looking statements discussed in this prospectus might not occur and our future results and our performance might differ materially from those expressed in these forward-looking statements due to, including, but not limited to, the factors mentioned above. Because of these uncertainties, you should not place undue reliance on these forward-looking statements when making an investment decision.

USE OF PROCEEDS

The gross proceeds from the offering, prior to deducting underwriting discounts and commissions and the estimated offering expenses payable by us, will be $17,400,000, based on the sale of 2,900,000 shares in this offering at the offering price of $6.00 per share.

We estimate that we will receive net proceeds of approximately $15.0 million, after deducting $1,522,500 for underwriting discounts and commissions and the underwriters' non-accountable expense allowance and other estimated expenses of approximately $926,500, which includes legal, accounting, printing costs, and various fees associated with the registration and listing of our shares.

We are undertaking this offering in order to access the public capital markets and to increase our liquidity. Based on approximately $15.0 million in net proceeds, we expect to use the net proceeds of this offering for the following purposes:

- $8.0 million to conduct and complete the planned Phase III clinical trial of iferanserin (VEN 309) in the treatment of hemorrhoids, consisting of an anticipated $750,000 for clinical testing supplies, $6.0 million for direct clinical trial costs including CRO fees, $270,000 for license fees to Amer, and $880,000 for carcinogenicity testing and pre-clinical dose ranging, with $100,000 set aside for unexpected budget items;
- $3.8 million to continue the development of diltiazem cream (VEN 307), consisting of $996,000 for license fees to S.L.A. Pharma, $1.4 million for indirect clinical trial costs to complete those trials in the European Union, $1.0 million for the development of an improved formulation for use in Phase III studies in the U.S., and $373,500 to repay a portion of the $800,000 promissory note issued to Israel Discount Bank of New York (we borrowed these funds in September 2010 to make the September 30, 2010 payment to S.L.A. Pharma); and
- $3.2 million for general and administrative expenses.

Our highest priority activity is the Phase III clinical trial of iferanserin (VEN 309).

As of the date of this prospectus, we had outstanding convertible notes in the principal amount of $11,923,586, which have a maturity date of December 31, 2010. The entire principal amount of these notes, plus accrued interest, will convert into shares of our common stock upon the completion of this offering. However, if the offering is not completed by December 31, 2010, the notes will be due and payable on that date. We do not expect to be able to repay all of the notes if they mature on December 31, 2010, given our current cash position. In such event, we would expect to either (i) seek a further extension of the December 31, 2010 maturity date or (ii) use a portion of the net proceeds of this offering to repay these notes.

The above list represents our estimate of the use of the net proceeds of this offering based upon our current plans and current economic and industry conditions, and is subject to reallocation of proceeds between or among the categories listed above or to new and additional areas of use. The actual cost, timing and amount of funds required for such uses cannot be determined precisely at this time and may be based, among other things, on economic, regulatory, competitive or other developments, the rate of our progress in research and development, the results of proposed preclinical studies and clinical trials, the timing of regulatory approvals, if any, payments under collaborative agreements and the availability of alternative methods of financing, if any. Other future events, including delays, expenses and complications frequently encountered by development-stage companies as well as changes in our planned business, the results of our research and development and testing activities may make shifts in the allocation of funds necessary or desirable. In addition, in the event that we deem it desirable to acquire assets, technologies or other entities in complementary fields, we may apportion proceeds of this offering to such acquisition or development. Accordingly, our management team will have significant flexibility in applying the net proceeds of this offering. Pending the use of the net proceeds of the offering, we intend to invest them in short-term, investment grade, interest bearing securities.

DIVIDEND POLICY

We currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors our board deems relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2010 (after giving effect to the 1-for-12.4 reverse stock split that we effected on November 10, 2010):

- on an actual basis;
- on a pro forma basis to reflect the conversion of outstanding convertible notes in the aggregate principal amount of $11,923,586, with accrued interest of $2,079,572 outstanding at December 22, 2010, the expected closing date of this offering, into 3,334,085 shares common stock upon the closing of this offering, based on the initial public offering price of $6.00, and to reflect the effect of the related beneficial conversion charge;
- on a pro forma basis to reflect the issuance of 64,933 shares to S.L.A. Pharma at the closing of this offering, as required under the terms of the license agreement between us and S.L.A. Pharma as a result of this offering, based on the initial public offering price of $6.00 per share; and
- on a pro forma, as adjusted basis to reflect the pro forma adjustments described above and our receipt of the estimated net proceeds from our sale of 2,900,000 shares of common stock in this offering based on the initial public offering price of $6.00, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	At September 30, 2010 (unaudited)		
	Actual	Pro Forma	Pro Forma, as Adjusted
Cash and cash equivalents	$ 271,075	$ 271,075	$ 15,222,075
2007 senior convertible notes	$ 5,305,000	$ —	$ —
2010 senior convertible notes	5,617,433	—	—
8% Paramount/Capretti Notes	1,001,153	—	—
Paramount Capital Partners notes	1,573,000	1,573,000	1,573,000
Bank line of credit borrowings	320,000	320,000	320,000
Term note[1]	800,000	800,000	800,000
	14,616,586	2,693,000	2,693,000
Stockholders' (deficiency) equity:			
Preferred stock, $0.001 par value: 5,000,000 shares authorized, actual, pro forma and pro forma, as adjusted; no shares issued and outstanding, actual, pro forma and pro forma, as adjusted	—	—	—
Common stock, $0.001 par value: 25,000,000 shares authorized[2], actual, pro forma and pro forma, as adjusted; 447,347 shares issued and outstanding, actual, and 3,846,365 shares issued and outstanding, pro forma and 6,746,365 shares issued and outstanding pro forma, as adjusted	447	3,846	6,746
Additional paid-in capital	6,860,716	28,875,918	43,824,018
Deficit accumulated during the development stage	(23,818,110)	(32,392,344)	(32,392,344)
Total stockholders' (deficiency) equity	(16,956,947)	(3,512,580)	11,438,420
Total capitalization (deficiency)	$ (2,340,361)	$ (819,580)	$ 14,131,420

(1) Does not reflect an additional term loan in the amount of $420,000 obtained on November 5, 2010 from the Israel Discount Bank of New York, of which $320,000 was used on that day to repay in full the bank line of credit borrowings of $320,000 reflected in the table.

(2) Effective November 10, 2010, the number of authorized shares of common stock was increased to 50,000,000.

The pro forma, as adjusted number of shares to be outstanding immediately after this offering as shown above assumes the offering was completed on September 30, 2010 and is based on 447,347 shares outstanding as of September 30, 2010 and excludes:

- 162,016 shares of common stock issuable upon the exercise of an option granted to our directors with an exercise price equal to the initial public offering price of $6.00 per share;
- shares of common stock issuable upon the exercise of options we are committed to issue to our Chief Executive Officer and Chief Financial Officer at the close of this offering and a warrant we have issued to a consultant that will be adjusted at the close of this offering, which, based on the sale of 2,900,000 shares in this offering, will result in 879,519 shares issuable under the options and 76,480 shares issuable under the warrant (the option and the warrant will have an exercise price equal to the initial public offering price of $6.00 per share);
- 11,290 shares of common stock issuable upon the exercise of warrants with an exercise price of $7.69 per share;
- 42,782 shares of common stock issuable upon the exercise of warrants with a weighted average exercise price of $12.40 per share;
- 9,947 shares of common stock issuable upon the exercise of warrants with a weighted average exercise price of $66.46 per share;
- 13,605 shares of common stock issuable upon the exercise of a warrant with an exercise price of $1.24 per share issued on August 30, 2010 to S.L.A. Pharma;
- 104,867 shares of common stock, based on the initial public offering price of $6.00 per share, issuable upon the exercise of warrants with an exercise price equal to $6.60 (110% of the initial public offering price); and
- shares of common stock issuable upon the exercise of warrants issued to our 2010 noteholders and placement agent, which, based on the initial public offering price of $6.00 per share, will result in an aggregate of 557,119 shares issuable under the warrants (the noteholder warrants will have an exercise price equal to 110% of the initial public offering price of $6.00 per share and the placement agent warrants will have an exercise price equal to 125% of the initial public offering price of $6.00 per share);
- 2,307,200 shares of common stock reserved for future grants under our 2010 Equity Incentive Plan (less the shares to be covered by the options to be granted to our Chief Executive Officer and Chief Financial Officer described above); and
- 197,200 shares of our common stock, representing 6.8% of the shares to be sold in this offering, that will be reserved for issuance under the warrant we will grant to the underwriters upon completion of this offering with an exercise price of 125% of the initial public offering price of $6.00 per share.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering.

Our net tangible book value (deficiency) as of September 30, 2010 (after giving effect to the 1-for-12.4 reverse stock split that we effected on November 10, 2010) was $(17,252,295), or $(38.57) per share of common stock. Net tangible book value (deficiency) per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding at that date. After giving effect to the conversion of our outstanding convertible notes, and the issuance and sale of 2,900,000 shares of our common stock in this offering at the initial public offering price of $6.00, and after deducting the underwriting discount and commissions and estimated offering expenses that we will pay, our pro forma as adjusted net tangible book value as of September 30, 2010 (after giving effect to the 1-for-12.4 reverse stock split that we effected on November 10, 2010) would have been $11,438,420, or $1.70 per share of common stock. This represents an immediate increase in net tangible book value of $40.27 per share to existing stockholders and an immediate dilution of $4.30 per share to new investors purchasing shares of common stock in this offering.

The following table illustrates this dilution:

Initial public offering price per share		$ 6.00
Net tangible book value (deficiency) per share as of September 30, 2010	$(38.57)	
Increase per share attributable to this offering	2.61	
Increase per share attributable to conversion of convertible notes	37.66	
Pro forma net tangible book value per share after this offering		1.70
Dilution per share to new investors		$ 4.30

The following table summarizes, as of September 30, 2010 (after giving effect to the 1-for-12.4 reverse stock split that we effected on November 10, 2010), on a pro forma basis, and assuming the offering was completed on September 30, 2010 with the initial public offering price of $6.00 per share, the total number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders, by current noteholders whose notes will convert to common stock upon the closing of this offering, and by new investors purchasing shares of common stock in this offering, before deducting the underwriting discount and commissions and estimated offering expenses that we will pay:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders[1]	512,280	7.59%	$ 4,531,081	12.61%	$ 8.84
Existing convertible noteholders[2]	3,334,085	49.42	$ 14,003,158	38.97	4.20
New investors	2,900,000	42.99	$ 17,400,000	48.42	6.00
Totals	6,746,365	100%	$ 35,934,239	100%	$ 5.33

(1) Includes 64,933 shares issuable to S.L.A. Pharma as a result of and upon completion of this offering.

(2) Upon the closing of this offering, all of our outstanding convertible notes will convert into common stock at 70% of the initial public offering price. At September 30, 2010, there was $11,923,586 of aggregate principal of the convertible notes, and as of December 22, 2010, the expected closing date of this offering, there would be $2,079,572 of accrued interest.

As of September 30, 2010, there was one award outstanding under our 2007 Stock Incentive Plan. An option to purchase 2,016 shares of common stock was issued on May 11, 2010 with an exercise price to be equal to the initial public offering price of $6.00 per share. This is the only award we have issued under the 2007 Plan. In August 2010 we terminated the 2007 Plan and we will not issue any more awards under it. Also in August 2010, we adopted, with stockholder approval, our 2010 Equity Incentive Plan. We have an aggregate of 2,467,200 shares of our common stock reserved for future issuance under our 2010 Equity Incentive Plan. We have issued options to purchase an aggregate of 160,000 shares under the 2010 Equity

Incentive Plan. We are committed to issue to our Chief Executive Officer and Chief Financial Officer at the close of this offering options to purchase shares of common stock in an amount equal to 7.5% and 4.0%, respectively, of our fully diluted capitalization on the date their employment agreements become effective, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan, with an exercise price equal to the initial public offering price of $6.00 per share.

As of September 30, 2010, we had issued the following warrants:

- warrants to purchase an aggregate of 11,290 shares of common stock at a weighted average exercise price of $7.69 per share;
- warrants to purchase 42,782 shares of common stock with a weighted average exercise price of $12.40 per share;
- warrants to purchase 9,947 shares of common stock with a weighted average exercise price of $66.46 per share;
- 104,867 shares of common stock, based on the initial public offering price of $6.00, issuable upon the exercise of warrants with an exercise price equal to $6.60 (110% of the initial public offering price); and
- a warrant to purchase 8,065 shares of common stock issued to a consultant that will be adjusted at the closing of this offering to be for 76,480 shares, which is equal to 1.0% of our outstanding common stock on a fully diluted basis, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan, with an exercise price equal to the initial public offering price of $6.00 per share.

We also have issued and outstanding warrants issued to our 2010 noteholders and placement agent, which, based on the initial public offering price of $6.00 per share, will result in an aggregate of 557,119 shares issuable under the warrants (the noteholder warrants will have an exercise price equal to 110% of the initial public offering price of $6.00 per share and the placement agent warrants will have an exercise price equal to 125% of the initial public offering price of $6.00 per share).

On August 30, 2010, we issued a warrant to purchase 13,605 shares of our common stock with an exercise price of $1.24 per share to S.L.A. Pharma.

We also will grant to the underwriters upon completion of this offering a warrant to purchase 6.8% of the shares sold in this offering, or 197,200 shares of our common stock, with an exercise price of 125% of the initial offering price of $6.00 per share.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with our financial statements and the notes to those statements included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

Unless otherwise indicated, all share amounts and prices take into account the 1-for-12.4 reverse stock split effected on November 10, 2010.

Overview

We are a pharmaceutical company that seeks to develop therapeutic products for the treatment of gastrointestinal disorders, specifically hemorrhoids, anal fissures and fecal incontinence. We have in-licensed all of the products in our current pipeline.

We have several proprietary product candidates that we have licensed that are in clinical development that address large market opportunities, including our most advanced product candidates, VEN 309 (iferanserin) and VEN 307 (diltiazem cream). VEN 309, a topical form of iferanserin which blocks peripheral (outside the central nervous system) serotonin receptors, is being developed for the topical treatment of hemorrhoids, where it can reduce the bleeding, itchiness, and pain associated with the condition. Approximately 12.5 million people in the U.S. suffer from hemorrhoids and we are not aware of any FDA approved prescription drugs for this condition. VEN 307 is a proprietary topical formulation of the drug diltiazem which we are developing for the treatment of anal fissures. Over 4 million people in the U.S. suffer from anal fissures and even though gastroenterology specialists will prescribe a pharmacy-prepared cream (made for each patient) of diltiazem or glyceryl trinitrate (a heart drug), to our knowledge, there are no drugs with FDA approval for this condition. Diltiazem is a drug that has been used in millions of patients orally for hypertension and angina, and our formulation, applied peri-anally, reduces the pain associated with the reduced blood supply in this disease, at a dose substantially below its usual oral dosage in hypertension and angina patients.

We have met with the FDA regarding our plans for the development of VEN 309, VEN 307 and VEN 308. We intend to initiate and conduct a Phase III clinical trial in the U.S. with VEN 309 beginning in the first half of 2011 and initiate a long term carcinogenicity study. Depending on our assessment of the data generated by the Phase III trial as well as on other factors, including our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate, we intend to initiate and conduct the second Phase III trial, which, together with the first study, other small pharmacology studies, and the carcinogenicity study (which we plan to complete after the second trial) will comprise the data needed to be able to submit a NDA to the FDA, which we anticipate could occur as early as 2014.

Our partner for VEN 307, S.L.A. Pharma, expects to conduct the first Phase III clinical trial with VEN 307 in Europe in 2010 and 2011. At the same time we intend to conduct a formulation program with contract manufacturers to create a new, improved formulation of topical diltiazem, with new intellectual property protections. We expect to receive the data from the first Phase III trial in the second quarter of 2012 and aim to have completed our formulation program by that time. Depending on our assessment of the data generated by this study and on whether the new formulation is superior to the existing version, as well as on other factors, including our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate, we intend to initiate either one additional Phase III study in the U.S. with the existing formulation or two additional Phase III clinical trials in the U.S. with the new formulation, to be run in parallel. We anticipate that both program options could provide sufficient data for a NDA submission to the FDA in 2013.

Since our inception, we have had no revenue from product sales, and have funded our operations principally through debt financings. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates and maintaining and improving our patent portfolio.

We have generated significant losses to date, and we expect to continue to generate losses as we progress towards the commercialization of our product candidates, including VEN 307 and VEN 309. As of September 30, 2010, we had a deficit accumulated during the development stage of $23,818,110. Because we do not generate revenue from any of our product candidates, our losses will continue as we advance our product candidates towards regulatory approval and eventual commercialization. As a result, our operating losses are likely to be substantial over the next several years. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

We believe that the net proceeds from this offering and existing cash will be sufficient to fund our projected operating requirements until data are available from the key clinical trials with VEN 307 and VEN 309. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements.

Financial Operations Overview

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. Our significant accounting policies are more fully described in Note 1 to the financial statements included in this prospectus. The following accounting policies are critical to fully understanding and evaluating our financial results.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements as well as the reported revenue, if any, and expenses during the reporting periods. On an ongoing basis, management evaluates their estimates and judgments. Management bases estimates on historical experience and on various other factors that they believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results might differ from these estimates under different assumptions or conditions.

Stock-Based Compensation

We account for stock options granted to employees according to the Financial Accounting Standards Board Accounting Standards Codification No. 718 (ASC 718), Compensation — Stock Compensation. Under ASC 718, share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis. We account for stock options and warrants granted to non-employees on a fair value basis in accordance with ASC 718 using the Black-Scholes option pricing model. The initial non-cash charge to operations for non-employee options and warrants with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and recognized as consulting expense over the related vesting period.

For the purpose of valuing options and warrants granted to employees and non-employees, we use the Black-Scholes option pricing model. To determine the risk-free interest rate, we utilize the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the awards. We estimated the expected life of the options granted based on anticipated exercises in the future periods assuming the success of our business model as currently forecasted. For warrants and non-employee options, we use the contractual term of the warrant, the length of the note or option as the expected term. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options will be calculated by examining historical volatilities for publicly traded industry peers as we do not now and for the near future will not have any trading history for our common stock. Forfeiture rates will be calculated based on the expected service period for our employees.

Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants

In accordance with ASC Topic 470-20, "*Debt with Conversion and Other Options*," the proceeds from any financing in which we issue warrants to purchase our common stock are first allocated to the warrants based upon their estimated relative fair values as of the closing date.

Warrants, or any other detachable instruments issued in connection with debt financing agreements, are accounted for using the relative fair value method and allocated to additional paid-in capital and recorded as a reduction in the carrying value of the related debt. This discount is amortized to interest expense from the issuance date through the maturity date of the debt using the straight-line method.

When the convertible feature of conventional convertible debt provides for a rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature, or BCF. Prior to the determination of the BCF, the proceeds from the debt instrument are first allocated between the convertible debt and any detachable free-standing instruments that are included, such as common stock warrants. We have disclosed the contingent nature of our BCFs but we have not recorded them as such. We will record a BCF if and when a conversion takes place.

Recent Accounting Pronouncements

In March 2010, the Financial Accounting Standards Board ratified the consensus of the Emerging Issues Task Force included in EITF Issue No. 08-9, "Milestone Method of Revenue Recognition" (ASC Topic 605-28; ASU No. 2010-17). The milestone method is optional by arrangement and generally provides that upon achievement of a substantially uncertain milestone, the related milestone payment may be recognized in income in its entirety. We have not yet evaluated the effects of this consensus and, accordingly, have not yet made an accounting policy decision for future arrangements. When the consensus becomes effective (years beginning on or after June 15, 2010; first quarter of 2011 for us), we will consider application of the consensus on a prospective or retrospective basis.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

Revenue

We have not generated any revenue since our inception and we do not expect to generate revenue within the foreseeable future. None of our existing product candidates is expected to be commercially available until 2012 at the earliest, if at all. To date, we have funded our operations primarily through debt financings. If our product development efforts result in clinical success, regulatory approval and successful commercialization of any of our products, we could generate revenue from sales or licenses of any such products.

Research and Development Expense

Research and development expenses consist primarily of costs associated with (i) internal costs associated with our development activities; (ii) payments we make to third party contract research organizations, contract manufacturers, and consultants; (iii) technology and intellectual property license costs; (iv) patent reimbursements. All research and development is expensed as incurred. License fees and pre-approved milestone payments due under each research and development arrangement that are paid prior to regulatory approval are expensed when the license is entered into or the milestone is achieved.

Conducting a significant amount of research and development is central to our business model. Through September 30, 2010, we incurred $13,529,007 in research and development expenses since our inception in October 2005. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of the clinical trials. We plan to increase our research and development expenses for the foreseeable future in order to complete development of our two most advanced product candidates, VEN 309 and VEN 307.

The following table summarizes the research and development expenses related to our two most advanced product candidates and other projects. The table reflects expenses directly attributable to each development candidate, which are tracked on a project basis.

	YE 2008	YE 2009	9 Mos. Ended September 30, 2010	Period from October 7, 2005 (inception) to Sept. 30, 2010
VEN 307	$2,265,000	$ 155,000	$ 812,200	$ 3,402,200
VEN 309	$3,123,714	$2,734,147	$ 177,626	$ 8,463,372
Other	$ 590,009	$ 53,845	$ 138,287	$ 1,663,435

The process of conducting pre-clinical studies and clinical trials necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine with certainty the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. Based on their current status, we anticipate that to complete the clinical trial process and commercialize our product candidates will cost approximately $15 million for VEN 307, $20 million for VEN 308 and $20 million for VEN 309. These estimates could change significantly depending on the progress, timing and results of non-clinical and clinical trials. We will need to raise additional funds following the completion of this offering in order to fully complete the development of VEN 307 and VEN 309.

General and Administrative Expense

General and administrative expense consists primarily of salaries and other related costs, professional fees for legal services and accounting services, insurance and travel expenses. We expect that our general and administrative expenses will increase as we add personnel and become subject to the reporting obligations applicable to public companies. From our inception in October 2005 through September 30, 2010, we spent $3,097,506 on general and administrative expense.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash. Interest expense consists of interest incurred on the 5% related parties' promissory notes from October 2005 to June 2008, the 8% related parties' promissory notes from July 2008 to September 2010, the 10% Paramount Credit Partners notes from January 2009 to June 2010, the 8% senior convertible notes from December 2007 to December 2008, the 10% senior convertible notes from December 2008 to September 2010, the 8% 2010 senior convertible notes from February 2010 to September 2010, our letter of credit borrowings and interest due on our license fee payments.

Results of Operations

Comparison of the Years Ended December 31, 2009 and December 31, 2008

Research and Development Expense

Research and development expense was $2,942,992 for the year ended December 31, 2009, a decrease of $3,035,731, or 51%, from $5,978,723 for the year ended December 31, 2008. The decrease was primarily attributable to our expense in 2008 of an initial licensing fee of $2,050,000 to Amer and our initial license payment to S.L.A. Pharma of $300,000. We expect to incur higher development costs in the future due to initiation of the Phase III clinical trial as well as product development and manufacturing costs to support the clinical study.

General and Administrative Expense

General and administrative expense was $397,238 for the year ended December 31, 2009, a decrease of $788,349, or 66%, from $1,185,587 for the year ended December 31, 2008. The decrease was primarily due to the departure of a key employee and our termination of various consulting arrangements in 2009.

Interest Income and Interest Expense

Interest income was $140 for the year ended December 31, 2009, a decrease of $12,951, or 99%, from $13,091 for the year ended December 31, 2008. The decrease was primarily due to lower cash balances during 2009 compared to 2008.

Interest expense was $1,199,315 for the year ended December 31, 2009, a decrease of $435,896, or 27%, from $1,635,211 for the year ended December 31, 2008. The decrease was primarily due to our expensing in 2008 $340,860 which resulted from our issuing warrants issued relating to the conversion of a 2008 promissory note and a decrease in amortization of deferred financing costs and debt discount of $575,955 in 2009. The aforementioned decreases in interest expense were offset by the increase in the interest rate on the Paramount BioSciences and Capretti Grandi notes from 8% to 10% and our paying interest in 2009 relating to the Amer license agreement of $320,000.

Comparison of the Nine Months Ended September 30, 2010 and September 30, 2009

Research and Development Expense

Research and development expense was $1,128,113 for the nine months ended September 30, 2010, a decrease of $945,416, or 46%, from $2,073,529 for the nine months ended September 30, 2009. The decrease was primarily attributable to a decrease in license expenses associated with S.L.A. Pharma of $892,400, decreases in consulting fees of $68,748, a payment to S.L.A. Pharma of $28,417 for services outside the scope of the agreement and stock-based compensation expense related to options of $175,043, which was partially offset by increases in patent fee expenses of $56,488 and licensing fees expenses to Amer of $55,126. We expect to incur higher development costs in the future due to initiation of the Phase III clinical trial as well as product development and manufacturing costs to support the clinical study.

General and Administrative Expense

General and administrative expense was $492,418 for the nine months ended September 30, 2010, an increase of $280,751, or 133%, from $211,667 for the nine months ended September 30, 2009. The increase was primarily due to $135,000 of management consulting fees, $50,000 of Board fees, audit fees of $195,000, legal fees of $23,000 and $20,000 of web site design and consulting expenses that were offset by a $129,167 decrease in salaries and $22,683 decrease in payroll tax expense due to the departure of a key employee in 2009.

Interest Income and Interest Expense

Interest income was $1,705 for the nine months ended September 30, 2010, an increase of $1,566, or 1,127%, from $139 for the nine months ended September 30, 2009. The increase was primarily due to higher cash balances during 2010 compared to 2009 because of the financings.

Interest expense was $4,305,555 for the nine months ended September 30, 2010, an increase of $3,667,515, or 575%, from $638,040 for the nine months ended September 30, 2009. The increase was primarily due to our expensing in 2010 of $944,274 of warrant discount which resulted from our issuing warrants relating to the conversion of a 2008 promissory note, increase in amortization of deferred financing costs and debt discount of $2,219,104 in 2010, $135,000 increase in interest in 2010 relating to the Amer license agreement, $251,907 increase due to 2010 senior convertible notes, $29,361 increase in 2010 due to the increased balance of the PCP notes, and a $51,662 increase due to related party notes.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through September 30, 2010

principally with $11,923,586 in convertible notes, $1,573,000 in non-convertible notes and $934,141 in equity financing. The following table summarizes our funding sources as of September 30, 2010:

Source	Amount Raised	Principal[1]	Accrued Interest	Convertible
Paramount Credit Partners	$ 1,573,000	$ 1,573,000	$ 148,211	No
Paramount BioSciences/Capretti	$ 1,001,153	$ 1,001,153	$ 112,289	Yes
2010 Senior Convertible Notes[2]	$ 3,425,000	$ 5,617,433	$ 251,907	Yes
2007 Senior Convertible Notes	$ 5,305,000	$ 5,305,000	$ 1,451,933	Yes
2008 Equity Offering, net	$ 929,457			
Founder/employee shares	$ 4,684			

(1) Excludes debt discount.

(2) Includes $2,192,433 of debt owed to Paramount BioSciences, LLC that converted to a 2010 senior convertible note on February 26, 2010.

Notes Payable

On October 7, 2005, we issued a 5% promissory note payable to Paramount BioSciences, LLC, an affiliate of Lindsay A. Rosenwald, a significant stockholder of our company. This note and all accrued interest were to mature on October 7, 2008, or earlier if certain events occurred. The note was amended to extend the maturity date to October 7, 2009. On June 16, 2008, this note was voluntarily converted into shares of our common stock and a warrant to purchase shares of our common stock (together, a "unit") at a price of $60.39 per unit, the price of a concurrent financing. At the time of the conversion, the outstanding balance due under this note was $1,396,672 which was converted into 23,128 shares of our common stock and a warrant to purchase 4,805 shares of our common stock for which we recorded a charge of $266,243. Upon conversion, the note was automatically cancelled.

On July 12, 2007, we issued an 8% promissory note payable to Paramount BioSciences. This note and all accrued interest mature on July 12, 2010, or earlier if certain events occur. On June 16, 2008, this note was voluntarily converted into shares of our common stock and a warrant to purchase shares of our common stock at a price of $60.39 per unit, the price of a concurrent financing. At the time of the conversion, the outstanding balance due under this note was $406,562 which was converted into 6,733 shares of our common stock and a warrant to purchase 1,347 shares of our common stock for which we recorded a charge of $74,617. Upon conversion, the note was automatically cancelled.

On July 23, 2008, we issued an 8% promissory note payable to Paramount BioSciences and on April 24, 2008, we issued an 8% promissory note payable to Capretti Grandi, LLC, an entity affiliated with Lindsay A. Rosenwald. Other than the maturity date, these notes have identical terms. All amounts outstanding under these notes originally were to mature and be payable on September 10, 2010 and April 24, 2012, respectively. Pursuant to an amendment dated December 21, 2009, all unpaid principal and accrued interest on these loans shall immediately and automatically be converted into the same equity or derivative securities as are issued in any equity financing consummated by us on or after September 30, 2009 of at least $8,853,976. As of September 30, 2010 and December 31, 2009, the principal amount outstanding under these notes is $1,001,153 and $2,025,591, respectively.

During 2009, we issued four separate 10% promissory notes (collectively, the "PCP Notes") to Paramount Credit Partners, LLC, an entity whose managing member is Lindsay A. Rosenwald. Specifically, the PCP Notes consist of a note in the principal amount of $1,100,000 issued on January 23, 2009, a note in the principal amount of $100,000 issued on March 25, 2009, a note in the principal amount of $250,000 issued on June 1, 2009 and a note in the principal amount of $123,000 issued on June 24, 2009. Interest on the PCP Notes is payable quarterly, in arrears, and the principal matures on the earlier of (i) December 31, 2013 or (ii) the completion by us of a transaction, including an equity offering after this initial public offering, sale of assets, licensing or strategic partnership, in which we raise at least $5,000,000 in gross cash proceeds. In addition, Paramount Credit Partners received five-year warrants ("PCP Warrants") to purchase, at an exercise price of 110% of the lowest price paid for securities in a Qualified Financing (as defined below), a

number of shares of our common stock equal to 40% of the principal amount of each PCP Note purchased divided by the lowest price paid for securities in a Qualified Financing prior to the two-year anniversary of such PCP Note. If the Qualified Financing does not occur on or before the two-year anniversary of a PCP Note, then the associated PCP Warrants will be exercisable for a number of shares of our common stock equal to 40% of the principal amount of such PCP Note purchased divided by $12.40, at a per share exercise price of $12.40. As of September 30, 2010 and December 31, 2009, the principal amount outstanding under these notes is $1,573,000. The PCP Notes are not convertible. We intend to pay the PCP Notes when due with the proceeds from a future financing.

We have paid interest owed to Paramount Credit Partners for the first and second quarters of 2010 and the first quarter of 2009. For the second, third and fourth quarters of 2009, we had insufficient funds to pay the quarterly interest amount owed to Paramount Credit Partners. Interest amounts for these three quarterly periods were paid directly by Lindsay A. Rosenwald to Paramount Credit Partners, pursuant to certain guarantee obligations owed by Dr. Rosenwald under Paramount Credit Partners' operating agreement.

2007 Senior Convertible Notes

During 2007 and 2008, we issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $5,305,000 (the "Bridge Notes"). The Bridge Notes were originally scheduled to mature on December 20, 2008, but we exercised our option to extend the maturity date to December 20, 2009, at an increased interest rate of 10%. We subsequently solicited the consent of the noteholders to an additional extension of the maturity date of the Bridge Notes to September 10, 2010, and in September 2010, obtained the consent for an additional extension of the maturity date to December 31, 2010. The Bridge Notes, plus all accrued interest thereon, will automatically convert into the same securities issued in our next Qualified Financing (as defined below), at a conversion price equal to 70% of the lowest per unit price paid for such securities in cash by investors in such Qualified Financing, and upon such other terms, conditions and agreements as may be applicable in such Qualified Financing. The Bridge Notes will also automatically convert into equity securities of ours immediately prior to a sale or merger of our company, as defined in the Bridge Notes. In the event that the Bridge Notes become due and payable (whether on the due date or earlier) prior to the consummation by us of a Qualified Financing, or a sale or merger of our company which converts the Bridge Notes into equity securities of our company, then, in connection with the repayment of the Bridge Notes, in addition to the payment of the unpaid principal amount and all accrued but unpaid interest on the Bridge Notes, we will be obligated to pay to the Noteholders, as a repayment premium, an amount in cash equal to 42.8571% of the aggregate principal amount plus all accrued and unpaid interest on the Bridge Notes. For purposes of the Bridge Notes, "Qualified Financing" means the sale of our equity securities in an equity financing or series of related equity financings in which we receive (minus the amount of aggregate gross cash proceeds to us from our arm's length sale of equity or debt securities, or incurrence of new loans, after December 21, 2009) aggregate gross proceeds of at least $10,000,000 (before brokers' fees or other transaction related expenses, and excluding any such proceeds resulting from any conversion of the Bridge Notes).

In connection with the offering of the Bridge Notes, Paramount BioCapital and third party agents received warrants (the "Placement Warrants") to purchase, at an exercise price of 110% of the lowest price paid for securities in a Qualified Financing, a number of shares of our common stock equal to 10% of the principal amount of the notes purchased, less any amount used to repay the related party notes, or amounts due to Paramount BioSciences or its affiliates or employees as finder's fees, payments under the consulting services agreement with Paramount Corporate Development LLC, an affiliate of Dr. Rosenwald or other similar payments, divided by the lowest price paid for securities in a Qualified Financing prior to December 21, 2009. If the Qualified Financing did not occur on or before December 21, 2009, the Placement Warrants will be exercisable for a number of shares of our common stock equal to 10% of the principal amount of the Notes purchased, less any amount used to repay the related party notes, or amounts due to Paramount BioSciences or its affiliates or employees as finder's fees, payments under the services agreement or other similar payments, divided by $12.40, at a per share exercise price of $12.40 and are exercisable for seven years. Since the Qualified Financing did not occur by such date, the Placement Warrants are now exercisable into 42,782 shares of our common stock, at a per share exercise price of $12.40.

2010 Senior Convertible Notes

In February, March, April and May 2010, we issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $3,425,000. These notes originally matured on September 10, 2010, but in September 2010, we obtained the consent of the noteholders to extend the maturity date to December 31, 2010. Upon the closing of a Qualified IPO (as defined below), the 2010 Notes plus any accrued but unpaid interest thereon will convert automatically into shares of our common stock at 70% of the price at which shares of common stock are sold in the Qualified IPO (the "IPO Price"), upon the terms and conditions on which such securities are issued in the Qualified IPO. For purposes hereof, "Qualified IPO" means the consummation of an initial public offering by us of units consisting of shares of common stock and warrants to purchase common stock resulting in aggregate gross cash proceeds (before commissions or other expenses) to us of at least $10,000,000. Each noteholder also holds a warrant to purchase a number of shares of our common stock equal to 50% of the principal amount of the notes purchased by it divided by the IPO Price at a per share exercise price equal to 110% of the IPO Price, subject to adjustment. Each of these warrants will expire and no longer be exercisable after February 26, 2015. Notwithstanding the foregoing, if a Qualified IPO does not occur on or before February 26, 2012, then each warrant will be exercisable for that number of shares of our common stock equal to 50% of the principal amount of the 2010 Note purchased by the original holder divided by $12.40, at a per share exercise price of $12.40. In the event of a sale of our company (whether by merger, consolidation, sale or transfer of our capital stock or assets or otherwise) prior to, but not in connection with, a Qualified IPO, the warrants shall continue to be exercisable pursuant to their terms.

On February 26, 2010, a note similar to those discussed above in the aggregate principal amount of $2,192,433 (which maturity date also was extended to December 31, 2010) and related warrant were issued to Paramount BioSciences for the cancellation of a portion of the debt outstanding under the 8% promissory note issued to Paramount BioSciences on July 23, 2008, which is not included in the $3,425,000 of aggregate principal amount of notes issued in the 2010 senior convertible note private placement. Including such converted debt, the total aggregate principal amount of 2010 senior convertible notes is $5,617,433.

Net Cash Used in Operating Activities

Net cash used in operations was $3,483,919 for the year ended December 31, 2009. The net loss for the year ended December 31, 2009 was higher than cash used in operating activities by $1,055,486. The primary reasons for the difference are adjustments for non-cash charges such as a $123,758 expense for warrants granted to consultants as compensation, amortization of deferred financing costs and debt discount of $116,952, an increase in interest payable of $737,389, stock issued in connection with license agreements and vendor of $30,000 and a net increase in operating assets and liabilities of $39,876. The increase in net operating liabilities resulted from a decrease of prepaid research and development and other assets of $802,649 and a decrease in accounts payable and accrued expenses of $762,773.

Net cash used in operations was $4,147,204 for the year ended December 31, 2008. The net loss for the year ended December 31, 2008 is higher than cash used in operating activities by $4,639,226. The primary reasons for the difference are adjustments for non-cash charges such as a $460,822 expense for warrants granted to consultants as compensation, a $340,860 expense for warrants issued in connection with a conversion of notes into equity, amortization of deferred financing costs and debt discount of $692,907, an increase in interest payable of $461,446, and an increase in changes in net operating liabilities of $2,577,921. The increase in net operating liabilities resulted from an increase in accounts payable and accrued expenses of $3,375,368 and an increase of prepaid research and development and other assets of $797,447. Prepaid research and development asset of $800,000 recorded in 2008 was for the payment to S.L.A. Pharma for Phase III clinical testing.

Net cash used in operations was $3,996,026 for the nine-month period ended September 30, 2010. The net loss for the nine-month period ended September 30, 2010 was higher than cash used in operating activities by $1,928,355. The primary reasons for the difference are adjustments for non-cash charges consisting primarily of $944,274 expense for warrants issued in connection with related party note conversion into equity, amortization of deferred financing costs and debt discount of $2,307,284, an increase in interest payable of $837,376, a decrease in stock-based compensation of $82,446 and a decrease in net operating

liabilities of $2,081,835. The decrease in net operating liabilities resulted primarily from a decrease of accounts payable and accrued expenses of $2,080,328.

Net cash used in operations was $2,259,884 for the nine-month period ended September 30, 2009. The net loss for the nine-month period ended September 30, 2009 was higher than cash used in operating activities by $663,213. The primary reasons for the difference are a reversal of prepaid research and development expense of $800,000, adjustments for non-cash charges consisting primarily of a $92,597 expense for warrants granted to consultants as compensation, amortization of deferred financing costs and debt discount of $88,180, an increase in interest payable of $523,144, and a net decrease in operating assets and liabilities of $44,411. The decrease in net operating liabilities resulted from a decrease in accounts payable and accrued expenses of $845,549.

Net Cash Used in Investing Activities

No significant cash was used in investing activities for the years ended December 31, 2009 and 2008 or the nine months ended September 30, 2010 and 2009.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $3,551,929 for the year ended December 31, 2009. Net cash provided by financing activities consisted primarily of proceeds from notes of $3,478,390, which were offset by cash paid for financing costs of $76,461, and proceeds from a line of credit of $150,000. Net cash provided by financing activities was $2,498,171 for the year ended December 31, 2008. Net cash provided by financing activities consisted primarily of notes through which we received gross proceeds of $4,141,024, which were offset by cash paid for financing costs of $312,853, and proceeds from a line of credit of $170,000. The cash provided by financing activities was also reduced by repayment of loans to related parties of $1,500,000.

Net cash provided by financing activities was $4,185,813 for the nine-month period ended September 30, 2010. Net cash provided by financing activities consisted primarily of proceeds from notes of $3,425,000, proceeds from notes payable to related parties of $950,562 and a term note issued to Israel Discount Bank for $800,000, which were offset by cash paid for financing costs of $989,749. Net cash provided by financing activities was $2,371,540 for the nine months ended September 30, 2009. Net cash provided by financing activities consisted primarily of proceeds from PCP notes through which we received $1,573,000, proceeds from related party notes of $690,000, and proceeds from a line of credit of $150,000, which were offset by cash paid for financing costs of $41,460.

Funding Requirements

Given our capital position and the payment of $373,500 we had to make to S.L.A. Pharma on September 30, 2010, as well as our general operating costs, on September 23, 2010, we borrowed $800,000 from Israel Discount Bank of New York. We used $373,500 to pay the September 30, 2010 payment due S.L.A. Pharma, which we paid on September 29, 2010. We will use the remainder for general and administrative expense. The promissory note we issued to Israel Discount Bank to evidence the loan is guaranteed by Dr. Lindsay Rosenwald, our largest stockholder and the sole member of Paramount BioSciences LLC. The interest rate on the note is equal to the interest rate that Israel Discount bank will pay on the cash accounts at the Bank maintained by Dr. Rosenwald and pledged to secure the note, plus 1%. The note is due on September 22, 2011.

We expect to incur losses for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that our general and administrative expenses will also increase as we expand our finance and administrative staff, add infrastructure, and incur additional costs related to being a public company, including directors' and officers' insurance, investor relations programs, and increased professional fees. Our future capital requirements will depend on a number of factors, including the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates.

Our expected future expenditures related to product development are as follows:

- conduct a Phase III clinical trial of iferanserin (VEN 309) in the treatment of hemorrhoids, carcinogenicity testing and developing new intellectual property: $8,000,000;
- payment to S.L.A. Pharma of our licensing obligations for diltiazem cream (VEN 307) and development of an improved formulation for use in Phase III studies in the U.S. on completion of S.L.A. Pharma's European study, payment to S.L.A. Pharma of our licensing obligations for phenylephrine gel and preparation of a Phase II clinical trial: $4,200,000 (includes the repayment of the $800,000 note issued to Israel Discount Bank); and
- general and administrative expenses: $2,900,000.

We believe that the net proceeds from this offering, together with our existing cash, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through the third quarter of 2012. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, which would cause us to require additional capital earlier. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

We do not anticipate that we will generate product revenue for at least the next several years. In the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters and years.

We may need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. We do not currently have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable. We may seek to sell additional equity or debt securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations.

Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Material Weaknesses in Internal Control Over Financial Reporting

Our independent registered public accounting firm has identified material weaknesses in our financial reporting process with respect to lack of accounting expertise, segregation of duties and lack of independent review over financial reporting. Our independent registered public accounting firm also identified numerous errors in the accounting for routine transactions and non-routine, complex transactions, including with respect to the valuation of common stock and derivative securities, the recording of debt discount and related amortization for warrants issued in connection with debt financings and calculation of deferred tax assets. The material weaknesses identified with respect to lack of accounting expertise and segregation of duties relate to the policies and procedures that:

- pertain to the procedures to ensure that information required to be disclosed is properly gathered and reported;
- pertain to the maintenance of records that accurately and fairly reflect our transactions and dispositions of our assets;

- provide reasonable assurance that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- 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 financial statements.

