Filed Pursuant to Rule 424(b)(1)
Registration Nos. 333-174747 and 333-175543

PROSPECTUS

4,500,000 Shares of Common Stock

We are selling 4,500,000 shares of our common stock.

Our common stock is quoted on the NASDAQ Capital Market under the symbol "VTUS." On July 13, 2011, the last reported sale price of our common stock on the NASDAQ Capital Market was $11.91 per share.

Investing in our common stock involves a high degree of risk. Before buying any shares you should read the discussion of material risks of investing in our common stock in "Risk Factors" beginning on page 11.

	Per Share	Total
Public Offering Price	$ 10.00	$45,000,000
Underwriting Discounts and Commissions(1)	$ 0.60	$ 2,700,000
Proceeds to us, before expenses	$ 9.40	$42,300,000

(1) Does not include financial advisory fees payable to the co-managers of the offering. See "Underwriting" for a description of compensation and other items of value payable to the underwriters.

We have granted a 30-day option to the underwriters to purchase up to 675,000 additional shares of our common stock (15% of the shares sold) solely to cover over-allotments, if any.

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.

The underwriters expect to deliver the shares to purchasers on or about July 19, 2011 through the book-entry facilities of the Depository Trust Company.

Leerink Swann **Lazard Capital Markets**

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

The date of this prospectus is July 13, 2011.

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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," "our company," "we," "us," "our" and similar names refer to Ventrus Biosciences, Inc.

INDUSTRY AND MARKET DATA

We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. Industry and general publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these publications, studies and surveys are reliable, we have not independently verified the data contained in them. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source.

PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all information you should consider before investing in our common stock. You should carefully read the whole prospectus, including the section entitled "Risk Factors" beginning on page 11 and our financial statements for the years ended December 31, 2009 and 2010 and the three months ended March 31, 2010 and 2011, and related notes, which are included in this prospectus.

Company Overview

We are a specialty pharmaceutical company currently focused on the development and commercialization of late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoids, anal fissures and fecal incontinence, which are three of the 10 most prevalent gastrointestinal disorders in the U.S. We are not aware of any prescription drugs for the treatment of hemorrhoids or fecal incontinence that have been approved by the U.S. Food and Drug Administration, or FDA, yet there are approximately 12.5 million Americans who are currently suffering from symptomatic hemorrhoids and seven million from fecal incontinence. While there are approximately four million Americans currently suffering from anal fissures, we are aware of only one drug that has received FDA approval for the treatment of pain associated with anal fissures and is expected to come to market in the first quarter of 2012. Our product candidate portfolio consists of three late-stage in-licensed drugs intended to treat these three conditions, including one new chemical entity, or NCE, and two previously approved molecules that will have data exclusivity for new topical gastrointestinal indications.

Based on our meetings with the FDA, we believe that VEN 309, our NCE for the topical treatment of hemorrhoids, is ready for Phase III trials in the U.S. Our development partner, S.L.A. Pharma, AG, is conducting a Phase III trial for VEN 307 for the topical treatment of anal fissures in Europe that it began in November 2010. In addition, we believe that VEN 308, for the topical treatment of fecal incontinence, is ready to begin Phase IIb trials.

Our Product Candidates

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, symptomatic hemorrhoids currently affect approximately 12.5 million people in the U.S. Despite such a high prevalence, we are not aware of any FDA-approved prescription drugs for the treatment of hemorrhoids in the U.S. According to IMS Health, Inc. (2009), 4.2 million prescriptions are written per year in the U.S. for hemorrhoid prescription products and 22 million units are sold per year in the U.S. for the over-the-counter, or OTC, hemorrhoid products.

Current Treatments. While there are commonly used prescription drugs in the U.S. for hemorrhoids, such as intra-anal or intra-rectal steroids, none have been approved by the FDA or have been designated by the FDA as safe and effective. Various combination products (such as the Preparation H® line of products) are available in the U.S. OTC under the FDA's OTC monograph rule. The great majority of these treatments provide only temporary relief from the symptoms of hemorrhoids and do not address the cause of hemorrhoids. The mechanism of action for these treatments is either generally anti-inflammatory, such as with steroids, or acting as a protective coating on the hemorrhoid or acting as local anesthetics, in the case of most of the OTC products, or unknown, in the case of herbal remedies. We are not aware of any clinical trials published in medical journals on the efficacy or safety of any prescription or OTC topical or oral drug currently marketed in the U.S. for the treatment of hemorrhoids.