We intend to take the following measures to address the material weaknesses identified by our independent registered public accounting firm during the audit and improve our periodic financial statement reporting process:

- hire a permanent Chief Financial Officer (our current Chief Financial Officer is serving part-time pursuant to a six-month consulting agreement) to strengthen our internal staffing and technical expertise in financial accounting and reporting;
- limit access to the accounting and information systems and related data to strengthen segregation of duties;
- upgrade our accounting software system; and
- implement procedures and controls in the financial statement close process to improve the accuracy and timeliness of the preparation of quarterly and annual financial statements.

There can be no assurance that we will be able to successfully implement our plans to remediate the material weaknesses in our financial reporting process. Our failure to successfully implement our plans to remediate these material weaknesses could cause us to fail to meet our reporting obligations, to produce timely and reliable financial information, and to effectively prevent fraud.

BUSINESS

Overview

We are a development stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders for which there are no approved prescription drugs in the U.S., specifically hemorrhoids, anal fissures and fecal incontinence. We are not aware of any FDA approved prescription treatments for these conditions, yet there are approximately 12.5 million Americans suffering from hemorrhoids, 7 million from fecal incontinence and over 4 million from anal fissures. Our lead product, Inferanserin (VEN 309) is a NCE for the topical treatment of hemorrhoids. In multiple clinical studies in 359 patients, VEN 309 demonstrated good tolerability and no severe adverse events, and statistically significant improvements in bleeding, itchiness and pain. We have filed a SPA with the FDA to allow us to begin the first of two Phase III clinical trials for VEN 309.

Our additional product candidate portfolio consists of two in-licensed late-stage drugs intended to treatanal fissures (VEN 307) and fecal incontinence (VEN 308). These candidates are two molecules that were previously approved and marketed for other indications and that have been formulated into our proprietary topical treatments for these new gastrointestinal indications. In August 2007, we had a pre-IND meeting with the FDA concerning VEN 307 (diltiazem cream for the treatment of pain from anal fissures) where it was established that next clinical studies needed for approval were two pivotal Phase III trials, preceded (if conducted in the U.S.) by three short-term dermal toxicology studies. In June 2007, we had a pre-IND meeting with the FDA concerning VEN 308 (phenylephrine gel for the treatment of fecal incontinence associated with ileal pouch anal anastomosis) where it was established that the next clinical study in the program should be a Phase II(b) study where multiple doses will be assessed and that existing toxicology data are sufficient to support this study. We have not had further meetings with the FDA on either VEN 307 or VEN 308 since the meetings in 2007. The development of the three products, VEN 307, VEN 308 and VEN 309, was delayed subsequent to the FDA meetings due to a lack of financial resources. We intend to use the proceeds from this offering to advance VEN 309 and VEN 307 through the next stage of development.

Major pharmaceutical progress has been made in the gastrointestinal therapeutic areas of gastroesophageal reflux, peptic ulcer disease and inflammatory bowel disease. However, many major gastrointestinal disorders still lack medical treatments. Ventrus is pursuing treatments for three of the ten most prevalent gastrointestinal disorders in the U.S. We estimate that the patient population of these three disorders exceeds 25 million adults in the U.S., based on the data we cite for each indication in this prospectus.

Our Products and Development Strategy

Our three late-stage product candidates are:

Iferanserin ointment (VEN 309) for the topical treatment of hemorrhoids. Hemorrhoids, which are characterized by the inflammation and swelling of veins around the anus or lower rectum, can cause bleeding, itching, pain and difficulty defecating. Iferanserin (VEN 309), a NCE formulated as an ointment for intra-anal application, has highly selective, antagonistic activity against peripheral 5-$HT_{2\ A}$ receptors involved in clotting and the contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. By limiting 5-$HT_{2\ A}$ receptor activity, VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain. As reported by the National Institute of Diabetes and Digestive Kidney Diseases, hemorrhoids affect approximately 12.5 million adults in the U.S. Despite such a high prevalence, we are not aware of any FDA-approved prescription or OTC drugs for the treatment of hemorrhoids in the U.S. While there are commonly used prescription and OTC products for hemorrhoids in the U.S., such as Anusol, Preparation H and some herbal preparations, none has been approved by the FDA because they entered the market prior to 1962. The great majority of these treatments provide only temporary relief from the symptoms of hemorrhoids and do not address the cause of hemorrhoids. These treatments' mechanism of action is either general, such as steroids, or unknown, in the case of herbal remedies, and we are not aware of any reports published in medical journals on the efficacy or safety of any product currently marketed in the U.S. for the treatment of hemorrhoids. We believe VEN 309 to be more effective than the currently available conventional

hemorrhoid topical therapies and more attractive than surgical procedures, which are the only other currently validated treatment options.

We have licensed Iferanserin ointment (VEN 309) from Sam Amer & Co., Inc., or Amer, who had developed VEN 309 through Phase II studies and up to readiness for Phase III studies in the U.S. and Europe. Our license includes rights to all existing intellectual property and any further improvements on VEN 309 owned by Amer for the topical treatment of anorectal disorders.

Diltiazem cream (VEN 307), a topical treatment for the relief of pain associated with anal fissures. Anal fissures, or small tears or cuts in the skin that lines the anus. They can be extremely painful, cause bleeding and often require surgery, which itself can have unsatisfactory outcomes. At present, we are not aware of any FDA-approved drugs for the treatment of anal fissures. Diltiazem cream, however, is currently used as the preferred treatment by many gastroenterologists across the U.S. in a version that must be specially mixed for each patient in the pharmacy. Topical nitroglycerine has also been used in this way but has a higher rate of side effects than topical diltiazem, notably headaches. Custom-mixed diltiazem, however, is not an FDA-approved use nor is the cost reimbursed by Medicare or health insurance plans. When applied topically for the treatment of anal fissures, diltiazem, which has been used for decades for hypertension and angina, dilates the blood vessels supplying the region, reduces anal sphincter tone, and thereby substantially decreases pain. In the majority of multiple clinical trials conducted against placebo or topical nitroglycerine conducted between 1999 and 2002 by various researchers, diltiazem cream significantly reduced the pain associated with anal fissures. Our product VEN 307 is a proprietary formulation of diltiazem that when applied topically is only minimally absorbed, at one-tenth the amount of the lowest dose used for cardiovascular treatment. We believe this low absorption improves VEN 307's safety profile and lowers the risk of side effects. We expect to capture immediate market share if VEN 307 is approved due to its known efficacy among gastroenterologists, its ease of prescription as a pre-formulated FDA-approved product with no need for custom mixing necessary at the pharmacy, and the ability for patients to be reimbursed through their health plan or Medicare.

We have licensed the exclusive North American rights to VEN 307 for the topical treatment of anal fissures from S.L.A. Pharma who has completed early-stage clinical trials, toxicology studies and manufacturing for VEN 307 up to the end of Phase II.

Phenylephrine gel (VEN 308) for the treatment of fecal incontinence associated with ileal pouch anal anastomosis, an FDA orphan indication. Ileal pouch anal anastomosis, or IPAA, is a surgical procedure used as part of a colectomy, which is a treatment for patients with ulcerative colitis. Fecal incontinence resulting from dysfunctional sphincter tone is a common consequence of this procedure. According to a U.S. community based epidemiology study (Nelson et al., JAMA, 1995), 2.2% of U.S. adults suffer from fecal incontinence, which we estimate to be approximately 7 million people, based on 2009 Census Bureau adult population estimates. Currently, there are few options available to treat this problem, consisting of bulk laxatives, fiber diets, Imodium, which is a treatment for diarrhea, and invasive surgical procedures. In addition, Oceana Therapeutics is developing Solesta™, an injectable inert bulking agent product approved in the European Union for the treatment of fecal incontinence in adult patients who have failed conservative therapy. Solesta is injected submucosally around the anal sphincter and consequently has to be administered in an outpatient setting by qualified physicians. Oceana Therapeutics is currently pursuing approval of Solesta by the FDA. Also, Norgine plans to conduct a Phase I trial with NRL001, a suppository formulation of an alpha adrenergic stimulating agent for the treatment of fecal incontinence, which is anticipated to start in Europe in early 2011. We are not aware of any FDA-approved drugs for fecal incontinence. In multiple clinical trials with patients suffering from IPAA-associated fecal incontinence, topical phenylephrine significantly (and in some patients, dramatically) improved patient bowel control. In clinical trials with other forms of incontinence, improvements were also observed following application of topical phenylephrine, depending on the cause of the incontinence. Our product VEN 308 is a gel formulation of phenylephrine. Applied topically, VEN 308 increases anal sphincter tone, thereby improving fecal incontinence in patients where sphincter tone is the major cause of their symptoms, such as post-IPAA surgery. We believe VEN 308 has significant

advantages over the limited treatment options currently available for fecal incontinence associated with IPAA including, but not limited to, increased efficacy and/or reduced invasiveness.

We have licensed the exclusive North American rights to VEN 308 from S.L.A. Pharma who developed the specific formulation of phenylephrine for the topical use in fecal incontinence and developed the manufacturing method. S.L.A. Pharma's previous partner, Solvay, conducted important pharmacokinetic studies.

Our Development Efforts

We do not own and did not develop any of our product candidates. We have licensed our three product candidates from third parties. All clinical trials to date have been conducted either by the licensor, the licensor's previous partners or by independent investigators, as have the preclinical studies and product formulation activities. Since the time we licensed these products, we have focused our efforts on establishing and clarifying the regulatory pathway for late phase clinical trials and regulatory approval, and on establishing the contract manufacturing capacity and methods necessary to allow late phase clinical trials to proceed, all of which will be conducted by contracted third parties under our direction. These development efforts have not required many employees and we have historically operated with only a handful of employees with the scientific expertise necessary to progress our product candidates down the development path outlined above. This has helped us contain our operating costs. As a result, however, we are dependent on the availability and competency of these third parties for the continued development of our product candidates.

Our Management

Although incorporated in 2005, we began active operations in the spring of 2007 upon the licensing of VEN 307 and VEN 308 by Paramount BioSciences from S.L.A. Pharma. Shortly thereafter, we hired Thomas Rowland as our chief executive officer (who was then and remains one of our directors), Dr. Terrance Coyne as our chief medical officer, and Dr. John Dietrich as our vice president of clinical operations, as well as other employees. Due to our lack of capital, Drs. Coyne and Dietrich resigned in February 2009. Mr. Rowland resigned as our chief executive officer in February 2009, but he continued to act as our president from the date of his resignation in February 2009 until May 2010. Simultaneously with the resignation of Dr. Dietrich, we entered into a consulting agreement with him whereby he provides consultation on manufacturing, preclinical and clinical aspects of our drug programs on an as-needed basis. These arrangements with Mr. Rowland and Dr. Dietrich allowed us to continue minimal operations following their resignations until June 2010. Between February 2009 and June 2010, our only business activities consisted of maintaining our licenses with S.L.A. Pharma and Amer and financing and business development activities.

Upon the successful completion of our convertible promissory note offering in May 2010, our Board of Directors determined to proceed with this offering to raise capital to finance the partial development of VEN 309 and VEN 307. To conserve our resources, and recognizing that permanent employment would be dependent on our raising capital in this offering, in June 2010, we entered into consulting agreements with Dr. Russell Ellison, our Chief Executive Officer and Chief Medical Officer, and David Barrett, our Chief Financial Officer. Since June 2010, our only business activities have consisted of maintaining our licenses with S.L.A. Pharma and Amer and activities connected with this offering.

We also have entered into employment agreements with Dr. Ellison and Mr. Barrett that will automatically become effective on the closing of this offering. Assuming the successful completion of this offering, we expect to retain Dr. Dietrich as our Vice President of Clinical Operations pursuant to either a consulting or an employment agreement, and we also plan to add a clinician, two clinical project managers, a business development and marketing professional and an executive assistant, some or all of whom may work on a contract or permanent employment basis.

IFERANSERIN OINTMENT (VEN 309)

Background on hemorrhoids

Incidence and prevalence

Hemorrhoids are a common anal disorder, characterized by bleeding, itching, pain, swelling, tenderness and difficulty defecating. Based on information from an article entitled The Prevalence of Hemorrhoids and Chronic Constipation by J. Johanson and A. Sonnenberg published in Gastroenterology (1990; 98: 380-386),

the prevalence of hemorrhoids in the U.S. adult population is approximately 5.7%, representing approximately 12.5 million cases based on 2009 population data published by the U.S. Census Bureau. The prevalence of hemorrhoids peaks in adults aged 45 to 65 years.

Patho-physiology of hemorrhoids

Hemorrhoids are symptomatic abnormalities of normal vascular structures in the anal canal that are manifested by dilation of the local arteries and veins due to constriction and partial obstruction of the exiting colonic veins. Although the exact mechanism for hemorrhoid formation is not clear, the progressive occlusion of venous exit vessels (e.g., as seen in straining during defecation, heavy lifting and pregnancy) is thought to produce stretching of the vessels in the hemorrhoidal plexus combined with vascular stasis. This stasis causes platelet clumping with the release of the platelet's artery and vein constricting contents: platelet-releasing factor and serotonin, resulting in localized constriction of the exit arteries and veins, where most of the vascular smooth muscles are, and a cascade effect producing clot formation. These events result in additional stasis of the blood, perpetuating and further worsening the situation. As hemorrhoids worsen, the trapped blood forms piles (protruding skin folds filled with static and thrombosed blood), initially above the pectinate line (internal hemorrhoids) and then below the pectinate line (external hemorrhoids).

The classification of internal hemorrhoid grades by Banov is accepted by most specialists. This system consists of four grades and symptoms: first degree (grade I): hemorrhoids bleed but do not protrude; second degree (grade II): hemorrhoids protrude but reduce on their own; third degree (grade III): hemorrhoids protrude and require manual re-insertion; and fourth degree (grade IV): hemorrhoids protrude and cannot be manually re-inserted.

The cardinal symptom and most common manifestation of internal hemorrhoids is bleeding. Bleeding is often the only sign in grade I hemorrhoids, but it can also be accompanied by other symptoms as the hemorrhoids further enlarge, such as discomfort, itching, prolapse, and fecal soilage.

Current treatments

Despite the high prevalence of hemorrhoids, we are not aware of any FDA-approved prescription drugs for the treatment of hemorrhoids in the U.S. While there are commonly used prescription and over the counter, or OTC, products for hemorrhoids in the U.S., such as Anusol, Preparation H and some herbal preparations, none has been approved by the FDA because they entered the market prior to 1962. The great majority of these treatments provide only temporary relief from the symptoms of hemorrhoids and do not address the cause of hemorrhoids. These treatments' mechanism of action is either general, such as steroids, or unknown, in the case of herbal remedies, and we are not aware of any reports published in medical journals on the efficacy of safety of any product currently marketed in the U.S. By contrast, our product, iferanserin ointment (VEN 309), has highly selective, antagonistic activity against peripheral 5-$HT_{2\ A}$ receptors ($5HT_{2\ A} > 5HT_{2C} >> 5HT_{2B}$) involved in clotting and the contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. By limiting 5-$HT_{2\ A}$ receptor activity, VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain. We believe that the potential for side effects is likely to be limited because iferanserin is topically applied and iferanserin does not enter the brain to affect $5HT_2$ CNS receptors, at the exposures seen with topical application. In multiple clinical trials, iferanserin ointment significantly reduced bleeding, pain and itchiness compared to placebo with minimal adverse effects. As a result, we believe VEN 309 to be more effective and/or less invasive than the currently available conventional hemorrhoid topical therapies and more attractive than surgical procedures, which are the only other currently validated treatment options.

Patients with persistent symptoms, especially bleeding, usually require an invasive procedure. The most common is rubber band ligation, which involves banding the internal hemorrhoid for four to seven days. Other procedures are the injection of a sclerosing agent, electrocoagulation, light therapy and hemorrhoidectomy.

Most physicians treating hemorrhoids start with conservative therapy consisting of diet modification, fiber, sitz baths and stool softeners. In addition to this conservative therapy, physicians might prescribe topical steroids. The only other alternatives are invasive procedures and/or surgery. Because of the lack of effective prescription products, most hemorrhoid patients will use over-the-counter preparations or the prescription drugs available, which are similar to the over-the-counter treatment, but formulated with a higher dose of topical steroid. According to IMS Health (2006), 4.0 million prescriptions are written per year in the U.S. for

unapproved hemorrhoid prescription products and 22 million units per year are sold in the U.S. for the unapproved OTC hemorrhoid products. If VEN 309 receives FDA approval in the U.S., we expect our competition for patient use and physician prescribing will be these drugs which have not been approved by the FDA and lack any medical study dated supporting their efficacy and safety.

In Europe it appears that, from our discussions with experts and staff from other companies, many products exist, differently from country to country, and are mostly herbal extracts and mixtures in topical and systemic forms which are either prescribed or available over-the-counter. We do not have market data concerning these products in Europe, other than product acceptance market research, nor is their precise regulatory status clear to us.

INFERANSERIN OINTMENT (VEN 309) DEVELOPMENT

Background on Iferanserin

The early proof of concept for the utilization of a 5-$HT_{2\ A}$ antagonist for the treatment of hemorrhoid was developed by Sam Amer PhD, a former director of research and development at Bristol Myer. Dr. Amer explored the potential application of serotonin drugs, which would not enter the brain at therapeutic concentrations, for use in various venous conditions. After successful pre-clinical and clinical experiments, Dr. Amer filed a method of use patent covering this molecule in 1992. Dr. Amer subsequently separated the s-isomer from this racemic mixture and filed new composition of matter patents for the s-isomer in 1998. Also in 1998, the early stage product was licensed to Tsumura, a Japanese company. Tsumura conducted over 350 pre-clinical and six clinical studies, but was not able to continue development due to financial difficulty and returned the product to Dr. Amer. Upon the return, Dr. Amer's company, Sam Amer & Co., Inc., or Amer, conducted a double-blind, placebo controlled, multi-center confirmatory non-pivotal phase III study in Europe. After the successful completion of that study in 2003, Novartis Pharmaceuticals licensed iferanserin from Amer to be part of its gastroenterology portfolio strategy. Novartis improved the iferanserin manufacturing processes and completed important toxicology and metabolite studies. In 2005, Novartis' lead gastroenterology product, Zelnorm® was experiencing increased FDA scrutiny on the safety of that product, which would ultimately lead to its eventual withdrawal from the market. We believe that with the impending loss of their lead gastroenterology product, Novartis decided to dissolve the gastrointestinal franchise. In 2005, Novartis returned iferanserin to Amer. According to Amer, no safety or clinical issues were ever communicated as reasons for the return.

On February 5, 2008, in conjunction with Amer, we held an End of Phase II meeting with the FDA, to confirm the U.S. regulatory status and pathway to a NDA for iferanserin ointment where it was agreed that the product may enter late-stage Phase III development. In March 2008, we licensed exclusive worldwide rights to develop and market iferanserin ointment for the treatment of anorectal disorders from Amer.

Mechanism of action on iferanserin

Iferanserin has selective antagonistic activity against 5-HT_2 receptors, especially against those involved in contraction of vascular smooth muscle and platelet aggregation (clotting), the $5HT_{2A}$ receptors. It is a particularly potent high-affinity antagonist of $5HT_{2A}$, has less affinity for and is a moderate antagonist of $5HT_{2C}$ and has considerably less affinity for $5HT_{2B}$ receptors. In a specific valid model, iferanserin did not demonstrate any agonism activity at $5HT_{2B}$ receptors, but did demonstrate moderate antagonistic activity. Unlike other $5HT_2$ receptor antagonists, iferanserin's $5HT_2$ receptor antagonism, clinically, is entirely peripheral, meaning it occurs outside the central nervous system because iferanserin does not cross the blood-brain barrier except in extremely high exposures far above those seen with topical application.

Studies conducted in 1997 and 1998 by Amer in rats addressed the potential effects of iferanserin on impaired rectal mucosal blood flow and increased peripheral vascular resistance after administration of serotonin or thrombin. At doses of 3 mg/kg and above administered intrarectally, iferanserin improved rectal mucosal blood flow and normalized the peripheral vascular resistance. Iferanserin had minimal effects on arterial blood pressure.

Preclinical safety

Iferanserin has been extensively tested in multiple preclinical models. The iferanserin exposure from dosing in humans topically using 0.5% applied twice daily (the dose to be used in our planned studies) ranges

from 1/17th to 1/88th of the exposure that produces toxicity and from 1/45th to 1/85th of the exposure that produces cardiovascular effects in animal toxicology studies and 1/60th – 1/100th of the exposure that produces these effects in vitro.

Clinical trials and patent status

A total of seven clinical trials with iferanserin have been completed by Amer (excluding Japan) and Tsumura in Japan between 1993 and 2003. One Phase 1 study and one Phase II study were completed using the racemic mixture of iferanserin. After the successful Phase II proof-of-principle study, the licensor, Amer, separated the R- and S-isomers (the two active components of most small molecule pharmaceuticals), determined that the primary activity was focused in the S-isomer and filed a patent claiming this isomer. The patent issued in the U.S. and other countries and expires in 2015. In the U.S., the patent was filed with Dr. Amer as the inventor and in all foreign countries with Amer as the assignee.

After the development of the S-isomer in the mid 1990s and the patent filing in 1998, the remaining studies — two Phase I studies, two Phase II studies, and one Phase III study — were all conducted with the S-isomer product. This development progression (racemic to S-isomer) is a common pharmaceutical practice, enabling companies to use the purest form of the molecule in late-stage clinical trials.

Our license agreement with Amer includes the rights to all intellectual property owned by or assigned to Amer as well as to any new improvements owned by or assigned to Amer. Different concentrations of a drug are separately patentable. Because of unexpected differences between concentrations of the product that were were observed in the clinical program (i.e. that 0.5% concentration is superior to a 0.25% and a higher 1.0% concentration in the comprehensive reduction in hemorrhoid symptoms), which data has not been previously published, we filed in August 2010 a patent claiming our specific concentration range (among other claims) which, we believe, if issued, will block generic substitution for 20 additional years. Dr. Amer is the inventor in this U.S. application and the assignee in the patent application. However the original S isomer patent could be challenged by a third party and invalidated, and the concentration patent may never issue and even if issued could be challenged by a third party, in which case we would have five years of U.S. market exclusivity under the Hatch-Waxman Act.

An investigator IND for iferanserin was filed with the FDA in November 1991 and transferred to Amer as the sponsor in January 1994 and remains open.

Trial Results

Overall safety

In the seven clinical studies of iferanserin conducted by Amer and Tsumura in 359 individuals, of whom 220 were exposed to iferanserin, the adverse effects, at least possibly related to the iferanserin administration, were mostly gastrointestinal (diarrhea, lower abdominal discomfort, residual stools, and anal irritation). These events were considered mild by the investigators and required no medical treatment. There were no serious adverse events judged by the investigator as related to iferanserin and no mortality in these studies. There was one report of exacerbation of atopic dermatitis requiring observation in hospital with an uncertain relationship to iferanserin.

Clinical Pharmacology in Normal Volunteers (Phase I)

Two clinical pharmacology studies were conducted in Japan by Tsumura in 1998 and 1999 in 18 healthy volunteers exposed to a single dose and in six healthy volunteers exposed to six days of dosing with the 1% preparation. Three mild adverse events where the drug could not be ruled out were observed in three patients in the single dose group and four mild adverse events were observed in three patients in the multi-dose group. There is no accumulation of the drug on twice daily dosing and the half life at one and six days is 1.6 hours. Peak concentrations are similar at one and six days and well below the lowest exposure where toxicity was observed in toxicology experiments in animals.

One patient was identified as having a very compromised activity of an enzyme, CYP2D6, and the maximum concentration of the drug in this patient was three times the maximum observed in the other patients and the total exposure (AUC) was 17 times that observed in the other patients. However, these exposures to the drug were still well below the lowest exposures where toxicity was observed in animal toxicology experiments, and this patient did not experience any adverse events.

As is typical of several modern drugs for depression such as Fluoxetine and older drugs such as tri-cyclic anti-depression agents and other drugs extensively prescribed, iferanserin is an inhibitor of the enzyme CYP2D6 and is at least partially dependant on this enzyme for its metabolism. Therefore kinetic interactions with other drugs that are potent inhibitors of CYP2D6 and or are highly dependent on CYP2D6 for their metabolism are possible. There are several of these drugs and most are psychiatric medications, and one is tamoxifen. We will exclude patients from the clinical trials who are taking such drugs, and will be conducting extensive drug-drug interaction studies as part of our clinical pharmacology program to clarify which drugs could be affected by or could affect iferanserin. We intend to conduct these studies contingent on having sufficient resources after the completion of the first planned Phase III trial.

Proof-of-concept study (U.S.)

A double-blind, placebo-controlled study of 26 patients conducted by Amer that was completed in August 1992 and published in August 1994 was the first clinical trial to test the activity of the racemic mixture of iferanserin. Topical 1% iferanserin ointment was applied three times daily for five days to calculate the effect on bleeding and other symptoms in patients with grade I to III external hemorrhoids. Treatment produced statistically significant improvements in ease of defecation, throbbing, fullness, bleeding and tenderness. Itchiness and pain were also reduced following treatment. These positive treatment effects started immediately after treatment and were maintained throughout the study.

Early Phase II dose-ranging study (Japan)

Topical iferanserin ointment, in twice-a-day doses of 0.25%, 0.5%, and 1.0%, was provided to 72 patients for 14 days to treat symptomatic internal and mixed internal/external hemorrhoids. A total of 68 patients were evaluable for analysis: 23 patients in the 0.25% dose group, 24 patients in the 0.5% dose group, and 21 patients in the 1.0% dose group.

There was a significant change in ease of defecation between dose groups by day 7 but no other differences in improvements of symptoms among the three dose groups. Anal discomfort and pain persistence improved with increasing dose on a visual analog scale, or VAS, of pain. For the symptom of bleeding, a significant difference between dose levels ($P = 0.016$) and a paired comparison statistical analysis showed that the 0.5% dose was more effective than either the 0.25% dose or the 1.0% dose. By day 14, hemorrhoid swelling was reduced in the 0.5% dose group (41%) and the 1.0% dose group (43%). A review of patient diaries revealed that all symptoms started improvement on day 1, with improvement peaking at day 7 and being maintained to day 14. Comparison of all doses showed, unexpectedly, that the 0.5% dose provided the most consistent improvements.

There were 45 adverse events, but only five (11%) were judged as related to iferanserin ointment. These iferanserin-related adverse events were mostly mild diarrhea or lower abdominal discomfort, which required no medical treatment. Laboratory tests were generally normal, with the exception of one case of mild elevation of total bilirubin one month after trial completion, which required no therapy. Further evaluation of metabolites revealed no relationship to adverse events.

The unexpected and novel finding that 0.5% concentration is superior to both a lower (0.2%) and higher (1%) concentration supports our patent claiming a specific concentration range that we filed in August 2010, which, if issued will expire in 2030.

Late Phase II study (Japan)

A double-blind, placebo-controlled trial was conducted by Tsumura Company with three different concentrations of iferanserin ointment (0.25%, 0.5% and 1%) administered twice daily for four weeks for treatment of 104 patients with grade I to III internal hemorrhoids. The study was completed in July 2002 and published in February 2003. Inclusion criteria required a minimal degree of either bleeding or prolapse. The primary endpoint was physician-rated size reduction of the hemorrhoids; secondary endpoints included subjective symptoms as assessed by patient diaries and VAS.

By day 28, compared with placebo, the concentrations of 0.5% and 1% of iferanserin showed the most consistent improvements across groups for secondary symptoms, such as bleeding, pain severity and duration, and ease of defecation.

PhaseIIB/III study (E.U.)

Based on the results of the two Tsumura Phase II trials, a double-blind, randomized, placebo-controlled study was conducted by Amer to compare 0.5% iferanserin ointment with placebo when administered twice daily for 14 days for treatment of 121 patients with symptomatic grade I to III internal hemorrhoids. The disease specific inclusion criterion was diagnosis of grade I – III hemorrhoids with bleeding episodes of at least every other day during the last two weeks before enrollment in the study. Exclusion criteria included patients with protruding or irreducible hemorrhoids (grade IV), and patients with anal fistulas, periproctitis or hemorrhagic diathesis. Daily patient diaries for bleeding, itching and pain/discomfort were recorded for 14 days, and patient assessments were recorded at days 7 and 14 based on a 10-point scale. A physician evaluation for prolapse and size occurred at baseline and day 14.

Fifty-six patients, each in the active and placebo treatment groups, were evaluable for the primary endpoint, which was bleeding. Not all patients had each of the other symptoms, but sufficient numbers were available for statistical analyses to be performed for bleeding, pain, itching and dyschezia, which is extensive straining with stools.

Compared with placebo, iferanserin ointment significantly reduced bleeding ($P < 0.05$) by day 3, a reduction maintained to day 14 (**Figure 1**). Total cessation of bleeding occurred in 89% of the iferanserin-treated patients versus 68% of the placebo-treated patients. Compared with placebo, iferanserin ointment also significantly reduced itching ($P < 0.05$) by day 3. Total elimination of itching by day 14 was achieved in 90% of the iferanserin-treated patients versus 62% of the placebo-treated patients. Finally, compared with placebo, iferanserin ointment significantly reduced pain ($P < 0.05$) by day 3, effecting a total elimination of pain in 78% of patients versus 46% of patients in the placebo group. There were also no clinically significant adverse findings for either iferanserin or placebo.

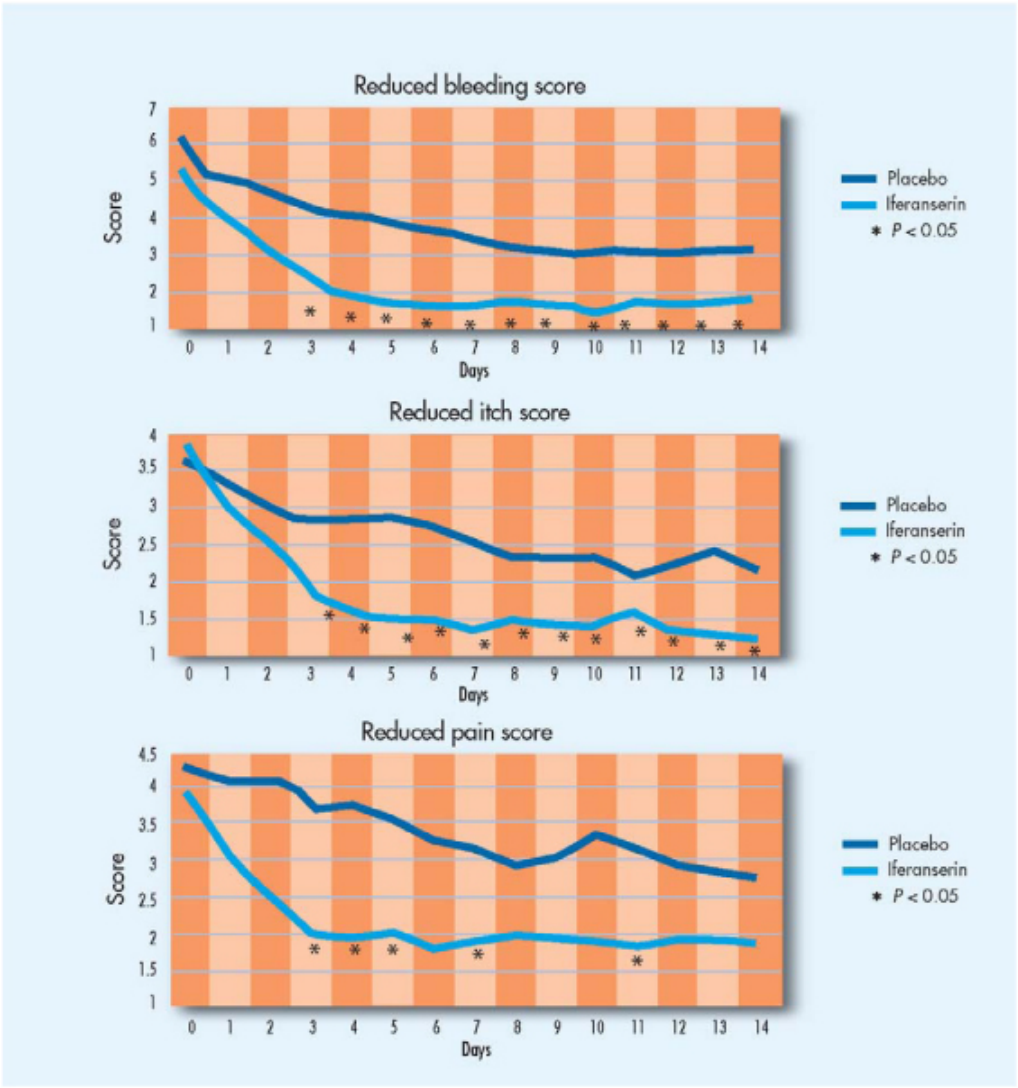

Figure 1. In a Phase III double-blind, randomized, placebo-controlled study of 121 patients with grades I to III internal hemorrhoids, iferanserin ointment significantly improved bleeding, itching, and pain.

After the end of Phase II meeting with the FDA and as part of the SPA review process, we commissioned a *post hoc* analysis of the study for the end point that the FDA agreed would be the primary efficacy endpoint for the pivotal trials. This endpoint is defined as time to cessation of bleeding that lasts for three days or more for which iferanserin 0.5% twice daily will be compared with placebo. In this analysis, the median time to cessation of bleeding in this 14 day study was 10.5 days in the placebo group and 4.5 days in the treatment group which was statistically significant ($P < 0.01$) (**Figure 2**).

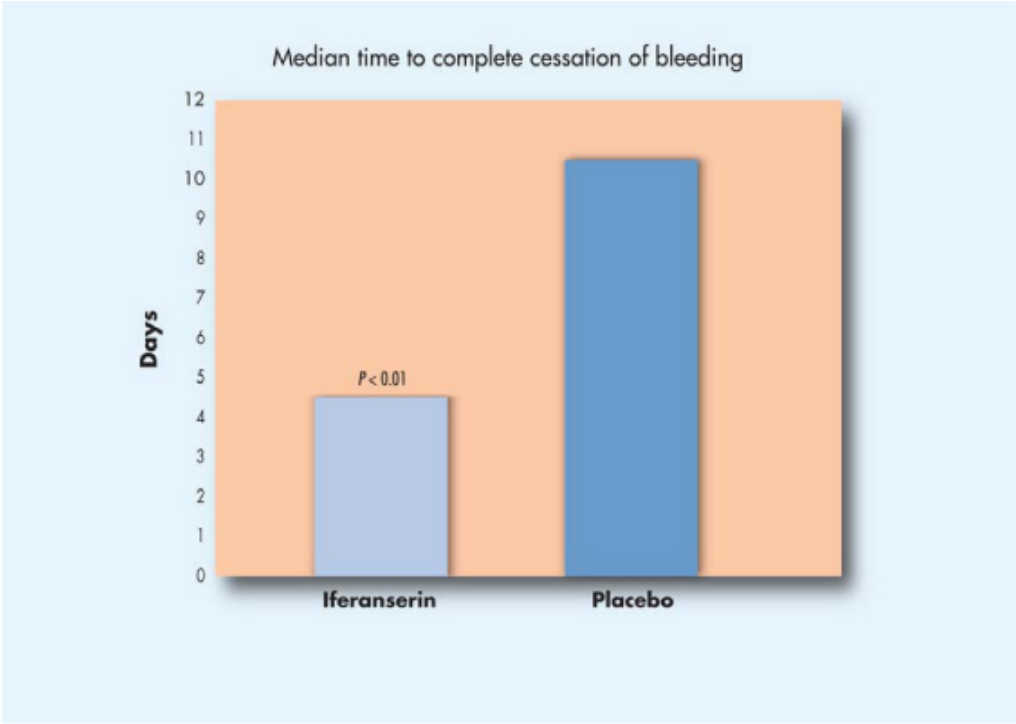

Figure 2. In a Phase III double-blind, randomized, placebo-controlled study of 121 patients with grades I to III internal hemorrhoids, the median time to complete cessation of bleeding was 4.5 days for iferanserin ointment versus 10.5 days for placebo (p 0.01).

In this Phase III double-blind, randomized, placebo-controlled study of 121 patients with grades I to III internal hemorrhoids, iferanserin provided rapid and sustained improvements of the main symptoms of this disorder: bleeding, itching and pain. Maximal improvements of symptoms occurred by day 7 and were maintained to day 14 at the end of the trial.

Iferanserin ointment (VEN 309) development plan

At the end-of Phase II meeting held in February 2008, the FDA advised us that, as is common for chronic or repeated use drugs, it would require for submission of the NDA:

- a total safety database of 1,500 patients exposed to iferanserin, a proportion of which need to be followed for repeat use for six months and 12 months (standard International Conference on Harmonization recommendation);
- included in this safety database, two placebo controlled studies would be required with the primary endpoint being time to cessation of bleeding for a minimum of three days;
- also included in the safety database a clinical pharmacology program consisting of a thorough QT study (standard for most drugs), drug-drug interaction studies, and pharmacology in special populations will be required; and
- as is usual for chronic or repeated use drugs, carcinogenicity studies in two species exposed for 104 weeks, preceded by dose ranging studies and 6 months toxicology in rats and 9 months in dogs.

As the carcinogenicity study (including the prior dose ranging study) will take up to 40 months to complete, we intend to conduct the Phase III studies sequentially as this will not delay the program, will conserve funds and allow adjustments (for example, increased sample size) to the second Phase III study to optimize its potential. We anticipate that we will initiate the first patient randomized into the first Phase III trial on or about the end of the second quarter of 2011, and that data will be available in the first quarter of 2012. We also intend to initiate the dose ranging part of the carcinogenicity studies in 2011, and, if the

underwriters exercise their overallotment option, which would provide us with approximately $2.6 million in additional gross proceeds, to initiate the carcinogenicity studies themselves in the second half of 2011.

We originally filed in June 2008 a special protocol assessment, or SPA, with the FDA to ensure their explicit agreement with our Phase III protocol for VEN 309. Due to lack of funds we could not follow up or complete the process but were able to resume with another filing in March 2010 and received comments in May 2010. We filed another submission in July 2010 which could not be processed because the FDA required us to reformulate the questions set forth in the filing. In August and September 2010, we had a series of emails and telephone calls with the FDA in which we believe that agreement has been reached on the precise definition of the endpoints and how to assess recurrence of hemorrhoids in the study and on October 28, 2010 we filed another submission reflecting these discussions. The FDA has 45 days to respond to this submission and we expect to complete the SPA process by the end of the first quarter of 2011. The SPA dialogue with the FDA concerns primarily the precise definition of the primary endpoint, how to assess itching and pain, and how to assess recurrence. As the SPA dialogue is not yet complete it is possible that any of the design elements given below may change.

We are proposing for the pivotal trial design:

- 400 patients randomized, double blind, to either placebo ointment or iferanserin 0.5%, both applied twice daily (to be conducted in 60 community sites in the U.S. and Canada);
- 14 days treatment with follow up at 28 days;
- Rolling over all patients to active treatment after 28 days double blind follow up visit, to be followed for 12 months, with retreatment for recurrence monitored;
- Inclusion criteria to include patients with symptomatic Grade I to III internal hemorrhoids, bleeding from hemorrhoids every day for the two days immediately preceding the day that they are randomized and study medication applied, with pain or itching accompanying the bleeding for the two days;
- Exclusion criteria to exclude patients with grade IV hemorrhoids; thrombosed internal or external hemorrhoids: laxatives, anticoagulants, over-the-counter anti-hemorrhoidal agents, topical steroids, suppositories of any kind, non-steroidal anti-inflammatory drugs (NSAIDs), Cox-2 inhibitors, and other drugs and conditions including potent inhibitors of CYP2D6 such as fluoxitene; and
- The primary endpoint will be time to cessation of bleeding for a minimum of 3 days and secondary endpoints will be cessation of pain and cessation of itching for three days.

After the results of the Phase III study are available, and if we raise additional capital, we intend to continue the carcinogenicity study, conduct the 6 and 9 month chronic toxicology studies and launch either an identical Phase III trial and a safety study, or a larger Phase III trial to provide adequate numbers of patients exposed, and to complete the clinical pharmacology program which, will include extensive drug-drug interaction studies to clarify the CYP2D6 interactions and a “thorough QT study” to test the arrythmogenic potential, which studies are routinely required by the FDA. We will also explore at that time the feasibility of lifecycle options for follow-on products such as combinations with steroids and other agents or different formulations such as suppositories, which could be developed for launch after approval of the original VEN 309 product.

We expect that the earliest we will be able to file a NDA with the FDA will be mid 2014, and the earliest the product could be approved in the U.S. would be in 2015. However, the Phase III trial may not meet the primary endpoint, or unexpected safety problems could arise, or even if the study is successful we may not be able to obtain more capital for other reasons, in which case we may not be able to complete the development of the product and we may not be able to effect the payments due to Amer on a timely basis, which could result in the loss of our rights to the product.

Commercial summary for iferanserin (VEN 309)

Market research regarding hemorrhoids

Market research conducted in 2001 by Amer with both patients and physicians shows a significant dissatisfaction with current treatment options and the need for a product that relieves multiple hemorrhoidal symptoms. In a survey conducted with 57 hemorrhoid patients, average satisfaction with current prescription treatment was rated at 6.0 on a 10-point scale. The most desired treatment effects of a new hemorrhoidal medication that patients described would be “fast onset,” and “bleeding cessation.” The most frequent hemorrhoidal symptoms these patients reported experiencing were itching (79%), bleeding (77%) and pain (68%).

A research study conducted by Amer of 40 physicians (30 primary-care physicians, five proctologists, and five colon and rectal surgeons) evaluated their satisfaction with current treatment for hemorrhoidal treatment on a 10-point scale. The level of satisfaction with current treatment for reducing bleeding was 6.4; for relieving itch, 7.1; and for reducing pain, 6.8. The physicians indicated that the most desirable treatment effects of new hemorrhoidal medication would be “fast onset (2 to 3 days)” and “multi-symptom relief.” Another research study of 98 physicians showed that most physicians would replace their current first line therapy with iferanserin ointment, if it is approved.

DILTIAZEM CREAM (VEN 307)

Background on anal fissure

Incidence and prevalence

Anal fissure, which is a crack in the skin of the anal canal that results from reduced blood supply to the area and/or from increased sphincter tone, is a common anal disorder characterized by severe anal pain and bleeding with or after bowel movements. Because there are no approved pharmacological treatments for anal fissure, many cases progress to surgery because of the severe pain. There are no formal epidemiology studies for anal fissure, but its prevalence has been estimated indirectly. When 1,500 unselected neurological inpatients were screened in studies between 1990 and 1998 conducted in the U.S. by Dr. Wolfgang Jost, the prevalence of anal fissure was estimated at 1.6% in males and 2.2% in females. By extrapolation to the 2009 U.S. population of 227 million adults, we estimate that the general prevalence rate is 1.9%, with approximately 4.3 million current cases.