Our Product. Our product, VEN 309, an 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. Seven clinical studies of VEN 309 have been completed, and five of these studies demonstrated that VEN 309 significantly improved and in many cases eliminated the pain, bleeding and itching associated with hemorrhoids versus placebo ointment. We believe

VEN 309 has the potential to be more effective than the currently available conventional hemorrhoid topical therapies and more attractive than surgical procedures, which are the only currently validated treatment options.

Our Development Status. Based on our clinical experience, we filed a Special Protocol Assessment, or SPA, with the FDA for our two proposed pivotal Phase III trials for VEN 309 for the treatment of hemorrhoids. During that process, we addressed all recommendations of the FDA to date including the definitions of the primary and secondary endpoints along with the other important design elements of the trial. However, we have determined to not further pursue the SPA so as not to delay the start of our planned Phase III trial for VEN 309 for the treatment of hemorrhoids. We have begun contracting with sites for the first of the two planned pivotal Phase III trials and expect to begin the trial in the summer of 2011, complete enrollment by January 2012, and have data available in the first quarter of 2012.

Our Intellectual Property. We have licensed VEN 309 from Sam Amer & Co., Inc., or Amer, who had developed VEN 309 through Phase II trials and up to readiness for Phase III trials 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 related to the use of the product for the topical treatment of anorectal disorders. VEN 309 is covered for composition of matter in patents that will expire in August 2015 in the U.S. and February 2018 elsewhere. If approved, VEN 309 will receive five years of data exclusivity in the U.S. as an NCE under the Hatch-Waxman Act and 10 years from the date of approval in Europe. We filed a new concentration range patent in August 2010, which, if issued, would grant patent protection until 2030 and prevent substitutable generic competition. On June 5, 2011, we entered into an agreement to purchase all rights, title and interest to VEN 309 from Amer, and we intend to use a portion of the proceeds from this offering for that purchase.

Diltiazem cream (VEN 307), a topical treatment for the relief of pain associated with anal fissures. Anal fissures are 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. In 2010, it was estimated by SDI Health LLC that there were approximately 1.1 million office visits in the U.S. per year for anal fissures and we estimate that there are currently up to 4.3 million cases in the U.S.

Current Treatments. At present, we are aware of only one FDA-approved drug for the treatment of pain associated with anal fissures. Rectiv™ (nitroglycerin) ointment 0.4%, for the treatment of moderate to severe pain associated with chronic anal fissures, received FDA approval in late June 2011, and is expected to come to market in the first quarter of 2012. Topical nitroglycerin, the active ingredient in Rectiv, also has been used to treat anal fissures, but has a substantially higher rate of side effects than topical diltiazem, notably moderate and severe headaches, which also are experienced with Rectiv. We also are aware of limited use of Botox® as an injection into the anal sphincter to treat this condition. Several topical forms of nifedipine, a calcium-channel blocker, also are used to treat pain from anal fissures. Diltiazem cream, also a calcium-channel blocker, however, is currently used as the preferred treatment by many gastroenterologists across the U.S. in a version that must be specially mixed, or compounded, for each patient in the pharmacy. Neither compounded diltiazem nor nitroglycerin itself, however, is FDA-approved to treat anal fissures nor is the cost typically reimbursed by Medicare or health insurance plans. We expect that VEN 307 and Rectiv would be reimbursable under Medicare and 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 nitroglycerin conducted between 1999 and 2007 by various researchers, diltiazem cream significantly reduced the pain associated with anal fissures and with a substantially lower rate of headaches reported as a side effect as compared to clinical trials reported in the Rectogesicš professional label (summary of product characteristics) in Europe and clinical trials with nitroglycerin.

Our Product. Our product, VEN 307, is a pre-mixed and pre-packaged proprietary formulation of diltiazem that when applied topically yields lower blood levels, at less than one-tenth the amount of the lowest oral dose used for cardiovascular treatment and yet has a considerably greater effect on sphincter tone than diltiazem taken orally. We believe these low blood levels improve VEN 307's safety profile and lower the risk of side effects. If VEN 307 is approved, we believe we have the potential to capture immediate

market share due to the familiarity of gastroenterologists with the current use of diltiazem to treat anal fissures, its ease of prescription as a pre-formulated FDA-approved product with no need for compounding necessary at the pharmacy, and the expected ability for patients to be reimbursed through their health insurance plans or Medicare.