Physiology of anal fissure

Although hypertonia, or an increase in tightness of muscle tone, of the internal anal sphincter, or IAS, is associated with anal fissure, its contribution to the cause of anal fissure remains unclear. Hypertonia of the IAS does, however, contribute to chronic anal fissure. Anatomical, angiographic, and blood-flow studies have shown that the vascular supply of the anal epithelium, or tissue lining the anus, is very poor in the posterior midline, the anal area most commonly affected by fissures. Thus, it is possible that decreased anodermal blood supply to this area contributes to the pain and ischemia, or decrease in the blood supply, of traumatized anal epithelium, perpetuating ulceration and preventing healing. Whether the primary event for anal fissure is hypertonia of the IAS or decreased blood supply, hypertonia itself reduces vascular perfusion in the anal area. This reduction of vascular perfusion has been compared with that associated with ischemic pain in the lower limbs.

Current treatments

Presently, there are no FDA approved drugs of which we are aware for the treatment of anal fissure in the U.S. The clinical goal in treating anal fissures is to reduce the pain associated with the fissure long enough for it to heal naturally and prevent the patient from having to resort to surgery. Currently, most physicians start treatment with diet modification, fiber, sitz baths and stool softeners. If these conservative treatments fail, physicians proceed to pharmacologic therapy, prescribing topical steroids or by directing special pharmacies create compound topical formulations by mixing raw diltiazem, and in some cases nitroglycerin, into a cream for topical use by fissure patients. If these pharmacologic treatments fail to manage the pain, physicians consider, and often perform, surgery. In some instances, physicians initially prescribe pharmacologic therapy in addition to conservative treatments; in other instances because of the severe pain, they initially perform surgery.

The purpose of surgery is to reduce hypertonia of the IAS by either manual dilatation or lateral sphincterotomy. Both procedures are highly successful in relieving the pain and promoting healing of fissures. Although a relatively simple and effective surgical procedure, lateral sphincterotomy is also associated with short-term mild-to-moderate fecal incontinence. This is not an insignificant adverse effect and can become permanent or at least chronic in a fairly high percentage of patients. Studies have shown 6-8% of patients had incontinence to flatus or minor fecal soiling at a time greater than five years after surgery. In another study, at a mean follow-up time of 66.6 months (range 30-84 months), 10% of patients who had a lateral internal sphincterotomy were incontinent.

Over the last decades, a drug developer attempted to gain FDA approval for the topical treatment of anal fissures with nitroglycerin, an agent that reduces IAS and anal fissure pain. Early attempts to develop nitroglycerin utilizing a healing endpoint failed as it was discovered most fissures will heal naturally if the patient can endure the pain for the first several weeks of the disorder. However, it was discovered during development that lowering IAS hypertonia did have a significant benefit in reducing the pain associated with anal fissures. The subsequent pivotal studies with pain as a primary endpoint demonstrated a 33% reduction in pain scores in patients with baseline pain score >48 (1-100 mm on the visual analog scale, or VAS). However because the developer did not use minimum pain scores as an inclusion criteria, the overall effect was diluted to 22%. In addition, 64% of subjects reported headaches, which is a known systemic side effect of nitroglycerin. The FDA denied its approval, concluding that the risk benefit ratio for nitroglycerin as topical treatment for anal fissure pain was not favorable due to the modest overall effect and high incidence of systemic side effects. We have planned a clinical program that focuses on pain as the primary endpoint and includes only patients who have adequate pain scores on entry into the studies, which we believe will avoid the modest effects seen in the earlier study. In addition, based on results of previously published trials (such as Kocher et al. 2002; see Table 1 below), we believe that the side effects of diltiazem cream are likely to be less than those observed with topical nitroglycerin, which primarily were headaches.

DILTIAZEM CREAM (VEN 307) DEVELOPMENT

Background on diltiazem

Diltiazem was first approved in 1982 in oral form for the treatment of angina and high blood pressure. It has been prescribed in the U.S. for millions of patients in oral dosages typically from 240 mg to 360 mg per day. In contrast, daily doses of VEN 307 for treatment of anal fissures will range from 15 to 45 mg. Because of the extensive patient exposure to diltiazem as a cardiovascular agent and the wide safety margin as a low dose topical therapy, we intend to develop the topical formulation as a Section 505(b)(2) NDA, as agreed with the FDA at our pre- IND meeting in August 2007. A special NDA procedure, known as a “section 505(b)(2) application” or a “paper NDA,” allows an applicant to seek approval on the basis of a combination of a prior approval of a similar product or published literature, and some new clinical studies conducted or sponsored by the applicant. Section 505(b)(2) applications are often used for changes in a drug that require clinical investigations and thus cannot be handled through the generic drug process, such as a new indication or change in dosage.

Compounded diltiazem (prepared by the pharmacist, for each patient, using a general cream base and diltiazem from oral formulations) is currently listed in the U.S. and E.U. anal fissure treatment guidelines as a preferred agent prior to attempting surgery. According to advice we have received from members of our scientific advisory board, who are experts in gastroenterology and gastrointestinal surgery, compounded diltiazem is utilized by many colorectal and gastroenterology specialists each year for the treatment of anal fissures and, according to these experts, has also reduced the number of surgeries required. As a result, awareness and utilization of diltiazem as an effective treatment for anal fissures is high among physicians that treat this disorder. However, compounded diltiazem for anal fissure is not an FDA-approved use nor is it an FDA-approved product, and as such, the cost is not reimbursed by Medicare or health insurance plans. Data on unit and dollar volumes of compounded preparations are not routinely collected and not available to us.

We expect to capture immediate market share if VEN 307 is approved due to its known efficacy and the current use of the compounded version. We expect that VEN 307 will be highly competitive with the compounded version because of the ease of prescription (already formulated, and approved by FDA), with no need for custom mixing at the pharmacy, and because VEN 307 will be eligible for reimbursement under

Medicare and other health plans, which the compounded version is not. For these reasons, we believe that the use of the compounded form of diltiazem will greatly decrease if VEN 307 is approved.

The use of diltiazem for the treatment anal fissures was first discovered at St. Mark gastroenterology teaching hospital in London. Professors Kamm and Robins filed the original method of use patent application in 1996. In 1997, diltiazem patent application and rights were assigned to S.L.A. Pharma, who filed the current patent application in 1998 (the original 1996 patent had lapsed). In 2001, North American rights were licensed to Solvay Pharmaceuticals, SA. During the time that Solvay held the rights, it improved the manufacturing processes and formulation and conducted important pharmacokinetic studies. In 2004, the new CEO of Solvay Pharmaceuticals refocused the R&D strategy on CNS and cardio-metabolic programs, discontinuing gastroenterology and women's health projects. Consequently, in 2005, the license rights to diltiazem cream were returned to S.L.A. Pharma. From 2005 to the March 2007 licensing by Paramount BioSciences, S.L.A. Pharma focused on regulatory and manufacturing priorities, preparing diltiazem for further development.

In August 2007, we acquired North American rights to diltiazem from Paramount BioSciences, which previously acquired rights from S.L.A. Pharma in the United Kingdom for developing and marketing a proprietary diltiazem cream for relief of pain associated with anal fissures. We incurred a liability to Paramount BioSciences in the amount of $1,087,876, which represented the fees Paramount BioSciences had paid through August 2007 for both VEN 307 and VEN 308. Paramount BioSciences had acquired the S.L.A. rights in March 2007 and began working with Ventrus immediately to advance the development of these assets while an asset transfer agreement was finalized. S.L.A. Pharma is developing diltiazem cream for the European market, and we anticipate that S.L.A. Pharma began a Phase III clinical trial in the E.U. in November 2010. We are financially supporting the E.U. trial and are obligated to make the following payments to S.L.A. Pharma for VEN 307 development milestones.

Amount Due	Date Due	Fee Description
$41,500	Monthly beginning October 1, 2010, and continuing until S.L.A. Pharma is no longer managing the development program for VEN 307.	Project management fees for VEN 307.
$600,000	December 31, 2010	Development costs for VEN 307.
$800,000	Upon the completion of enrollment into the Phase III clinical trial that S.L.A. Pharma is conducting in Europe, anticipated at the end of 2011.	Development costs for VEN 307.
Up to $400,000	If contingencies are met, payable monthly as invoiced by S.L.A. Pharma.	Development expenses for VEN 307. Contingent upon (i) receipt of a final study report from the S.L.A. Pharma Phase III VEN 307 trial in Europe (anticipated in the third quarter of 2012), and (ii) if we have raised net proceeds of at least $20.0 million from sales of securities and/or licensing of rights to our products by that time.

In August 2007, we concluded a pre-IND meeting with the FDA in anticipation of our IND submission for permission to initiate Phase III trials in the U.S. This meeting also afforded us an opportunity to gain agreement on the key design issues of the studies (including the one which S.L.A. Pharma is implementing) and additional information required for an approval of an NDA. We anticipate the availability of data from the S.L.A Phase III study in the second quarter of 2012 and, if the E.U. trial is successful, we plan to initiate the U.S. pivotal program by the second half of 2012, contingent on the availability of additional capital. We expect to collaborate closely with S.L.A. Pharma in order to leverage clinical data for different regulatory agencies and to rationalize manufacturing capacity.

Mechanism of action

The mechanism of action for topical diltiazem cream was demonstrated in human pharmacodynamic studies that showed an anal maximal resting pressure, or MRP, reduction of 28% that was sustained for 3 – 5 hours. This MRP reduction is believed to decrease the pain associated with anal fissures by normalizing internal anal sphincter pressure, which improves vascular blood supply and reduces ischemic pain.

Preclinical safety

Studies have been conducted in rabbits and guinea pigs to assess the topical safety of diltiazem cream. Clinicians treated rabbits in and around the anus with 2% diltiazem or placebo cream twice daily for 90 days to evaluate the chronic safety of the product. Although exterior anal tissue showed an increase in erythema, or redness of the skin, and edema, or accumulation of fluid beneath the skin, the clinicians concluded that these effects were due to the application procedure, to a possible reaction to latex gloves or to both. There were no histological findings. In this study, topical 2% diltiazem cream had no other adverse effects. Clinicians used guinea pigs to assess the potential for 2% diltiazem cream to elicit contact sensitization, or skin reaction to the application. This study did not demonstrate any sensitization potential of the diltiazem cream in guinea pigs.

Investigator-initiated clinical studies (studies sponsored by individual clinicians)

The investigator studies conducted with diltiazem cream applied topically in the perianal area in normal subjects and in patients with anal fissures are summarized in **Table 1.** These studies were conducted by independent investigators and not by us or any partner of ours. The year the study was published is given in the column headed “Study.”

Table 1. Summary of Investigator-initiated clinical studies.

Study	Condition, treatment, dosage	Study design, endpoints	Efficacy	Adverse events
Carapeti, E.A., et al, Gut, 45:719 – 722, 1999	10 normal subjects; placebo (PBO) or diltiazem (DTZ) gel (0.1%, 0.5%, 1%, 2%, 5%, and 10%)	DTZ or PBO gel applied once to anal margin; maximum resting anal pressure (MRP) and anodermal blood flow measured starting 1 hour after treatment	DTZ decreased MRP at concentrations of 1% and higher, maximum decrease of 28% at 2% gel, no further effect of 5% or 10%; effect at 2% lasted 3 – 5 hours; no change in blood flow	No local or systemic adverse events (AEs) reported
Carapeti, E.A., et al, Dis Colon rectum, 43:1359 – 1362, 2000	15 patients with chronic anal fissures (CAF); 2% DTZ gel, three times-per-day (TID) for 8 weeks	DTZ gel applied to anal margin; MRP, anodermal blood flow and healing rate monitored every 2 weeks, daily diary cards for worst pain (scale of 0 – 10) of the day	Fissures healed in 67% of subjects; significant decrease in MRP and pain (decreased from 5.5 pretreatment to 1 post-treatment); no effect on blood flow	No AEs

Study	Condition, treatment, dosage	Study design, endpoints	Efficacy	Adverse events
Bhardwaj, R., et al, Annual Meeting of British Association of Colon proctologists, Brighton, United Kingdom, 2000	44 patients with CAF, 2% DTZ gel, TID for 8 weeks	27 patients assessed at 2 months, 15 patients evaluated at 4 months (included 9 who had healed at 2 months and remained healed); assessed for healing, pain, rectal bleeding, MRP	Fissures healed in 56% of subjects at 2 months, 73% at 4 months; pain abolished in 88%, bleeding in 92%; MRP decreased by 24% at 2 months	1 patient had minor incontinence to flatus
Jonas, M., et al, Dis Colon rectum, 44:1074 – 1078, 2001	50 patients with CAF, 24 treated with oral DTZ (60 mg), 26 with topical DTZ (2% gel), twice per day (BID) for 8 weeks	DTZ gel applied 1cm inside anus and to anal margin; pain, bleeding, perianal irritation (all 3 measured on a scale of 1 – 100 mm), MRP, healing monitored every 2 weeks	Fissures healed in 38% of subjects (oral) vs. 65% (topical) (9 in each group had previously failed on glyceryl trinitrate (GTN); 7 of these healed on topical vs. 1 on oral DTZ); both oral and topical DTZ decreased MRP; pain, bleeding and irritation reduced by both formulations (pain went from 70 to 7 after 8 weeks on oral, from 68 to 3 on topical)	No AEs in topical group; AEs reported in 8 patients on oral DTZ (headaches, nausea and/or vomiting, rash, decreased sense of taste and smell)
Knight, J,S., et al, Br J Surg, 88:553 – 556, 2001	71 patients with CAF, 2% DTZ gel, BID, additional 8-12 weeks for subjects who did not heal on original regimen	DTZ applied perianally; healing monitored;	75% healed after 2-3 months, a total of 89% healed after a median duration of 9 weeks (range of 2-16 weeks); after a median of 32 weeks follow-up (range 14 – 67 weeks) 66% symptom-free, 17% had mild symptoms, and 7% had reoccurrence	4 patients reported perianal dermatitis, 1 reported headache

Study	Condition, treatment, dosage	Study design, endpoints	Efficacy	Adverse events
Griffin, N., et al, Colorectal Dir, 4:430 – 435, 2002	47 patients with CAF who failed topical GTN, 2% DTZ cream, BID for 8 weeks	Treatment administered in anal verge; daily diary for pain, bleeding and itching (scale of 0 – 100); healing monitored	Fissures healed in 48% of subjects; pain and bleeding decreased after 8 weeks, no effect on itching; 2 patients relapsed after median duration of follow-up 45 weeks (range 23 – 54)	1 patient developed a local perianal rash; up to 25% reported increased perianal itch
DasGupta, R., et al, Colorectal Dir, 4:20 – 22, 2002	23 patients with CAF, 2% DTZ gel, TID for up to 12 weeks	DTZ applied to lower half of anal canal, healing monitored	Fissures healed in 48% of subjects, in a median of 8 weeks (range 1 – 12 weeks); of 8 who had previously failed GTN, 6 (75%) healed; no recurrences at 3 months	No AEs
Kocher, H.M., et al, Br J Surg, 89:413 – 417, 2002	60 patients with CAF, 0.2% GTN ointment (29 patients) or 2% DTZ cream (31 patients), BID for 6 – 8 weeks	DTZ or GTN applied to anal verge, monitored every 3 weeks for healing; pain recorded on VAS (0 – 100) scale	At 8 weeks fissures healed or improved in 12 and 13 patients, respectively, after GTN (86%) vs. 8 (healed) and 16 (improved) after DTZ (77%); both decreased pain to approximately same extent; at 12 weeks 2 GTN patients had recurred vs. none in the DTZ group	21/29 GTN subjects (72%) reported AEs vs. 13/31 (42%) in DTZ group; 17 /29 in GTN group had headaches, vs. 8/31 of DTZ patients
Bielecki, K., et al, Colorectal Dir, 5:256 – 257, 2003	43 patients with CAF, 0.5% GTN ointment (21 patients) or 2% DTZ ointment (22 patients), BID for 8 weeks	Patients monitored 3 times during treatment	Fissures healed in 86% of GTN, 86% of subjects with DTZ, 3 failures in each group	Mainly headache in 7 GTN patients (33%), no AEs reported in DTZ patients

Study	Condition, treatment, dosage	Study design, endpoints	Efficacy	Adverse events
Shrivastava, U.K., et al, Surg Today, 37:482 – 485, 2007	90 patients with CAF; 2% DTZ ointment (30 patients), 0.2% GTN ointment (30 patients), BID; no treatment (30 patients)	Treatments applied BID to anus, patients monitored for healing and pain (VAS) twice 2 per week then every 2 weeks	Fissures healed in 80%, 73% and 33% for DTZ, GTN and control subjects, respectively; mean time for healing 6.6 weeks, 7.0 weeks and 7.6 weeks for DTZ, GTN and controls, respectively; pain decreased by 75% for DTZ, 59% for GTN and 29% for controls at 6 weeks; recurrence rate 12.5%, 32% and 50% for DTZ, GTN and controls, respectively	No AEs in DTZ patients, 67% of GTN patients had headaches

DTZ = diltiazem; GTN = glyceryltrinitrate (nitroglycerin)

Clinical trials of diltiazem cream sponsored by S.L.A. Pharma

In 2004 and 2005, S.L.A. Pharma assessed the pharmacokinetic profile of topical diltiazem cream over a four-day period in subjects with anal fissure. Clinical dosing was completed in November 2005 and published in January 2007. Clinicians treated patients with eight doses of either 2%, 4%, or 8% diltiazem cream. Clinicians administered a single dose perianally on day 1, followed by doses three times a day on days 2 and 3, followed by another single dose on day 4. The clinicians collected blood over 24 hours on days 1 and 4. Maximum blood levels and area under the curve increased with the dose, and there appeared to be accumulation of diltiazem in blood on day 4 after multiple dosing. The time to maximum blood levels was five to seven hours, and the plasma half-life was less than 12 hours. However, the maximum amount of diltiazem that was absorbed was much less (at least five-fold less) than observed after oral dosing. Side effects, such as anal irritation, headache, and nausea, were mild.

Blood pressure was measured at the following times after the single dose on days 1 and 4: predose, 15, 30 and 45 minutes and 1, 1.5, 2, 4 and 8 hours after dosing. The relatively small maximum mean decreases (mmHg) in blood pressure in patients receiving 2%, 4% and 8% cream (3-4 patients per group) by day 4 ranged from 4 to 8mmHg systolic blood pressure, or SBP, and 4 to 6 mmHg diastolic blood pressure, or DBP. The changes were, in general, transient and asymptomatic and blood pressure had returned to at or near baseline by the next reading. There was no clear dose-related effect among the 2%, 4% and 8% creams with respect to decreases in blood pressure. In clinical trials with oral diltiazem for hypertension, the patients receiving placebo had mean decreases of blood pressure from 2 to 4 mmHg.

S.L.A. Pharma compared the effect of 2% diltiazem cream with 0.2% glyceryltrinitrate cream in subjects with chronic anal fissure. This study was completed in January 2001 and published in October 2001. Clinicians applied the preparations in and around the anus twice daily for six weeks. Nine of the 31 patients treated with diltiazem and three of the 29 patients treated with glyceryltrinitrate withdrew from the study by eight weeks. In the diltiazem group, 26% of the patients experienced healed fissures and 52% of patients experienced improved fissures. In the glyceryltrinitrate group, 41% of patients experienced healed fissures and

45% of patients experienced improved fissures. There was no significant difference in the healing rates between the groups. Both treatments resulted in a significant decrease in pain. Four weeks after the end of treatment, no fissures recurred in patients treated with diltiazem, but fissures recurred in two patients treated with glyceryltrinitrate. Compared with 18 treatment-emergent adverse events reported by 13 patients (42%) receiving diltiazem, there were 33 adverse events reported by 21 patients (72%) receiving glyceryltrinitrate. Eight patients receiving diltiazem complained of nine headaches, 17 patients receiving glyceryltrinitrate complained of 20 headaches.

Similar to the early glyceryltrinitrate, or GTN, development program that found healing to be a difficult and inappropriate endpoint for registration trials, S.L.A. Pharma also pursued a healing endpoint strategy in early development. In an exploratory trial sponsored by S.L.A. Pharma that was completed in February 2002 and published in February 2003, the effects of 2% diltiazem cream on healing rates were compared with placebo cream in patients with severe chronic anal fissure. Thirty one patients were randomized to each treatment group. Creams were applied twice daily for eight weeks. At the end of eight weeks, there was no difference in the healing rates between patients receiving diltiazem (10%) and patients receiving placebo (19%). No difference was observed in the secondary endpoints, which is likely due to the assessment being made only at the end of the study, not daily as in the other trials, which showed a positive outcome in these endpoints. Fifteen patients receiving diltiazem reported 28 adverse events and 12 patients receiving placebo received 18 adverse events. Seven patients receiving diltiazem and three patients receiving placebo reported a rash or pruritus, or itchiness. Headaches were reported in the same number of patients in both treatment groups.

Summary of studies to date

The topical application of diltiazem cream provides pain relief associated with anal fissure and has also been found to be associated with healing. The effects of diltiazem cream are comparable to those observed for treatment of anal fissure with topical application of GTN, but diltiazem cream is much better tolerated.

Based on currently available data and discussion with the FDA, we think it is clear that relief of pain associated with anal fissures is the preferred clinical endpoint. Our belief is supported by the study by U.K. Shrivastava, et al., published in Surgery Today, 37:482 – 485, 2007 (see **Table 1** above), which compared GTN and diltiazem perianally compared with standard care alone. In this trial pain decreased by 75% for diltiazem compared with 29% for controls at six weeks. In almost all studies with either GTN or diltiazem where pain was measured results are consistent whereas with healing as an endpoint results are variable.

Our belief that relief of pain associated with anal fissures is the preferred clinical endpoint is further supported by market research that identified clinicians' primary treatment goal as pain relief. Importantly, the diltiazem mechanism of action for pain relief is to reduce IAS pressure which addresses the underlying cause of anal fissure pain.

Diltiazem cream (VEN 307) development plan

In August 2007, we had a pre-IND meeting with the FDA concerning VEN 307 (diltiazem cream for the treatment of pain from anal fissures) where it was established that next clinical studies needed for approval were two pivotal Phase III trials, preceded (if conducted in the U.S.) by three short-term dermal toxicology studies. Prior to conducting clinical Phase III studies in the U.S., we must complete three short-term dermal toxicology studies and file an IND for FDA approval. We plan to employ a two-pronged development strategy for VEN 307. While S.L.A. Pharma is conducting the first Phase III clinical trial in the E.U. which is anticipated to be complete in the second quarter of 2012, we intend to initiate development of a superior formulation with new intellectual property in the form of an extended release formulation. There are several proven methodologies for extended release topical formulations, and we believe that diltiazem is readily drugable in this regard. We intend to assess three to four alternatives preclinically with multiple contractors, and then assess absorption and effect on IAS pressure with the most promising, while we will file PCP applications for the specific technology combined with diltiazem for all formulations that are technically feasible.

The patent for the existing formulation that S.L.A. Pharma is using has not yet been issued for reasons of lack of novelty and inventiveness (prior art) and S.L.A. Pharma filed an appeal to the USPTO Board of

Appeal. The Appeal of US Patent Application No. 09/355,928 was addressed on August 31, 2010 wherein the Appeal Board affirmed the novelty of the topical use of diltiazem while maintaining the lack of inventive step rejection over the prior art, with the proviso that additional data were necessary to show unexpected results. As such, on October 25, 2010, S.L.A. Pharma filed a Request for Continued Examination, or RCE, to continue prosecution of the pending application and to provide the additional data requested by the Appeal Board. S.L.A Pharma also introduced additional arguments to the PTO Examiner to address recent legal decisions by the Federal Circuit Courts, relevant to the inventive step for the topical use of diltiazem, which have not been previously considered by the PTO examiner. We expect the first PTO action to be made within 12 months.

If there is successful completion of the E.U. trial, we will make the final decision on which formulation to pursue depending on several factors, including whether the new formulation is clinically superior, our access to capital, clinical and regulatory considerations, and our assessment of the then-current state of our intellectual property estate. If the new U.S. developed formulation is superior and the other factors are met, we plan to initiate two pivotal trials in parallel in order to complete the NDA for an estimated FDA submission in 2013. If the new formulation is not superior, and/or we judge the existing formulation to be patentable, we plan to finish clinical development utilizing the current formulation which would require one additional pivotal Phase III study in the U.S., and expect to continue to pursue other lifecycle options such as combination with other drugs. Both development pathways could result in a NDA submission in 2013.

Commercial summary for diltiazem cream (VEN 307)

Market research regarding anal fissure

Eidetics, a Boston-based research company, conducted quantitative market research in 2003 and reported that on average primary-care physicians see 23 anal fissure patients per month, gastroenterologists see 17 anal fissure patients per month, and colon and rectal surgeons see 31 anal fissure patients per month.

Physicians in all three medical specialties indicated that there is a significant unmet need for therapeutic choices for anal fissure. Only 8% of primary-care physicians, 5% of gastroenterologists, and 27% of colon and rectal surgeons reported being “very satisfied” with current treatment options. All three medical specialties reported failure rates exceeding 50% for current first-line therapy in patients with anal fissure. Given this unmet medical need and the absence of other approved drugs in the U.S., we believe that up to 2.0 million patients per year could benefit from treatment with VEN 307.

PHENYLEPHRINE GEL (VEN 308)

Background on fecal incontinence

Incidence and prevalence

According to a U.S. community based epidemiology study (Nelson et al., JAMA, 1995), 2.2% of U.S. adults suffer from fecal incontinence, which we estimate to be approximately 7 million people, based on 2009 Census Bureau adult population estimates.

The IPAA orphan population

Patients with an ileal pouch anal anastomosis, or IPAA, secondary to a total colectomy tend to have a high incidence of fecal incontinence, up to 30%, according to a 1987 study conducted by Dr. John Pemberton and others at the Mayo Medical School. The surgery associated with IPAA can weaken sphincters and muscles necessary for continence and therefore can result in incontinence. About 30% of patients with ulcerative colitis, a form of inflammatory bowel disease which has a prevalence of 700,000 patients in the U.S. (according to Datamonitor 2008) will have had a colectomy, almost always an IPAA procedure (according to McGlauchlin and Clark, Practical Gastroenterology, 8/2008). IPAA-related fecal incontinence is considered an orphan indication by the FDA and the European Medicines Agency, or EMEA. Patients who undergo ileal pouch anal anastomosis are prone to fecal incontinence. In 2006, the total population of patients with IPAA-related fecal incontinence in the U.S. was estimated to be 50,000 to 100,000, according to IMS Health, Inc.

Physiology of fecal incontinence

Continence is a complex physiological action that requires the presence of a series of anatomical barriers preventing the movement of feces through the anus. The puborectalis muscle works with the internal and

external anal sphincters to control continence. If any of these three barriers are dysfunctional, incontinence can occur in a wide range of severity. Specifically, anal sphincter weakness has long been associated with fecal incontinence. Abnormal fibrosis, reduced elasticity, insensitivity to norepinephrine and spontaneous relaxation are associated with anal sphincter weakness.

Current treatments

To our knowledge, there are no FDA approved drugs for the treatment of fecal incontinence. Most physicians start with conservative therapy, which consists of diet modification, sitz baths and over-the-counter antidiarrheal medication. In addition to conservative therapy, physicians might prescribe antidiarrheal medication or recommend surgery.

The most common surgical procedure is sphincteroplasty for patients with physical injury to the anal sphincter. Success rates for this type of surgery are low and most of the benefit decreases with time.

Solesta™, which is being developed by Oceana Therapeutics, is an injectable inert bulking agent product approved in the European Union for the treatment of fecal incontinence in adult patients who have failed conservative therapy. Solesta is injected submucosally around the anal sphincter and consequently has to be administered in an outpatient setting by qualified physicians. Oceana Therapeutics is currently pursuing approval of Solesta by the FDA. In addition, Norgine plans to conduct a Phase I trial with NRL001, a suppository formulation of an alpha adrenergic stimulating agent for the treatment of fecal incontinence, which is anticipated to start in Europe in early 2011.

Background on phenylephrine

Phenylephrine has been available since the early 1940s in oral and nasal form for the treatment of nasal congestion. It has also been used as a topical ophthalmic agent since 1936. Phenylephrine is prescribed more than 17 million times per year in the United States, with 99% of the prescriptions being for cough/cold oral preparations. The typical oral dosing is 40 mg to 60 mg per day. Because of the extensive patient exposure to phenylephrine, we intend to develop the topical formulation as a Section 505(b)(2) NDA.

The use of phenylephrine for the treatment fecal incontinence was first discovered at St. Mark gastroenterology teaching hospital in London. Professors Kamm and Robins filed the original method of use patents in 1996. In 1997, phenylephrine patent application and rights were assigned to S.L.A. Pharma. In 2001, S.L.A. Pharma licensed North American rights to Solvay Pharmaceuticals, SA. During the time that Solvay held the rights, it improved the manufacturing processes and formulation and conducted important pharmacokinetic studies. In 2004, the new CEO of Solvay Pharmaceuticals refocused its R&D strategy on CNS and cardio-metabolic programs, discontinuing gastroenterology and women's health projects. Consequently, in 2005, the licensed rights to phenylephrine gel were returned to S.L.A. Pharma. From 2005 to the March 2007 licensing by Paramount BioSciences, S.L.A. Pharma focused on regulatory and manufacturing priorities, preparing the asset for further development.

In August 2007, we acquired North American rights to phenylephrine gel from Paramount BioSciences, which previously acquired rights from S.L.A. Pharma in the United Kingdom in March 2001 for developing and marketing a proprietary phenylephrine gel for the treatment of fecal incontinence. We incurred a liability to Paramount BioSciences of $1,087,876, which represented the fees Paramount BioSciences had paid through August 2007 for both VEN 307 and VEN 308. Paramount BioSciences had acquired the S.L.A. rights in March 2007 and began working with Ventrus immediately to advance the development of these assets while an asset transfer agreement was finalized.

We expect to collaborate closely with S.L.A. Pharma to leverage clinical data for different regulatory agencies and to rationalize manufacturing capacity.

Our total payment obligation for VEN 308 will not exceed $1,200,000. S.L.A. Pharma has billed us for, and we have paid, $973,500 of services through September 30, 2010. This leaves $226,500 in possible additional payments. However, we currently have no further payment obligations for VEN 308 unless we agree with S.L.A. Pharma to additional services outside the scope of the agreement.

Mechanism of action (MOA)

The MOA for topical phenylephrine gel is to increase resting anal sphincter pressure, thus increasing patient bowel control. Phenylephrine gel's MOA makes it an attractive candidate for any patient population that suffers from incontinence characterized as leaking/seeping fecal incontinence.

Preclinical safety

A mouse lymph node assay conducted by S.L.A. Pharma did not show phenylephrine hydrochloride to be a sensitizer (meaning a chemical that induces an allergic reaction after repeated exposure) because the drug was not associated with any type of delayed hypersensitization. In another S.L.A. Pharma study, contact sensitization potential, as measured in guinea pigs, under the conditions of the study, a 20% gel was considered to be a strong sensitizer to guinea pig skin. A 28-day study by S.L.A. Pharma in rabbits, in which 10% and 20% phenylephrine gel (900 mg) was applied three times each day to the dorsum, demonstrated mild inflammation which may have been exacerbated by animals biting the site of application. These studies were primarily conducted at St. Mark's Hospital in the U.K. in the 1990s.

Investigator-initiated clinical studies

A number of investigator studies have been conducted with phenylephrine applied topically for the treatment of fecal incontinence and are summarized in Table 2. These studies were conducted by independent investigators and not by us or any partner of ours. The year the study was published is given under the column headed "Study." One of these studies was conducted in patients with IPAA-related fecal incontinence. In one specific randomized controlled trial, phenylephrine significantly reduced the incontinence score ($P = 0.015$) and improved subjective measures ($P = 0.04$) compared with placebo. For some patients in this study, phenylephrine totally eliminated nocturnal episodes of fecal incontinence. No patient discontinued treatment during the study due to side effects. Studies in patients whose incontinence was more related to factors other than anal sphincter tone (many patients in the passive fecal incontinence studies) showed less response. As a result, our development plan will initially focus on the orphan IPAA indication.

Table 2. Investigator-initiated studies of topical phenylephrine gel for treatment of fecal incontinence.

Study	Condition, treatment, dosage	Summary of results
Carapeti, E.A., et al, Br J Surg. 86:267 – 270, 1999	Normal subjects, phenylephrine gel (5%, 10%, 20%, 30%) applied once to anal verge	Resting anal pressure increased by 8% to 33%, effect lasted for median of 7 hours, no change in pulse
Carapeti, E.A., et al, Dis Colon rectum, 43:1059 – 1063, 2000	IPAA-related FI, 10% phenylephrine or placebo gel, 2 times/day for 4 weeks	50% (6/12) of phenylephrine subjects improved vs 8% (1/12) placebo, 33% had cessation of FI on phenylephrine, 0% on placebo, phenylephrine increased anal pressure. No reported side effects.
Carapeti, E.A., et al, Br J Surg, 87:35 – 42, 2000	Passive FI, 10% phenylephrine vs placebo cream, 2 times/day for 4 weeks	No effect of phenylephrine or placebo on incontinence or anal pressure, 17% of phenylephrine and 6% of placebo patients had > 75% improvement
Cheetham, M.J., et al, 2000	Passive FI, 20% phenylephrine or placebo gel, 2 times/day for 4 weeks	No effect of phenylephrine or placebo on incontinence, anal pressure, blood pressure, or pulse rate
Sasse, K.L., et al, Dis Colon rectum, 43:A2, 2000	FI, 10% phenylephrine cream, 24 weeks	Increased anal pressure, improved incontinence
Cheetham, M.J., et al, Gut, 43:356 – 359, 2001	Passive FI, placebo or phenylephrine gel (10%, 20%, 30%, or 40%) as single application	Anal pressure increased in dose-related manner after phenylephrine, no effect on pulse, transient perianal burning

Study	Condition, treatment, dosage	Summary of results
Mutch, M.G., et al, 2002	Passive FI, 10% phenylephrine cream, 3 times/day for 30 days	Phenylephrine improved incontinence score, anal pressure, and anal sphincter length

FI = fecal incontinence; IPAA = ileal pouch anal anastomosis

Clinical trials

Solvay Pharmaceuticals assessed the safety and pharmacokinetic profile of intra-anal and perianal application of phenylephrine gel in healthy volunteers in 2004 in a study completed in March 2004 and published in May 2004. The phenylephrine gel was applied as a single dose either intra-anally at doses of 5, 10, 25, 50, or 100 mg, or perianally at doses of 100, 200, or 400 mg. Blood samples were collected out to 24 hours after dosing.

Perianal application of phenylephrine gel resulted in much less absorption than intra-anal application: at a perianal dose of 400 mg, blood levels were comparable to what was seen after intra-anal treatment with 10 mg to 25 mg.

Intra-anal application of phenylephrine was associated with increased blood pressure that lasted for approximately three hours, whereas these effects were not seen with perianal treatment. The most frequent side effects were headache and goosebumps after intra-anal application of phenylephrine gel which were not seen with perianal application, and anal/rectal pain after perianal application of phenylephrine gel.

Summary of studies to date

Topical phenylephrine gel has demonstrated efficacy for the treatment of fecal incontinence associated with IPAA. Pharmacokinetic studies have shown a superiority of perianal dosing which yielded low systemic absorption while still providing the desired local therapeutic effect. No hemodynamic effects where observed when phenylephrine gel was administered perianally at up to 8 times the therapeutic dose. Therefore, further development of the drug will focus solely on perianal application.

Phenylephrine gel (VEN 308) development plan

Based on pre-IND meetings with the FDA in 2007, we are planning to initiate the U.S. Phase IIb dose ranging study in support of the orphan indication of IPAA-related fecal incontinence. We plan to start this study in 2012 to finalize the dose and clinical endpoints. We expect to conclude VEN 308 development and submit the orphan NDA in 2015. Orphan status provides seven years exclusivity from the date of approval during which time we will pursue several potential lifecycle opportunities.

Commercial summary for phenylephrine gel (VEN 308)

Market research regarding fecal incontinence

Quantitative market research conducted in 2003 by Eidetics reported that, on average, primary-care physicians see 23 fecal incontinence patients per month, gastroenterologists see 20 fecal incontinence patients per month, and colon and rectal surgeons see 14 fecal incontinence patients per month. Physicians categorize fecal incontinence according to its underlying cause. This market research was not designed to eliminate double counting of referred patients and has not been used in calculating commercial potential. However, these data do indicate the volume of patients seen at each type of practice irrespective of whether the same patient has been seen by another physician, and any one of these physicians can initiate a prescription for the product.

Physicians in all three medical specialties indicated that there is a significant unmet need for therapeutic choices for fecal incontinence. Only 4% of primary-care physicians, 3% of gastroenterologists, and 7% of colon and rectal surgeons reported being “very satisfied” with current treatment options.

Government Regulation

General

The production, distribution, and marketing of products employing our technology, and its development activities, are subject to extensive governmental regulation in the U.S. and in other countries. In the U.S., our

products are regulated as drugs and are subject to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations of the FDA, as well as to other federal, state, and local statutes and regulations. These laws, and similar laws outside the U.S., govern the clinical and preclinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, recordkeeping, reporting, advertising, and promotion of our products. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violations of regulatory requirements at any stage may result in various adverse consequences, including the FDA's and other health authorities' delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions.

The following provides further information on legal and regulatory matters that have the potential to affect our operations or future marketing of products.

Research, Development and Product Approval Process

The research, development, and approval process in the U.S. and elsewhere is intensive and rigorous and generally takes many years to complete. The typical process the FDA requires before a therapeutic drug may be marketed in the U.S. includes:

- preclinical laboratory and animal tests performed under the FDA's Good Laboratory Practices regulations, or GLPs;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may commence;
- preliminary human clinical studies to evaluate the drug and its manner of use;
- adequate and well-controlled human clinical trials to establish whether the drug is safe and effective for its intended uses;
- FDA review of whether the facility in which the drug is manufactured, processed, packed, or held meets standards designed to assure the product's continued quality; and
- submission of a marketing application to the FDA, and review and approval of the application by the FDA.

During preclinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. These studies are subject to GLP requirements. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. An IND must be submitted to the FDA and become effective before studies in humans may commence.

Clinical trial programs in humans generally follow a three-phase process. Typically, Phase I studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase I studies are conducted to determine the metabolic and pharmacological action of the product candidate in humans and the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase II, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product candidate and optimal dosing. This phase also helps determine further the safety profile of the product candidate. In Phase III, large-scale clinical trials are generally conducted in patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate as required by U.S. and foreign regulatory agencies.

Before proceeding with a study, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment, or SPA. Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product's efficacy. SPAs help establish up-front agreement with the FDA about the adequacy of a

clinical trial design to support a regulatory approval, but the agreement is not binding if new circumstances arise. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

United States law requires that studies conducted to support approval for product marketing be "adequate and well controlled." In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice requirements, and informed consent must be obtained from all study subjects.

The clinical trial process for a new compound can take 10 years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from the beginning or may be terminated by institutional review boards, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market.

Following the completion of clinical trials, the data are analyzed to determine whether the trials successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the U.S., if the product is regulated as a drug, a new drug application, or NDA, must be submitted and approved before commercial marketing may begin. The NDA must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal, and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling. A special NDA procedure, known as a "section 505(b)(2) application" or a "paper NDA," allows an applicant to seek approval on the basis of a combination of a prior approval of a similar product or published literature, and some new clinical studies conducted or sponsored by the applicant. Section 505(b)(2) applications are often used for changes in a drug that require clinical investigations and thus cannot be handled through the generic drug process, such as a new indication or change in dosage form.

Each domestic and foreign manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA and must be registered with the FDA. The application generally will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug product, and determines that the facility is in compliance with cGMP requirements.

Each NDA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will "file" the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. The FDA has established performance goals for the review of NDAs — 6 months for priority applications and 10 months for standard applications. However, the FDA is not legally required to complete its review within these periods, and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an "action letter" that describes additional work that must be done before the application can be approved. The FDA's review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval.

Significant legal and regulatory requirements also apply after FDA approval to market under an NDA. These include, among other things, requirements related to adverse event and other reporting, product advertising and promotion and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product

labeling, or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

The regulatory framework applicable to the production, distribution, marketing, and/or sale, of our products may change significantly from the current descriptions provided herein in the time that it may take for any of our products to reach a point at which an NDA is approved.

Overall research, development, and approval times depend on a number of factors, including the period of review at FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA's questions, the severity or life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials, and the risks and benefits demonstrated in the clinical trials.

Orphan Drugs

Under the Orphan Drug Act, special incentives exist for companies to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the U.S. Companies may request that the FDA grant a drug orphan designation prior to approval. Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications, and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity prevents FDA approval of applications by others for the same drug and the designated orphan disease or condition. The FDA may approve a subsequent application from another entity if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. A grant of an orphan designation is not a guarantee that a product will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another entity or a similar drug from receiving approval for the same or other uses.

Other United States Regulatory Requirements

In the U.S., the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services (for example, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing, and scientific/ educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provision of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

Moreover, we are now, and in the future may become subject to, additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Foreign Regulatory Requirements

Ventrus and its collaborative partners may be subject to widely varying foreign regulations, which may be quite different from those of the FDA, governing clinical trials, manufacture, product registration and approval, and pharmaceutical sales. Whether or not FDA approval has been obtained, Ventrus or its collaboration partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries,

regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current U.S. law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

Reimbursement and Pricing Controls

In many of the markets where Ventrus or its collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject, by law, to direct price controls and to drug reimbursement programs with varying price control mechanisms. Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence and whether or not such uses have been approved by the FDA. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supported by one or more citations in the American Hospital Formulary Service Drug Information, the American Medical Association Drug Evaluations, or the U.S. Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

License Agreements & Intellectual Property

General

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

We do not own and did not develop any of our product candidates. We have licensed our three product candidates from third parties. All clinical trials to date have been conducted either by the licensor, the licensor’s previous partners or by independent investigators, as have the preclinical studies and product formulation activities. Since we licensed these products, we have focused our efforts on establishing and clarifying the regulatory pathway for late phase clinical trials and regulatory approval, and on establishing the contract manufacturing capacity and methods necessary to allow late phase clinical trials to proceed, all of which will be conducted by contracted third parties under our direction. We are dependent on the availability and competence of these third parties for the continued development of our product candidates.