Our Development Status. S.L.A. Pharma is conducting a Phase III clinical trial in the E.U., which was begun in November 2010 and is anticipated to be complete in the second quarter of 2012. Because diltiazem was previously approved as a systemic agent for hypertension and angina, we intend to develop the topical formulation as a Section 505(b)(2) new drug application, or NDA, based on our discussions with the FDA at our pre-investigational new drug, or pre-IND, meeting in August 2007. This 505(b)(2) application procedure will allow us to seek approval on the basis of a combination of the prior FDA approval of diltiazem, the Phase III trial being conducted by S.L.A. Pharma and the Phase III trial we plan to conduct in the U.S. Assuming positive results from that trial, the design of which was based on our pre-IND meeting with the FDA, we intend to conduct three short-term dermal toxicology studies and file an IND with the FDA for one pivotal Phase III trial or two parallel pivotal Phase III trials. Depending on the results of those trials, we anticipate filing an NDA with the FDA in 2013.

Our Intellectual Property. 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. We are using our current cash resources to pursue the development of VEN 307. VEN 307 is covered by method of use in a patent that will expire in February 2018. If approved, VEN 307 will receive three years of data exclusivity in the U.S. under the Hatch-Waxman Act.

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 the U.S. population suffers from fecal incontinence, which we estimate to be approximately seven million people, based on 2009 Census Bureau population estimates.

Current Treatments. We are not aware of any FDA-approved drugs for fecal incontinence. Currently, there are few options available to treat this disorder, consisting of bulk laxatives, fiber diets, Imodium, which is a treatment for diarrhea, and invasive surgical procedures. In addition, Solesta™, an injectable inert bulking agent product, was approved as a device by the FDA in May 2011 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. In addition, Norgine is conducting a European Phase II program with NRL001, a suppository formulation of an alpha adrenergic stimulating agent for the treatment of fecal incontinence.

Our Product. Topical phenylephrine significantly (and in some patients, dramatically) improved patient bowel control in multiple clinical trials with patients suffering from IPAA-associated fecal incontinence. 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 that we believe 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. 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 in the case of post-IPAA surgery.

Our Development Status. We are not actively pursuing the development of VEN 308 at this time. The FDA has granted VEN 308 orphan status for the treatment of IPAA-related fecal incontinence. In the U.S., orphan drug designation is given to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Assuming sufficient resources in the future, we could initiate as early as 2012 a Phase IIb dose ranging trial in the U.S. in support of the orphan indication of IPAA-related fecal incontinence. Depending on the results of that trial, we would expect

to conclude VEN 308 development and submit the orphan NDA in 2015. Orphan status provides seven years of data exclusivity in the U.S. from the date of approval, during which time we would expect to pursue several potential lifecycle opportunities. Because of the extensive patient exposure to phenylephrine as an oral preparation for cough/cold, we intend to develop VEN 308 as a topical formulation through a Section 505(b)(2) NDA. This 505(b)(2) application procedure would allow us to seek approval on the basis of a combination of the prior FDA approval of phenylephrine and any trial we conduct.

Our Intellectual Property. 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. We do not expect to continue developing VEN 308 in the short term and do not expect to use any of the proceeds of this offering to develop VEN 308. VEN 308 is covered by a patent that will expire in December 2017. If approved, VEN 308 will receive seven years of data exclusivity in the U.S. under the Orphan Drug Act.

Our Strategy

Our objective is to develop and commercialize our product candidates to treat hemorrhoids, anal fissures and fecal incontinence, for all of which there are no FDA-approved prescription drugs in the U.S. To achieve this objective, we intend to:

- initiate one of two planned pivotal Phase III trials in the U.S. of VEN 309 for the treatment of hemorrhoids, expected to begin in the summer of 2011;
- assuming positive data from the Phase III trials for VEN 309, including an additional Phase III recurrence trial, as well as positive results of clinical pharmacology and other non-clinical activities, such as carcinogenicity and toxicology studies, prepare and file an NDA for VEN 309 for the treatment of hemorrhoids in mid-2014;
- assuming VEN 309 is approved by the FDA, and because there are no FDA-approved prescription drug competitors in the U.S., we intend to commercialize the product in the U.S. using either our own sales force or through an agreement with a suitable partner and to license the product for sale outside of the U.S.;
- conduct one pivotal trial or two parallel pivotal trials and short-term dermal toxicology studies for VEN 307, assuming receipt of positive data from an ongoing European Phase III trial of VEN 307, expected in the second quarter of 2012, with the goal to prepare and file an NDA for a Phase III trial of VEN 307 for the topical treatment of pain associated with anal fissures in 2013; and
- assuming VEN 307 is approved by the FDA, and because topical diltiazem is already used by colorectal surgeons in the U.S., we intend to engage our own gastrointestinal specialty sales force and marketing staff to commercialize this product and/or engage a suitable partner in the U.S. and to license it for sale in Canada.

Our Management

Our management team consists of Russell H. Ellison, Chief Executive Officer and Chairman of the Board of Directors, who has over 30 years of experience in the pharmaceutical industry, including serving as vice president — medical affairs and chief medical officer of Roche Laboratories, Inc., USA. and Sanofi-Synthelabo, USA, and David J. Barrett, Chief Financial Officer, previously chief financial officer of Neuro-Hitech, Inc., a publicly traded pharmaceutical company with development stage and marketed products. Beginning in January 2011, we have increased the number of our employees to five and have contracted with three consultants on manufacturing, preclinical and clinical aspects of our drug programs. We use these consulting agreements to avoid the costs customarily associated with employees until our financial resources allow us to hire additional employees. We believe that the addition of these employees and consultants to the Ventrus team will help us advance our product candidates to the next stage of development.

Recent Developments

We had filed an SPA with the FDA to ensure its explicit agreement with our first pivotal Phase III protocol for VEN 309, using the 0.5% dose. As part of that process, we have had extensive discussions with

FDA about the protocol and filed a revised protocol on May 16, 2011. In late June 2011, the FDA issued its response and requested that additional information be included in the protocol pertaining to some details of the study, and therefore did not issue an agreement letter for the SPA. The FDA's recommendations included adding a standardized methodology to the protocol to assess patients' comprehension of symptoms and symptom terms, such as "anus" or "anal-rectal area"; addressing the possibility that women in menses may not be able to determine whether the source of their bleeding is from hemorrhoids; and adding more clarity to the protocol regarding maintenance of blinding while preserving accurate dosing in the seven-day treatment arm. In addition, the FDA recommended adding a stratification to the efficacy analysis and a rewording for better clarity of the endpoint definition. None of these recommendations affect the previous recommendations of the FDA for the endpoints, overall statistical powering and subject number, and the overall clinical design. We have incorporated these latest changes into the protocol and, in order to maintain our timelines for the trial, we intend to file the protocol to our existing IND with the FDA, and to not continue to pursue the SPA process.

On June 6, 2011, we amended our license agreement with S.L.A. Pharma. The amendment eliminates our potential $800,000 payment to S.L.A. Pharma for the development of VEN 307, previously payable upon the completion of enrollment into the Phase III clinical trial that S.L.A. Pharma is conducting in Europe. It also eliminates S.L.A. Pharma's ability to terminate the license agreement at any time, with one month's notice, in the event that we had failed to make a required payment and a third party wished to enter into a license agreement for VEN 307 and VEN 308, provided the termination would not have been effective if within that one-month period we paid all then required payments under the agreement. Pursuant to the amendment, we must pay S.L.A. Pharma up to $1,000,000 in milestone payments, payable in four equal installments of $250,000 once specified thresholds of randomized patients are achieved in the Phase III trial for VEN 307 that S.L.A. Pharma is conducting in Europe. Additionally, upon our receipt of a quality controlled final study report of the Phase III trial for VEN 307 in Europe, we must pay S.L.A. Pharma $400,000 in development costs for VEN 307.

On June 5, 2011, we entered into an agreement with Amer to acquire all rights, title and interest to VEN 309. We paid $500,000 on execution and will pay $12 million for the asset at closing, which we expect to occur by November 15, 2011. Closing is subject to our raising net proceeds of a certain minimum amount, as well as customary closing conditions. Closing is also subject to, in respect of the first pivotal Phase III trial and any recurrence treatment for VEN 309, the absence through November 10, 2011 of any serious severe adverse events that are life threatening with a risk of serious morbidity that have occurred in one or more subjects receiving VEN 309 which are either determined to be at least probably caused by VEN 309 or have been disclosed by us in a public securities filing. We will pay Amer royalties of between 3.0% and 4.0% on net annual sales in the U.S. and between 1.0% and 1.33% on gross annual sales outside the U.S. (subject to a minimum royalty payment on both U.S. and ex-U.S. sales), which, in addition to an approximately 50% reduction in milestone payments under the current license agreement, represents an approximately 66% decrease in the royalty fees due to Amer under the current license agreement. For more information, see "Business — License Agreements & Intellectual Property — License Agreements."