License Agreements

In March 2007, pursuant to an Exclusive License Agreement, S.L.A. Pharma granted Paramount an exclusive, royalty-bearing license to sell, make and use diltiazem for treatment, through topical administration, of anal fissures and phenylepherine for treatment, through topical administration, of fecal incontinence in the U.S., Canada and Mexico. Pursuant to the Exclusive License Agreement, Paramount BioSciences was obligated to form a company to develop the technologies referenced in the Exclusive License Agreement and issue to S.L.A. Pharma that number of shares equal to 5% of such company's outstanding common stock as of the effective date of the Exclusive License Agreement. To satisfy this obligation, Paramount BioSciences formed our company and we issued 18,401 shares of our common stock to S.L.A. Pharma in August 2007. In the event we close an equity financing with gross proceeds of not less than $5,000,000 and the 18,401 shares issued to S.L.A. Pharma do not have a fair market value at least equal to $500,000 (calculated by multiplying the number of shares by the price per share paid in the financing), we must issue to S.L.A. Pharma that number of additional shares of our common stock so that, when added to the 18,401 shares initially issued, the new and old shares have a fair market value equal to $500,000 (based on the price per share paid in the financing). Upon the closing of this offering, based on the initial offering price of $6.00, we will be obligated to issue S.L.A. Pharma 64,933 shares of our common stock.

In August 2007, pursuant to an Assignment and Assumption Agreement, Paramount BioSciences sold all of its rights in and arising out of the Exclusive License Agreement with S.L.A. Pharma to us for $1,087,876, which represented the fees Paramount BioSciences had paid through August 2007 for both VEN 307 and VEN 308. The corresponding U.S. and foreign patents and applications for the two compounds have been licensed to us under the Assignment and Assumption Agreement (the technology referred to collectively as the Compound Technology). As consideration in part for the rights to the Compound Technology, an initial licensing fee of $250,000 was paid to S.L.A. Pharma (this amount was paid by Paramount BioSciences and was included in the consideration paid by us to Paramount BioSciences in connection with the Assignment and Assumption Agreement). In the event that the Compound Technology is commercialized, we are obligated to pay to S.L.A. Pharma annual royalties ranging from the mid to upper single digit percentages, based upon net sales of the product. In addition, we are required to make payments to S.L.A. Pharma up to an aggregate amount of $20 million upon the achievement of various milestones related to regulatory events. Should we make any improvements regarding the Compound Technology, we are required to grant S.L.A. Pharma licenses to use such improvements.

We also are required to reimburse S.L.A. Pharma for clinical development costs associated with the technology development of both VEN 307 and VEN 308. Our total payment obligation for these development costs for VEN 307 will not exceed $4,000,000. As of September 30, 2010, we had made $2,600,000 of such payments. We expect to make the remaining payments as follows: (i) on December 31, 2010, we are obligated to pay S.L.A. Pharma $600,000; and (ii) upon completion of enrollment into the Phase III trial in Europe, which we anticipate to occur at the end of 2011, we will be obligated to pay S.L.A. Pharma $800,000. The $600,000 we are obligated to pay represents past development costs and we have accrued this amount as of September 30, 2010. S.L.A. has not completed recruitment of patients into the Phase III trial and therefore we have not recorded the $800,000 expense at September 30, 2010. In addition, both we and S.L.A. Pharma have agreed to add additional services outside the scope of the agreement in which case we are obligated to pay an additional $400,000 above the $4,000,000 cap. The additional amount will begin to be due only if and when we receive a final study report from S.L.A. Pharma from the Phase III VEN 307 trial in Europe (anticipated in the third quarter of 2012) and if we have raised net proceeds of at least $20.0 million from sales of securities and or the licensing of rights to the products. S.L.A. Pharma has not provided the services for this additional work and therefore we have not recorded any additional expenses.

As of September 30, 2010, we had made $973,500 in payments to S.L.A. Pharma relating to developing VEN 308, including a payment of $373,500 on September 29, 2010 for services related to managing the project from January 2010 through September 2010. These project management fees are terminated effective October 1, 2010. We do not expect to continue developing VEN 308 in the short term and therefore do not expect to make any additional payments.

Our future known payment obligations to S.L.A. Pharma are as follows.

Amount Due	Date Due	Fee Description
$41,500	Monthly beginning October 1, 2010, and continuing until S.L.A. Pharma is no longer managing the development program for VEN 307.	Project management fees for VEN 307.
$600,000	December 31, 2010	Development costs for VEN 307.
$800,000	Upon the completion of enrollment into the Phase III clinical trial that S.L.A. Pharma is conducting in Europe, anticipated at the end of 2011.	Development costs for VEN 307.
Up to $400,000	If contingencies are met, payable monthly as invoiced by S.L.A. Pharma.	Development expenses for VEN 307. Contingent upon (i) receipt of a final study report from the S.L.A. Pharma Phase III VEN 307 trial in Europe (anticipated in the third quarter of 2012), and (ii) if we have raised net proceeds of at least $20.0 million from sales of securities and/or licensing of rights to our products by that time.

We issued an additional 2,016 shares of our common stock to S.L.A. Pharma pursuant to the terms of the fourth amendment to the license agreement entered into in December 2009 and issued a warrant to purchase 13,605 shares of our common stock at an exercise price of $1.24 per share pursuant to the terms of the sixth amendment entered into on August 30, 2010. The sixth amendment benefited us by providing for an extension of the next $600,000 development fee, due September 30, 2010 to December 31 2010, an extension of the next $800,000 payment for diltiazem (VEN 307) development costs, due February 28, 2011 to within 14 days of S.L.A. Pharma providing us with written notification of the completion of enrollment in its Phase III trial for VEN 307 in Europe, which we expect to occur in the third quarter of 2011, and the cancellation of all future phenylephrine (VEN 308) monthly project management fees of $41,500 per month beginning after September 30, 2010, resulting in significant short term savings.

The Exclusive License Agreement with S.L.A. Pharma is terminable by us for any reason upon 90 days' written notice, and by either party in the event of a material breach or default of the Exclusive License Agreement or either party becomes bankrupt or insolvent. In addition, the Exclusive License Agreement is terminable immediately by S.L.A. Pharma if we do not consummate this offering or another financing by December 31, 2010 with net proceeds of at least $10.0 million. We intend this offering to satisfy this requirement. In addition, S.L.A. Pharma may terminate the Exclusive License Agreement at any time, even during or after the successful completion of this offering, with one month's notice in the event that a third party wishes to enter into a license agreement for VEN 307 and VEN 308 and has entered into an agreement to that effect, provided that within that the termination will not be effective if within that one-month period we pay all then required payments under the agreement. If the license is terminated in any of these situations, we would have no further payment obligations to S.L.A. Pharma. In the event we have a "change in control" prior to the completion of the Phase III study for VEN 307 and we terminate the license within 30 days of the change in control, we must pay the balance of all payments (including the contingent $400,000) owed for VEN 307 even if S.L.A. Pharma has not actually incurred those costs. In the event we have a "change in control" after the completion of the Phase III study for VEN 307 and we terminate the license within 30 days of the change in control, we must pay the balance of all payments (including the contingent $400,000) owed for VEN 307 even if S.L.A. Pharma has not actually incurred those costs plus any other development expenses mutually agreed upon, but excluding the $41,500 monthly payments for VEN 307 and any monthly payments that might have been agreed to and initiated for VEN 308. A "change in control" is defined as a merger or other reorganization of our company in which our stockholders prior to the

transaction do not own a majority of the voting stock of the surviving or successor entity, the sale by one or more of our stockholder of a majority of our voting securities, or the sale of all or substantially all of our assets related to VEN 307 and VEN 308. A "change in control" does not include a bona fide financing transaction in which voting control transfers to one or more persons or entities who acquire our securities in the transaction.

The patents for the intellectual property that we have licensed from S.L.A. Pharma are summarized below.

VEN 307: Diltiazem Cream for Anal Fissure

United States Patent Application No. 09/335,928

- Title: "Topical Pharmaceutical Composition comprising a Cholinergic Agent or a Calcium Channel Blocker." This application is still pending and currently under appeal in the United States Patent and Trademark Office, or USPTO.
- Filed under Patent Treaty Cooperation: February 23, 1998
- Filed in the United States: August 12, 1999
- The patent for the existing formulation that S.L.A. Pharma is using have not yet been issued for reasons of lack of novelty and inventiveness (prior art) and S.L.A. Pharma filed an appeal to the PTO Board of Appeal. The Appeal of U.S. Patent Application No. 09/355,928 was addressed on August 31, 2010 wherein the Appeal Board affirmed the novelty of the topical use of diltiazem while maintaining the lack of inventive step rejection over the prior art, with the proviso that additional data were necessary to show unexpected results. As such, on October 25, 2010, S.L.A. Pharma filed a Request for Continued Examination (RCE) to continue prosecution of the pending application and to provide the additional data requested by the Appeal Board to show the unexpected results of using topical diltiazem. S.L.A. Pharma introduced additional arguments to the PTO examiner to address recent legal decisions by the Federal Circuit Courts, relevant to the inventive step for the topical use of diltiazem, which decisions have not been previously considered by the PTO examiner. We expect the first PTO action to be made within 12 months.
- The inventors are: Michael A. Kamm and Robin K.S. Phillips
- The original assignee of the patent was: S.L.A. Pharma AG
- S.L.A. Pharma AG is responsible for the prosecution of this patent and we are responsible for the costs of such prosecution:
- Expiration Date: If the patent application is found allowable by the Appeal Board at the USPTO the patent will expire on February 23, 2018, if all maintenance fees are paid.

Canadian Patent No. 2,281,755

- Title: "Topical Pharmaceutical Composition comprising a Cholinergic Agent or a Calcium Channel Blocker"
- Filed under Patent Treaty Cooperation: February 23, 1998
- Entered National Stage in Canada: August 23, 1999
- The Patent was granted on: November 11, 2006
- The inventors of the patent are: Michael A. Kamm and Robin K.S. Phillips
- The original assignee of the patent was: S.L.A. Pharma AG
- S.L.A. Pharma AG is responsible for the prosecution of this patent and Ventrus Biosciences is responsible for the costs of such prosecution.
- Expiration date of the patent: February 23, 2018, assuming all maintenance fees are paid.

VEN 308: Phenylephrine gel for fecal incontinence

U.S. Patent No. 6,635,678

- Title: “Pharmaceutical composition for treating fecal incontinence”
- Filed under Patent Treaty Cooperation: December 23, 1997
- Entered National Stage in U.S.: August 24, 1999
- The Patent was granted on: October 21, 2003
- The inventors of the patent are: Michael A. Kamm and Robin K.S. Phillips
- The original assignee of the patent was: S.L.A. Pharma AG
- S.L.A. Pharma AG is responsible for the prosecution of this patent and Ventrus Biosciences is responsible for the costs of such prosecution
- Expiration date of the patent: December 23, 2017, assuming all maintenance fees are paid.

Canadian Patent No. 2,275,663

- Title: “Pharmaceutical compositions comprising alpha-adrenergic agonists for the treatment of fecal incontinence”
- Filed under Patent Treaty Cooperation: December 23, 1997
- Entered National Stage in Canada: June 18, 1999
- The Patent was granted on: March 18, 2008
- The inventors of the patent are: Michael A. Kamm and Robin K.S. Phillips
- The original assignee of the patent was: S.L.A. Pharma AG
- S.L.A. Pharma AG is responsible for the prosecution of this patent and Ventrus BioSciences is responsible for the costs of such prosecution
- Expiration date of the patent: December 23, 2017, assuming all maintenance fees are paid.

In March 2008, we entered into a license agreement with Amer whereby we acquired patent rights to iferanserin (VEN 309) for the topical treatment of any anorectal disorders. At this time we are only pursuing VEN 309 as a treatment for hemorrhoids. However, Amer has rights to the use of VEN for wound healing to which we also would have rights to develop VEN 309 as a topical treatment for anorectal wounds. We have no current plans to pursue this indication. Amer also has a patent application pending for iferanserin as a treatment for pulmonary arterial hypertension, or PAH, which is not an anorectal disorder and to which we have no rights. The administration of iferanserin for PAH would not be a topical formulation, but instead would be systemic (taken orally or by injection) or used in a pulmonary formulation, such as an inhaler, and therefore would not compete with VEN 309.

We may be required to make future milestone payments to Amer totaling up to $20 million upon the achievement of various milestones related to regulatory or commercial events. In the event that the VEN 309 is commercialized, we are obligated to pay to Amer annual royalties ranging from the upper single to lower double digit percentages for sales in the U.S. and ranging from the low to mid single digit percentages for sales outside of the U.S. The license agreement is terminable by either party for cause, upon 30 days notice and subject to a 60-day cure period, upon notice if either party becomes bankrupt or insolvent or at any time after the expiration of the Royalty Period for any Licensed Product (as such terms are defined in the Exclusive License Agreement) upon 90 days’ written notice. We may terminate the license agreement upon 30 days’ written notice in the event any safety, efficacy or regulatory issues prevent development or commercialization of the VEN 309.

The patents for the intellectual property that we have licensed from Amer are summarized below.

US Patent No. 5,266,571 "Treatment of Hemorrhoids with 5-HT_2 Antagonists"

- Filed in United States, Europe (EP 0684816) (Germany, Great Britain, Austria, Greece, France, Portugal, Luxemburg, Ireland, Spain, Denmark, Switzerland, Belgium, Sweden, and Netherland), Japan (2807092), and Korea (0278522).
- All patents have been granted.
- In the U.S. the patent was filed with the Sam Amer as the inventor and in all foreign countries, Sam Amer & Co., Inc. as the assignee.
- Ventrus is responsible for further prosecution.
- U.S. patent will expire on January 9, 2012, all other foreign patents will expire on February 19, 2013, if all maintenance fees are timely paid.

US Patent No. 5,605,902 "5-HT2 Receptor Antagonist Compositions Useful in Treating Venous Conditions"

- Filed in the United States only.
- Patent has been granted.
- In the U.S. the patent was filed with the Sam Amer as the inventor.
- Ventrus is responsible for further prosecution.
- U.S. patent will expire on January 9, 2012, if all maintenance fees are timely paid.

US Patent No. 5,780,487 "S-2'-[2-(1-Methyl-2-Piperidyl) ethyl] Cinnamanilide" (this is the VEN 309 compound being developed by Ventrus)

- Filed in United States, Europe (EP 0973741) (Germany, Great Britain, France, Switzerland, Spain), Japan (520835/98), Norway (19994181) and Korea (10-997007763).
- U.S. and Europe granted patent, Norway, Japan and Korea are pending.
- In the U.S. the patent was filed with the Sam Amer as the inventor and in all foreign countries, Sam Amer & Co., Inc. as the assignee.
- Ventrus is responsible for further prosecution.
- U.S. patent will expire on August 7, 2015, all other foreign patents will expire on January 23, 2018, if all maintenance fees are timely paid.

Newly Filed Applications "Methods and Compositions for Treating Internal and External Hemorrhoids"

US Patent Application No. 12/860,974 filed on August 23, 2010

PCT International Application No. PCT/US2010/046260, filed on August 23, 2010

- Both patents are still pending.
- In the U.S. the patent application was filed with the Sam Amer as the inventor and in the PCT International application, Sam Amer & Co., Inc. as the assignee.
- Ventrus is responsible for further prosecution.
- Any patent that is granted from these applications will expire on August 23, 2030.

Under both the S.L.A. Pharma and the Amer license agreements, we are responsible for the costs of prosecution of the patent, as well as any new patent filings for the licensed products. While we will pay these costs, S.L.A. Pharma and Amer will retain ownership of the respective patents although we will have the rights to license the technology underlying the patents for the duration of the respective license agreement

Employees

Our activities to date have consisted of establishing and clarifying the regulatory pathway for the late phase clinical trials and regulatory approval of our product candidates, primarily VEN 309 and VEN 307, and on establishing the contract manufacturing capacity and methods necessary to allow those late phase clinical trials to proceed. All of these planned trials will be conducted by third parties. All clinical trials to date have been conducted either by the licensor, the licensor's previous partners or by independent investigators, as have the preclinical studies and product formulation activities. Consequently, we have needed only a few employees with medical expertise and drug development experience and a limited number of administrative employees.

As of November 30, 2010, we had no employees. Dr. Russell Ellison, our Chief Executive Officer and Chief Medical Officer, and David Barrett, our Chief Financial Officer, are serving under consulting agreements that we entered into in July 2010. In addition, in March 2009, we entered into a consulting agreement with Dr. John Dietrich, our former Vice President of Clinical Operations, whereby he provides consultation on manufacturing, preclinical and clinical aspects of our drug programs on an as-needed basis. We also we entered into a consulting agreement in May 2010 with Timothy Hofer, one of our former directors, to assist us with general business matters and company development matters. These consulting agreements are described in detail under "Management — Consulting and Employment Agreements." We use these consulting agreements to avoid the costs customarily associated with employees until our financial resources will allow us to hire employees. This offering, if successful, will provide us with the resources to proceed with hiring employees as noted below.

Effective upon the completion of this offering, Dr. Ellison and Mr. Barrett will begin serving under employment agreements. Assuming the successful completion of this offering, we also expect to retain Dr. Dietrich as our Vice President of Clinical Operations pursuant to either a consulting or an employment agreement and we also plan to add a clinician, two clinical project managers, a business development and marketing professional and an executive assistant, some or all of whom may work on a contract or permanent employment basis. The cost of these employees has been factored into the cost of developing our product candidates as set forth under "Use of Proceeds."

Properties

We occupy space at no charge on the 48th floor at 787 7th Avenue, New York, New York 10019, which are the offices of Paramount BioSciences, LLC. We believe our current facilities are suitable and adequate for our activities until such time as we hire a significant number of additional employees or consultants. Assuming the successful completion of this offering, we expect to begin hiring additional employees or consultants and, therefore, expect to relocate to other premises for which we will pay rent. These personnel and premises costs are included in the anticipated general and administrative costs for which we expect to use the net proceeds from this offering.

Legal Proceedings

In June 2010, we were sued for non-payment of approximately $123,000 that we owed to a company with which we had contracted to provide drug development services. On August 25, 2010, we reached a settlement with the service provider, paid the $123,000 and the suit was terminated on August 27, 2010. We had previously accrued $123,000 for this settlement. This is the only legal proceeding to which we have been a party. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business. Except as discussed above, we are not aware of any claims or actions pending or threatened against us.

MANAGEMENT

Overview

Although incorporated in 2005, we began active operations in the spring of 2007 upon the licensing by Paramount BioSciences of VEN 307 and VEN 308 from S.L.A. Pharma. Shortly thereafter, we hired Thomas Rowland as our chief executive officer (who was then and remains one of our directors), Dr. Terrance Coyne as our chief medical officer, and Dr. John Dietrich as our vice president of clinical operations, as well as other employees. Drs. Coyne and Dietrich resigned in February 2009 due to our lack of capital, and we terminated our other employees at the same time. Mr. Rowland resigned in February 2009, but he continued to act as our president from the date of his resignation in February 2009 until May 2010 although this service was not pursuant to any agreement between him and us and for which he was not paid. In consideration of payment of back pay and acceleration of the unvested stock grants, Mr. Rowland and Drs. Coyne and Dietrich accepted termination of their employment agreements. Simultaneously with the resignation of Dr. Dietrich, we entered into a consulting agreement with him whereby he provides consultation on manufacturing, preclinical and clinical aspects of our drug programs on an as-needed basis. Pursuant to this agreement, Dr. Dietrich has assisted us in regulatory filings, manufacturing planning, pre-clinical planning and clinical protocol development. These arrangements with Mr. Rowland and Dr. Dietrich allowed us to continue minimal operations following their resignations until July 2010 when we hired a new chief executive officer. Dr. Dietrich's consulting agreement remains in effect. Our business operations consist of establishing and clarifying the regulatory pathway for the late phase clinical trials and regulatory approval of our product candidates, primarily VEN 309 and VEN 307, and on establishing the contract manufacturing capacity and methods necessary to allow those late phase clinical trials to proceed. These activities can be managed by relatively few individuals.

To conserve our resources, and recognizing that permanent employment would be dependent on our raising capital in this offering, in July 2010 we entered into consulting agreements with Dr. Russell Ellison, our Chief Executive Officer and Chief Medical Officer, and David Barrett, our Chief Financial Officer. We have entered into employment agreements with Dr. Ellison and Mr. Barrett that will automatically become effective on the closing of this offering.

Assuming the successful completion of this offering, we expect to retain Dr. Dietrich as our Vice President of Clinical Operations pursuant to either a consulting or an employment agreement.

From the spring of 2007 until November 2007, our Board of Directors consisted of Mr. Rowland and two individuals affiliated with Paramount BioSciences. Between November 2007 and March 2008, we added two independent directors and one director who was an affiliate of Paramount BioSciences, each of whom subsequently resigned. These resignations were not related to any disagreement with management. Dr. Joseph Felder joined our Board in May 2008. From June 2009 until June 2010, Dr. Felder and Mr. Rowland were our only directors. Dr. Ellison joined the Board in June 2010 at the same time he became our Chief Executive Officer and Chief Medical Officer. Prior to his engagement in July 2010, Dr. Ellison began a search for additional independent directors. As a result of that search, Messrs. Cohen and Holubiak joined the Board in July 2010. Mr. Cohen, who is a director of Rodman & Renshaw, LLC, one of the co-managing underwriters in this offering, resigned in November 2010 to resolve any potential conflict. Mark Auerbach was appointed in November 2010 to fill Mr. Cohen's vacancy.

Officers & Directors

Our bylaws provide that the number of our directors is to be within a range of three to nine, with the exact number set by the Board. Our Board has set the number of directors at five although the Board might decide to increase the number of directors, within the range, if suitable candidates with desired experience and expertise are found.

Our Board of Directors has determined to apply the Nasdaq Capital Market's test for director independence to all of our directors. Using that test, the Board has determined that directors Mark Auerbach, Joseph Felder and Myron Z. Holubiak are independent under Nasdaq's rules, as of the date of this prospectus. Thomas Rowland is not deemed independent because he was our Chief Executive Officer from April 2007 through February 2009. Russell Ellison is not independent because he is our Chief Executive Officer. As part

of such determination of independence, our Board has affirmatively determined that each of Mr. Auerbach, Dr. Felder and Mr. Holubiak does not have a relationship with our company that would interfere with the exercise of independent judgment in carrying out his responsibilities as a director.

In consideration of his guaranteeing the $800,000 promissory note we issued to Israel Discount Bank of New York in September 2010, we entered into a letter agreement with Dr. Rosenwald whereby Dr. Rosenwald has the right to attend our Board meetings and to appoint two directors to our Board. Dr. Rosenwald has not exercised his right to appoint a director. If and when appointed, these directors would be subject to stockholder approval at the expiration of their terms.

The following table sets forth the names, ages and positions of each of our directors and executive officers.

Name	Age	Positions
Russell H. Ellison, M.D.	63	Director and Chief Executive Officer and Chief Medical Officer
Thomas Rowland	44	Director and Chairman of the Board
Joseph Felder, M.D.	48	Director
Mark Auerbach	72	Director
Myron Z. Holubiak	63	Director
David J. Barrett	34	Chief Financial Officer

Russell H. Ellison, M.D., M.Sc. — Director, Chief Executive Officer, Chief Medical Officer — Dr. Ellison joined us as a director, Chief Executive Officer and Chief Medical Officer in June 2010. From July 2007 to January 2010, Dr. Ellison has served as Executive Vice President of Paramount BioSciences LLC, a global pharmaceutical development and healthcare investment firm. From October 2005 until June 2007, Dr. Ellison served as the Vice President of Clinical Development of Fibrogen, Inc., a privately held biotechnology company. From August 2002 to December 2004, Dr. Ellison served as Vice President of Medical Affairs and Chief Medical Officer of Sanofi-Synthelabo, USA, a pharmaceutical company. From May 1997 to August 2002, Dr. Ellison served as Vice President, Medical Affairs and Chief Medical Officer of Hoffman-La Roche, Inc., a pharmaceutical company. Dr. Ellison also serves as a director of CorMedix, Inc., a pharmaceutical company, and several privately held development stage biotechnology companies. Dr. Ellison holds an M.D. from the University of British Columbia and an M.Sc. (with distinction) from The London School of Tropical Medicine and Hygiene. Among other experience, qualifications, attributes and skills, Dr. Ellison's medical training, extensive management experience in the pharmaceutical industry and experience in the capital markets, as well as his experience serving on the board of directors of a public pharmaceutical company and on the boards of several private pharmaceutical companies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Thomas Rowland — Director — Mr. Rowland joined Ventrus Biosciences in April 2007 as a director, a position he still holds, and as our Chief Executive Officer, a position he held until February 2009. From March 2009 to June 2010, he served as our Acting President. Prior to Ventrus, Mr. Rowland was founder and principal of his own consulting firm, consulting to various pharmaceutical and biotechnology companies in the areas of business development, marketing and launch preparation. Mr. Rowland started consulting in 2006 after serving as Vice President of the Gastroenterology and Women's Health Business Unit at Solvay Pharmaceuticals, Inc., where he oversaw all commercial operations for the over $250 million and 250 person unit. Prior to being named Vice President, Rowland successfully led the turnaround of the gastrointestinal franchise, returning the franchise to positive sales growth, record sales and profitability. Mr. Rowland had commercial responsibilities for the gastroenterology franchise at Solvay from 2000 to 2005. During that time Mr. Rowland was the commercial lead in the licensing of diltiazem and phenylephrine from S.L.A. Pharma. Mr. Rowland's responsibilities included the commercial assessment and strategic guidance of diltiazem and phenylephrine. The Solvay R&D department, however, was responsible for the development of diltiazem and phenylephrine and Mr. Rowland was not part of that department. Mr. Rowland's initial work in the gastroenterology therapeutic area started when he joined Scandipharm, Inc. in 1998 as Director of Marketing to assist in the company turnaround which resulted in the sale of the company to Axcan Pharmaceuticals. Mr. Rowland started his career in 1990 at UCB Pharma, Inc. where he spent over eight years in various

positions of increasing responsibility including sales, market research and product management. Throughout his career, Mr. Rowland has participated in numerous successful new product and line extension launches. In addition, in senior management roles, he has contributed to several product, franchise and company turnarounds. Mr. Rowland earned his B.S. in Finance from Metropolitan State University in Denver, Colorado in 1989. Among other experience, qualifications, attributes and skills, Mr. Rowland's extensive experience in managing pharmaceutical companies, including his prior employment with our company, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure. Mr. Rowland was elected Chairman of the Board of Directors in May 2010.

Joseph Felder, M.D. — Director — Dr. Felder joined our Board of Directors in May 2008. Dr. Felder has been a gastroenterologist since 1992 after having completed his post-doctoral training and fellowship at Lenox Hill Hospital in New York City. He is currently in private practice in Manhattan. He received his Bachelor of Science degree from the City University of New York and his Medical Degree from the University of Texas at San Antonio in 1987. He practices out of Lenox Hill Hospital, a major teaching affiliate of the New York University School of Medicine, where he is an adjunct and attending physician in the departments of Medicine and Gastroenterology. His responsibilities there include extensive teaching obligations. He has done significant clinical research in gastroenterology, specifically in the subject of Inflammatory Bowel Disease and is published in this field in various international journals as well as textbooks. He lectures on this subject matter as well. He is a co-chairman of the medical advisory board of the Crohn's and Colitis Foundation of America in New York. His interests are in ongoing clinical research and product development. Among other experience, qualifications, attributes and skills, Dr. Felder's knowledge and experience in the medical industry and in senior leadership roles in research and teaching organizations led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Mark Auerbach — Director — Mr. Auerbach was elected to our Board in November 2010. Over the last 17 years, Mr. Auerbach had served as directors for several companies. Mr. Auerbach currently is a director and chairman of the audit committee of Optimer Pharmaceuticals (NASDAQ: OPTR), a publically traded company. He has held those positions since June 2005. From January 2006 through March 2010, Mr. Auerbach served as the chairman of the board of directors for Neuro-Hitech, Inc., an early stage pharmaceutical company specializing in brain degenerative diseases. From June 2007 through August 2009, he served as a director for Collexis, a company which develops knowledge management and discovery software. From July 2007 through February 2009, Mr. Auerbach also served as a director for RxElite Holdings, Inc., a company which develops, manufactures, and markets generic prescription drug products in specialty generic markets. From September 2003 through October 2006, Mr. Auerbach served as executive chairman of the board of directors for Par Pharmaceutical Companies, Inc., a manufacturer and marketer of generic pharmaceuticals and the parent of Par Pharmaceutical, Inc., and served as chair of the audit committee prior to becoming executive chairman. From 1993 to 2005, Mr. Auerbach served as chief financial officer of Central Lewmar LLC, a national fine paper distributor. Mr. Auerbach received his B.S. degree in accounting from Rider University. Among other experience, qualifications, attributes and skills, Mr. Auerbach's extensive financial experience, his accounting degree and his experience as a director of several public companies, including his service as the chair of the audit committee of one of those public companies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Myron Z. Holubiak — Director — Mr. Holubiak joined our Board of Directors in July 2010. Mr. Holubiak currently serves as President of 1-800-DOCTORS, Inc., a position he has held since May, 2007. Mr. Holubiak is the former President of Roche Laboratories, Inc., USA, a major research-based pharmaceutical company, a position he held from December 1998 to August 2001. He held many sales and marketing positions at Roche Laboratories in his 19 year tenure. Mr. Holubiak was a director and the President and Chief Operating Officer of HealthSTAR Communications, Inc, the largest, private health care marketing communications company in the U.S. from November 2003 to April 2007, and he served as HealthSTAR Group's President, Field Level Marketing Group, from August 2002 to October 2003. Mr. Holubiak served on the Board of Trustees of the Robert Wood Johnson Hospital Foundation in 2000 and 2001. Since September 2002 he has served on the Board of Directors of BioScrip, Inc., a specialty pharmacy company. Mr. Holubiak previously served on the Board of Directors of Nastech, Inc., a biotechnology based pharmaceutical company now called mdRNA, Inc.

Mr. Holubiak is also on the Board of Directors of the Children of Chernobyl Relief and Development Foundation. Mr. Holubiak received his B.S. in Molecular Biology and Biophysics from the University of Pittsburgh. Among other experience, qualifications, attributes and skills, Mr. Holubiak's medical training and his extensive experience managing pharmaceutical and healthcare companies, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

David J. Barrett — Chief Financial Officer — Mr. Barrett joined us as Chief Financial Officer in July 2010. From April 2006 to September 2009, Mr. Barrett served as Chief Financial Officer of Neuro-Hitech, Inc., a company focused on developing, marketing and distributing branded and generic pharmaceutical products. From September 2003 to April 2006, Mr. Barrett was the Chief Financial Officer /Vice President of Finance of Overture Asset Managers and Overture Financial Services, which, at the time, was a start-up asset management firm that assembled investment products and platforms to distribute turnkey and unbundled investment solutions to financial intermediaries and institutional investors. From July 1999 to September 2003, Mr. Barrett was employed as a Manager at Deloitte & Touche, LLP. Mr. Barrett received his B.S. in Accounting and Economics in May of 1998 and his M.S. in Accounting in May of 1999 from the University of Florida. He is a certified public accountant.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth all compensation we paid in the fiscal years ended December 31, 2009 and 2008 to our named executive officers.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)	All Other Compensation ($)[4]	Total
Thomas Rowland	2009	50,000	—	—	62,500	112,500
Acting President[1]	2008	237,500	45,000	—	—	282,500
Terrance Coyne, M.D.	2009	48,333	—	—	60,417	108,750
Senior Vice President;	2008	229,583	30,146	—	—	259,729
Chief Medical Officer[2]						
John Dietrich, Ph.D.	2009	30,833	—	—	38,542	69,375
Vice President of Clinical	2008	142,500	16,291	—	—	158,791
Operations[3]						

(1) Mr. Rowland resigned on February 28, 2009.

(2) Dr. Coyne resigned on February 28, 2009.

(3) Dr. Dietrich resigned on February 28, 2009.

(4) Consists of severance payments.

Option Holdings and Fiscal Year-End Option Values

The following table shows information concerning unexercised options outstanding as of December 31, 2009 for each of our named executive officers.

Outstanding Equity Awards at Fiscal Year-End 2009

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Thomas Rowland	—	—	—	—
Terrance Coyne	—	—	—	—
John Dietrich	—	—	—	—

Consulting and Employment Control Agreements

Chief Executive Officer

Dr. Ellison currently serves as our Chief Executive Officer pursuant to an amended and restated consulting agreement dated July 19, 2010. The agreement provides for a term of six months with the option to extend the agreement for an additional year. Dr. Ellison receives a consulting fee of $30,000 per month. In addition, if we complete a partnership or licensing transaction or we or any of our assets are acquired by another entity prior to completing a financing resulting in gross proceeds of at least $8 million, then he will receive a fee equal to 4% of the gross proceeds of such transaction. Dr. Ellison provides us with all services customarily associated with a chief executive officer, including: strategic planning, business development, and managing business relationships. These duties are particularly important in light of this offering and our planned future as a public company. Our agreement with Dr. Ellison calls for him to provide us these services when we request them and Dr. Ellison has been devoting all of his time to providing these services to us. Our Board believed it was critical that Dr. Ellison begin work prior to our becoming a public company so that he would be able to guide the direction of our company in anticipation of the completion of this offering, assist in the preparation of the filing with the SEC of the registration statement of which this prospectus is a part, and be able to represent our company as part of this offering and afterward. Pursuant to the terms of the consulting agreement, Dr. Ellison is to provide his services to our company at such times as we reasonably request. However, Dr. Ellison has been providing his services on a full-time basis since he began working with us in June 2010.

We also have executed an amended and restated employment agreement with Dr. Ellison, which will become effective upon the closing of this offering and has a term of three years. The employment agreement provides for full-time employment at a base salary of $375,000 per year, a guaranteed bonus of $75,000 per year and an annual performance-based bonus of up to 50% of his base salary. The agreement also provides a first incentive bonus of $250,000 in the event that our market capitalization exceeds $100 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day and a second incentive bonus of $500,000 in the event that our market capitalization exceeds $250 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day. Dr. Ellison will also receive a grant of options to purchase our common stock at the initial public offering price in an amount equal to 7.5% of our fully diluted capitalization on the date the employment agreement becomes effective, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan. One-third of the option vests on grant, one-third vests one year later and the remainder vests two years after grant.

Under the employment agreement, Dr. Ellison is prohibited for six months after termination from (a) engaging in any business within a restricted territory that develops or commercializes prescription drugs for the specific disease treatment of hemorrhoids, anal fissures, and fecal incontinence or other products that compete with products we are developing or selling at the time of his termination, (b) soliciting or working within a restricted territory with our competitors or any other entity that could benefit from Dr. Ellison's use of our confidential information, (c) becoming financially interested with one of our competitors within a restricted territory, (d) soliciting or accepting business from our competitors, and (e) inducing any employee or consultant of ours to terminate employment or a contractual relationship with us.

Set forth below is a description of the potential payments we will need to make upon termination of Dr. Ellison's employment or upon a change in control of our company.

Termination due to Death, Disability or Change of Control

If Dr. Ellison's employment is terminated as a result of his death, disability or change of control, we must pay him or his estate, as applicable, his then current base salary for a period of six months following the date of termination and any earned but unpaid incentive bonus and expense reimbursement through the date of his death or disability. All stock options that are scheduled to vest on the next succeeding anniversary of the effective date of the agreement will be accelerated and deemed to have vested as of the termination date. All

stock options that have not vested or been deemed to have vested as of the date of termination will be forfeited. Stock options that have vested as of Dr. Ellison's termination will remain exercisable for 360 days following his termination.

Termination by us For Cause

If we terminate Dr. Ellison for cause (as defined in the agreement), we must pay his then current base salary through the date of his termination and any expense reimbursement amounts owed through the date of termination.

Termination by us for other than Cause or by Dr. Ellison for Good Reason

If Dr. Ellison's employment is terminated (i) by us other than for cause or (ii) by Dr. Ellison for good reason (as defined in the agreement), then we must (1) continue to pay Dr. Ellison his then current base salary and all fringe benefits for a period of six months following such termination, (2) any expense reimbursement amounts owed through the date of termination, (3) pay any accrued but unpaid bonus and (4) all stock options granted to Dr. Ellison that are scheduled to vest by the end of the term of the employment agreement shall be accelerated and deemed to have vested as of the termination date.

In the agreement, the term "change in control" is defined generally as the acquisition by any person of more than 50% of the voting power of our then outstanding securities; and/or the merger or consolidation of our company or the sale of any or substantially all of our assets.

In the agreement, the term "cause" is defined generally as follows: (i) willful failure, disregard or continuing refusal by Dr. Ellison to perform his duties; (ii) willful, intentional or grossly negligent act by Dr. Ellison that injures, in a material way, our business or reputation; (iii) insubordination by Dr. Ellison with respect to lawful directions received from our Board of Directors; (iv) indictment for any felony or a misdemeanor involving moral turpitude; (v) Dr. Ellison engaging in some form of harassment prohibited by law; (vi) any misappropriation or embezzlement of our property; (vii) willful violation of the noncompetition, nonsolicitation and confidentiality provisions of the agreement; and/or (viii) breach by Dr. Ellison of any other provision of the agreement that, if capable of being cured, is not cured by him within 30 business days.

In the agreement, the term "good reason" is defined generally as: (i) the assignment to Dr. Ellison of duties materially inconsistent with his position and duties as chief executive officer; (ii) any reduction by us of Dr. Ellison's compensation or benefits; and/or (iii) any requirement that he relocate outside a 30 mile radius of New York, New York.

Chief Financial Officer

Mr. Barrett currently serves as our Chief Financial Officer pursuant to an amended and restated consulting agreement dated July 19, 2010. The agreement provides for a term of six months with the option to extend the agreement for an additional year. Mr. Barrett receives a consulting fee of $15,000 per month. Mr. Barrett provides us with all services customarily associated with that of a chief financial officer, including: preparing the operating budget; overseeing the management and coordination of all fiscal reporting activities, including revenue/expense and balance sheet reports; assessing the economic impact of all current and prospective contracts; and ensuring adequate cash flow to meet our needs. These duties are particularly important in light of this offering and our planned future as a public company. Our Board believed it was critical that Mr. Barrett begin work prior to our becoming a public company so he could prepare our financial statements that are included in this prospectus, assist in the preparation of the filing with the SEC of the registration statement of which this prospectus is a part, and begin establishing necessary accounting controls prior to our becoming a public company. Pursuant to the terms of the consulting agreement, Mr. Barrett currently provides services to Ventrus at such times as the company reasonably requests and serves on a part-time basis.

We also have executed an employment agreement with Mr. Barrett, which will become effective upon the closing of this offering and has a term of three years. The employment agreement provides for full-time employment at a base salary of $250,000 per year. The agreement also provides a first incentive bonus of $250,000 in the event that our market capitalization exceeds $100 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000

shares per trading day and a second incentive bonus of $500,000 in the event that our market capitalization exceeds $250 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day. Mr. Barrett will also receive a grant of options to purchase our common stock at the initial public offering price in an amount equal to 4.0% of our fully diluted capitalization on the date the employment agreement becomes effective, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan. One-third of the option vests on grant, one-third vests one year later and the remainder vests two years after grant.

Under the employment agreement, Mr. Barrett is prohibited for six months after termination from (a) engaging in any business within a restricted territory that develops or commercializes prescription drugs for the specific disease treatment of hemorrhoids, anal fissures, and fecal incontinence or other products that compete with products we are developing or selling at the time of his termination, (b) soliciting or working within a restricted territory with our competitors or any other entity that could benefit from Mr. Barrett's use of our confidential information, (c) becoming financially interested with one of our competitors within a restricted territory, (d) soliciting or accepting business from our competitors, and (e) inducing any employee or consultant of ours to terminate employment or a contractual relationship with us. Set forth below is a description of the potential payments we will need to make upon termination of Mr. Barrett's employment or upon a change in control of our company.

Termination due to Death, Disability or Change of Control

If Mr. Barrett's employment is terminated as a result of his death, disability or change of control, we must pay him or his estate, as applicable, his then current base salary for a period of six months following the date of termination and any earned but unpaid incentive bonus and expense reimbursement through the date of his death or disability. All stock options that are scheduled to vest on the next succeeding anniversary of the effective date of the agreement will be accelerated and deemed to have vested as of the termination date. All stock options that have not vested or been deemed to have vested as of the date of termination will be forfeited. Stock options that have vested as of Mr. Barrett's termination will remain exercisable for 360 days following his termination.

Termination by us For Cause

If we terminate Mr. Barrett for cause (as defined in the agreement), we must pay his then current base salary through the date of his termination and any expense reimbursement amounts owed through the date of termination.

Termination by us for other than Cause or by Mr. Barrett for Good Reason

If Mr. Barrett's employment is terminated (i) by us other than for cause or (ii) by Mr. Barrett for good reason (as defined in the agreement), then we must (1) continue to pay Mr. Barrett his then current base salary and all fringe benefits for a period of six months following such termination, (2) any expense reimbursement amounts owed through the date of termination, (3) pay any accrued but unpaid bonus and (4) all stock options granted to Mr. Barrett that are scheduled to vest by the end of the term of the employment agreement shall be accelerated and deemed to have vested as of the termination date.

In the agreement, the term "change in control" is defined generally as the acquisition by any person of more than 50% of the voting power of our then outstanding securities; and/or the merger or consolidation of our company or the sale of any or substantially all of our assets.

In the agreement, the term "cause" is defined generally as follows: (i) willful failure, disregard or continuing refusal by Mr. Barrett to perform his duties; (ii) willful, intentional or grossly negligent act by Mr. Barrett that injures, in a material way, our business or reputation; (iii) insubordination by Mr. Barrett with respect to lawful directions received from our Board of Directors; (iv) indictment for any felony or a misdemeanor involving moral turpitude; (v) Mr. Barrett engaging in some form of harassment prohibited by law; (vi) any misappropriation or embezzlement of our property; (vii) willful violation of the noncompetition, nonsolicitation and confidentiality provisions of the agreement; and/or (viii) breach by Mr. Barrett of any other provision of the agreement that, if capable of being cured, is not cured by him within 30 business days.

In the agreement, the term “good reason” is defined generally as: (i) the assignment to Mr. Barrett of duties materially inconsistent with his position and duties as chief financial officer; (ii) any reduction by us of Mr. Barrett’s compensation or benefits; and/or (iii) any requirement that he relocate outside a 30 mile radius of New York, New York.

Others

Upon his resignation as our Vice President of Clinical Operations, on March 1, 2009, we entered into a consulting agreement with Dr. John Dietrich. Pursuant to the agreement, Dr. Dietrich provides us with consultation on manufacturing, preclinical and clinical aspects of our drug programs on an as-needed basis. The agreement had an initial term of six months, but renews automatically every six months for an additional six months upon our mutual written agreement. For his services, we pay Dr. Dietrich $150 per hour and reimburse him for his reasonable and necessary expenses incurred in providing us his services. We must pre-approve such expenses in writing. Either we or Dr. Dietrich may terminate the agreement upon three days notice.

To assist us with general business matters and company development matters after Mr. Rowland ceased acting as our president, in May 2010 we entered into a consulting agreement with Timothy Hofer. Mr. Hofer served as a director of our company from its inception until June 2009. Mr. Hofer is the senior vice president, legal affairs of Paramount BioSciences. Mr. Hofer provided us with general business advice, without compensation, the value of which was not significant, from late 2009 through April 2010, primarily in connection with our capital raising efforts. Mr. Hofer will provide consulting services for one year for which we issued him a warrant to purchase 8,065 shares of our common stock, which number of shares will automatically adjust so that the amount of shares covered by the warrant will be an amount equal to 1% of the fully-diluted shares of our company outstanding immediately after this offering, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan. We also will reimburse Mr. Hofer for his reasonable and necessary expenses incurred in providing us his services. We must pre-approve such expenses in writing. Either we or Mr. Hofer may terminate the agreement upon 30 days notice.

Equity Compensation Plan Information

2007 Stock Incentive Plan

In October 2007 our stockholders adopted the 2007 Stock Incentive Plan. The 2007 Stock Plan authorized us to issue equity incentive awards in the form of shares, options or other awards based on our common stock as part of an overall compensation package to provide performance-based compensation to attract and retain qualified personnel. The 2007 Plan reserved up to 483,871 shares of our common stock. As of November 30, 2010, we have granted options to purchase an aggregate of 2,016 shares of our common stock under the 2007 Plan. In August 2010 our board of directors voted to terminate the 2007 Plan. As a result, we may not grant any future awards under the 2007 Plan; however, all awards we granted under the 2007 Plan prior to the termination of the 2007 Plan remain in effect, subject to the terms of the 2007 Plan and the individual award.

2010 Equity Incentive Plan

In August 2010 our board of directors and our stockholders adopted the 2010 Equity Incentive Plan. The 2010 Equity Plan authorizes us to issue equity incentive awards in the form of shares, options or other awards based on our common stock as part of an overall compensation package to provide performance-based compensation to attract and retain qualified personnel. The plan reserves up to 2,467,200 shares of our common stock. In November 2010, our Board granted options to non-employee directors to purchase an aggregate of 160,000 shares under the plan, as described under “Director Compensation” below. In addition, under Dr. Ellison’s and Mr. Barrett’s respective employment agreements, we committed to grant Dr. Ellison and Mr. Barrett options to purchase shares of our common stock at a price equal to the initial public offering price in an amount equal to 7.5% and 4.0%, respectively, of our fully diluted capitalization on the date the employment agreement becomes effective.

Director Compensation

The following table shows the compensation earned by each of our non-employee directors for the year ended December 31, 2009.

Non-Employee Director Compensation in Fiscal 2009

Name	Fees Earned or Paid in Cash	Option Awards	Total ($)
Joseph Felder, M.D.(1)	$ —	$ —	$ —

(1) At December 31, 2009, Dr. Felder had no options outstanding and no options had been granted to any director. In May 2010, we granted an option to purchase 2,016 shares of our common stock to Dr. Felder under the 2007 plan.

In November 2010, our Board established the non-employee director compensation structure, which consists of cash and equity compensation. Upon a director's first election to the Board, he or she will be granted an option to purchase 35,000 shares of the company's common stock. Each director will be granted an option annually for his or her prior year's service on the Board in an amount to be determined by the Board. The grant to a director, who, at the time of the grant, has served less than a full year prior to the date of grant, will be pro-rated for that portion of the year actually served.

The cash compensation component will not become effective until such time as we have raised cumulative net proceeds from equity financings (including this offering) and partnership and licensing transactions of $20 million. The cash compensation will consist of an annual cash fee of $5,000. Committee members will receive an additional $5,000, the Chairs of the Nominating and Governance Committee and the Compensation Committee will each receive an additional $2,500 and the Chair of the Audit Committee will receive an additional $5,000.

In November 2010, effective immediately after the reverse stock split, our Board granted to our former director Richard Cohen, in consideration of his services as a director, an option to purchase 20,000 shares of our common stock and, pursuant to our non-employee director compensation structure, granted to each of Mark Auerbach, Joseph Felder, Myron Holubiak and Thomas Rowland an option to purchase 35,000 shares of our common stock. All of these options have a term of 10 years, have an exercise price equal to the initial public offering price of $6.00. In addition, one-third of each of these options vested on the respective vesting commencement date and the remaining two-thirds will vest in three equal annual installments after the respective vesting commencement date.

Corporate Governance

Independence of Directors

All of our directors, other than Dr. Ellison and Mr. Rowland, qualify as independent directors as defined in Rule 4200 of the Nasdaq Marketplace rules for listed companies.

Each expected member of each of our Compensation, Nominating and Governance and Audit Committees is also expected to qualify as independent under Nasdaq's Marketplace rules for listed companies.

Board Committees

Our Board has established the following three standing committees: Audit Committee; Compensation Committee; and Nominating and Governance Committee. Directors Auerbach, Ellison and Holubiak are the members of the Audit Committee and Mr. Auerbach qualifies as an "audit committee financial expert" as that term is defined in Item 407(d) of Regulation S-K promulgated by the SEC. Pursuant to rules of the Nasdaq Capital Market, Dr. Ellison, who is not an independent director, may serve on the Audit Committee for up to one year from the completion of this offering. At that time, all members of the Audit Committee must be independent. Directors Felder and Holubiak are the members of the Compensation Committee. Directors Felder and Holubiak are the members of the Nominating and Governance Committee.

Audit Committee

The primary purpose of our Audit Committee is to oversee our accounting and financial reporting process and the audits of our combined financial statements, and on our compliance with legal and regulatory requirements.

The functions of our Audit Committee include:

- Hiring the independent registered public accounting firm to conduct the annual audit of our financial statements and monitoring their independence and performance;
- Reviewing and approving the planned scope of the annual audit and the results of the annual audit;
- Pre-approving all audit services and permissible non-audit services provided by our independent registered public accounting firm;
- Reviewing the accounting and reporting principles we apply in preparing our financial statements;
- Reviewing our internal financial, operating and accounting controls with management and our independent registered public accounting firm;
- Reviewing with management and our independent registered public accounting firm, as appropriate, our financial reports and our compliance with legal and regulatory requirements; and
- Reviewing and approving any transaction that may present potential for conflict of interest pertaining to accounting, internal control or auditing, such as with our officers, directors or significant stockholders.

Our Audit Committee is responsible for reviewing and approving all related party transactions, including transactions with executive officers and directors, for potential conflicts of interests or other improprieties. Under SEC rules, related party transactions are those transactions to which we are or may be a party in which the amount involved exceeds $120,000, and in which any of our directors or executive officers or any other related person had or will have a direct or indirect material interest, excluding, among other things, compensation arrangements with respect to employment and Board membership. Our Audit Committee could approve a related party transaction if it determined that the transaction is in our best interests.

Our directors are required to disclose to this committee or the full Board any potential conflict of interest, or personal interest in a transaction that our Board is considering. Our executive officers will be required to disclose any related party transaction to the Audit Committee. We also plan to poll our directors on an annual basis with respect to related party transactions and their service as an officer or director of other entities.

Any director involved in a related person transaction that is being reviewed or approved must recuse himself or herself from participation in any related deliberation or decision. Whenever possible, the transaction should be approved in advance and if not approved in advance, must be submitted for ratification as promptly as practical.

Prior to July 2010, our full Board of Directors reviewed and, if deemed beneficial to our company and our stockholders, approved any related party transactions.

Compensation Committee

The primary purpose of our Compensation Committee is to discharge our Board’s responsibilities relating to compensation of our executive officers and employees and to administer our equity compensation and other benefit plans. In carrying out these responsibilities, our Compensation Committee will review all components of executive officer and employee compensation for consistency with our Compensation Committee’s compensation philosophy, as in effect from time to time.

The functions of our Compensation Committee include:

- Designing and implementing competitive compensation policies to attract and retain key personnel;
- Reviewing and formulating policy and determining the compensation of our executive officers and employees;

- Reviewing and recommending to the Board the compensation of our directors; and
- Administering our equity incentive plans and granting equity awards to our employees and directors under these plans.

Our principal executive officer will not participate in the determination of her own compensation or the compensation of directors. However, it is intended that he would make recommendations to our Compensation Committee regarding the amount and composition of the compensation of our other officers and participate in the Compensation Committee's deliberations about these other officers' compensation.

The Compensation Committee has the authority to engage compensation consultants or other advisors that it deems appropriate to assist it with its duties.

Our Compensation Committee may engage independent compensation consultants to provide:

- Assistance in selecting a peer group of companies for executive compensation comparison purposes;
- Comparative market data on officer and board of director compensation practices and programs of peer companies and competitors;
- Guidance on industry best practices and emerging trends and developments in officer and board director compensation; and
- Advice on determining the total compensation of each of our officers and the material elements of total compensation, including (1) annual base salaries, (2) target cash bonus amounts, (3) stock option awards and (4) restricted stock awards.

Nominating and Governance Committee

The primary purpose of our Nominating and Governance Committee is to:

- Identify and evaluate individuals for possible Board members;
- Select, and recommend to our Board, director nominees for each election of directors;
- Develop and recommend to our Board criteria for selecting qualified director candidates;
- Recommend any corporate governance guidelines it deems appropriate; and
- Provide oversight in the evaluation of our Board and each committee of our Board.

Our Nominating and Governance Committee will regularly assess the optimum size of our Board and its committees and the needs of our Board for various skills, background and business experience in determining whether it is advisable to consider additional candidates for nomination.

In fulfilling its responsibilities to select, and recommend to our Board, director nominees for each election of directors, our Nominating and Governance Committee will consider the following factors:

- the appropriate size of our Board and its committees;
- the perceived needs of our Board for particular skills, background and business experience;
- the skills, background, reputation, and business experience of nominees compared to the skills, background, reputation, and business experience already possessed by other Board members;
- nominees' independence from management; and
- applicable regulatory and listing requirements, including independence requirements and legal considerations.

The goal of our Nominating and Governance Committee will be to assemble a Board that brings to Ventrus a variety of perspectives and skills derived from high quality business and professional experience. Directors should possess high personal and professional ethics, integrity and values, and be committed to representing the best interests of our stockholders. They must also have an inquisitive and objective perspective and mature judgment. Director candidates, in the judgment of our Nominating and Governance

Committee, must also have sufficient time available to perform all Board and committee responsibilities. Board members are expected to prepare for, attend and participate in all Board and applicable committee meetings.

Other than the foregoing, there are no stated minimum criteria for director nominees, although our Nominating and Governance Committee may also consider such other factors as it may deem, from time to time, to be in the best interests of the company and our stockholders.

Our Nominating and Governance Committee will annually evaluate our Board members who are willing to continue in service against the criteria set forth above in determining whether to recommend these directors for re-election.

Candidates for nomination as director may come to the attention of our Nominating and Governance Committee from time to time through incumbent directors, management, stockholders or third parties. These candidates may be considered at meetings of our Nominating and Governance Committee at any point during the year. Such candidates will be evaluated against the criteria set forth above. If our Nominating and Governance Committee believes at any time that it is desirable that our Board consider additional candidates for nomination, the Committee may poll directors and management for suggestions or conduct research to identify possible candidates and may, if our Nominating and Governance Committee believes it is appropriate, engage a third-party search firm to assist in identifying qualified candidates.

Our Nominating and Governance Committee's policy will be to evaluate any recommendation for director nominee proposed by a stockholder. Our bylaws permit stockholders to nominate directors for consideration at an annual meeting, subject to certain conditions. Any recommendation for director nominee must be submitted in writing to:

Ventrus Biosciences, Inc.
Attention: Corporate Secretary
787 7th Avenue, 48th Floor
New York, New York 10019

Our bylaws require that any director nomination made by a stockholder for consideration at an annual meeting must be received in writing not more than 90 days nor less than 60 days in advance of the meeting, and at a special meeting called for the purpose of the election of directors not later than the close of business on the 10th business day following the date on which notice of such meeting is first given to our stockholders.

Each written notice containing a stockholder nomination of a director at an annual or special meeting must include:

- the name and address of the stockholder who intends to make the nomination and any stockholder associated with such stockholder, and the name and residence address of the person or persons to be nominated;
- the class and number of shares that are beneficially owned by the stockholder and any associated stockholder;
- a representation that the stockholder is a holder of record of stock entitled to vote at the meeting and intends to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice;
- a description of all arrangements or understandings between the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nomination or nominations are to be made by the stockholder;
- such other information regarding each nominee proposed by such stockholder as would be required to be disclosed in solicitations of proxies for election of directors, or as would otherwise be required, in each case pursuant to Regulation 14A under the Exchange Act including any information that would be required to be included in a proxy statement filed pursuant to Regulation 14A had the nominee been nominated by the board of directors;

- the written consent of each nominee to be named in a proxy statement and to serve as director of the corporation if so elected;
- whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of, or any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares) has been made, the effect or intent of which is to mitigate loss to or manage risk or benefit of share price changes for, or to increase or decrease the voting power of, such stockholder of any associated stockholder with respect to any share of our common stock; and
- to the extent known by the stockholder giving the notice, the name and address of any other stockholder supporting the nominee for election or reelection as a director or the proposal of other business on the date of such stockholder's notice.

The provisions of our bylaws requiring advance notice of director nominees and the process by which the Nominating and Governance Committee assesses and recommends director nominees do not apply to the two director appointees that Lindsay Rosenwald may appoint to our Board of Directors.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock, as of November 30, 2010 (taking into account the 1-for-12.4 reverse stock split that we effected on November 10, 2010), for:

- each of our named executive officers;
- each of our directors;
- all our current executive officers and directors as a group; and
- each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock.

For purposes of the table below, the percentage ownership calculations for beneficial ownership prior to this offering are based on 447,347 shares of our common stock outstanding as of November 30, 2010 (taking into account the 1-for-12.4 reverse stock split that we effected on November 10, 2010). The table does not give effect to the conversion of notes that will convert in this offering that are held by any of our named executive officers, directors or 5% stockholders.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of November 30, 2010, pursuant to the exercise of options, warrants or other rights, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. The address for each director and executive officer listed is: c/o Ventrus Biosciences, Inc., 787 7th Avenue, 48th Floor, New York, New York 10019.

Name	Shares Beneficially Owned Prior to the Offering*		Shares Beneficially Owned After the Offering**	
	Number	Percentage	Number	Percentage
Named Executive Officers and Directors:				
Russell H. Ellison	8,065(1)	1.8%	199,264(2)	2.9%
Thomas Rowland	37,831(3)	8.1%	37,831(3)	***
Joseph Felder, M.D.	29,238(4)	6.1%	29,238(4)	***
Mark Auerbach	11,666(5)	2.5%	11,666(5)	***
Myron Z. Holubiak	11,666(5)	2.5%	11,666(5)	***
David J. Barrett	—	—	101,973(6)	1.5%
All executive officers and directors as a group (six persons)	97,390	18.7%	930,616	5.5%
5% Stockholders:				
Lindsay A. Rosenwald, M.D. c/o Paramount BioSciences, LLC 787 7th Avenue, 48th Floor New York, New York 10019	144,008(7)	31.9%	518,324(8)	7.6%
Hillel Gross(9) c/o AmTrust Financial Services 59 Maiden Lane, 6th Floor New York, New York 10038	64,516	14.4%	64,516	1.0%
S.L.A. Pharma AG Rebgasse 2 Postfach Ch-4410 Liestal, Switzerland	32,006(10)	6.9%	96,939(11)	1.4%
Jeffrey Serbin c/o Roswell Park Cancer Institute Elm and Carlton Streets Carlton House A-320 Buffalo, New York 14226	25,806	5.8%	25,806	***

* Unless otherwise noted, the number and percentage of outstanding shares of our common stock is based upon 447,347 shares outstanding on November 30, 2010, taking into account the 1-for-12.4 reverse stock split effected on November 10, 2010.

** Unless otherwise noted, the number and percentage of outstanding shares of our common stock is based upon 6,746,365 shares outstanding after the closing of this offering and the conversion of all notes to common stock in connection with this offering.

***Represents less than 1%.

(1) Consists of 8,065 shares of our common stock issuable upon exercise of a warrant.

(2) Consists of (i) 8,065 shares of our common stock issuable upon exercise of a warrant and (ii) the one-third vested portion of the 573,599 shares of our common stock issuable pursuant to an option that we are obligated to issue to Dr. Ellison, our Chief Executive Officer, upon the closing date of this offering, which is equal to 7.5% of the fully diluted shares of our company outstanding immediately after this offering, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for future grants under our 2010 Equity Incentive Plan.

(3) Includes 19,444 shares of our common stock issuable upon exercise of options.

(4) Consists of 29,238 shares of our common stock issuable upon exercise of options.

(5) Consists of 11,666 shares of our common stock issuable upon exercise of an option.

(6) Consists of the one-third vested portion of the 305,920 shares of our common stock issuable pursuant to an option that we are obligated to issue to Mr. Barrett, our Chief Financial Officer, upon the closing date of this offering, which is equal to 4.0% of the fully diluted shares of our company outstanding immediately after this offering, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for future grants under our 2010 Equity Incentive Plan.

(7) Includes 23,128 shares of common stock and 4,805 shares of common stock underlying warrants held by Paramount BioSciences, LLC, of which Dr. Rosenwald is the sole member. Does not include (i) shares issuable upon the conversion of convertible promissory notes issued to Paramount BioSciences and Capretti Grandi, LLC, each affiliates of Dr. Rosenwald, for which the amount issuable upon conversion was historically indeterminable, or (ii) shares issuable upon the exercise of warrants held by Paramount Credit Partners, LLC for which the number of shares was historically indeterminable. Does not include 6,733 shares of common stock and 1,347 shares of common stock underlying warrants held by a trust established for the benefit of Dr. Rosenwald's children, or 64,516 shares of common stock held by four trusts established for the benefit of Dr. Rosenwald and his family because Dr. Rosenwald disclaims beneficial ownership of all of these shares, except to the extent of his pecuniary interest therein.

(8) Includes (i) 23,128 shares of common stock and 4,805 shares of common stock underlying warrants held by Paramount BioSciences, LLC, of which Dr. Rosenwald is the sole member, (ii) 104,867 shares issuable upon the exercise of warrants held by Paramount Credit Partners, LLC, and (iii) 269,449 shares issuable upon the automatic conversion upon the closing of this offering of convertible promissory notes issued to Paramount BioSciences and Capretti Grandi, LLC, each affiliates of Dr. Rosenwald. The shares issuable upon exercise of the warrant and conversion of the convertible promissory notes are only included in the pro forma column because the number of shares can only be calculated based on the specific terms of this offering and are otherwise indeterminable. Does not include 6,733 shares of common stock and 1,347 shares of common stock underlying warrants held by a trust established for the benefit of Dr. Rosenwald's children, or 64,516 shares of common stock held by four trusts established for the benefit of Dr. Rosenwald and his family because Dr. Rosenwald disclaims beneficial ownership of all of these shares, except to the extent of his pecuniary interest therein.

(9) Mr. Gross is the trustee of the four trusts established for the benefit of Dr. Rosenwald and his family, which own 64,516 shares of our common stock in the aggregate. Mr. Gross might be deemed to beneficially own the shares held by these trusts because he has sole voting and dispositive control over all shares held by these trusts.

(10) Includes 13,605 shares of our common stock underlying a warrant.

(11) Includes (i) 13,605 shares of our common stock underlying a warrant and (ii) 64,933 shares of our common stock that we are obligated to issue to S.L.A. Pharma upon the closing of this offering, based on the initial offering price of $6.00, pursuant to an agreement that in the event we close an equity financing with gross proceeds of not less than $5,000,000 and the 18,401 shares initially issued in 2007 to S.L.A. Pharma do not have a fair market value of at least $500,000 (calculated by multiplying the number of shares by the price per share paid in the financing), we would issue S.L.A. Pharma that number of additional shares of our common stock that when added to the 18,401 shares would have a fair market value equal to $500,000 (based on the price per share paid in the financing).

DESCRIPTION OF CAPITAL STOCK

Common Stock

On November 10, 2010, we effected a 1-for-12.4 reverse stock split of all of our shares of common stock. The ratio for the reverse split was determined by our Board of Directors. The purpose of the reverse split was to ensure that the price per share of the common stock offered in this offering would be within the $6.00 to $7.00 price range set forth on the cover page of this prospectus. The reverse stock split was also approved by our stockholders. All share amounts referred to herein have been adjusted to reflect the effect of our 1-for-12.4 reverse stock split. All disclosures regarding common stock in this registration statement have taken into account this reverse stock split unless otherwise stated.

The reverse stock split was effected by filing an amended and restated certificate of amendment, which also increased our authorized shares as described below.

Our authorized capital stock consists of 50,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of November 30, 2010, we had outstanding 447,347 shares of common stock, held of record by 120 stockholders, and no shares of preferred stock. Assuming the automatic conversion of all outstanding convertible promissory notes into common stock immediately prior to the closing of this offering at the initial public offering price of $6.00 per share, we will issue an additional 3,334,085 shares. In addition, as of November 30, 2010, we also had issued options to acquire 162,016 shares of common stock and warrants, with established exercise prices and share amounts, to acquire 85,689 shares of common stock. On the closing date of this offering, we are obligated to issue options to Russell Ellison, our Chief Executive Officer, and David J. Barrett, our Chief Financial Officer, to acquire a number of shares equal to 7.5% and 4.0%, respectively, of the fully-diluted shares of our company outstanding immediately after this offering, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan. In addition on the closing date of this offering, a warrant we issued in May 2010 to a consultant for the purchase of 8,065 shares will automatically adjust so that the amount of shares covered by the warrant will be an amount equal to 1% of the fully-diluted shares of our company outstanding immediately after the offering, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan. Finally, in the event we close an equity financing with gross proceeds of not less than $5,000,000 and the 18,401 shares issued to S.L.A. Pharma do not have a fair market value at least equal to $500,000 (calculated by multiplying the number of shares by the price per share paid in the financing), we must issue to S.L.A. Pharma that number of additional shares of our common stock so that, when added to the 18,401 shares initially issued, the new and old shares have a fair market value equal to $500,000 (based on the price per share paid in the financing). Upon the closing of this offering, based on the initial offering price of $6.00, we will be obligated to issue S.L.A. Pharma 64,933 shares of our common stock.

Voting. Holders of the common stock are entitled to one vote for each outstanding share common stock owned by that stockholder on every matter properly submitted to the stockholders for their vote. Stockholders are not entitled to vote cumulatively for the election of directors.

Dividend Rights. Subject to the dividend rights of the holders of any outstanding series of preferred stock, holders of the common stock are entitled to receive ratably such dividends and other distributions of cash or any other right or property as may be declared by our board of directors out of our assets or funds legally available for such dividends or distributions.

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of our company's affairs, holders of the common stock would be entitled to share ratably in our assets that are legally available for distribution to stockholders after payment of liabilities. If we have any preferred stock outstanding at such time, holders of the preferred stock may be entitled to distribution and/or liquidation preferences. In either such case, we must pay the applicable distribution to the holders of our preferred stock (if any) before we may pay distributions to the holders of common stock.

Conversion, Redemption and Preemptive Rights. Holders of our common stock have no conversion, redemption, preemptive, subscription or similar rights.

Preferred Stock

In addition to our authorized common stock, we have authorized 5,000,000 shares of preferred stock. Our board of directors has the authority to establish the rights and preferences of shares of preferred stoic without the approval of our stockholders. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock.

Options

As of November 30, 2010, one option to purchase 2,016 shares of common stock was outstanding under the 2007 Stock Incentive Plan. In August 2010, we terminated the 2007 Plan and no additional awards are available for issuance under it. In August 2010, our stockholders approved the 2010 Equity Incentive Plan, under which 2,467,200 shares of common stock are available for future issuance. As of November 30, 2010, we had issued options to purchase an aggregate of 160,000 shares under the 2010 Equity Incentive Plan. At November 30, 2010 we had an obligation under the employment agreements with Dr. Ellison and Mr. Barrett to issue options on the closing date of this offering to purchase a number of shares equal to 7.5% and 4.0%, respectively, of our fully diluted capitalization, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan.

Warrants

As of November 30, 2010, we had two warrants outstanding to purchase an aggregate of 11,290 shares of our common stock with an exercise price of $7.69 per share issued to Russell Ellison, prior to his becoming our Chief Executive Officer, and another individual for consulting services. Each warrant has a net exercise provision under which the holder in lieu of payment of the exercise price in cash can surrender the warrant and receive a net number of shares of common stock based on the fair market value of such stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Unless earlier exercised, these warrants will expire on November 8, 2014.

As of November 30, 2010, we had warrants outstanding to purchase an aggregate of 42,782 shares of our common stock with an exercise price of $12.40 per share. These warrants were originally issued to Paramount BioCapital, Inc. as part of its compensation for acting as placement agent in our 2008 common stock and warrant financing. Paramount BioCapital subsequently transferred the warrant among various of its employees. These warrants have a net exercise provision under which the holder in lieu of payment of the exercise price in cash can surrender the warrant and receive a net number of shares of common stock based on the fair market value of such stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Unless earlier exercised, these warrants will expire on December 21, 2014.

As of November 30, 2010, we had 44 warrants outstanding to purchase an aggregate of 9,947 shares of our common stock with an exercise price of $66.46 per share issued to investors in our 2008 common stock and warrant financing. Unless earlier exercised, these warrants will expire between June and August 2015.

As of November 30, 2010, we had four warrants outstanding to purchase an aggregate number of shares of common stock equal to $629,200 divided by the public offering price in this offering with an exercise price of 110% of the public offering price per share. These warrants were issued to Paramount Credit Partners, LLC in connection with loans made to us under promissory notes we issued to Paramount Credit Partners. Each of these warrants is redeemable at a price of $0.0124 per share at any time after trading in our common stock begins on an exchange or the over-the-counter bulletin board and the closing price of our common stock is at least twice the exercise price for a period of 30 consecutive days, provided the common stock underlying such warrants are registered for resale. Unless earlier exercised, these warrants will expire between January and June 2014.

As of November 30, 2010, we had 53 warrants to purchase an aggregate number of shares of common stock equal to 50% of $5,617,433 divided by the public purchase price in this offering with an exercise price of 110% of the initial public offering price per share. These warrants were issued to investors in our 2010 senior convertible note financing. Each of these warrants is redeemable at a price of $0.0124 per share at any

time after trading in the common stock begins on an exchange or the over-the-counter bulletin board and the closing price of the common stock is at least twice the exercise price for a period of 30 consecutive days, provided that the shares of common stock underlying these warrants have been registered for resale under the Securities Act or are otherwise freely tradable. Unless earlier exercised, these warrants will expire on February 26, 2015.

As of November 30, 2010, we had one warrant outstanding to purchase 8,065 shares of our common stock with an exercise price equal of the initial public offering price in this offering, provided that if the offering is not consummated by January 31, 2011, then the exercise price per share shall equal the fair market value of a share of our common stock on such date. This warrant was issued to a consultant, Timothy Hofer. This warrant has an anti-dilution provision which provides that upon completion of this offering the number of shares for which it is exercisable will be automatically adjusted to equal 1% of our then-current capitalization on a fully diluted basis, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan. This warrant also has a net exercise provision under which the holder in lieu of payment of the exercise price in cash can surrender the warrant and receive a net number of shares of common preferred stock based on the fair market value of such stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Unless earlier exercised, this warrant will expire on September 10, 2020.

As of November 30, 2010, we had four warrants outstanding to purchase an aggregate of 89,000 shares of common stock with an exercise price of 125% of the initial public offering price per share. These warrants were issued to National Securities Corporation as part of its compensation for acting as placement agent in our 2010 senior convertible note financing and, prior to their amendment originally covered a number of shares equal to 10% of the number of shares into which the 2010 senior convertible notes convert in this offering with an exercise price of 110% of the initial public offering price. Each of these warrants is redeemable at a price of $0.0124 per share at any time after trading in our common stock begins on an exchange or the over-the-counter bulletin board and the closing price of our common stock is at least twice the exercise price for a period of 30 consecutive days, provided that the shares of common stock underlying these warrants have been registered for resale under the Securities Act or are otherwise freely tradable. This warrant also has a net exercise provision under which the holder in lieu of payment of the exercise price in cash can surrender the warrant and receive a net number of shares of common preferred stock based on the fair market value of such stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Unless earlier exercised, this warrant will expire on February 26, 2015.

On August 30, 2010, we issued a warrant to purchase 13,605 shares of our common stock to S.L.A. Pharma in consideration of the amendment to the Exclusive License Agreement that was effective the same day. The warrant expires on August 30, 2013 and has an exercise price of $1.24 per share.

Registration Rights

Upon completion of this offering, and after the expiration of the customary 180-day lock-up agreements, holders of the substantial majority of our common stock will be entitled to rights to register the shares held by them under the Securities Act pursuant to registration rights granted to such holders of these securities. If we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the holders of these shares are entitled to notice of the registration and are entitled to include, at our expense, their shares of common stock in the registration and any related underwriting, provided, among other conditions and limitations, that the underwriters may limit the number of shares to be included in the registration and in some cases exclude these shares entirely.

In addition, the holders of these shares may require us to file a registration statement under the Securities Act with respect to their shares of common stock, and we will be required to use our best efforts to effect the registration.

The following table sets forth the number of shares of common stock that are subject to registration rights:

Description of Financing	Shares Issued in Financing	Shares Issuable upon Conversion of Notes	Shares Subject to Warrants	Shares Subject to Placement Agent Warrant
2007 Convertible Note Financing	—	1,642,802	—	42,782
2008 Common Stock and Warrant Financing	18,977	—	3,796	—
2008 Common Stock and Warrant Financing —Debt Conversion (1)	29,861	—	6,152	—
Promissory Notes Issued to Capretti Grandi, LLC and Paramount Biosciences, LLC	—	269,449	—	—
Paramount Credit Partners, LLC – Note and Warrant Purchase Agreements	—	—	104,867	—
2010 Convertible Promissory Note and Warrant Financing	—	1,421,834	468,119	89,000
TOTAL	48,838	3,334,085	582,934	131,782

(1) In connection with the 2008 common stock and warrant financing, we converted previously existing notes issued to Paramount BioSceinces, LLC and The Lindsay Rosenwald 2000 Family Trusts Dated December 15, 2000, into shares of common stock and warrants.

Transfer Agent and Registrar

The transfer agent and registrar for the common stock is Onyx Stock Transfer, LLC. The transfer agent's address is 2672 Bayshore Parkway, Suite 1055, Mountain View, California 94043 and its telephone number is (650) 215-4880.

Nasdaq Capital Market

Our common stock has been approved for listing on The Nasdaq Capital Market under the symbol "VTUS."

Anti-takeover Effects of our Amended and Restated Certificate of Incorporation and Bylaws and Delaware Law

Provisions of our amended and restated certificate of incorporation and bylaws and of Delaware law could make the following more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or
- removal of our incumbent officers and directors.

These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board. We believe that the benefits of increased protection give us the potential ability to negotiate with the proponent of an unsolicited proposal to acquire or restructure us and outweigh the disadvantages of discouraging those proposals because negotiation of the proposals could result in an improvement of their terms.

Exclusive Rights to Fix Size of Board of Directors and to Fill Vacancies

Our bylaws provide that the number of directors in our Board, which may range from three to nine directors, shall be exclusively fixed by our Board, which has set the number of directors at five. Pursuant to our amended and restated certificate of incorporation and bylaws newly created directorships resulting from any increase in our authorized number of directors and any vacancies in our Board resulting from death,

resignation, retirement, disqualification or other cause (including removal from office by a vote of the stockholders) will be filled by a majority of our Board then in office.

Elimination of Stockholder Action by Written Consent

Upon successful completion of this offering, our amended and restated certificate of incorporation and bylaws will expressly eliminate the right of our stockholders to act by written consent. Stockholder action must take place at the annual or special meeting of our stockholders.

Special Stockholder Meetings

Our amended and restated certificate of incorporation and bylaws provide that only our Board or such person or persons designated by our Board may call special meetings of our stockholders.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Upon successful completion of this offering, our bylaws will have advance notice procedures with respect to stockholder proposals and nominations of candidates for election as directors, other than nominations made by or at the direction of our Board or a committee of our Board. The business to be conducted at a meeting will be limited to business properly brought before the meeting by or at the direction of our Board or a duly authorized committee thereof or by a stockholder of record who has given timely written notice to our secretary of that stockholder's intention to bring such business before such meeting.

Delaware Anti-takeover Law

Upon the distribution, we will be governed by Section 203 of the DGCL, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; or
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85.0% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding specified shares; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder. The stockholders cannot authorize the business combination by written consent.

The application of Section 203 may limit the ability of stockholders to approve a transaction that they may deem to be in their best interests.

In general, Section 203 defines "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder; or
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10.0% or more of the assets of the corporation to or with the interested stockholder; or
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any of its stock to the interested stockholder; or
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any person that is:

- the owner of 15% or more of the outstanding voting stock of the corporation; or

- an affiliate or associate of the corporation who was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately prior to the relevant date; or
- the affiliates and associates of the above.

Under specific circumstances, Section 203 makes it more difficult for an "interested stockholder" to effect various business combinations with a corporation for a three-year period, although the stockholders may, by adopting an amendment to the corporation's certificate of incorporation or bylaws, elect not to be governed by this section, effective 12 months after adoption.

Our certificate of incorporation and bylaws do not exclude us from the restrictions imposed under Section 203. We anticipate that the provisions of Section 203 might encourage companies interested in acquiring us to negotiate in advance with our Board since the stockholder approval requirement would be avoided if a majority of the directors then in office approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder.

No Cumulative Voting

Our bylaws do not provide for cumulative voting in the election of directors.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Dr. Rosenwald is the Chairman, Chief Executive Officer and sole stockholder of Paramount BioCapital, Inc., or Paramount, and is the sole member of Paramount BioSciences, LLC. As of November 30, 2010, Dr. Rosenwald beneficially owned approximately 31.9% of our issued and outstanding common stock, including shares issuable upon the exercise of warrants, but excluding shares issuable upon the conversion of convertible promissory notes. As of November 30, 2010, trusts established for the benefit of Dr. Rosenwald and his family owned approximately 14.4% of our issued and outstanding common stock, including shares issuable upon the exercise of warrants, but Dr. Rosenwald disclaims beneficial ownership of these shares. Moreover, Dr. Rosenwald has the right to purchase additional shares of our common stock pursuant to purchase right agreements with certain employees of Paramount BioSciences or its affiliate. As well, Dr. Ellison, a director and our chief executive officer, was employed by Paramount BioSciences until December 31, 2009.

Effective August 2007, we began accruing monthly fees for consulting services at a rate of $25,000 per month to Paramount Corporate Development, LLC, an affiliate of Dr. Rosenwald. These services consisted of clinical and regulatory support, including preparation for the initial meeting with the FDA for diltiazem, pheneylephrine and iferanserin, and corporate, legal and accounting services. This agreement was terminated as of August 31, 2008, but as of September 30, 2010 there was an unpaid balance under this agreement of $100,000. Paramount continued to provide accounting and legal assistance to us after the termination, but did not charge us for those services, and the fair value of those services was not deemed significant. We have from time to time, engaged other persons or entities to provide similar services after the termination of this agreement to deal with time sensitive regulatory and planning matters.

On July 23, 2008, we issued an 8% promissory note payable to Paramount BioSciences LLC and on April 24, 2008, we issued an 8% promissory note payable to Capretti Grandi, LLC, an entity affiliated with Lindsay A. Rosenwald, under each of which we may draw funds as approved by the respective noteholder. These notes have identical terms. Pursuant to an amendment to the notes dated December 21, 2009, all amounts outstanding under these notes on or after September 30, 2009 shall immediately and automatically mature and be converted into the same equity or derivative securities as are issued in any equity or derivative equity financing consummated by us on or after September 30, 2009 (that does not otherwise constitute a Qualified Financing, as defined below), on the same terms and conditions that such equity securities are offered in such non-Qualified Financing. A “Qualified Financing” means the closing of an equity financing or series of related equity financings by us resulting in aggregate gross cash proceeds (before brokers’ fees or other transaction expenses) of at least $8.8 million. We drew a total of $2,975,591 on the Paramount BioSciences note and a total of $190,000 on the Capretti Grandi note. We used the proceeds from these notes for general operating purposes as well as payments to S.L.A. Pharma. On February 26, 2010, $2,192,433 outstanding under the Paramount BioSciences note (consisting of $2,165,000 of principal and $27,433 of accrued interest) was converted into 2010 convertible promissory notes as part of our private placement of these notes, which reduced the current principal balance to $811,153. As of September 30, 2010, the aggregate principal amount outstanding under these notes was $1,001,153, all of which will convert into shares of our common stock upon the completion of this offering.

During 2009, we issued four separate 10% promissory notes, referred to collectively as the PCP Notes, to Paramount Credit Partners, LLC, or PCP, an entity whose managing member is Dr. Rosenwald. Specifically, the PCP Notes consist of a note in the principal amount of $1,100,000 issued on January 23, 2009, a note in the principal amount of $100,000 issued on March 25, 2009, a note in the principal amount of $250,000 issued on June 1, 2009 and a note in the principal amount of $123,000 issued on June 24, 2009. Interest on the PCP Notes is payable quarterly, in arrears, and the principal matures on the earliest of December 31, 2013 or the completion by us of a transaction, including an equity offering, sale of assets, licensing or strategic partnership, in which we raise at least $5,000,000 in gross cash proceeds. The PCP Notes are not convertible. In addition, Paramount Credit Partners received five-year warrants to purchase, at an exercise price of 110% of the issue price in this offering, a number of shares of our common stock equal to 40% of the principal amount of each PCP Note purchased divided by the issue price in this offering.

On December 3, 2008, we, Paramount BioSciences and various other private pharmaceutical companies in which Dr. Rosenwald is a significant investor and stockholder, entered into a loan agreement with Bank of America, N.A. for a line of credit of $2,000,000. Paramount BioSciences pledged certain of its assets as collateral to secure our and the other borrowers' obligations to Bank of America under the loan agreement. Interest on amounts borrowed under the line of credit accrues and is payable on a monthly basis at an annual rate equal to the London Interbank Offered Rate (LIBOR) plus 1%. On November 10, 2009, the parties entered into Amendment No. 1 to the Loan Agreement, which extended the initial one-year term for an additional year, such that it currently matures on November 5, 2010, and reduced the aggregate amount available under the line of credit to $1,000,000. Under the loan agreement, our liability under the line of credit is several, not joint, with respect to the payment of all obligations thereunder. In 2008, proceeds of $170,000 from line of credit with Bank of America were primarily used for the payments of $100,000 to S.L.A. Pharma and a bonus of $25,000 to our then Chief Executive Officer Thomas Rowland. In 2009, proceeds of $150,000 from line of credit with Bank of America were primarily used for the license payments to Amer and severance payments to Thomas Rowland, Terrance Coyne and John Dietrich in the aggregate of $161,459. As of September 30, 2010, the amounts borrowed by us that were outstanding under this line of credit were $320,000. The line of credit was due on November 5, 2010, at which time we repaid it.

On September 23, 2010, we borrowed $800,000 from Israel Discount Bank of New York. The promissory note we issued to Israel Discount Bank to evidence the loan is guaranteed by Dr. Lindsay Rosenwald, our largest stockholder and the sole member of Paramount BioSciences LLC. The interest rate on the note is equal to the interest rate that Israel Discount bank will pay on the cash accounts at the Bank maintained by Dr. Rosenwald and pledged to secure the note, plus 1%. The note is due on September 22, 2011. In consideration of his guaranteeing the $800,000 promissory note we issued to Israel Discount Bank of New York, we entered into a letter agreement with Dr. Rosenwald whereby Dr. Rosenwald has the right to attend our Board meetings and to appoint two directors to our Board. Dr. Rosenwald has not exercised his right to appoint these directors. If and when appointed, these directors would be subject to stockholder approval at the expiration of their terms.

On November 5, 2010, we borrowed $420,000 from Israel Discount Bank of New York. The promissory note we issued to Israel Discount Bank to evidence the loan is guaranteed by Dr. Lindsay Rosenwald. The interest rate on the note is equal to the interest rate that Israel Discount bank will pay on the cash accounts at the Bank maintained by Dr. Rosenwald and pledged to secure the note, plus 1%. The note is due on demand or on November 4, 2011.

In addition, Paramount acted as lead placement agent or co-placement agent on certain of our prior financings. Pursuant to the placement agency agreements we entered into, the company has agreed to indemnify Paramount against liabilities arising out of such financings.

Effective May 11, 2010, we entered into a consulting agreement with Timothy Hofer, pursuant to which Mr. Hofer provides us with general consulting services focused on general business and company development. Mr. Hofer is also an employee of Paramount BioSciences. This consulting agreement is for a period of one year, subject to renewal for such longer period as we may agree in writing with Mr. Hofer, and may be terminated by either party upon 30 days' prior written notice. As compensation for his services under the agreement, we granted Mr. Hofer a ten-year warrant to purchase 8,065 shares of our common stock, subject to adjustment as described below. The warrant will have an exercise price per share equal to the price at which shares of our common stock are issued in a Qualified Financing. If a Qualified Financing does not occur on or before January 31, 2011, then the exercise price per share of the warrant will be equal to the fair market value of our common stock, as determined pursuant to a valuation performed by an independent appraisal firm. Under the terms of the warrant, if we consummate a Qualified Financing, the number of shares of common stock issuable upon exercise of the warrant will be automatically adjusted so that such number of shares is equal to 1.0% of our outstanding common stock on a fully diluted basis, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan. For purposes of the warrant, a "Qualified Financing" means our next equity financing (or series of related equity financings) sufficient to trigger conversion of all amounts then outstanding under our convertible bridge notes issued in 2007 and 2008.

On October 5, 2010, Lindsey A. Rosenwald, our largest stockholder, indirectly acquired a controlling interest in National Securities Corporation, a co-managing underwriter in this offering, through an investment in securities in National Holdings Corporation, the 100% owner and parent of National Securities Corporation. The investment, led by Opus Point Partners, LLC, was for an aggregate of 60,000 shares of Series D Convertible Preferred Stock and warrants to purchase an aggregate of 6,000,000 shares of common stock of National Holdings Corporation, for an aggregate purchase price of $3,000,000. After the transaction, Opus Point Partners, LLC beneficially owns approximately 23.6% of National Holdings Corporation. Dr. Rosenwald beneficially owns a 50% interest in Opus Point Partners, LLC. Dr. Rosenwald's pecuniary interest in National Holdings Corporation is in excess of 10%.

We occupy space at no charge on the 48th floor at 787 7th Avenue, New York, New York 10019, which are the offices of Paramount BioSciences. There is no written agreement for this arrangement between us and Paramount BioSciences. Our occupancy began in June 2010.

Each of these transactions was approved by our board of directors prior to the time we entered into the agreement for the respective transaction.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, or the perception that such sales could occur, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities. Furthermore, because only a limited number of shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our common stock in the public market after the restrictions lapse. This may adversely affect the prevailing market price and our ability to raise equity capital in the future. While our common stock has been approved for listing on the Nasdaq Capital Market under the symbol "VTUS," we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares outstanding as of November 30, 2010, upon completion of this offering, 6,746,365 shares of common stock will be outstanding, assuming no exercise of the underwriters' overallotment option. Of the shares to be outstanding immediately after the closing of this offering, 2,900,000 shares of common stock to be sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act.