On May 26, 2011, the U.S. Patent and Trademark Office, or PTO, found our claims for VEN 307 patentable and issued a notice of allowance for a patent that would cover topical treatment for the relief of pain associated with anal fissures. The U.S. patent expires in February 2018. If approved, VEN 307 will receive three years of data exclusivity in the U.S. under the Hatch-Waxman Act.

Corporate History and 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. We began operations in April 2007 upon the acquisition of the licenses to VEN 307 and VEN 308 and the hiring of a development team. We acquired the license to VEN 309 in March 2008. We conducted operations until March 2009 when we terminated our employees due to a lack of financial resources. We retained the services of our then executive team through consulting agreements, pursuant to which those individuals, from February 2009 to June 2010, conducted minimal activities consisting of maintaining the licenses to our product candidates and business development and financing activities. We completed a series of convertible note financings in February, April and May of 2010 that provided us funds to hire as consultants our current chief executive officer and chief financial officer

and undertake our initial public offering. The completion of our initial public offering in December 2010 and the related exercise of the underwriters' over-allotment option in January 2011 raised approximately $17.5 million in net proceeds. We have used a portion of those net proceeds to resume the development of VEN 309 and VEN 307, including hiring employees, contracting with consultants, contracting with contract research organizations who will be assisting us in executing our planned Phase III trials for VEN 309 for the treatment of hemorrhoids, and contracting with manufacturers of clinical trial supplies for those studies.

Our executive offices are located at 99 Hudson Street, 5th Floor, New York, New York 10013. Our telephone number is (646) 706-5208. 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 11.

Conflicts of Interest

One of our principal stockholder's beneficial interest in both our stock and National Holdings Corporation, the parent corporation of National Securities Corporation, one of the underwriters in this offering, results in us being deemed to be under "common control" with National Securities Corporation pursuant to FINRA rules. Additionally, we intend to repay certain promissory notes issued to Paramount Credit Partners, LLC using the net proceeds of the offering received by us. Paramount Credit Partners, LLC is also under "common control" with National Securities Corporation. As a result, this offering is being conducted in accordance with FINRA Rule 5121. Neither Leerink Swann LLC nor Lazard Capital Markets LLC, who will act as lead underwriters, nor any affiliates of Leerink Swann LLC nor Lazard Capital Markets LLC have a conflict of interest as defined in FINRA Rule 5121. Therefore, a "qualified independent underwriter" will not be necessary for this offering.

THE OFFERING

Common stock offered	4,500,000 shares of common stock
Common stock to be outstanding after this offering	11,729,183 shares of common stock(1)
Use of proceeds	We expect to use the net proceeds from this offering for the following purposes: $12,000,000 to acquire all rights, title and interest in VEN 309 from Amer; repayment of $1,573,000 in principal of, and all accrued interest on, promissory notes issued to Paramount Credit Partners, LLC (the repayment of which will be triggered upon the closing of this offering); the development of VEN 309 through two pivotal Phase III trials; working capital; and general corporate purposes. See "Use of Proceeds" beginning on page 33.
NASDAQ Capital Market symbol	"VTUS"

(1) The number of shares of common stock to be outstanding after this offering, is based on 7,229,183 shares outstanding as of June 30, 2011, and does not include, as of that date:

- 1,958,455 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2011 with a weighted average exercise price of $6.76 per share;
- 958,902 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2011 with exercise prices ranging from $1.24 to $66.46 per share; and
- 2,008,745 shares of our common stock reserved for future issuance under our 2010 Equity Incentive Plan as of June 30, 2011.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the underwriters' over-allotment option.