The remaining 3,846,365 shares of common stock will be "restricted securities" under Rule 144.

Subject to the lock-up agreements described below and the provisions of Rule 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

Date Available for Sale	Shares Eligible for Sale	Description
Date of Prospectus	378,357	Shares saleable under Rule 144 that are not subject to a lock-up
90 Days after Date of Prospectus	291,746	Shares saleable under Rules 144 and 701 that are not subject to a lock-up
180 Days after Date of Prospectus	3,176,262	Lock-up released; shares saleable under Rules 144 and 701

In addition, of the 162,016 shares of our common stock that are issuable upon the exercise of stock options outstanding as of November 30, 2010, 78,330 of these shares have vested and upon exercise will be eligible for sale subject to the lock-up agreements described below and/or Rules 144 and 701 under the Securities Act. Of the 767,895 shares issuable pursuant to warrants outstanding as of November 30, 2010, based on the initial public offering price of $6.00, warrants for an aggregate of 744,342 shares have a net exercise provision whereby, upon exercise, those shares will be eligible for sale subject to the lock-up agreements described below, other lock-up provisions and/or Rule 144 under the Securities Act.

Rule 144

In general, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares of our common stock to be sold for at least six months, would be entitled to sell an unlimited number of shares of our common stock, provided current public information about us is available. In addition, under Rule 144, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares of our common stock proposed to be sold for at least one year, would be entitled to sell an unlimited number of shares beginning one year after this offering without regard to whether current public information about us is available. Our affiliates who have beneficially owned shares of our common stock for at least six months are entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 63,200 shares immediately after this offering, and

- the average weekly trading volume in our common stock on the Nasdaq Capital Market during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales by affiliates under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Rule 701

In general, under Rule 701 under the Securities Act, any of our employees, consultants or advisors who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell those shares 90 days after the effective date of this offering in reliance on Rule 144, but without compliance with the various restrictions, including the holding period, contained in Rule 144.

Lock-up Agreements

In connection with this offering, we, our officers and directors, and certain stockholders have each entered into a lock-up agreement with the underwriters of this offering that restricts the sale of shares of our common stock by those parties for a period of 180 days after the date of this prospectus, subject to extension in certain circumstances. The underwriters may, in their sole discretion, choose to release any or all of the shares of our common stock subject to these lock-up agreements at any time prior to the expiration of the lock-up period without notice. For more information, see “Underwriting.”

Registration Rights

Following the completion of this offering, and based on the initial public offering price of $6.00, stockholders holding approximately 3,382,923 shares of our common stock, including shares issued upon conversion of our convertible notes, and holders of warrants to purchase an aggregate of 714,716 shares of our common stock, will have the right, subject to various conditions and limitations, to include their shares in registration statements relating to our securities. Pursuant to the lock-up agreements described above, certain of our stockholders have agreed not to exercise those rights during the lock-up period without the prior written consent of the underwriters of this offering. For a description of these registration rights, see “Description of Capital Stock — Registration Rights.”

UNDERWRITING AND PLAN OF DISTRIBUTION (CONFLICTS OF INTEREST)

Subject to the terms and conditions of an underwriting agreement, dated December 16, 2010, we have agreed to sell to Rodman & Renshaw, LLC and National Securities Corporation, the joint book running co-managing underwriters, and such underwriters have severally agreed to purchase, on a firm commitment basis the number of shares offered in this offering set forth below, at the public offering price, less the underwriting discount set forth on the cover page of this prospectus.

Name	Number of Shares
Rodman & Renshaw, LLC	1,450,000
National Securities Corporation	1,450,000
Total	2,900,000

Nature of Underwriting Commitment

The underwriting agreement provides that the underwriters are committed to purchase all shares offered in this offering, other than those covered by the over-allotment option described below, if the underwriters purchase any of these securities. The underwriting agreement provides that the obligations of the underwriters to purchase the shares offered hereby are conditional and may be terminated at its discretion based on its assessment of the state of the financial markets. The obligations of the underwriters may also be terminated upon the occurrence of other events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the obligations of the underwriters are subject to the authorization and the validity of the shares being accepted for listing on The Nasdaq Capital Market and to various other customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions of our counsel.

Other than as underwriters in this offering and National Securities Corporation's acting as our placement agent in our 2010 senior convertible promissory note offering, neither National Securities Corporation, Rodman & Renshaw, LLC nor any of their respective affiliates have provided services to us or our affiliates in the past.

State Blue Sky Information

We intend to offer and sell the shares offered hereby to retail customers and institutional investors in all 50 states. However, we will not make any offer of these securities in any jurisdiction where an offer is not permitted.

Pricing of Securities

The underwriters have advised us that they propose to offer the shares directly to the public at the public offering price set forth on the cover page of this prospectus, and to certain dealers that are members of the Financial Industry Regulatory Authority, or FINRA, at such price less a concession not in excess of $0.24 per share. After this offering, the offering price and concessions and discounts to brokers and dealers and other selling terms may from time to time be changed. These prices should not be considered an indication of the actual value of our shares and are subject to change as a result of market conditions and other factors. No variation in those terms will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

Prior to this offering, there has been no public market for the shares. The public offering price for the shares was determined by negotiation between us and the underwriters.

The principal factors considered in determining the public offering price of the shares included:

- the information in this prospectus and otherwise available to the underwriters;
- the history and the prospects for the industry in which we will compete;
- the valuation of our company based on, among other factors, the offering prices of our recent private offerings;
- our current financial condition and the prospects for our future cash flows and earnings;

- the general condition of the economy and the securities markets at the time of this offering;
- the recent market prices of, and the demand for, publicly-traded securities of generally comparable companies;
- the public demand for our securities in this offering; and
- other factors as were deemed relevant.

We cannot be sure that the public offering price will correspond to the price at which our shares will trade in the public market following this offering or that an active trading market for our shares will develop and continue after this offering.

Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol "VTUS."

Commissions and Discounts

The following table summarizes the compensation to be paid to the underwriters by us and the proceeds, before expenses, payable to us, based on the $6.00 offering price. The information assumes either no exercise or full exercise by the underwriters of the over-allotment option.

	Per Share	Total	
		Without Over-Allotment	With Over-Allotment
Public offering price	$ 6.00	$ 17,400,000	$20,010,000
Underwriting discount[1]	$ 0.435	$ 1,261,500	$ 1,450,725
Non-accountable expense allowance[2]	$ 0.09	$ 261,000	$ 261,000
Proceeds, before expenses, to us[3]	$ 5.475	$ 15,877,500	$18,298,275

(1) Underwriting discount is $0.435 per share.

(2) The expense allowance of 1.5% is not payable with respect to the shares sold upon exercise of the underwriters' over-allotment option. We have already paid $50,000 of the expense allowance.

(3) We estimate that the total expenses of this offering, excluding the underwriting discount and expense allowance, are approximately $926,500. These expenses include up to $130,000 of other expenses of the underwriters which we have agreed to reimburse at the closing of this offering.

Over-allotment Option

We have granted the underwriters an option, exercisable for 45 days after the closing date of this offering, to purchase up to 15% of the shares of common stock sold in the offering (435,000 additional shares) solely to cover over-allotments, if any, at the same price as the initial shares offered.

Conflicts of Interest

Lindsay A. Rosenwald currently owns approximately 31.9% of our issued and outstanding capital stock. Dr. Rosenwald also owns, indirectly, through Opus Point Partners, LLC, a controlling interest in National Holdings Corporation, the 100% owner and parent of National Securities Corporation. Thus, in connection with Dr. Rosenwald's beneficial ownership interests in our stock and National Holdings Corporation, we are under common control with National Securities Corporation.

Because we are under common control with National Securities Corporation, a "conflict of interest" is deemed to exist under the applicable provisions of Rule 2720 of the FINRA rules. Accordingly, this offering will be made in compliance with the applicable provisions of FINRA Rule 2720. Rule 2720 currently requires that a "qualified independent underwriter," as defined by the FINRA rules, participate in the preparation of the registration statement and the prospectus and exercise the usual standards of due diligence in respect thereto. In addition to acting as a co-managing underwriter in this offering, Rodman & Renshaw, LLC has agreed to act as qualified independent underwriter for the offering and to perform a due diligence investigation and review and participate in the preparation of the prospectus.

Lock-ups

All of our officers and directors have agreed that, for a period of six months from the effective date of the registration statement of which this prospectus forms a part, they will not sell, contract to sell, grant any option for the sale or otherwise dispose of any of our equity securities, or any securities convertible into or exercisable or exchangeable for our equity securities, except securities acquired after the closing of this offering, without the consent of the co-managing underwriters except for exercise or conversion of currently outstanding warrants, options and convertible notes, as applicable; and exercise of options under an acceptable stock incentive plan. It is expressly agreed that the holder is expressly precluded from engaging in any hedging or other transaction with respect to their securities during the lock-up period which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of their securities, even if such securities would be disposed of by someone other than the holder. Such prohibited hedging or other transactions would include without limitation any short sale or any purchase, sale or grant of any put or call option or other right. The co-managing underwriters may consent to an early release from the lock-up period if, in their opinion, the market for the common stock would not be adversely impacted by sales and in cases of a financial emergency of an officer, director or other stockholder. We are unaware of any officer or director who intends to ask for consent to dispose of any of our equity securities during the lock-up period.

In addition, National Securities Corporation and “associated persons” of National Securities Corporation received warrants to purchase an aggregate of 89,000 shares of Common Stock at an exercise price of 125% of the public offering price or $7.50 in connection with our 2010 senior convertible note and warrant financing. The Common Stock issuable upon exercise of such warrants held by National Securities Corporation and/or “associated persons” of National Securities Corporation are subject to a 180 day lock-up agreement in accordance with the requirements of FINRA Rule 5110(g)(1) and will not be sold, pledged, assigned, transferred or hypothecated for a period of 180 days from the effective date of this prospectus except in accordance with the requirements of FINRA Rule 5110(g)(2).

Underwriters Warrant

We have agreed to issue to the co-managing underwriters a warrant to purchase up to a total of 197,200 shares of common stock (6.8% of the shares of common stock sold). This warrant is exercisable at $7.50 per share (125% of the per share price of the common stock sold in this offering), commencing on a date which is one year from the effective date of the registration statement and expiring five years from the effective date of the registration statement. The warrant and the 197,200 shares of common stock underlying the warrant have been deemed compensation by the FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of the FINRA. The co-managing underwriters (or permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate this warrant or the securities underlying this warrant, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of this warrant or the underlying securities for a period of 180 days from the date of this prospectus. Additionally, the warrant may not be sold transferred, assigned, pledged or hypothecated for a one-year period (including the foregoing 180-day period) following the effective date of the registration statement except to any underwriter and selected dealer participating in this offering and their bona fide officers or partners. The warrant grants the holder a one time demand registration right, as well as “piggy back” registration rights. These rights apply to all of the securities directly and indirectly issuable upon exercise of the warrant. We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrant, other than underwriting commissions incurred and payable by the holder. The exercise price and number of shares issuable upon exercise of the warrant may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation.

This warrant will be valued based on the underlying shares of common stock obtainable and valuation factors appropriate at the time it is issued. We currently estimate that value to be approximately $997,000, based on the number of shares of common stock subject to this warrant, the offering price of the shares of $6.00, the resulting exercise prices related to the warrant on the shares of common stock, the five-year term of the warrant, a risk-free interest rate of 1.53% currently commensurate with that term, no dividend yield and estimated volatility of 119.68%, based on a review of our historical volatility. The initial value of this warrant will be charged to additional paid-in capital as part of costs of this offering.

Other Terms

In connection with this offering, the underwriters or certain of the securities dealers may distribute prospectuses electronically. No forms of prospectus other than printed prospectuses and electronically distributed prospectuses that are printable in Adobe® PDF format will be used in connection with this offering.

The underwriters have informed us that they do not expect to confirm sales of shares of common stock by this prospectus to accounts over which they exercise discretionary authority without obtaining the specific approval of the account holder.

Regulatory Restrictions on Purchase of Securities

We have been advised by the underwriters that, in accordance with Regulation M under the Securities Act, some persons participating in this offering may engage in transactions, including syndicate covering transactions, stabilizing bids or the imposition of penalty bids, that may have the effect of stabilizing or maintaining the market price of the shares at a level above that which might otherwise prevail in the open market.

A "syndicate covering transaction" is a bid for or the purchase of shares on behalf of the underwriters to reduce a syndicate short position incurred by the underwriters in connection with this offering. The underwriters may create a syndicate short position by making short sales of our shares and may purchase our shares in the open market to cover syndicate short positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. Short sales can be either "covered" or "naked." "Covered" short sales are sales made in an amount not greater than the underwriters' over-allotment option to purchase additional shares from us in this offering. "Naked" short sales are sales in excess of the over-allotment option. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in this offering. If the underwriters create a syndicate short position, they may choose to reduce or "cover" this position by either exercising all or part of the over-allotment option to purchase additional shares from us or by engaging in "syndicate covering transactions." The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares in the open market. The underwriters must close out any naked short position by purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

A "stabilizing bid" is a bid for or the purchase of shares on behalf of the underwriters for the purpose of fixing or maintaining the price of our common stock. A "penalty bid" is an arrangement that permits the lead underwriter to reclaim the selling concession from another underwriter or a syndicate member when shares sold by such underwriter or syndicate member are purchased by the lead underwriter in a syndicate covering transaction and, therefore, have not been effectively placed by the underwriter or syndicate member.

Indemnification

The underwriting agreement provides for indemnification between us and the underwriters against specified liabilities, including liabilities under the Securities Act, and for contribution by us and the underwriters to payments that may be required to be made with respect to those liabilities. We have been advised that, in the opinion of the SEC, indemnification for liabilities under the Securities Act is against public policy as expressed in the Securities Act, and is therefore, unenforceable.

Electronic Delivery of Prospectus

In connection with this offering, the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Foreign Regulatory Restrictions on Purchase of the Common Stock

We have not taken any action to permit a public offering of the shares outside the United States or to permit the possession or distribution of this prospectus outside the United States. Persons outside the

United States who come into possession of this prospectus must inform themselves about and observe any restrictions relating to this offering and the distribution of the prospectus outside the United States.

United Kingdom

No offer of shares has been made or will be made to the public in the United Kingdom within the meaning of Section 102B of the Financial Services and Markets Act 2000, as amended, or FSMA, except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority, or FSA. The underwriter: (i) has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of FSMA) to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which Section 21 of FSMA does not apply to us; and (ii) has complied with, and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, which we refer to as a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, which we refer to as the Relevant Implementation Date, no offer of shares has been made and or will be made to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of shares may be made to the public in that Relevant Member State at any time: (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities; (b) to any legal entity which has two or more of (i) an average of at least 250 employees during the last financial year; (ii) a total balance sheet of more than €43 million; and (iii) an annual net turnover of more than €50 million, as shown in its last annual or consolidated accounts; or (c) in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive. For the purposes of this provision, the expression an “offer of ordinary shares to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/ EC and includes any relevant implementing measure in each Relevant Member State.

Germany

Any offer or solicitation of shares within Germany must be in full compliance with the German Securities Prospectus Act (Wertpapierprospektgesetz — WpPG). The offer and solicitation of securities to the public in Germany requires the approval of the prospectus by the German Federal Financial Services Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht — BaFin). This prospectus has not been and will not be submitted for approval to the BaFin. This prospectus does not constitute a public offer under the German Securities Prospectus Act (Wertpapierprospektgesetz). This prospectus and any other document relating to the shares, as well as any information contained therein, must therefore not be supplied to the public in Germany or used in connection with any offer for subscription of the shares to the public in Germany, any public marketing of the shares or any public solicitation for offers to subscribe for or otherwise acquire the shares. The prospectus and other offering materials relating to the offer of the shares are strictly confidential and may not be distributed to any person or entity other than the designated recipients hereof.

Greece

This prospectus has not been approved by the Hellenic Capital Markets Commission or another E.U. equivalent authority and consequently is not addressed to or intended for use, in any way whatsoever, by

Greek residents. The shares have not been offered or sold and will not be offered, sold or delivered directly or indirectly in Greece, except (i) to "qualified investors" (as defined in article 2(f) of Greek Law 3401/2005); and/or (ii) to less than 100 individuals or legal entities, who are not qualified investors (article 3, paragraph 2(b) of Greek Law 3401/2005), or otherwise in circumstances which will not result in the offer of the new shares being subject to the Greek Prospectus requirements of preparing a filing a prospectus (under articles 3 and 4 of Greek Law 3401/2005).

Italy

This offering of the shares has not been cleared by Consob, the Italian Stock Exchanges regulatory agency of public companies, pursuant to Italian securities legislation and, accordingly, no shares may be offered, sold or delivered, nor may copies of this prospectus or of any other document relating to the shares be distributed in Italy, except (1) to professional investors (operatori qualificati); or (2) in circumstances which are exempted from the rules on solicitation of investments pursuant to Decree No. 58 and Article 33, first paragraph, of Consob Regulation No. 11971 of May 14, 1999, as amended. Any offer, sale or delivery of the shares or distribution of copies of this prospectus or any other document relating to the shares in Italy under (1) or (2) above must be (i) made by an investment firm, bank or financial intermediary permitted to conduct such activities in Italy in accordance with the Decree No. 58 and Legislative Decree No. 385 of September 1, 1993, or the Banking Act; (ii) in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy, as amended from time to time, pursuant to which the issue or the offer of securities in Italy may need to be preceded and followed by an appropriate notice to be filed with the Bank of Italy depending, inter alia, on the aggregate value of the securities issued or offered in Italy and their characteristics; and (iii) in compliance with any other applicable laws and regulations.

Cyprus

The underwriter has agreed that (i) it will not be providing from or within Cyprus any "Investment Services", "Investment Activities" and "Non-Core Services" (as such terms are defined in the Investment Firms Law 144(I) of 2007 (the "IFL"), in relation to the shares, or will be otherwise providing Investment Services, Investment Activities and Non-Core Services to residents or persons domiciled in Cyprus. The underwriter has agreed that it will not be concluding in Cyprus any transaction relating to such Investment Services, Investment Activities and Non-Core Services in contravention of the IFL and/or applicable regulations adopted pursuant thereto or in relation thereto; and (ii) it has not and will not offer any of the shares other than in compliance with the provisions of the Public Offer and Prospectus Law, Law 114(I)/2005.

Switzerland

This document does not constitute a prospectus within the meaning of Art. 652a of the Swiss Code of Obligations. The shares may not be sold directly or indirectly in or into Switzerland except in a manner which will not result in a public offering within the meaning of the Swiss Code of Obligations. Neither this document nor any other offering materials relating to the shares may be distributed, published or otherwise made available in Switzerland except in a manner which will not constitute a public offer of the shares of in Switzerland.

Norway

This prospectus has not been approved or disapproved by, or registered with, the Oslo Stock Exchange, the Norwegian Financial Supervisory Authority (Kredittilsynet) nor the Norwegian Registry of Business Enterprises, and the shares are marketed and sold in Norway on a private placement basis and under other applicable exceptions from this offering prospectus requirements as provided for pursuant to the Norwegian Securities Trading Act.

Botswana

We hereby represent and warrant that we have not offered for sale or sold, and will not offer or sell, directly or indirectly the shares to the public in the Republic of Botswana, and confirms that this offering will not be subject to any registration requirements as a prospectus pursuant to the requirements and/or provisions of the Companies Act, 2003 or the Listing Requirements of the Botswana Stock Exchange.

Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA. Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and shares of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the shares under Section 275 except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (ii) where no consideration is given for the transfer; or (iii) by operation of law.

People's Republic of China

This prospectus has not been and will not be circulated or distributed in the PRC, and shares may not be offered or sold, and will not be offered or sold to any person for re-offering or resale, directly or indirectly, to any resident of the PRC except pursuant to applicable laws and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

Israel

This prospectus does not constitute an offer to sell the shares to the public in Israel or a prospectus under the Israeli Securities Law, 5728-1968 and the regulations promulgated thereunder, or the Israeli Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, pursuant to an exemption afforded under the Israeli Securities Law, this prospectus may be distributed only to, and may be directed only at, investors listed in the first addendum to the Israeli Securities Law, or the Addendum, consisting primarily of certain mutual trust and provident funds, or management companies thereto, banks, as defined under the Banking (Licensing) Law, 5741-1981, except for joint service companies purchasing for their own account or for clients listed in the Addendum, insurers, as defined under the Supervision of Financial Services Law (Insurance), 5741-1981, portfolio managers purchasing for their own account or for clients listed in the Addendum, investment advisers purchasing for their own account, Tel Aviv Stock Exchange members purchasing for their own account or for clients listed in the Addendum, underwriters purchasing for their own account, venture capital funds, certain corporations which primarily engage in the

capital market and fully-owned by investors listed in the Addendum and corporations whose equity exceeds NIS250 Million, collectively referred to as institutional investors. Institutional investors may be required to submit written confirmation that they fall within the scope of the Addendum.

United Arab Emirates

This document has not been reviewed, approved or licensed by the Central Bank of the United Arab Emirates, or UAE, Emirates Securities and Commodities Authority or any other relevant licensing authority in the UAE including any licensing authority incorporated under the laws and regulations of any of the free zones established and operating in the territory of the UAE, in particular the Dubai International Financial Services Authority (the "DFSA"), a regulatory authority of the Dubai International Financial Centre, referred to as the DIFC. The issue of shares does not constitute a public offer of securities in the UAE, DIFC and/or any other free zone in accordance with the Commercial Companies Law, Federal Law No. 8 of 1984 (as amended), DFSA Offered Securities Rules and the Dubai International Financial Exchange Listing Rules, accordingly, or otherwise. The shares may not be offered to the public in the UAE and/or any of the free zones including, in particular, the DIFC. The shares may be offered and this document may be issued, only to a limited number of investors in the UAE or any of its free zones (including, in particular, the DIFC) who qualify as sophisticated investors under the relevant laws and regulations of the UAE or the free zone concerned. Our company's' management and the underwriter represent and warrant that the shares will not be offered, sold, transferred or delivered to the public in the UAE or any of its free zones including, in particular, the DIFC.

Oman

For the attention of the residents of Oman:

The information contained in this memorandum neither constitutes a public offer of securities in the Sultanate of Oman ("Oman") as contemplated by the Commercial Companies Law of Oman (Sultani Decree 4/74) or the Capital Market Law of Oman (Sultani Decree 80/98), nor does it constitute an offer to sell, or the solicitation of any offer to buy non-Omani securities in Oman as contemplated by Article 6 of the Executive Regulations to the Capital Market Law of Oman (issued vide Ministerial Decision No 4/2001), and nor does it constitute a distribution of non-Omani securities in Oman as contemplated under the Rules for Distribution of Non-Omani Securities in Oman issued by the Capital Market Authority of Oman ("CMA"). Additionally, this memorandum is not intended to lead to the conclusion of any contract of whatsoever nature within the territory of Oman. This memorandum has been sent at the request of the investor in Oman, and by receiving this memorandum, the person or entity to whom it has been issued and sent understands, acknowledges and agrees that this memorandum has not been approved by the CMA or any other regulatory body or authority in Oman, nor has any authorization, license or approval been received from the CMA or any other regulatory authority in Oman, to market, offer, sell, or distribute the shares within Oman.

No marketing, offering, selling or distribution of any financial or investment products or services has been or will be made from within Oman and no subscription to any securities, products or financial services may or will be consummated within Oman. The underwriter is not a company licensed by the CMA to provide investment advisory, brokerage, or portfolio management services in Oman, nor banks licensed by the Central Bank of Oman to provide investment banking services in Oman. The underwriter does not advise persons or entities resident or based in Oman as to the appropriateness of investing in or purchasing or selling securities or other financial products.

Nothing contained in this memorandum is intended to constitute Omani investment, legal, tax, accounting or other professional advice. This memorandum is for your information only, and nothing herein is intended to endorse or recommend a particular course of action. You should consult with an appropriate professional for specific advice on the basis of your situation. Any recipient of this memorandum and any purchaser of the shares pursuant to this memorandum shall not market, distribute, resell, or offer to resell the shares within Oman without complying with the requirements of applicable Omani law, nor copy or otherwise distribute this memorandum to others.

Canada

Resale Restrictions

The distribution of our securities in Canada is being made only on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of our securities are made. Any resale of our securities in Canada must be made under applicable securities laws that will vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of our securities.

Representations of Purchasers

By purchasing our securities in Canada and accepting a purchase confirmation a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase our securities without the benefit of a prospectus qualified under those securities laws;
- where required by law, that the purchaser is purchasing as principal and not as agent;
- the purchaser has reviewed the text above under Resale Restrictions; and
- the purchaser acknowledges and consents to the provision of specified information concerning its purchase of our securities to the regulatory authority that by law is entitled to collect the information.

Further details concerning the legal authority for this information are available on request.

Rights of Action — Ontario Purchasers Only

Under Ontario securities legislation, certain purchasers who purchase a security offered by this prospectus during the period of distribution will have a statutory right of action for damages, or while still the owner of our securities, for rescission against us in the event that this prospectus contains a misrepresentation without regard to whether the purchaser relied on the misrepresentation. The right of action for damages is exercisable not later than the earlier of 180 days from the date the purchaser first had knowledge of the facts giving rise to the cause of action and three years from the date on which payment is made for our securities. The right of action for rescission is exercisable not later than 180 days from the date on which payment is made for our securities. If a purchaser elects to exercise the right of action for rescission, the purchaser will have no right of action for damages against us. In no case will the amount recoverable in any action exceed the price at which our securities were offered to the purchaser and if the purchaser is shown to have purchased the securities with knowledge of the misrepresentation, we will have no liability. In the case of an action for damages, we will not be liable for all or any portion of the damages that are proven to not represent the depreciation in value of our securities as a result of the misrepresentation relied upon. These rights are in addition to, and without derogation from, any other rights or remedies available at law to an Ontario purchaser. The foregoing is a summary of the rights available to an Ontario purchaser. Ontario purchasers should refer to the complete text of the relevant statutory provisions.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of our securities should consult their own legal and tax advisors with respect to the tax consequences of an investment in our securities in their particular circumstances and about the eligibility of our securities for investment by the purchaser under relevant Canadian legislation.

LEGAL MATTERS

The legality of the securities being offered hereby will be passed upon for us by Wyrick Robbins Yates & Ponton LLP, Raleigh, North Carolina. Littman Krooks LLP, New York, New York, is acting as counsel for the underwriters in connection with this offering.

EXPERTS

J.H. Cohn LLP, our independent registered public accounting firm, has audited our balance sheets as of December 31, 2009 and 2008, and the related statements of operations, changes in stockholders' deficiency and cash flows for the years ended December 31, 2009 and 2008 and the period from October 7, 2005 (inception) to December 31, 2009, as set forth in their report, which includes an explanatory paragraph relating to our ability to continue as a going concern. We have included our financial statements in this prospectus and in this registration statement in reliance on J.H. Cohn LLP's report given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered hereby. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. Some items are omitted in accordance with the rules and regulations of the SEC. For further information with respect to us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus as to the contents of any contract, agreement or any other document are summaries of the material terms of this contract, agreement or other document. With respect to each of these contracts, agreements or other documents filed as an exhibit to the registration statement, reference is made to the exhibits for a more complete description of the matter involved. A copy of the registration statement, and the exhibits and schedules thereto, may be inspected without charge at the public reference facilities maintained by the SEC at 100 F. Street, N.E., Washington, D.C. 20549. Copies of these materials may be obtained by writing to the Public Reference Section of the SEC at 100 F. Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facility. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC's website is *http://www.sec.gov.*

DISCLOSURE OF SEC POSITION ON INDEMNIFICATION FOR SECURITIES LAW VIOLATIONS

Our amended and restated bylaws provide for indemnification of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, or DGCL. However, insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors and officers pursuant to the bylaws or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director or officer in a successful defense of any action, suit or proceeding) is asserted by such director or officer in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

FINANCIAL STATEMENTS

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Ventrus BioSciences, Inc.

We have audited the accompanying balance sheets of Ventrus BioSciences, Inc. (A Development Stage Company) as of December 31, 2009 and 2008, and the related statements of operations, changes in stockholders' deficiency and cash flows for the years then ended and the period from October 7, 2005 (Inception) to December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Ventrus BioSciences, Inc. as of December 31, 2009 and 2008, and its results of operations and cash flows for the years then ended and the period from October 7, 2005 (Inception) to December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company incurred a net loss of $4,539,405 for the year ended December 31, 2009 and, as of that date, had a deficit accumulated during the development stage of $17,893,729 and a working capital deficiency of $12,273,641. These matters, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ J.H. Cohn LLP

Roseland, New Jersey
July 19, 2010, except for the effects of the matter discussed
in the last paragraph of Note 1 which are as of November 10, 2010

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Balance Sheets

	December 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash	**$ 81,288**	$ 15,851
Prepaid research and development	**—**	800,000
Other current assets	**2,519**	5,167
Total current assets	**83,807**	821,018
Office equipment, net of accumulated depreciation of $14,734 and $7,223	**12,525**	17,463
Deferred financing costs	**69,922**	31,910
Total assets	**$ 166,254**	$ 870,391
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current liabilities:		
Accounts payable and accrued expenses	**$ 3,362,460**	$ 4,125,233
2007 Senior convertible notes	**5,305,000**	—
Interest payable – 2007 senior convertible notes	**986,838**	413,130
Notes payable – related parties PBS	**2,215,591**	—
Interest payable – related parties PBS	**59,719**	3,877
Borrowings under line of credit	**320,000**	170,000
Interest payable – Paramount Credit Partners, LLC	**107,840**	—
Total current liabilities	**12,357,448**	4,712,240
Notes payable – Paramount Credit Partners, LLC (net of discount of $401,546)	**1,171,454**	—
2007 Senior convertible notes	**—**	5,305,000
Notes payable – related parties	**—**	310,201
Total liabilities	**13,528,902**	10,327,441
Commitments		
Stockholders' deficiency:		
Preferred stock, $.001 par value; 5,000,000 shares authorized, none issued	**—**	—
Common stock, $.001 par value; 25,000,000 shares authorized; 447,347 and 444,928 issued and outstanding at December 31, 2009 and 2008	**447**	445
Additional paid-in capital	**4,530,634**	3,896,829
Deficit accumulated during the development stage	**(17,893,729)**	(13,354,324)
Total stockholders' deficiency	**(13,362,648)**	(9,457,050)
Total liabilities and stockholders' deficiency	**$ 166,254**	$ 870,391

See Notes to Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statements of Operations

	Year Ended December 31, 2009	Year Ended December 31, 2008	Period from October 7, 2005 (Inception) to December 31, 2009
Operating expenses:			
Research and development	**$ 2,942,992**	$ 5,978,723	$ 12,400,894
General and administrative	**397,238**	1,185,587	2,605,088
Loss from operations	**(3,340,230)**	(7,164,310)	(15,005,982)
Interest income	**140**	13,091	13,989
Interest expense, including amortization of debt discount and deferred financing costs and charge related to conversion of related party notes	**(1,199,315)**	(1,635,211)	(2,901,736)
Net loss	**$ (4,539,405)**	$ (8,786,430)	$ (17,893,729)
Basic and diluted net loss per common share	**$ (10.20)**	$ (20.83)	
Weighted average common shares outstanding – basic and diluted	**445,040**	421,721	

See Notes to Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statement of Changes in Stockholders' Deficiency
Period from October 7, 2005 (Inception) to December 31, 2009

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Issuance of common stock to founders and employees at $0.0124 per share in March and April 2007	368,012	$ 368	$ 4,196		$ 4,564
Issuance of common stock to employees at $0.0124 per share in May and June 2007	9,677	10	110		120
Issuance of common stock to licensor at $0.0124 per share in August 2007	18,401	18	210		228
Stock-based compensation	—	—	16,655		16,655
Warrants issued in connection with senior convertible notes	—	—	164,284		164,284
Net loss	—	—		$ (4,567,894)	(4,567,894)
Balance at December 31, 2007	396,090	396	185,455	(4,567,894)	(4,382,043)
Warrants issued in connection with senior convertible notes	—	—	177,050		177,050
Issuance of common stock in financing at $60.39 per share in June and September 2008 (net of expenses of $216,567)	18,977	19	929,438		929,457
Conversion of related party notes and interest payable at $60.39 per share	29,861	30	1,803,204		1,803,234
Warrants issued in connection with related party note conversion	—	—	340,860		340,860
Stock-based compensation	—	—	460,822		460,822
Net loss	—	—		(8,786,430)	(8,786,430)
Balance at December 31, 2008	444,928	445	3,896,829	(13,354,324)	(9,457,050)
Stock-based compensation	—	—	**123,758**		**123,758**
Warrants issued in connection with Paramount Credit Partners notes	—	—	**480,049**		**480,049**
Common Stock issue to licensor in December 2009 at $12.40 per share	**2,016**	**2**	**24,998**		**25,000**
Common Stock issue to vendor in December 2009 at $12.40 per share	**403**		**5,000**		**5,000**
Net loss				**(4,539,405)**	**(4,539,405)**
Balance at December 31, 2009	**447,347**	**$ 447**	**$4,530,634**	**$(17,893,729)**	**$(13,362,648)**

See Notes to Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statements of Cash Flows

	Year ended December 31, 2009	Year ended December 31, 2008	Period from October 7, 2005 (Inception) to December 31, 2009
Cash flows from operating activities:			
Net loss	**$(4,539,405)**	$(8,786,430)	$(17,893,729)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	**123,758**	460,822	601,235
Stock issued in connection with license agreement	**25,000**	—	25,228
Stock issued to vendor	**5,000**	—	5,000
Warrants issued in connection with related party note conversion	**—**	340,860	340,860
Amortization of deferred financing costs and debt discount	**116,952**	692,907	809,859
Non-cash research and development	**—**	—	1,087,876
Interest payable – senior convertible notes	**573,708**	407,530	986,838
Expenses paid on behalf of the Company satisfied through the issuance of notes	**—**	100,620	227,910
Interest payable – related parties PBC	**55,841**	53,916	171,367
Interest payable – Paramount Credit Partners, LLC	**107,840**	—	107,840
Depreciation	**7,511**	4,650	14,734
Changes in operating assets and liabilities:			
Prepaid research and development	**800,000**	(800,000)	—
Other current assets	**2,649**	(1,507)	(2,518)
Other assets	**—**	4,060	—
Accounts payable and accrued expenses	**(762,773)**	3,375,368	3,362,460
Net cash used in operating activities	**(3,483,919)**	(4,147,204)	(10,155,040)
Cash flows from investing activities:			
Purchase of office and computer equipment	**(2,573)**	(2,876)	(27,259)
Cash flows from financing activities:			
Proceeds from notes payable to Paramount Credit Partners, LLC	**1,573,000**	—	1,573,000
Proceeds from notes payable to related party PBC	**1,905,390**	210,000	4,091,390
Proceeds from 2007 senior convertible notes	**—**	2,785,000	5,305,000
Proceeds from private placements	**—**	1,146,024	1,146,024
Payments for deferred financing costs	**(76,461)**	(312,853)	(676,511)
Proceeds from utilization of line of credit	**150,000**	170,000	320,000
Repayment of amounts loaned under related party notes	**—**	(1,500,000)	(1,500,000)
Proceeds from receipt of stock issuances	**—**	—	4,684
Net cash provided by financing activities	**3,551,929**	2,498,171	10,263,587
Net (decrease) / increase in cash	**65,437**	(1,651,909)	81,288
Beginning of period	**15,851**	1,667,760	—
End of period	**$ 81,288**	$ 15,851	$ 81,288
Supplemental schedule of non-cash financing activities:			
Warrants issued to placement agent	**$ —**	$ 177,050	$ 341,334
Debt discount on Paramount Credit Partners, LLC notes	**$ 480,049**	$ —	$ 480,049
Related party notes converted to 2010 Senior convertible notes	**$ —**	$ 1,803,234	$ 1,803,234
Supplemental disclosure – cash paid for interest	**$ 344,974**	$ 139,998	$ 484,972

See Notes to Financial Statements

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 1 — Organization, Business and Basis of Presentation:

Organization and business:

Ventrus BioSciences, Inc., formerly known as South Island BioSciences, Inc. ("Ventrus" or the "Company") was incorporated in the State of Delaware on October 7, 2005. The Company changed its name from South Island BioSciences, Inc. to Ventrus BioSciences, Inc. on April 5, 2007. Ventrus is a specialty pharmaceutical company focused on the late-stage development and commercialization of gastrointestinal products.

Basis of presentation:

The Company's primary activities since incorporation have been organizational activities, including recruiting personnel, establishing office facilities, acquiring licenses for its pharmaceutical compound pipeline, performing business and financial planning, performing research and development and raising funds through the issuance of debt and common stock. The Company's planned principal operations have not yet commenced; accordingly, the Company is considered to be in the development stage.

The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments through the normal course of business. For the year ended December 31, 2009 and the period from October 7, 2005 (inception) to December 31, 2009, the Company incurred net losses of $4,539,405 and $17,893,729, respectively. The Company has a working capital deficiency as of December 31, 2009 of $12,273,641. Management believes that the Company will continue to incur losses for the foreseeable future and will need additional equity or debt financing or will need to generate revenue from the licensing of its products or by entering into strategic alliances to be able to sustain its operations until it can achieve profitability and positive cash flows, if ever. Management plans to seek additional debt and/or equity financing for the Company, but cannot assure that such financing will be available on acceptable terms, or at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On November 10, 2010, the Company effected a 1-for-12.4 reverse stock split of its Common Stock. All share and per share information in these financial statements have been adjusted to give effect to the reverse stock split.

Note 2 — Summary of Significant Accounting Policies:

Cash:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. The Company maintains its cash in bank deposit and other accounts, the balances of which, at times, may exceed Federally insured limits.

Use of estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Office equipment:

Office equipment is stated at cost and depreciated using the straight-line method over the estimated useful life of the related assets of five years.

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 2 — Summary of Significant Accounting Policies: – (continued)

Stock based compensation:

The Company accounts for stock options granted to employees according to Financial Accounting Standards Board Accounting Standards Codification No. 718 ("ASC 718"), "Compensation — Stock Compensation". Under ASC 718, share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis. The Company accounts for stock options and warrants granted to non-employees on a fair value basis in accordance with ASC 718 using the Black-Scholes option pricing model. The initial non-cash charge to operations for non-employee options and warrants with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and recognized as consulting expense over the related vesting period.

Warrants — Convertible Notes:

For the purpose of valuing the warrants as part of the convertible notes, the Company used the Black-Scholes option pricing model utilizing the assumptions noted in the following table. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company estimated the expected life of the options granted based on anticipated exercises in the future periods assuming the success of its business model as currently forecasted. The expected dividend yield reflects the Company's current and expected future policy for dividends on its common stock. The expected stock price volatility for the Company's stock options was calculated by examining historical volatilities for publicly traded industry peers as the Company does not have any trading history for its common stock. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available.

	2007	2008	2009
Risk-free interest rate	3.84%	3.01% – 3.89%	1.64% – 2.58%
Expected volatility	66.36%	63.69% – 128.18%	104.11% – 110.89%
Expected life of warrants	7 years	7 years	5 years
Expected dividend yield	0%	0%	0%

In accordance with ASC Topic 470-20, "*Debt with Conversion and Other Options*," the proceeds from any financing in which the Company issues warrants to purchase the Company's common stock are first allocated to the warrants based upon their estimated relative fair values as of the closing date.

Warrants, or any other detachable instruments issued in connection with debt financing agreements, are accounted for using the relative fair value method and allocated to additional paid-in capital and recorded as a reduction in the carrying value of the related debt. This discount is amortized to interest expense from the issuance date through the maturity date of the debt using the straight-line method.

When the conversion feature of conventional convertible debt provides for a rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature ("BCF"). Prior to the determination of the BCF, the proceeds from the debt instrument are first allocated between the convertible debt and any detachable free standing instruments that are included, such as common stock warrants. The Company has disclosed the contingent nature of its BCFs, but the Company has not recorded the effects of such contingent BCFs pursuant to ASC Topic 470-20. The Company will record the BCF if and when the conversion takes place.

Research and development:

Research and development costs, including license fees, are expensed as incurred.

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Financial Statements

Note 2 — Summary of Significant Accounting Policies: – (continued)

Income taxes:

Under Financial Accounting Standards Board Accounting Standards Codification No. 740 ("ASC 740"), "Income Taxes", deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.

Loss per common share:

Basic earnings (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per common share reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity. Since the Company has only incurred losses, basic and diluted loss per share is the same. The amount of potentially dilutive securities excluded at December 31, 2009 and 2008 was 117,808 and 66,945, respectively.

Fair value measurements:

The carrying value of the senior convertible notes, related party notes, and Paramount Credit Partners, LLC notes approximate fair value due to the short-term nature of these notes and the related interest rates approximate market rates.

Recent Accounting Pronouncements:

In March 2010, the Financial Accounting Standards Board ratified the consensus of the Emerging Issues Task Force included in EITF Issue No. 08-9, "Milestone Method of Revenue Recognition" (ASC Topic 605.28; ASU No. 2010-17). The milestone method is optional by arrangement and generally provides that upon achievement of a substantially uncertain milestone, the related milestone payment may be recognized in income in its entirety. The Company has not yet evaluated the effects of this consensus and, accordingly, has not yet made an accounting policy decision for future arrangements. When the consensus becomes effective (years beginning on or after June 15, 2010; first quarter of 2011 for the Company), the Company will consider application of the consensus on a prospective or retrospective basis.

Note 3 — Related Party Transactions:

Consulting services:

Effective August 2007, the Company began accruing monthly fees for consulting services at a rate of $25,000 per month to Paramount Corporate Development, LLC ("Paramount"), which was an affiliate of Lindsay A. Rosenwald, M.D., a significant investor in and stockholder of the Company. Consulting services expense was $0, $200,000 and $425,000 for the years ended December 31, 2009 and 2008 and the period from October 7, 2005 (inception) to December 31, 2009, respectively. As of December 31, 2009, the Company had $100,000 outstanding under this arrangement which is included in accrued expenses as of December 31, 2009. This agreement was terminated as of August 31, 2008.

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 3 — Related Party Transactions: – (continued)

Notes payable:

On October 7, 2005, the Company issued a 5% promissory note payable to Paramount BioSciences, LLC ("PBS"), an affiliate of a significant stockholder of the Company. This note and all accrued interest were to mature on October 7, 2008, or earlier if certain events occurred. The note was amended to extend the maturity date to October 7, 2009. On June 16, 2008, this note was voluntarily converted into one common stock share and one warrant of the Company at a price of $60.39 per unit, the price of a concurrent financing (see Note 6). At the time of the conversion, the outstanding balance due under this note was $1,396,672, which was converted into 23,128 shares of the Company's common stock and a warrant to purchase 4,805 shares of the Company's common stock for which the Company recorded charge of $266,243. Upon conversion, the note was automatically cancelled. Each warrant has a seven-year term and an exercise price of $66.46.

On July 12, 2007, the Company issued an 8% promissory note payable to an entity related to the sole member of PBS. This note and all accrued interest mature on July 12, 2010, or earlier if certain events occur. On June 16, 2008, this note was voluntarily converted into common stock shares and warrants of the Company at a price of $60.39 per unit, the price of a concurrent financing. At the time of the conversion, the outstanding balance due under this note was $406,562 which was converted into 6,733 shares of the Company's common stock and a warrant to purchase 1,347 shares of the Company's common stock for which the Company recorded charge of $74,617. Upon conversion, the note was automatically cancelled. Each warrant has a seven-year term and an exercise price of $66.46.

The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	3.89%
Expected volatility	128.18%
Expected life of warrants	7 years
Expected dividend yield	0%

On July 23, 2008, the Company issued an 8% promissory note payable to PBS. Originally, all amounts outstanding under this note matured and were payable on July 23, 2010. On December 21, 2009, this note was amended to provide that all loans (including principal and accrued interest thereon) made by PBS to the Company under this note on or after September 30, 2009 shall immediately and automatically be converted into the same equity or derivative securities as are issued in any equity or derivative equity financing consummated by the Company on or after September 30, 2009 (that does not otherwise constitute a Qualified Financing, as defined below), on the same terms and conditions that such equity securities are offered in such non-Qualified Financing. A "Qualified Financing" means the closing of an equity financing or series of related equity financings by the Company resulting in aggregate gross cash proceeds (before brokers' fees or other transaction related expenses) of at least $10,000,000. As of December 31, 2009 and 2008, the principal amount outstanding under this note is $2,025,591 and $310,201, respectively.

On April 24, 2009, the Company issued an 8% promissory note payable to an entity related to Lindsay A. Rosenwald, M.D., the sole member of PBS and a significant investor in and stockholder of the Company. Originally, all unpaid principal and accrued and unpaid interest outstanding under this note matured and was payable on April 24, 2012. Effective December 21, 2009, this note was amended so that it is convertible and repayable on the same terms and conditions as the PBS note discussed above. As of December 31, 2009, the principal amount outstanding under this note is $190,000.

During 2009, the Company issued four separate 10% promissory notes (collectively, the "PCP Notes") to Paramount Credit Partners, LLC ("PCP"), an entity whose managing member is Lindsay A. Rosenwald, M.D., a significant investor in and stockholder of the Company. Specifically, the PCP Notes consist of a

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Notes to Financial Statements

Note 3 — Related Party Transactions: – (continued)

note in the principal amount of $1,100,000 issued on January 23, 2009, a note in the principal amount of $100,000 issued on March 25, 2009, a note in the principal amount of $250,000 issued on June 1, 2009 and a note in the principal amount of $123,000 issued on June 24, 2009. Interest on the PCP Notes is payable quarterly, in arrears, and the principal matures on the earlier of (i) December 31, 2013 or (ii) the completion by the Company of a transaction, including an equity offering, sale of assets, licensing or strategic partnership, in which the Company raises at least $5,000,000 in gross cash proceeds. In addition, PCP received five-year warrants ("PCP Warrants") to purchase, at an exercise price of 110% of the lowest price paid for securities in a Qualified Financing, a number of shares of the Company's common stock equal to 40% of the principal amount of each PCP Note purchased divided by the lowest price paid for securities in a Qualified Financing prior to the two-year anniversary of such PCP Note. If the Qualified Financing does not occur on or before the two-year anniversary of a PCP Note, then the associated PCP Warrants will be exercisable for a number of shares of the Company's common stock equal to 40% of the principal amount of such PCP Note purchased divided by $12.40 (which would equal 50,742 shares), at a per share exercise price of $12.40. The Company allocated proceeds of $480,049 from the sale of the PCP Notes to the warrants at the time of issuance, which are recorded as a debt discount and reduced the carrying values of the PCP Notes. Such discount is being amortized to interest expense over the term of the PCP Notes. As of December 31, 2009, the principal amount outstanding under these notes is $1,573,000. The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	1.64% – 2.58%
Expected volatility	104.11% – 110.89%
Expected life of warrants	5 years
Expected dividend yield	0%

Subsequent Event (2010 Senior Convertible Notes):

On February 26, 2010, $2,192,433 outstanding under the PBS notes was converted into 2010 Notes (the "2010 Notes") (see Note 9). Effective December 21, 2009, this note was further amended to provide that all remaining amounts outstanding under this note will automatically convert into the Company's equity securities issued in the Company's next equity financing (or series of related equity financings), including, without limitation, a firm commitment underwritten initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, involving the sale of securities in which the Company receives in arm's length non-related party transaction(s) at least $8,853,976 in aggregate gross cash proceeds (before brokers' fees or other transaction related expenses, and excluding any such proceeds resulting from any conversion of the Company's then-existing convertible bridge notes minus the amount of aggregate gross cash proceeds to the Company from the sale of equity or debt securities of the Company after December 21, 2009 (but not to be reduced below $5,000,000) (a "Qualified Financing")), at a conversion price equal to 70% of the lowest per unit price paid for such securities in cash by investors in such Qualified Financing, and upon such other terms, conditions and agreements as may be applicable in such Qualified Financing. The Company valued the beneficial conversion feature of the 2010 Notes at $939,614, which will be recorded as interest expense only if a Qualified Financing is completed. The Company computed the conversion feature to be $939,614 by dividing the amount of debt ($2,192,433), which is convertible into common stock by the conversion rate (70%). From this amount ($3,132,047) the amount of debt ($2,192,433) was subtracted to determine the amount by which the instrument if-converted exceeds the conversion amount ($939,614).

Each 2010 Noteholder also holds a warrant to purchase a number of shares of the Company's common stock equal to 50% of the principal amount of the 2010 Notes purchased by it divided by the "IPO Price"(see Note 9) at a per share exercise price equal to 110% of the IPO Price, subject to adjustment. Each of these warrants will expire and no longer be exercisable after February 26, 2015. Notwithstanding

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 3 — Related Party Transactions: – (continued)

the foregoing, if a Qualified Financing does not occur on or before February 26, 2012, then each warrant will be exercisable for that number of shares of the Company's common stock equal to 50% of the principal amount of the 2010 Note purchased by the original holder divided by $12.40, at a per share exercise price of $12.40 (which would be 226,509 shares). In the event of a sale of the Company (whether by merger, consolidation, sale or transfer of the Company's capital stock or assets or otherwise) the warrants shall continue to be exercisable pursuant to their terms. The Company valued these warrants at approximately $1,468,000 using the Black-Scholes option pricing model, and the Company expensed the entire amount during the three months ended March 31, 2010 as interest expense. The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	2.30% – 2.55%
Expected volatility	124.46% – 129.05%
Expected life of warrants	5 years
Expected dividend yield	0%

This note will also automatically convert into equity securities of the Company immediately prior to a sale or merger of the Company, as defined in the notes. In the event that this note becomes due and payable (whether on the due date or earlier) prior to the consummation by the Company of a Qualified Financing, or a sale or merger of the Company which converts the note into equity securities of the Company, then, in connection with the repayment of the note, in addition to the payment of the unpaid principal amount and all accrued but unpaid interest on the note, the Company will be obligated to pay to the noteholder, as a repayment premium, an amount in cash equal to 42.8571% of the aggregate outstanding principal amount plus all accrued and unpaid interest on the note.

On February 26, 2010, a 2010 Note in the aggregate principal amount of $2,192,433 and related warrant were issued to PBS for the cancellation of certain debt (as discussed in Note 3 above), which is not included in the $3,425,000 of aggregate principal amount of 2010 Notes issued in the private placement. Including such converted debt, the total aggregate principal amount of 2010 Notes is $5,617,433.

Properties:

Starting June 2010, the Company occupies space at the offices of PBS.

Line of Credit:

On December 3, 2008, the Company, PBS and various other private pharmaceutical companies in which Lindsay A. Rosenwald, M.D. is a significant investor and stockholder, entered into a loan agreement with Bank of America, N.A. for a line of credit of $2,000,000. PBS pledged collateral securing the Company's and the other borrowers' obligations to Bank of America, N.A. under the loan agreement. Interest on amounts borrowed under the line of credit accrues and is payable on a monthly basis at an annual rate equal to the London Interbank Offered Rate (LIBOR) plus 1%. On November 10, 2009, the parties entered into Amendment No. 1 to the Loan Agreement, which extended the initial one-year term for an additional year, such that it currently matures on November 5, 2010, and reduced the aggregate amount available under the line of credit to $1,000,000. Under the loan agreement, the Company's liability under the line of credit is several, not joint, with respect to the payment of all obligations thereunder. As of December 31, 2009 and 2008, the amounts borrowed by the Company that were outstanding under this line of credit were $320,000 and $170,000, respectively.

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Notes to Financial Statements

Note 3 — Related Party Transactions: – (continued)

The Company has paid interest owed to PCP for the first quarters of 2010 and 2009. For the second, third and fourth quarters of 2009, the Company had insufficient funds to pay the quarterly interest amount owed to PCP. Interest amounts for these three quarterly periods were paid directly by Lindsay A. Rosenwald, M.D. to PCP, pursuant to certain guarantee obligations owed by Dr. Rosenwald under PCP's operating agreement.

Note 4 — Income Taxes:

There was no net current or deferred income tax provision for the years ended December 31, 2009 and 2008.

The Company's deferred tax assets as of December 31, 2009 and 2008 consist of the following:

	2009	2008
Net operating loss carryforwards – Federal	$ 4,931,000	$ 3,414,000
Net operating loss carryforwards – State	870,000	603,000
Totals	5,801,000	4,017,000
Less valuation allowance	(5,801,000)	(4,017,000)
Deferred tax assets	$ —	$ —

At December 31, 2009, the Company had potentially utilizable Federal and state net operating loss tax carryforwards of approximately $14,502,000, expiring through 2029.

The utilization of the Company's net operating losses may be subject to a substantial limitation due to the "change of ownership provisions" under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation may result in the expiration of the net operating loss carryforwards before their utilization.

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2009 and 2008 and for the period from October 7, 2005 (inception) to December 31, 2009 was $1,784,000, $2,191,000 and $5,801,000, respectively. The tax benefit assumed the Federal statutory tax rate of 34% and a state tax rate of 6% and has been fully offset by the aforementioned valuation allowance.

	2009	2008
Statutory Federal tax rate	(34.0)%	(34.0)%
Statutory income tax rate (net of Federal)	(6.0)%	(6.0)%
Warrants issued in connection with related party note conversion	—%	2%
Debt discount amortization	1%	—%
Effect of valuation allowance	39%	38%
Effective tax rate	—%	—%

The Company accounts for uncertain tax positions in accordance with Financial Accounting Standards Board Accounting Standards Codification No. 740 ("ASC 740"), "Income Taxes". The Company adopted ASC 740 as of January 1, 2007.

Management believes that the Company does not have any tax positions that will result in a material impact on the Company's financial statements because of the adoption of ASC 740. However, management's conclusion may be subject to adjustment at a later date based on factors including additional implementation guidance from the Financial Accounting Standards Board and ongoing analyses of tax laws, regulations and related interpretations.

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 5 — Commitments:

Employment agreements:

Presently, the Company has no employees and is managed by its Board of Directors, one of whom, Thom Rowland, acts as the Company's President. Mr. Rowland originally joined the Company in April 2007, and was employed as its Chief Executive Officer from April 2007 through February 2009, at which time his employment agreement was terminated without cause. Pursuant to that employment agreement, during his term of employment, Mr. Rowland received an annual base salary of $300,000, plus an annual bonus of up to 40% of base salary based upon attainment of certain financial, clinical development and business milestones. No bonuses were earned under such employment agreement. Mr. Rowland received an initial grant of restricted stock under his employment agreement, all of which is currently vested. Pursuant to the termination of his employment, the Company was obligated to make certain severance payments to Mr. Rowland, the receipt of which Mr. Rowland waived in return for his retention as a consultant to the Company.

Terrance Coyne, M.D., joined the Company in June 2007, and served as the Company's Senior Vice President and Chief Medical Officer from June 2007 through February 2009, at which time his employment agreement was terminated without cause. Pursuant to that employment agreement, during his term of employment, Dr. Coyne received an annual base salary of $290,000, plus an annual bonus of up to 25% of base salary based upon attainment of certain financial, clinical development and business milestones. No bonuses were earned under such employment agreement. Dr. Coyne received an initial grant of restricted stock under his employment agreement, all of which is currently vested. Pursuant to the termination of his employment, the Company was obligated to make certain severance payments to Dr. Coyne, the receipt of which Dr. Coyne waived in return for his retention as a consultant to the Company.

John Dietrich, Ph.D. joined the Company in April 2007, and served as the Company's Vice President, Clinical Operations from April 2007 through February 2009, at which time his employment agreement was terminated without cause. Pursuant to that employment agreement, during his term of employment, Dr. Dietrich received an annual base salary of $185,000, plus an annual bonus of up to 20% of base salary based upon attainment of certain financial, clinical development and business milestones. No bonuses were earned under such employment agreement. Dr. Dietrich received an initial grant of restricted stock under his employment agreement, all of which is currently vested. Pursuant to the termination of his employment, the Company was obligated to make certain severance payments to Dr. Dietrich, the receipt of which Dr. Dietrich waived in return for his retention as a consultant to the Company.

Dr. Ellison currently serves as the Company's Chief Executive Officer pursuant to an amended and restated consulting agreement dated July 19, 2010. The agreement provides for a term of six months with the option to extend the agreement for an additional year. Dr. Ellison receives a consulting fee of $30,000 per month. In addition, if the Company completes a partnership or licensing transaction or the Company or any of the Company' assets are acquired by another entity prior to completing a financing resulting in gross proceeds of at least $8,000,000, then he will receive a fee equal to 4% of the gross proceeds of such transaction.

The Company also has executed an employment agreement with Dr. Ellison, which will become effective upon a financing of $8,000,000 in gross proceeds and has a term of three years. When the employment agreement becomes effective, his consulting agreement will terminate and Dr. Ellison will become President, CEO and Chairman of the Board. The employment agreement provides for a base salary of $375,000 per year, a guaranteed bonus of $75,000 per year and an annual performance-based bonus of up to 50% of his base salary. The agreement also provides a first incentive bonus of $250,000 in the event that the Company's market capitalization exceeds $100 million for a period of 30 consecutive trading

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Notes to Financial Statements

Note 5 — Commitments: – (continued)

days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day and a second incentive bonus of $500,000 in the event that the Company's market capitalization exceeds $250 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day. Dr. Ellison will also receive a grant of options to purchase the Company's common stock at the offering price of an offering generating a minimum of $8,000,000 in gross proceeds in an amount equal to 7.5% of the Company's fully diluted capitalization on the date the employment agreement becomes effective, giving effect to all shares issuable under all convertible notes, warrants and options outstanding on such date, but excluding shares reserved for grants not issued under our 2010 Equity Incentive Plan.

Consulting Agreements

Mr. Barrett currently serves as our Chief Financial Officer pursuant to an amended and restated consulting agreement dated July 19, 2010. The agreement provides for a term of six months with the option to extend the agreement for an additional year. Mr. Barrett receives a consulting fee of $15,000 per month.

Effective May 11, 2010, the Company entered into a consulting agreement with Timothy Hofer, pursuant to which Mr. Hofer provides the Company with general consulting services focused on general business and company development. Mr. Hofer is also a employee of Paramount Biosciences, LLC, a related party. This consulting agreement is for a period of one year, subject to renewal for such longer period as the Company may agree in writing with Mr. Hofer, and may be terminated by either party upon 30 days' prior written notice.

Under the terms of the consulting agreement with Mr. Hofer and as compensation for his services thereunder, the Company granted Mr. Hofer a ten-year warrant to purchase 8,065 shares of the Company's common stock, subject to adjustment as described below (the "Hofer Consultant Warrant"). The Hofer Consultant Warrant will have an exercise price per share equal to the price at which shares of the Company's common stock are issued in a Qualified Financing. If a Qualified Financing does not occur on or before September 10, 2010, then the exercise price per share of the Hofer Consultant Warrant will be equal to the fair market value of the Company's common stock, as determined pursuant to a valuation performed by an independent appraisal firm. Under the terms of the Hofer Consultant Warrant, if the Company consummates a Qualified Financing, the number of shares of common stock issuable upon exercise of the Hofer Consultant Warrant will be automatically adjusted so that such number of shares is equal to 1.0% of the Company's outstanding common stock on a fully diluted basis, after giving effect to such Qualified Financing (including the conversion of any of the Company's convertible bridge notes issued in 2007 – 2008 triggered by such Qualified Financing). This adjustment provision will terminate once the Company consummates a Qualified Financing. For purposes of the Hofer Consultant Warrant, a "Qualified Financing" means the Company's next equity financing (or series of related equity financings) sufficient to trigger conversion of all amounts then outstanding under the Company's convertible PBS notes issued in 2007 and 2008.

Note 6 — Stockholders' Deficiency:

Common Stock:

During March and April 2007, the Company issued 368,012 shares of common stock to its founders for $4,564, or $0.0124 per share.

During May and June 2007, the Company issued 9,677 shares of common stock to its employees for $120, or $0.0124 per share.

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 6 — Stockholders' Deficiency: – (continued)

During August 2007, the Company issued 18,401 shares of common stock in accordance with a license agreement at $0.0124 per share. During 2007, the Company recorded $228 of research and development expense in connection with this license.

During June and September 2008, the Company issued 18,977 shares of common stock and 3,796 warrants at $60.39 per unit in connection with a private placement financing at $60.39 per share. Each warrant has a seven-year term and an exercise price of $66.46.

During July 2008, the Company issued 29,861 shares of common stock and 6,151 warrants at $60.39 per unit to related parties in connection with the conversion of amounts outstanding under certain promissory notes (see Note 3). Each warrant has a seven-year term and an exercise price of $66.46.

The fair value of the warrants granted, mentioned in the two preceding paragraphs, was based on the following assumptions:

Risk-free interest rate	3.89%
Expected volatility	128.18%
Expected life of warrants	5 years
Expected dividend yield	0%

During December 2009, the Company issued 2,016 shares of common stock to one of its licensors and 403 shares of common stock to a vendor, each at a value of $12.40 per share.

Common stock options and warrants related to compensation:

In 2007, the Company established a stock incentive plan (the "Plan") under which incentive stock and/or options may be granted to officers, directors, consultants and key employees of the Company for the purchase of up to 483,871 shares of the Company's common stock. The options have a maximum term of ten years, vest over a period to be determined by the Company's Board of Directors and have an exercise price at or above fair market value on the date of grant.

On May 11, 2010, the Company granted options to purchase 2,016 shares of its common stock to director Joseph Felder under the 2007 Plan with an exercise price to be determined in the next Qualified Financing.

There were no options issued under the 2007 Plan in 2008 or 2009.

The Company expects all outstanding options will vest by the end of 2010.

During 2007, the Company granted 12,903 warrants outside the Plan to various consultants with an exercise price of $7.69 per share. Each warrant granted during 2007 vests equally over a three-year period and has a seven-year term. The Company recorded $123,758 and $460,822 of compensation expense during 2009 and 2008, respectively. During 2008, 1,613 of these warrants were forfeited due to the consultant's relationship with the Company ending prior to the vesting period. The fair value of the warrants granted, and the related fair value adjustments at the end of each reporting period, were based on the following assumptions:

	2007	2008	2009
Risk-free interest rate	4.00%	1.55% – 3.61%	1.67% – 2.69%
Expected volatility	65.55%	104.78% – 219.91%	128.96% – 163.74%
Expected life of warrants	7 years	7 years	7 years
Expected dividend yield	0%	0%	0%

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 6 — Stockholders' Deficiency: – (continued)

In connection with the Company's financings, the Company issued warrants to purchase shares of the Company's common stock (See Note 3 and Note 8).

The weighted average remaining contractual life of warrants outstanding at December 31, 2009 is nine months.

As of December 31, 2009, the total compensation expense related to non-vested warrants not yet recognized totaled approximately $59,000. The weighted-average vesting period over which the total compensation expense related to non-vested warrants not yet recognized at December 31, 2009 was approximately 0.22 years.

Note 7 — License Agreements:

In March 2007, pursuant to an "Exclusive License Agreement," S.L.A. Pharma AG, a Swiss corporation ("S.L.A.") granted PBS an exclusive, royalty-bearing license to sell, make and use diltiazem for treatment, through topical administration, of anal fissures and phenylepherine for treatment, through topical administration, of fecal incontinence in the United States, Canada and Mexico. Pursuant to the Exclusive License Agreement, PBS was obligated to form a company to develop the technologies referenced in the Exclusive License Agreement and issue a number of shares equal to 5% of such company's outstanding Common Stock as of the effective date of the Exclusive License Agreement. On August 2, 2007, the Company issued 18,401 shares to S.L.A. to satisfy this obligation. In the event the Company closes an equity financing with gross proceeds of not less than $5,000,000 and the issued shares do not have a fair market value at least equal to $500,000, then the Company shall issue to S.L.A. that number of additional shares of common stock so that the number of shares following such issuance have a fair market value equal to $500,000.

In August 2007, pursuant to an Assignment and Assumption Agreement, PBS sold all of its rights in and arising out of the Exclusive License Agreement with S.L.A. to Ventrus for $1,087,876. The corresponding U.S. and foreign patents and applications for the two compounds have been licensed to Ventrus under the Assignment and Assumption Agreement (the technology referred to collectively as the Compound Technology). As consideration in part for the rights to the Compound Technology, an initial licensing fee of $250,000 was paid to S.L.A. and $50,000 for reimbursement of clinical development costs incurred by S.L.A. (these amount were paid by PBS and was included in the consideration paid by us to PBS in connection with the Assignment and Assumption Agreement). In the event that the Compound Technology is commercialized, the Company is obligated to pay to S.L.A. annual royalties ranging from the mid to upper single digit percentages, based upon net sales of the product. In addition, the Company is required to make payments to S.L.A. up to an aggregate amount of $20 million upon the achievement of various milestones related to regulatory events. Should the Company make any improvements regarding the Compound Technology, the Company is required to grant S.L.A. licenses to use such improvements.

As compensation for S.L.A.'s participation in the management and the development of the technologies, Ventrus is required to make separate payments to S.L.A. equal to $41,500 per month ("Monthly Payments") for both diltiazem and phenylephrine. Per the agreement, Ventrus' obligation to make these monthly payments was to terminate upon an NDA filing. Pursuant to certain amendments to the Exclusive License Agreement, the Company has deferred certain payment requirements that had come due under the Exclusive License Agreement. From January 31, 2010 until September 30, 2010, the Company is obligated to pay S.L.A. $41,500 per month, and has been current in such obligations, and to accrue an additional $41,500 per month towards the Company's obligations to S.L.A.'s development costs.

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 7 — License Agreements: – (continued)

Ventrus is also required to reimburse S.L.A. for clinical development costs associated with the technology development of both diltiazem and phenylephrine. Ventrus' total payment obligation for the diltiazem project shall not exceed $4,000,000. Ventrus made $1,650,000 of payments to S.L.A. prior to December 31, 2009 and either has made or expects to make the payments as follows: (i) January 31, 2010, Ventrus made a $350,000 payment to S.L.A., (ii) on June 30, 2010, Ventrus paid S.L.A. $600,000, (iii) on December 31, 2010, Ventrus is obligated to pay S.L.A. $600,000, and (iv) upon completion of recruitment into the Phase III trial in Europe, Ventrus is obligated to pay S.L.A. $800,000. The $600,000 Ventrus is obligated to pay represents past development costs and Ventrus has accrued this amount as of December 31, 2009. S.L.A. has not completed the recruitment of patients into the Phase III trial and therefore Ventrus has not recorded the $800,000 expense at December 31, 2009. In addition, both Ventrus and S.L.A. have agreed to add additional services outside the scope of the agreement in which case Ventrus is obligated to pay an additional $400,000. The additional amount will be paid if Ventrus has raised net proceeds of at least $20.0 million from sales of securities and or the licensing of rights to the products. S.L.A. has not provided the services for this additional work and therefore Ventrus has not recorded any additional expenses. Ventrus' total payment obligation for the phenylephrine project shall not exceed $1,200,000. S.L.A. has provided and billed Ventrus for $600,000 of services through December 31, 2009.

The Exclusive License Agreement with S.L.A. is terminable by the Company for any reason upon 90 days' written notice, and by either party in the event of a material breach or default of the Exclusive License Agreement or either party becomes bankrupt or insolvent. In addition, the Exclusive License Agreement is terminable immediately by S.L.A. if the Company does not consummate a financing by December 31, 2010 with net proceeds of at least $10.0 million. In addition, S.L.A. may terminate the Exclusive License Agreement at any time, even during or after the successful completion of a financing, with one month's notice in the event that a third party wishes to enter into a license agreement for diltiazem and phenylepand has entered into an agreement to that effect, provided that within that the termination will not be effective if within that one-month period the Company pays all then required payments under the agreement.

In March 2008, Ventrus entered into an exclusive worldwide license agreement with Sam Amer & Co., Inc., a California company ("Amer"), whereby Ventrus acquired certain patent rights to iferanserin (the "Technology") for the topical treatment of any anorectal disorders. Ventrus is obligated to pay Amer (i) a monthly consulting fee of $7,500 through May 2010, (ii) a license fee of $2,050,000, (iii) late fees of $7,500 per month starting July 2009 until the successful completion of the Phase III trials (iv) interest payments totaling $595,000 and (v) additional late fees of $7,500 per month if an NDA is not submitted by September 2010. In addition, Ventrus may be required to make future milestone payments totaling up to $20 million upon the achievement of various milestones related to regulatory or commercial events. In the event that the technology is commercialized, we are obligated to pay to Amer annual royalties ranging from the upper single to lower double digit percentages for sales in the U.S. and ranging from the low to mid single digit percentages for sales outside of the U.S. The license agreement is terminable by either party for cause, upon 30 days notice and subject to a 60-day cure period, upon notice if either party becomes bankrupt or insolvent or at any time after the expiration of the Royalty Period for any Licensed Product (as such terms are defined in the Exclusive License Agreement) upon 90 days' written notice. The Company may terminate the license agreement upon 30 days' written notice in the event any safety, efficacy or regulatory issues prevent development or commercialization of the technology.

In December 2009, the Company and Amer supplemented the license agreement and added an additional licensing fee of $20,000 for six months. After the fourth month, the Company and Amer agreed that the additional license would not be needed and, therefore, the Company did not pay the last two months.

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 8 — Private Placements:

2007 Senior convertible notes:

During 2007 and 2008, the Company issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $5,305,000 (the "Bridge Notes"). The Bridge Notes were originally scheduled to mature on December 20, 2008, but the Company exercised its option to extend the maturity date to December 20, 2009, at an increased interest rate of 10%. The Company subsequently obtained the consent of the Noteholders to an additional extension of the maturity date of the Bridge Notes to September 10, 2010. After giving effect to such consent, the Bridge Notes, plus all accrued interest thereon, will automatically convert into the same securities issued in the Company's next Qualified Financing (as defined below), at a conversion price equal to 70% of the lowest per unit price paid for such securities in cash by investors in such Qualified Financing, and upon such other terms, conditions and agreements as may be applicable in such Qualified Financing. The Bridge Notes will also automatically convert into equity securities of the Company immediately prior to a sale or merger of the Company, as defined in the Bridge Notes. In the event that the Bridge Notes become due and payable (whether on the due date or earlier) prior to the consummation by the Company of a Qualified Financing, or a sale or merger of the Company which converts the Bridge Notes into equity securities of the Company, then, in connection with the repayment of the Bridge Notes, in addition to the payment of the unpaid principal amount and all accrued but unpaid interest on the Bridge Notes, the Company will be obligated to pay to the Noteholders, as a repayment premium, an amount in cash equal to 42.8571% of the aggregate principal amount plus all accrued and unpaid interest on the Bridge Notes. For purposes of the Bridge Notes, "Qualified Financing" means the sale of the Company's equity securities in an equity financing or series of related equity financings in which the Company receives (minus the amount of aggregate gross cash proceeds to the Company from Company's arm's length sale of equity or debt securities, or incurrence of new loans, after December 21, 2009) aggregate gross proceeds of at least $10,000,000 (before brokers' fees or other transaction related expenses, and excluding any such proceeds resulting from any conversion of the Bridge Notes).

In connection with the offering of the Bridge Notes, Paramount Biocapital, Inc. ("PCI") and the Company entered into a placement agency agreement dated October 9, 2007, pursuant to which the Company paid PCI and third party agents cash commissions of $243,600 and $19,250, respectively, for its services. The Company also had agreed to pay to PCI a commission on sales by the Company of securities during the 18-month period subsequent to March 11, 2008 to the purchasers of the Bridge Notes who were introduced to the Company by PCI. The Company also granted PCI the right of first refusal to act as exclusive finder, placement agent or other similar agent in relation to any securities offerings on its behalf during the 18-month period following March 11, 2008. Each of these 18-month periods expired without any further commissions being paid. PCI is a related party to the Company since it is wholly owned by Lindsay A. Rosenwald, M.D., a significant investor in and stockholder of the Company.

In addition, PCI and third party agents received warrants (the "Placement Warrants") to purchase, at an exercise price of 110% of the lowest price paid for securities in a Qualified Financing, a number of shares of the Company's common stock equal to 10% of the principal amount of the Notes purchased, less any amount used to repay the related party notes, or amounts due to PBS or their affiliates or employees as finder's fees, payments under the services agreement or other similar payments, divided by the lowest price paid for securities in a Qualified Financing prior to December 21, 2009. If the Qualified Financing did not occur on or before December 21, 2009, the Placement Warrants will be exercisable for a number of shares of the Company's common stock equal to 10% of the principal amount of the Notes purchased, less any amount used to repay the related party notes, or amounts due to PBS or their affiliates or employees as finder's fees, payments under the services agreement or other similar payments, divided by $12.40, at a per share exercise price of $12.40 and are exercisable for seven years. Since the Qualified Financing did not occur by such date, the Placement Warrants are now exercisable into 42,782 shares of the Company's common stock, at a per share exercise price of $12.40. PCI subsequently

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 8 — Private Placements: – (continued)

transferred the warrant among various of its employees. The Company estimated the value of the warrants using the Black-Scholes option pricing model at approximately $341,000 and recorded them as deferred financing costs, which were amortized to interest expense over the term of the Notes. The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	3.01% – 3.84%
Expected volatility	63.69% – 123.73%
Expected life of warrants	7 years
Expected dividend yield	0%

PCI acted as placement agent for the private placement of the Company's senior convertible notes in the aggregate principal amount of $5,305,000 during 2007 and 2008.

Note 9 — Subsequent Events:

2010 Senior convertible notes:

In February, March, April and May 2010, the Company issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $3,425,000 (the "2010 Notes"). The 2010 Notes mature on September 10, 2010. Upon the closing of a Qualified Financing (as defined below), the 2010 Notes plus any accrued but unpaid interest thereon will convert automatically into shares of the Company's common stock at 70% of the price at which shares of common stock are sold in the Qualified Financing (the "IPO Price"), upon the terms and conditions on which such securities are issued in the Qualified Financing. For purposes hereof, "Qualified Financing" means the consummation of an initial public offering by the Company of units consisting of shares of common stock and warrants to purchase common stock resulting in aggregate gross cash proceeds (before commissions or other expenses) to the Company of at least $10,000,000. The Company valued the beneficial conversion feature of the 2010 Notes at $1,468,000, which will be recorded as interest expense only if a Qualified Financing is completed.

Each 2010 Noteholder also holds a warrant to purchase a number of shares of the Company's common stock equal to 50% of the principal amount of the 2010 Notes purchased by it divided by the IPO Price at a per share exercise price equal to 110% of the IPO Price, subject to adjustment in the event the outstanding shares of the Company's common stock are increased by a stock dividend payable in common stock, stock split or subdivision, decreased by a reverse stock split, combination or consolidation, reclassified, or the Company is subject to a reorganization, consolidation, merger, or sale, lease, license, exchange or other transfer of all or substantially all of the business and/or assets of the Company. Each of these warrants will expire and no longer be exercisable after February 26, 2015. Notwithstanding the foregoing, if a Qualified Financing does not occur on or before February 26, 2012, then each warrant will be exercisable for that number of shares of the Company's common stock equal to 50% of the principal amount of the 2010 Note purchased by the original holder divided by $12.40, at a per share exercise price of $12.40. In the event of a sale of the Company (whether by merger, consolidation, sale or transfer of the Company's capital stock or assets or otherwise) prior to, but not in connection with, a Qualified Financing, each of these warrants will terminate 90 days following such sale and the warrants shall continue to be exercisable pursuant to their terms during such 90-day period. The Company valued these warrants at $1,468,000 using the Black Scholes option pricing model and is amortizing such amount over the term of the Notes to interest expense. The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	2.30% – 2.55%
Expected volatility	124.46% – 129.05%
Expected life of warrants	5 years
Expected dividend yield	0%

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 9 — Subsequent Events: – (continued)

On February 26, 2010, a 2010 Note in the aggregate principal amount of $2,192,433 and related warrant were issued to PBS for the cancellation of certain debt (as discussed in Note 3 above), which is not included in the $3,425,000 of aggregate principal amount of 2010 Notes issued in the private placement. Including such converted debt, the total aggregate principal amount of 2010 Notes is $5,617,433.

In connection with the offering of the 2010 Notes and related warrants, National Securities Corporation ("National") and the Company entered into a placement agency agreement dated January 5, 2010, as amended on January 29, 2010, and a placement agency agreement dated April 14, 2010, as amended on April 30, 2010, pursuant to which the Company paid National cash fees of $671,592, which consisted of placement agent commissions of $561,743 and non-accountable expense reimbursements of $109,849. In addition, the Company issued National warrants to purchase an aggregate number of shares of common stock equal to 10% of the aggregate number of shares into which the 2010 Notes convert into upon the close of a Qualified Financing, with an exercise price of 110% of the IPO Price. In addition, the Company paid National's outside counsel $32,500 for its services as placement agent counsel.

The Company also granted National the exclusive right until May 6, 2011 to act as lead placement agent on the next private placement of the Company's securities, or as lead managing underwriter on the initial public offering of the Company's securities, with the compensation being paid to National with respect to such financing to be mutually agreed to by the parties in good faith with respect to such financing.

Legal Proceedings:

In June 2010, the Company was sued for non-payment of approximately $123,000 that it owed to a company with whom it had contracted to provide drug development services. The Company has paid the agreed upon amount in full settlement of the claim.

VENTRUS BIOSCIENCES, INC.
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Condensed Balance Sheets

	September 30, 2010 (Unaudited)	December 31, 2009 (Note 1)
ASSETS		
Current Assets:		
Cash and cash equivalents	**$ 271,075**	$ 81,288
Other current assets	**4,026**	2,519
Total current assets	**275,101**	83,807
Office equipment, net of accumulated depreciation	**8,823**	12,525
Deferred financing costs	**295,348**	69,922
Total Assets	**$ 579,272**	$ 166,254
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current Liabilities:		
Accounts payable and accrued expenses	**$ 1,282,132**	$ 3,362,460
2007 Senior convertible notes	**5,305,000**	5,305,000
Interest payable – 2007 Senior convertible notes	**1,451,933**	986,838
2010 Senior convertible notes	**5,617,433**	—
Interest payable – 2010 Senior convertible notes	**251,907**	—
Notes payable – related parties	**1,001,153**	2,215,591
Interest payable – related parties	**112,289**	59,719
Borrowings under line of credit	**320,000**	320,000
Borrowings under term note	**800,000**	—
Interest payable – Paramount Credit Partners, LLC	**148,211**	107,840
Total current liabilities	**16,290,058**	12,357,448
Notes payable – Paramount Credit Partners, LLC (net of discount of $326,839 in 2010 and $401,546 in 2009)	**1,246,161**	1,171,454
Total Liabilities	**17,536,219**	13,528,902
Commitments		
Stockholders' deficiency:		
Preferred Stock, $.001 par value, 5,000,000 shares authorized, none outstanding	**—**	—
Common Stock, $.001 par value, 25,000,000 shares authorized 447,347 shares issued and outstanding at September 30, 2010 and December 31, 2009	**447**	447
Additional paid-in capital	**6,860,716**	4,530,634
Deficit accumulated during the development stage	**(23,818,110)**	(17,893,729)
Total stockholders' deficiency	**(16,956,947)**	(13,362,648)
Total liabilities and stockholders' deficiency	**$ 579,272**	$ 166,254

See Notes to Unaudited Condensed Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Condensed Statements of Operations (Unaudited)

	Nine Months Ended September 30, 2010	Nine Months Ended September 30, 2009	Period from October 7, 2005 (Inception) to September 30, 2010
Operating expenses:			
Research and development	**$ 1,128,113**	$ 2,073,529	$ 13,529,007
General and administrative	**492,418**	211,667	3,097,506
Loss from operations	**(1,620,531)**	(2,285,196)	(16,626,513)
Interest income	**1,705**	139	15,694
Interest expense, including amortization of debt discount and deferred financing costs and charges related to conversion of related party notes	**(4,305,555)**	(638,040)	(7,207,291)
Net loss	**$ (5,924,381)**	$ (2,923,097)	$ (23,818,110)
Basic and diluted net loss per common share	**$ (13.24)**	$ (6.57)	
Weighted average common shares outstanding – basic and diluted	**447,347**	444,928	

See Notes to Unaudited Condensed Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Condensed Statement of Changes in Stockholders' Deficiency
Period from January 1, 2010 through September 30, 2010 (Unaudited)

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Balance at January 1, 2010	**447,347**	**$ 447**	**$4,530,634**	**$(17,893,729)**	**$(13,362,648)**
Stock-based compensation	—	—	**(82,446)**		**(82,446)**
Warrant issued to investors in connection with 2010 senior convertible notes	—	—	**2,412,528**		**2,412,528**
Net loss	—	—		**(5,924,381)**	**(5,924,381)**
Balance at September 30, 2010	**447,347**	**$ 447**	**$6,860,716**	**$(23,818,110)**	**$(16,956,947)**

See Notes to Unaudited Condensed Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Condensed Statements of Cash Flows (Unaudited)

	Nine months ended September 30, 2010	Nine months ended September 30, 2009	Period from October 7, 2005 (Inception) to September 30, 2010
Cash flows from operating activities:			
Net loss	**$ (5,924,381)**	$ (2,923,097)	$ (23,818,110)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	**(82,446)**	92,597	518,789
Stock issued in connection with license agreement	**—**	**—**	25,228
Stock issued to vendor	**—**	**—**	5,000
Warrants issued in connection with related party note conversion	**944,274**	—	1,285,134
Amortization of deferred financing costs and debt discount	**2,307,284**	88,180	3,117,143
Non-cash research and development			1,087,876
Interest payable – 2007 senior convertible notes	**465,095**	426,087	1,451,933
Interest payable – 2010 senior convertible notes	**251,907**	—	251,907
Expenses paid on behalf of the Company satisfied through the issuance of notes	**—**	—	227,910
Interest payable – related parties	**80,004**	28,342	251,372
Interest payable – Paramount Credit Partners, LLC	**40,370**	68,715	148,210
Depreciation	**3,702**	3,703	18,436
Changes in operating assets and liabilities:			
Deferred prepaid research and development	**—**	800,000	—
Other current assets	**(1,507)**	1,138	(4,026)
Accounts payable and accrued expenses	**(2,080,328)**	(845,549)	1,282,132
Net cash used in operating activities	**(3,996,026)**	(2,259,884)	(14,151,066)
Cash flows from investing activities:			
Purchase of office and computer equipment	**—**	—	(27,259)
Cash flows from financing activities:			
Proceeds from 2010 senior convertible notes	**3,425,000**	—	3,425,000
Proceeds from notes payable to Paramount Credit Partners, LLC	**—**	1,573,000	1,573,000
Proceeds from notes payable to related parties	**950,562**	690,000	5,041,952
Proceeds from 2007 senior convertible notes	**—**	—	5,305,000
Proceeds from private placement	**—**	—	1,146,024
Payment for deferred financing costs	**(989,749)**	(41,460)	(1,666,260)
Proceeds from utilization of line of credit	**—**	150,000	320,000
Proceeds from term note	**800,000**	—	800,000
Repayment of notes payable – related party	**—**	—	(1,500,000)
Proceeds from receipt of subscriptions	**—**	—	4,684
Net cash provided by financing activities	**4,185,813**	2,371,540	14,449,400
Net increase in cash	**189,787**	111,656	271,075
Beginning of period	**81,288**	15,851	—
End of period	**$ 271,075**	$ 127,507	$ 271,075
Supplemental schedule of non-cash financing activities:			
Debt discount on 2010 senior convertible notes	**$ 1,468,254**	$ —	$ 1,468,254
Warrants issued to placement agent	**$ —**	$ —	$ 341,334
Debt discount on Paramount Credit Partners, LLC notes	**$ —**	$ 480,049	$ 480,049
Related party notes converted to 2010 senior convertible notes	**$ 2,192,433**	$ —	$ 3,995,667
Supplemental disclosure – cash paid for interest	**$ 216,621**	$ 26,716	$ 701,592

See Notes to Unaudited Condensed Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Unaudited Condensed Financial Statements

Note 1 — Organization, Business and Basis of Presentation:

Organization and business:

VentrusBioSciences, Inc., formerly known as South Island BioSciences, Inc. ("Ventrus" or the "Company") was incorporated in the State of Delaware on October 7, 2005. The Company changed its name from South Island BioSciences, Inc. to VentrusBioSciences, Inc. on April 5, 2007. Ventrus is a specialty pharmaceutical company focused on the late-stage development and commercialization of gastrointestinal products.

Basis of presentation:

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and the rules of the Securities and Exchange Commission for interim financial information. Accordingly, the unaudited condensed financial statements do not include all information and footnotes required by accounting principles generally accepted in the United States of America for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed financial statements reflect all adjustments, consisting of only normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the full year ending December 31, 2010 or for any subsequent period. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto of the Company which are included elsewhere in this registration statement. The accompanying condensed balance sheet as of December 31, 2009 has been derived from the audited financial statements included elsewhere in this registration statement.

The Company's primary activities since incorporation have been organizational activities, including recruiting personnel, establishing office facilities, acquiring licenses for its pharmaceutical compound pipeline, performing business and financial planning, performing research and development and raising funds through the issuance of debt and common stock. The Company's planned principal operations have not yet commenced; accordingly, the Company is considered to be in the development stage.

The Company's financial statements have been prepared on a going concern basis which contemplates the realization of assets and the settlement of liabilities and commitments through the normal course of business. For the nine months ended September 30, 2010 and the period from October 7, 2005 (inception) to September 30, 2010, the Company incurred net losses of $5,924,381 and $23,818,110, respectively. The Company has a working capital deficiency as of September 30, 2010 of $16,014,957. Management believes that the Company will continue to incur losses for the foreseeable future and will need additional equity or debt financing and/or will need to generate significant revenue from the licensing of its products or by entering into strategic alliances to be able to sustain its operations until it can achieve profitability and positive cash flows, if ever. Management plans to seek additional debt and/or equity financing for the Company, but cannot assure that such financing will be available on acceptable terms, or at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On November 10, 2010, the Company effected a 1-for-12.4 reverse stock split of its Common Stock. All share and per share information in these financial statements have been adjusted to give effect to the reverse stock split.

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Unaudited Condensed Financial Statements

Note 2 — Summary of Significant Accounting Policies:

Use of estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Loss per common share:

Basic earnings (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per common share reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity. Since the Company has only incurred losses, basic and diluted loss per share are the same. The amount of potentially dilutive securities at September 30, 2010 and 2009 was 357,923 and 117,808, respectively.

The Company is also committed to issue to the Chief Executive Officer and one consultant at the close of a qualified offering an option or warrant, respectively, to purchase shares of common stock in an amount equal to 7.5% and 1%, respectively, of the Company's fully diluted shares immediately subsequent to the Qualified Financing. A "Qualified Financing" means the closing of an equity financing or series of related equity financings by the Company resulting in aggregate gross cash proceeds (before brokers' fees or other transaction related expenses) of at least $8,000,000, in the case of the Chief Executive Officer, and $10,000,000, in the case of the consultant. Such issuances would dilute any future earnings.

Fair value measurements:

The carrying value of the senior convertible notes, related party notes, and Paramount Credit Partners, LLC notes approximate fair value due to the short-term nature of these notes and the related interest rates approximate market rates.

Stock-Based Compensation:

The Company accounts for stock options granted to employees according to Financial Accounting Standards Board Accounting Standards Codification No. 718 ("ASC 718"), "Compensation — Stock Compensation". Under ASC 718, share-based compensation cost is measured at grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis. The Company accounts for stock options and warrants granted to non-employees on a fair value basis in accordance with ASC 718 using the Black-Scholes option pricing model. The initial non-cash charge to operations for non-employee options and warrants with vesting are revalued at the end of each reporting period based upon the change in the fair value of the options and recognized as consulting expense over the related vesting period.

Warrants-Convertible Notes:

For the purpose of valuing warrants as part of the convertible notes, the Company used the Black-Scholes option pricing model utilizing the assumptions noted in the following table. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company estimated the expected life of the options granted based on anticipated exercises in the future periods assuming the success of its business model as currently forecasted. The expected dividend yield reflects the Company's current and expected future policy for dividends on its common stock. The expected stock price volatility

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Notes to Unaudited Condensed Financial Statements

Note 2 — Summary of Significant Accounting Policies: – (continued)

for the Company's stock options was calculated by examining historical volatilities for publicly traded industry peers as the Company does not have any trading history for its common stock. The Company will continue to analyze the expected stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The fair value of the warrants granted was based on the following assumptions:

	Nine Months Ended September 30, 2010
Risk-free interest rate	2.30% – 2.55%
Expected volatility	124.46% – 129.05%
Expected life of warrants	5 years
Expected dividend yield	0%

In accordance with ASC Topic 470-20, *"Debt with Conversion and Other Options,"* the proceeds from any financing in which the Company issues warrants to purchase the Company's common stock are first allocated to the warrants based upon their estimated relative fair values as of the closing date.

Warrants, or any other detachable instruments issued in connection with debt financing agreements, are accounted for using the relative fair value method and allocated to additional paid-in capital and recorded as a reduction in the carrying value of the related debt. This discount is amortized to interest expense from the issuance date through the maturity date of the debt using the straight-line method.

When the conversion feature of conventional convertible debt provides for a rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature ("BCF"). Prior to the determination of the BCF, the proceeds from the debt instrument are first allocated between the convertible debt and any detachable free standing instruments that are included, such as common stock warrants. The Company has disclosed the contingent nature of its BCFs, but the Company has not recorded as such pursuant to ASC Topic 470-20. The Company will record the BCF if and when the conversion takes place.

Note 3 — Related Party Transactions:

Consulting services:

Effective August 2007, the Company began accruing monthly fees for consulting services at a rate of $25,000 per month to Paramount Corporate Development, LLC ("Paramount"), which was an affiliate of Lindsay A. Rosenwald, M.D., a significant investor in and stockholder of the Company. Consulting services expense was $0, $0 and $425,000 for the nine months ended September 30, 2010 and 2009 and the period from October 7, 2005 (inception) to September 30, 2010, respectively. As of September 30, 2010 and December 31, 2009, the Company had $100,000 outstanding under this arrangement which is included in accrued expenses. This agreement was terminated as of August 31, 2008.

Notes payable:

On October 7, 2005, the Company issued a 5% promissory note payable to Paramount BioSciences, LLC ("PBS"), an affiliate of a significant stockholder of the Company. This note and all accrued interest were to mature on October 7, 2008, or earlier if certain events occurred. The note was amended to extend the maturity date to October 7, 2009. On June 16, 2008, this note was voluntarily converted into one common stock share and one warrant (together, a "unit") of the Company at a price of $60.39 per unit, the price of a concurrent financing (see Note 7). At the time of the conversion, the outstanding balance due under this note was $1,396,672, which was converted into 23,128 shares of the Company's common stock and a warrant to purchase 4,805 shares of the Company's common stock for which the Company

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Notes to Unaudited Condensed Financial Statements

Note 3 — Related Party Transactions: – (continued)

recorded charge of $266,243. Upon conversion, the note was automatically cancelled. Each warrant has a seven-year term and an exercise price of $66.46.

On July 12, 2007, the Company issued an 8% promissory note payable to an entity related to the sole member of PBS. This note and all accrued interest mature on July 12, 2010, or earlier if certain events occur. On June 16, 2008, this note was voluntarily converted into common stock shares and warrants of the Company at a price of $60.39 per unit, the price of a concurrent financing. At the time of the conversion the outstanding balance due under this note was $406,562 which was converted into 6,733 shares of the Company's common stock and a warrant to purchase 1,347 shares of the Company's common stock for which the Company recorded charge of $74,617. Upon conversion, the note was automatically cancelled. Each warrant has a seven-year term and an exercise price of $66.46.

The fair value of the warrants granted, mentioned in the two preceding paragraphs, was based on the following assumptions:

Risk-free interest rate	3.89%
Expected volatility	128.18%
Expected life of warrants	7 years
Expected dividend yield	0%

On July 23, 2008, the Company issued an 8% promissory note payable to PBS. Originally, all amounts outstanding under this note matured and were payable on July 23, 2010. On December 21, 2009, this note was amended to provide that all loans (including principal and accrued interest thereon) made by PBS to the Company under this note on or after September 30, 2009 shall immediately and automatically be converted into the same equity or derivative securities as are issued in any equity or derivative equity financing consummated by the Company on or after September 30, 2009 (that does not otherwise constitute a Qualified Financing, as defined below), on the same terms and conditions that such equity securities are offered in such non-Qualified Financing. A "Qualified Financing" means the closing of an equity financing or series of related equity financings by the Company resulting in aggregate gross cash proceeds (before brokers' fees or other transaction related expenses) of at least $8,853,976. As of September 30, 2010 and December 31, 2009, the principal amount outstanding under this note is $811,153 and $2,025,591, respectively.

On April 24, 2009, the Company issued an 8% promissory note payable to an entity related to Lindsay A. Rosenwald, M.D., the sole member of PBS and a significant investor in and stockholder of the Company. Originally all unpaid principal and accrued and unpaid interest outstanding under this note was scheduled to mature and was payable on April 24, 2012. Effective December 21, 2009, this note was amended so that it is convertible and repayable prior to its maturity date on the same terms and conditions as the PBS note discussed above. As of September 30, 2010 and December 31, 2009, the principal amount outstanding under this note is $190,000.

During 2009, the Company issued four separate 10% promissory notes (collectively, the "PCP Notes") to Paramount Credit Partners, LLC ("PCP"), an entity whose managing member is Lindsay A. Rosenwald, M.D., a significant investor in and stockholder of the Company. Specifically, the PCP Notes consist of a note in the principal amount of $1,100,000 issued on January 23, 2009, a note in the principal amount of $100,000 issued on March 25, 2009, a note in the principal amount of $250,000 issued on June 1, 2009 and a note in the principal amount of $123,000 issued on June 24, 2009. Interest on the PCP Notes is payable quarterly, in arrears, and the principal matures on the earlier of (i) December 31, 2013 or (ii) the completion of a transaction, including an equity offering, sale of assets, licensing or strategic partnership, in which the Company raises at least $5,000,000 in gross cash proceeds. In addition, PCP received five-year warrants ("PCP Warrants") to purchase, at an exercise price of 110% of the lowest price paid for securities in a Qualified Financing, a number of shares of the Company's common stock equal to 40% of

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Notes to Unaudited Condensed Financial Statements

Note 3 — Related Party Transactions: – (continued)

the principal amount of each PCP Note purchased divided by the lowest price paid for securities in a Qualified Financing prior to the two-year anniversary of such PCP Note. If the Qualified Financing does not occur on or before the two-year anniversary of a PCP Note, then the associated PCP Warrants will be exercisable for a number of shares of the Company's common stock equal to 40% of the principal amount of such PCP Note purchased divided by $12.40 (which would equal 50,742 shares), at a per share exercise price of $12.40. The Company allocated proceeds of $480,049 from the sale of the PCP Notes to the warrants at the time of issuance, which are recorded as a debt discount and reduced the carrying values of the PCP Notes. Such discount is being amortized to interest expense over the term of the PCP Notes. As of September 30, 2010 and December 31, 2009, the principal amount outstanding under these notes is $1,573,000. The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	1.64% – 2.58%
Expected volatility	104.11% – 110.89%
Expected life of warrants	5 years
Expected dividend yield	0%

On February 26, 2010, $2,192,433 outstanding under the PBS notes was converted into 2010 Notes (the "2010 Notes") (see Note 7). Effective December 21, 2009, this note was further amended to provide that all remaining amounts outstanding under this note will automatically convert into the Company's equity securities issued in the Company's next equity financing (or series of related equity financings), including, without limitation, a firm commitment underwritten initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, involving the sale of securities in which the Company receives in arm's length non-related party transaction(s) at least $10,000,000 in aggregate gross cash proceeds (before brokers' fees or other transaction related expenses, and excluding any such proceeds resulting from any conversion of the Company's then-existing convertible bridge notes minus the amount of aggregate gross cash proceeds to the Company from the sale of equity or debt securities of the Company after December 21, 2009 (but not to be reduced below $5,000,000) (a "Qualified Financing")), at a conversion price equal to 70% of the lowest per unit price paid for such securities in cash by investors in such Qualified Financing (the "IPO Price"), and upon such other terms, conditions and agreements as may be applicable in such Qualified Financing. The convertible secured notes, including any accrued and unpaid interest, are convertible into common stock at 70% of the IPO Price. The Company valued the beneficial conversion of the 2010 Notes at $939,614, which will be recorded as interest expense only if a Qualified Financing is completed. The Company computed the conversion feature to be $939,614 by dividing the amount of debt ($2,192,433) which is convertible into common stock by the conversion rate (70%). From this amount ($3,132,047) the amount of debt ($2,192,433) was subtracted to determine the amount by which the instrument if-converted exceeds the conversion amount ($939,614). In connection with the conversion of the PBS notes the Company issued warrants, which were valued at approximately $944,000 using the Black-Scholes option pricing model, and the Company expensed the entire amount during the nine months ended September 30, 2010 as interest expense.

Each 2010 Noteholder also holds a warrant to purchase a number of shares of the Company's common stock equal to 50% of the principal amount of the 2010 Notes purchased by it divided by the "IPO Price" (see Note 7) at a per share exercise price equal to 110% of the IPO Price, subject to adjustment. Each of these warrants will expire and no longer be exercisable after February 26, 2015. Notwithstanding the foregoing, if a Qualified Financing does not occur on or before February 26, 2012, then each warrant will be exercisable for that number of shares of the Company's common stock equal to 50% of the principal amount of the 2010 Note purchased by the original holder divided by $12.40, at a per share exercise price of $12.40 (which would be 226,509 shares). In the event of a sale of the Company

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Notes to Unaudited Condensed Financial Statements

Note 3 — Related Party Transactions: – (continued)

(whether by merger, consolidation, sale or transfer of the Company's capital stock or assets or otherwise) the warrants shall continue to be exercisable pursuant to their terms. The Company valued these warrants at approximately $1,468,000 using the Black-Scholes option pricing model, and the Company is amortizing the related debt discount over the term of the 2010 Notes as interest expense. The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	2.30% – 2.55%
Expected volatility	124.46% – 129.05%
Expected life of warrants	5 years
Expected dividend yield	0%

This note will also automatically convert into equity securities of the Company immediately prior to a sale or merger of the Company, as defined in the notes. In the event that this note becomes due and payable (whether on the due date or earlier) prior to the consummation by the Company of a Qualified Financing, or a sale or merger of the Company which converts the note into equity securities of the Company, then, in connection with the repayment of the note, in addition to the payment of the unpaid principal amount and all accrued but unpaid interest on the note, the Company will be obligated to pay to the noteholder, as a repayment premium, an amount in cash equal to 42.8571% of the aggregate outstanding principal amount plus all accrued and unpaid interest on the note.

On February 26, 2010, a 2010 Note in the aggregate principal amount of $2,192,433 and related warrant were issued to PBS for the cancellation of certain debt (as discussed above), which is not included in the $3,425,000 of aggregate principal amount of 2010 Notes issued in the private placement. Including such converted debt, the total aggregate principal amount of 2010 Notes is $5,617,433.

On October 5, 2010, Lindsay A. Rosenwald, a significant investor in and stockholder of the Company, indirectly acquired "control" (as such term is defined by Financial Industry Regulatory Authority ("FINRA") Rule 2720) of National Holdings Corporation, the 100% owner and parent of National Securities Corporation, a managing underwriter in the Company's proposed initial public offering.

Properties:

Starting June 2010, the Company occupies space at the offices of PBS.

Line of Credit:

On December 3, 2008, the Company, PBS and various other private pharmaceutical companies in which Lindsay A. Rosenwald, M.D. is a significant investor and stockholder, entered into a loan agreement with Bank of America, N.A. for a line of credit of $2,000,000. PBS pledged collateral securing the Company's and the other borrowers' obligations to Bank of America, N.A. under the loan agreement. Interest on amounts borrowed under the line of credit accrues and is payable on a monthly basis at an annual rate equal to the London Interbank Offered Rate (LIBOR) plus 1%. On November 10, 2009, the parties entered into Amendment No. 1 to the Loan Agreement, which extended the initial one-year term for an additional year, such that it currently matures on November 5, 2010, and reduced the aggregate amount available under the line of credit to $1,000,000. Under the loan agreement, the Company's liability under the line of credit is several, not joint, with respect to the payment of all obligations thereunder. As of both September 30, 2010 and December 31, 2009, the amount borrowed by the Company that was outstanding under this line of credit was $320,000.

The Company has paid interest owed to PCP for the first and second quarters of 2010 and the first quarter of 2009. For the second, third and fourth quarters of 2009 and the third quarter of 2010, the Company had insufficient funds to pay the quarterly interest amount owed to PCP. Interest amounts for these three quarterly periods were paid directly by Lindsay A. Rosenwald, M.D. to PCP, pursuant to certain guarantee obligations by Dr. Rosenwald under PCP's operating agreement.

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Notes to Unaudited Condensed Financial Statements

Note 3 — Related Party Transactions: – (continued)

Term Note:

On September 21, 2010, the Company and Lindsay A. Rosenwald entered into a loan agreement with Israel Discount Bank of New York (the "Bank") for a term note of $800,000. Dr. Rosenwald, a significant stockholder of the Company and the sole member of Paramount BioSciences LLC, pledged time deposits at the Bank as collateral securing the Company's obligations to the Bank under the loan agreement. Interest on amounts borrowed under loan agreement accrues and is payable on a monthly basis at an annual rate equal to the interest rate payable on the pledged time deposits plus 1%. The loan matures on September 22, 2011. In consideration of his arranging for this short-term loan for the Company, the Company entered into a letter agreement on September 21, 2010 with Lindsay Rosenwald whereby Dr. Rosenwald has the right to attend the Company's Board meetings and to appoint two directors to the Company's Board. Dr. Rosenwald has not exercised his right to appoint these directors. If and when appointed, these directors would be subject to stockholder approval at the expiration of their terms.

Note 4 — Stockholders' Deficiency:

Common stock options and warrants:

In October 2007, the Company's stockholders adopted the 2007 Stock Incentive Plan (the "2007 Plan") under which incentive stock and/or options may be granted to officers, directors, consultants and key employees of the Company. The 2007 Plan reserved up to 483,871 shares of the Company's common stock. The Company has granted one option for 2,016 shares of common stock to a director of the Company, and this is the only award issued under the 2007 Plan. In August 2010, the Company terminated the 2007 Plan. As a result, the Company may not grant any future awards under the 2007 Plan; however, all awards granted under the 2007 Plan prior to its termination remain in effect. Pursuant to the terms of the 2007 Plan, all options have a maximum term of ten years, vest over a period to be determined by the Company's Board of Directors and have an exercise price at or above fair market value on the date of grant.

On May 11, 2010, the Company granted options to purchase 2,016 shares of its common stock to director Joseph Felder under the 2007 Plan with an exercise price to be determined in the next Qualified Financing.

In August 2010, the Company's stockholders adopted the 2010 Equity Incentive Plan (the "2010 Plan"). The 2010 Plan reserves up to 2,467,200 shares of the Company's common stock for issuance to directors, employees and consultants of the Company.

There were no options issued under the 2007 Plan in 2008 or 2009.

The Company expects that all outstanding options will vest in 2010.

On August 30, 2010, the Company issued a warrant to purchase 13,605 shares of its common stock with an exercise price of $1.24 per share to S.L.A. Pharma AG, a Swiss corporation ("S.L.A.") (see Note 5). The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	0.64%
Expected volatility	119.68%
Expected life of warrants	3 years
Expected dividend yield	0%

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Notes to Unaudited Condensed Financial Statements

Note 4 — Stockholders' Deficiency: – (continued)

In connection with the Company's financings, the Company issued warrants to investors and placement agents to purchase shares of common stock as well as certain consulting warrants (See Notes 3 and 7). A summary of the Company's warrant activity and related information is as follows:

	Nine Months Ended September 30, 2010	
	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	114,762	$ 17.11
Granted	240,114	$ 12.90
Outstanding at end of year	354,876	$ 14.26
Warrants exercisable at end of period	353,801	$ 14.26

The weighted average remaining contractual life of warrants outstanding at September 30, 2010 is four years.

As of September 30, 2010, the total compensation expense related to non-vested warrants not yet recognized totaled approximately $14,000. The weighted-average vesting period over which the total compensation expense related to non-vested warrants not yet recognized at September 30, 2010 was approximately one month.

Note 5 — License Agreements:

In March 2007, pursuant to an "Exclusive License Agreement," S.L.A. granted PBS an exclusive, royalty-bearing license to sell, make and use diltiazem for treatment, through topical administration, of anal fissures and phenylepherine for treatment, through topical administration, of fecal incontinence in the United States, Canada and Mexico. Pursuant to the Exclusive License Agreement, PBS was obligated to form a company to develop the technologies referenced in the Exclusive License Agreement and issue a number of shares equal to 5% of such company's outstanding Common Stock as of the effective date of the Exclusive License Agreement. On August 2, 2007, the Company issued 18,401 shares to S.L.A. to satisfy this obligation. In the event the Company closes an equity financing with gross proceeds of not less than $5,000,000 and the issued shares do not have a fair market value at least equal to $500,000, then the Company shall issue to S.L.A. that number of additional shares of common stock so that the number of shares following such issuance have a fair market value equal to $500,000.

In August 2007, pursuant to an Assignment and Assumption Agreement, PBS sold all of its rights in and arising out of the Exclusive License Agreement with S.L.A. to Ventrus for $1,087,876. The corresponding U.S. and foreign patents and applications for the two compounds have been licensed to Ventrus under the Assignment and Assumption Agreement (the technology referred to collectively as the Compound Technology). As consideration in part for the rights to the Compound Technology, an initial licensing fee of $250,000 was paid to S.L.A. and $50,000 for reimbursement of clinical development costs incurred by S.L.A. (these amounts were paid by PBS and were included in the consideration paid by us to PBS in connection with the Assignment and Assumption Agreement). In the event that the Compound Technology is commercialized, the Company is obligated to pay to S.L.A. annual royalties ranging from the mid to upper single digit percentages, based upon net sales of the product. In addition, the Company is required to make payments to S.L.A. up to an aggregate amount of $20 million upon the achievement of various milestones related to regulatory events. Should the Company make any improvements regarding the Compound Technology, the Company is required to grant S.L.A. licenses to use such improvements.

As compensation for S.L.A.'s participation in the management and the development of the technologies, Ventrus is required to make separate payments to S.L.A. equal to $41,500 per month ("Monthly Payments") for both diltiazem and phenylepherine. Per the agreement, Ventrus' obligation to make these

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Notes to Unaudited Condensed Financial Statements

Note 5 — License Agreements: – (continued)

monthly payments was to terminate upon an NDA filing. Beginning October 1, 2010, Ventrus is no longer required to make a separate payment of $41,500 per month for the management of the phenylepherine project. As compensation for SLA forgoing these payments, Ventrus has issued a warrant to purchase 13,605 shares of its common stock at an exercise price of $1.24 per share pursuant to the terms of Amendment No. 6 to Exclusive License Agreement entered into on August 30, 2010. Pursuant to certain amendments to the Exclusive License Agreement, the most recent of which was dated August 30, 2010, the Company has deferred certain payment requirements that had come due under the Exclusive License Agreement. From January 31, 2010 until September 30, 2010, the Company is obligated to pay S.L.A. $41,500 per month, and has been current in such obligations, and to accrue an additional $41,500 per month towards the Company's obligations to S.L.A.'s development costs. The Company paid $373,500 on September 29, 2010 for services related to managing the phenylephrine project from January 2010 through September 30, 2010.

Ventrus is also required to reimburse S.L.A. for clinical development costs associated with the technology development of both diltiazem and phenylephrine. Ventrus' total payment obligation for the diltiazem project shall not exceed $4,000,000, of which Ventrus has made $2,600,000 in payments. Ventrus expects to make the remaining payments as follows: (i) on December 31, 2010, Ventrus is obligated to pay S.L.A. $600,000; and (ii) upon completion of recruitment into the Phase III trial in Europe, Ventrus is obligated to pay S.L.A. $800,000. The $600,000 Ventrus is obligated to pay represents past development costs and Ventrus has accrued this amount as of September 30, 2010. S.L.A. has not completed recruitment of patients into the Phase III trial and therefore Ventrus has not recorded the $800,000 expense at September 30, 2010. In addition, both Ventrus and S.L.A. have agreed to add additional services outside the scope of the agreement in which case Ventrus is obligated to pay an additional $400,000. The additional amount will be paid if Ventrus has raised net proceeds of at least $20.0 million from sales of securities and or the licensing of rights to the products. S.L.A. has not provided the services for this additional work and therefore Ventrus has not recorded any additional expenses. Ventrus' total payment obligation for the phenylephrine project shall not exceed $1,200,000. S.L.A. has provided and billed Ventrus for $600,000 of services through September 30, 2010.

The Exclusive License Agreement with S.L.A. is terminable by the Company for any reason upon 90 days' written notice, and by either party in the event of a material breach or default of the Exclusive License Agreement or either party becomes bankrupt or insolvent. In addition, the Exclusive License Agreement is terminable immediately by S.L.A. if the Company does not consummate a financing by December 31, 2010 with net proceeds of at least $10.0 million. In addition, S.L.A. may terminate the Exclusive License Agreement at any time, even during or after the successful completion of this financing, with one month's notice in the event that a third party wishes to enter into a license agreement for diltiazem and phenylephrine and has entered into an agreement to that effect, provided that the termination will not be effective if within that one-month period the Company pays all then required payments under the agreement.

In March 2008, Ventrus entered into an exclusive worldwide license agreement with Sam Amer & Co., Inc., a California company ("Amer"), whereby Ventrus acquired certain patent rights to iferanserin (the "Technology") for the topical treatment of any anorectal disorders. Ventrus is obligated to pay Amer (i) a monthly consulting fee of $7,500 through May 2010, (ii) a license fee of $2,050,000, (iii) late fees of $7,500 per month starting July 2009 until the successful completion of the Phase III trials (iv) interest payments totaling $595,000 and (v) additional late fees of $7,500 per month if an NDA is not submitted by September 2010. In addition, Ventrus may be required to make future milestone payments totaling up to $20 million upon the achievement of various milestones related to regulatory or commercial events. In the event that the technology is commercialized, we are obligated to pay to Amer annual royalties ranging from the upper single to lower double digit percentages for sales in the U.S. and ranging from

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Notes to Unaudited Condensed Financial Statements

Note 5 — License Agreements: – (continued)

the low to mid single digit percentages for sales outside of the U.S. The license agreement is terminable by either party for cause, upon 30 days notice and subject to a 60-day cure period, upon notice if either party becomes bankrupt or insolvent or at any time after the expiration of the Royalty Period for any Licensed Product (as such terms are defined in the Exclusive License Agreement) upon 90 days' written notice. The Company may terminate the license agreement upon 30 days' written notice in the event any safety, efficacy or regulatory issues prevent development or commercialization of the technology.

In December 2009, the Company and Amer supplemented the license agreement and added an additional licensing fee of $20,000 for six months. After the fourth month, the Company and Amer agreed that the additional license would not be needed and, therefore, the Company did not pay the last two months.

Note 6 — Commitments:

Employment agreements:

The Company has no employees and is managed by its Board of Directors, one of whom, Thom Rowland, acts as the Company's President. Mr. Rowland originally joined the Company in April 2007, and was employed as its Chief Executive Officer from April 2007 through February 2009, at which time his employment agreement was terminated without cause. Pursuant to that employment agreement, during his term of employment, Mr. Rowland received an annual base salary of $300,000, plus an annual bonus of up to 40% of base salary based upon attainment of certain financial, clinical development and business milestones. No bonuses were earned under such employment agreement. Mr. Rowland received an initial grant of restricted stock under his employment agreement, all of which is currently vested. Pursuant to the termination of his employment, the Company was obligated to make certain severance payments to Mr. Rowland, the receipt of which Mr. Rowland waived in return for his retention as a consultant to the Company.

Terrance Coyne, M.D., joined the Company in June 2007, and served as the Company's Senior Vice President and Chief Medical Officer from June 2007 through February 2009, at which time his employment agreement was terminated without cause. Pursuant to that employment agreement, during his term of employment, Dr. Coyne received an annual base salary of $290,000, plus an annual bonus of up to 25% of base salary based upon attainment of certain financial, clinical development and business milestones. No bonuses were earned under such employment agreement. Dr. Coyne received an initial grant of restricted stock under his employment agreement, all of which is currently vested. Pursuant to the termination of his employment, the Company was obligated to make certain severance payments to Dr. Coyne, the receipt of which Dr. Coyne waived in return for his retention as a consultant to the Company.

John Dietrich, Ph.D. joined the Company in April 2007, and served as the Company's Vice President, Clinical Operations from April 2007 through February 2009, at which time his employment agreement was terminated without cause. Pursuant to that employment agreement, during his term of employment, Dr. Dietrich received an annual base salary of $185,000, plus an annual bonus of up to 20% of base salary based upon attainment of certain financial, clinical development and business milestones. No bonuses were earned under such employment agreement. Dr. Dietrich received an initial grant of restricted stock under his employment agreement, all of which is currently vested. Pursuant to the termination of his employment, the Company was obligated to make certain severance payments to Dr. Dietrich, the receipt of which Dr. Dietrich waived in return for his retention as a consultant to the Company.

Dr. Ellison currently serves as the Company's acting Chief Executive Officer pursuant to a consulting agreement dated June 2010. The agreement provides for a term of six months with the option to extend the agreement for an additional year. Dr. Ellison receives a consulting fee of $30,000 per month. In

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Notes to Unaudited Condensed Financial Statements

Note 6 — Commitments: – (continued)

addition, if the Company completes a partnership or licensing transaction or the Company or any of the Company's assets are acquired by another entity prior to completing a financing resulting in gross proceeds of at least $8 million, then he will receive a fee equal to 4% of the gross proceeds of such transaction.

The Company also has executed an employment agreement with Dr. Ellison, which will become effective upon a financing of $8,000,000 in gross proceeds and has a term of three years. When the employment agreement becomes effective, his consulting agreement will terminate and Dr. Ellison will become President, CEO and Chairman of the Board. The employment agreement provides for a base salary of $375,000 per year, a guaranteed bonus of $75,000 per year and an annual performance-based bonus of up to 50% of his base salary. The agreement also provides a first incentive bonus of $250,000 in the event that the Company's market capitalization exceeds $100 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day and a second incentive bonus of $500,000 in the event that the Company's market capitalization exceeds $250 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day. Dr. Ellison will also receive a grant of options to purchase the Company's common stock at the offering price of an offering generating a minimum of $8,000,000 in gross proceeds in an amount equal to 7.5% of the Company's fully diluted capitalization on the date the employment agreement becomes effective.

Consulting Agreements:

Mr. Barrett currently serves as our Chief Financial Officer pursuant to a consulting agreement dated June 15, 2010. The agreement provides for a term of six months with the option to extend the agreement for an additional year. Mr. Barrett receives a consulting fee of $15,000 per month.

Effective May 11, 2010, the Company entered into a consulting agreement with Timothy Hofer, pursuant to which Mr. Hofer provides the Company with general consulting services focused on general business and company development. Mr. Hofer is also a employee of Paramount Biosciences, LLC, a related party. This consulting agreement is for a period of one year, subject to renewal for such longer period as the Company may agree in writing with Mr. Hofer, and may be terminated by either party upon 30 days' prior written notice.

Under the terms of the consulting agreement with Mr. Hofer and as compensation for his services thereunder, the Company granted Mr. Hofer a ten-year warrant to purchase 8,065 shares of the Company's common stock, subject to adjustment as described below (the "Hofer Consultant Warrant"). The Hofer Consultant Warrant will have an exercise price per share equal to the price at which shares of the Company's common stock are issued in a Qualified Financing. If a Qualified Financing does not occur on or before January 31, 2011 (the original date was September 10, 2010), then the exercise price per share of the Hofer Consultant Warrant will be equal to the fair market value of the Company's common stock, as determined pursuant to a valuation performed by an independent appraisal firm. Under the terms of the Hofer Consultant Warrant, if the Company consummates a Qualified Financing, the number of shares of common stock issuable upon exercise of the Hofer Consultant Warrant will be automatically adjusted so that such number of shares is equal to 1.0% of the Company's outstanding common stock on a fully diluted basis, after giving effect to such Qualified Financing (including the conversion of any of the Company's convertible bridge notes issued in 2007 – 2008 triggered by such Qualified Financing). This adjustment provision will terminate once the Company consummates a Qualified Financing. For purposes of the Hofer Consultant Warrant, a "Qualified Financing" means the Company's next equity financing (or series of related equity financings) sufficient to trigger conversion of all amounts then outstanding under the Company's convertible PBS notes issued in 2007 and 2008.

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Notes to Unaudited Condensed Financial Statements

Note 7 — Private Placements:

2007 Senior convertible notes:

During 2007 and 2008, the Company issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $5,305,000 (the "Bridge Notes"). The Bridge Notes were originally scheduled to mature on December 20, 2008, but the Company exercised its option to extend the maturity date to December 20, 2009, at an increased interest rate of 10%. In September 2010, the Company obtained the consent of the Noteholders to extend the maturity date to December 31, 2010. After giving effect to such consent, the Bridge Notes, plus all accrued interest thereon, will automatically convert into the same securities issued in the Company's next Qualified Financing (as defined below), at a conversion price equal to 70% of the lowest per unit price paid for such securities in cash by investors in such Qualified Financing, and upon such other terms, conditions and agreements as may be applicable in such Qualified Financing. The Bridge Notes will also automatically convert into equity securities of the Company immediately prior to a sale or merger of the Company, as defined in the Bridge Notes. In the event that the Bridge Notes become due and payable (whether on the due date or earlier) prior to the consummation by the Company of a Qualified Financing, or a sale or merger of the Company which converts the Bridge Notes into equity securities of the Company, then, in connection with the repayment of the Bridge Notes, in addition to the payment of the unpaid principal amount and all accrued but unpaid interest on the Bridge Notes, the Company will be obligated to pay to the Noteholders, as a repayment premium, an amount in cash equal to 42.8571% of the aggregate principal amount plus all accrued and unpaid interest on the Bridge Notes. For purposes of the Bridge Notes, "Qualified Financing" means the sale of the Company's equity securities in an equity financing or series of related equity financings in which the Company receives (minus the amount of aggregate gross cash proceeds to the Company from Company's arm's length sale of equity or debt securities, or incurrence of new loans, after December 21, 2009) aggregate gross proceeds of at least $10,000,000 (before brokers' fees or other transaction related expenses, and excluding any such proceeds resulting from any conversion of the Bridge Notes).

In connection with the offering of the Bridge Notes, Paramount Biocapital, Inc. ("PCI") and the Company entered into a placement agency agreement dated October 9, 2007, pursuant to which the Company paid PCI and third party agents cash commissions of $243,600 and $19,250, respectively, for its services. The Company also had agreed to pay to PCI a commission on sales by the Company of securities during the 18-month period subsequent to March 11, 2008 to the purchasers of the Bridge Notes who were introduced to the Company by PCI. The Company also granted PCI the right of first refusal to act as exclusive finder, placement agent or other similar agent in relation to any securities offerings on its behalf during the 18-month period following March 11, 2008. Each of these 18-month periods expired without any further commissions being paid. PCI is a related party to the Company since it is wholly owned by Lindsay A. Rosenwald, M.D., a significant investor in and stockholder of the Company.

In addition, PCI and third party agents received warrants (the "Placement Warrants") to purchase, at an exercise price of 110% of the lowest price paid for securities in a Qualified Financing, a number of shares of the Company's common stock equal to 10% of the principal amount of the Notes purchased, less any amount used to repay the related party notes, or amounts due to PBS or their affiliates or employees as finder's fees, payments under the services agreement or other similar payments, divided by the lowest price paid for securities in a Qualified Financing prior to December 21, 2009. If the Qualified Financing did not occur on or before December 21, 2009, the Placement Warrants will be exercisable for a number of shares of the Company's common stock equal to 10% of the principal amount of the Notes purchased, less any amount used to repay the related party notes, or amounts due to PBS or their affiliates or employees as finder's fees, payments under the services agreement or other similar payments, divided by $12.40, at a per share exercise price of $12.40 and are exercisable for seven years. Since the

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Notes to Unaudited Condensed Financial Statements

Note 7 — Private Placements: – (continued)

Qualified Financing did not occur by such date, the Placement Warrants are now exercisable into 42,782 shares of the Company's common stock, at a per share exercise price of $12.40. PCI subsequently transferred the warrant among various of its employees. The Company estimated the value of the warrants using the Black-Scholes option pricing model at approximately $341,000 and recorded them as deferred financing costs, which were amortized to interest expense over the term of the Notes. The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	3.01% – 3.84%
Expected volatility	63.69% – 123.73%
Expected life of warrants	7 years
Expected dividend yield	0%

PCI acted as placement agent for the private placement of the Company's senior convertible notes in the aggregate principal amount of $5,305,000 during 2007 and 2008.

2010 Senior convertible notes:

In February, March, April and May 2010, the Company issued 8% senior convertible notes in connection with a private placement in the aggregate principal amount of $3,425,000 (the "2010 Notes"). The 2010 Notes originally were to mature on September 10, 2010. In September 2010, the Company obtained the consent of the Noteholders to extend the maturity date to December 31, 2010. Upon the closing of a Qualified Financing (as defined below), the 2010 Notes plus any accrued but unpaid interest thereon will convert automatically into shares of the Company's common stock at 70% of the price at which shares of common stock are sold in the Qualified Financing (the "IPO Price"), upon the terms and conditions on which such securities are issued in the Qualified Financing. For purposes hereof, "Qualified Financing" means the consummation of an initial public offering by the Company of units consisting of shares of common stock and warrants to purchase common stock resulting in aggregate gross cash proceeds (before commissions or other expenses) to the Company of at least $10,000,000. The convertible secured notes, including any accrued and unpaid interest, are convertible into common stock at 70% of the IPO Price. The Company valued the beneficial conversion feature of the 2010 Senior convertible notes at $1,468,000, which will be recorded as interest expense only if a Qualified Financing is completed. The Company computed the conversion feature to be $1,468,000 by dividing the total outstanding note ($3,425,000) by 70% and then subtracting the total outstanding note ($3,425,000).

Each 2010 Noteholder also holds a warrant to purchase a number of shares of the Company's common stock equal to 50% of the principal amount of the 2010 Notes purchased by it divided by the IPO Price at a per share exercise price equal to 110% of the IPO Price, subject to adjustment in the event the outstanding shares of the Company's common stock are increased by a stock dividend payable in common stock, stock split or subdivision, decreased by a reverse stock split, combination or consolidation, reclassified, or the Company is subject to a reorganization, consolidation, merger, or sale, lease, license, exchange or other transfer of all or substantially all of the business and/or assets of the Company. Each of these warrants will expire and no longer be exercisable after February 26, 2015. Notwithstanding the foregoing, if a Qualified Financing does not occur on or before February 26, 2012, then each warrant will be exercisable for that number of shares of the Company's common stock equal to 50% of the principal amount of the 2010 Note purchased by the original holder divided by $12.40, at a per share exercise price of $12.40. In the event of a sale of the Company (whether by merger, consolidation, sale or transfer of the Company's capital stock or assets or otherwise) the warrants shall continue to be exercisable pursuant to their terms. The Company valued these warrants at $1,468,000 using the Black-Scholes option pricing model and is amortizing such amounts over the term of the Notes to interest expense. The fair value of the warrants granted was based on the following assumptions:

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Notes to Unaudited Condensed Financial Statements

Note 7 — Private Placements: – (continued)

Risk-free interest rate	2.30% – 2.55%
Expected volatility	124.46% – 129.05%
Expected life of warrants	5 years
Expected dividend yield	0%

On February 26, 2010, a 2010 Note in the aggregate principal amount of $2,192,433 and related warrant were issued to PBS for the cancellation of certain debt (as discussed in Note 3 above), which is not included in the $3,425,000 of aggregate principal amount of 2010 Notes issued in the private placement. Including such converted debt, the total aggregate principal amount of 2010 Notes is $5,617,433.

In connection with the offering of the 2010 Notes and related warrants, National Securities Corporation (“National”) and the Company entered into a placement agency agreement dated January 5, 2010, as amended on January 29, 2010, and a placement agency agreement dated April 14, 2010, as amended on April 30, 2010, pursuant to which the Company paid National cash fees of $671,592, which consisted of placement agent commissions of $561,743 and non-accountable expense reimbursements of $109,849. In addition, the Company issued National warrants to purchase an aggregate number of shares of common stock equal to 10% of the aggregate number of shares into which the 2010 Notes convert into at upon the close of a Qualified Financing, with an exercise price of 110% of the IPO Price. These warrants were subsequently amended to cover an aggregate of 89,000 shares with an exercise price of 125% of the IPO Price. In addition, the Company paid National’s outside counsel $32,500 for its services as placement agent counsel.

The Company also granted National the exclusive right until May 6, 2011 to act as lead placement agent on the next private placement of the Company’s securities, or as lead managing underwriter on the initial public offering of the Company’s securities, with the compensation being paid to National with respect to such financing to be mutually agreed to by the parties in good faith with respect to such financing.

On October 5, 2010, Lindsay A. Rosenwald, a significant investor in and stockholder of the Company, indirectly acquired “control” (as such term is defined by FINRA Rule 2720) of National Holdings Corporation, the 100% owner and parent of National Securities Corporation, a managing underwriter in the Company’s proposed initial public offering.

Note 8 — Legal Proceedings:

In June 2010, the Company was sued for non-payment of approximately $123,000 that it owed to a company with which it had contracted to provide drug development services. The Company has entered into a settlement agreement and paid the agreed upon payment in full settlement on August 25, 2010.

Note 9 — Subsequent Events:

On November 5, 2010, the Company borrowed $420,000 from Israel Discount Bank of New York. The promissory note the Company issued to Israel Discount Bank to evidence the loan is guaranteed by Dr. Lindsay Rosenwald. The interest rate on the note is equal to the interest rate that Israel Discount bank will pay on the cash accounts at the Bank maintained by Dr. Rosenwald and pledged to secure the note, plus 1%. The note is due on demand or on November 4, 2011. The Company used a portion of the proceeds of the note to repay the $320,000 line of credit owed Bank of America that was due on November 5, 2010.

On November 10, 2010, the Company amended and restated its certificate of incorporation which, among other things, increased the authorized shares of common stock from 25,000,000 to 50,000,000 and effected the 1-for-12.4 reverse stock split.

In November 2010, the Company granted options to non-employee directors to purchase an aggregate of 160,000 shares of common stock. All of these options were effective after the 1-for-12.4 reverse stock

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Notes to Unaudited Condensed Financial Statements

Note 9 — Subsequent Events: – (continued)

split, have a term of 10 years, and will have an exercise price equal to the planned initial offering price per share or, if earlier, the Company's next qualified equity financing (as defined in the 2010 Notes). In addition, one-third of each of these options vested on the respective vesting commencement date and the remaining two-thirds will vest in three equal annual installments after the vesting commencement date.

On November 11, 2010, the Company executed an employment agreement with David J. Barrett, its Chief Financial Officer, which will become effective upon a financing of $8,000,000 in gross proceeds and has a term of three years. When the employment agreement becomes effective, Mr. Barrett's consulting agreement will terminate and Mr. Barrett will become the Company's full-time Chief Financial Officer. The employment agreement provides for a base salary of $250,000 per year. The agreement also provides a first incentive bonus of $250,000 in the event that the Company's market capitalization exceeds $100 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day and a second incentive bonus of $500,000 in the event that the Company's market capitalization exceeds $250 million for a period of 30 consecutive trading days with an average trading volume of the common stock during such period of at least 100,000 shares per trading day. Mr. Barrett will also receive a grant of options to purchase the Company's common stock at the offering price of an offering generating a minimum of $8,000,000 in gross proceeds in an amount equal to 4.0% of the Company's fully diluted capitalization on the date the employment agreement becomes effective.

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Until January 9, 2011, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

2,900,000 Shares of Common Stock

PROSPECTUS

Rodman & Renshaw, LLC

National Securities Corporation