Summary Financial Data

The following table presents summary financial data for the three months ended March 31, 2011 and 2010, the fiscal years ended December 31, 2010 and 2009, the period from October 7, 2005 (inception) to March 31, 2011 and the period October 7, 2005 (inception) to December 31, 2010. We derived the summary statement of operations data for the years ended December 31, 2010 and 2009 and the period from October 7, 2005 (inception) to December 31, 2010 from our audited financial statements included elsewhere in this prospectus. We derived the summary statement of operations data for the three months ended March 31, 2011 and 2010 and the period from October 7, 2005 (inception) to March 31, 2011 from our unaudited condensed 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 "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:

	Three Months Ended March 31,		Year Ended December 31,		Period from October 7, 2005 (inception) to	
	2011	2010	2010	2009	March 31, 2011	December 31, 2010
Operating expenses:						
Research and development	$ 970,762	$ 280,961	$ 1,850,667	$ 2,942,992	$ 15,222,323	$ 14,251,561
General and administrative	1,696,030	36,544	2,915,590	397,238	7,216,707	5,520,678
Loss from operations	(2,666,792)	(317,505)	(4,766,257)	(3,340,230)	(22,439,031)	(19,772,239)
Interest income	13,490	6	5,730	140	33,209	19,719
Interest expense:						
Beneficial conversion feature	—	—	(6,001,496)	—	(6,001,496)	(6,001,496)
Amortization of debt discount and warrants	(24,513)	(1,119,924)	(2,484,927)	(78,504)	(2,587,944)	(2,563,431)
Interest expense	(44,663)	(450,079)	(2,043,676)	(1,120,811)	(4,911,569)	(4,866,908)
Net loss	$ (2,722,478)	$ (1,887,502)	$(15,290,625)	$ (4,539,405)	$(35,906,832)	$(33,184,354)
Basic and diluted net loss per common share	$ (0.38)	$ (4.20)	$ (24.67)	$ (10.02)		
Weighted average number of common shares outstanding	7,147,624	447,347	619,923	445,040		
Pro forma weighted average number of common shares outstanding	11,647,624	4,947,347	5,119,923	4,945,040		
Pro forma net loss per share	$ (0.23)	$ (0.38)	$ (2.99)	$ (0.92)		

The following table presents a summary of our unaudited balance sheet data at March 31, 2011:

- on an actual basis; and
- on a pro forma basis reflecting our receipt of an estimated $39,697,000 in net proceeds from our sale of 4,500,000 shares of our common stock in this offering at the public offering price of $10.00 per share, after deducting the underwriting discounts and commissions, financial advisory fees and estimated offering expenses payable by us and the application of a portion of the net proceeds of this offering to repay outstanding indebtedness under notes payable but not including the issuance of 39,470 shares during the period April 1, 2011 through June 30, 2011 upon the exercise of 46,054 warrants (some of which were exercised utilizing a cashless exercise feature) and the related proceeds of $219,985.

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	Actual	Pro Forma
	(unaudited)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 14,000,524	$ 53,697,524
Working capital	13,791,623	53,488,623
Total assets	14,137,821	53,834,821
Total liabilities	1,605,618	32,618
Deficit accumulated during the development stage	(35,906,832)	(35,906,832)
Total stockholders' equity	12,532,203	53,802,203

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should carefully consider 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 meet our substantial obligations to our licensors, which 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. Our ability to make the payments required under our license agreements 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.

We license two of our product candidates, VEN 307 and VEN 308, from S.L.A. Pharma, a Swiss corporation, 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	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.
Up to $1,000,000	If contingencies are met, payable in four equal installments of $250,000	Milestone payments due once specified thresholds of randomized patients are achieved in the Phase III trial for VEN 307 in Europe
$400,000	Upon receipt of a quality controlled final study report of the Phase III trial for VEN 307 in Europe	Development expense for VEN 307

In the event that we are not current in our payments under the license agreement, S.L.A. Pharma may terminate the license agreement if we have not brought the payments current within three business days of receipt of notice from S.L.A. Pharma. Further, 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.

We also are party to a license agreement with Amer, a California company, from whom we acquired patent rights to VEN 309 for the topical treatment of anorectal disorders. Pursuant to the agreement, we pay Amer a monthly fee of $15,000. If and when we complete our planned Phase III trials for VEN 309, this monthly fee will decrease to $7,500. If and when we file an NDA for VEN 309 with the FDA, this monthly fee will cease. We also 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 VEN 309, 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 low single digit percentages for sales outside of the U.S., based upon sales of the product. In the event we breach these obligations and do not bring them current within 30 days of notice of breach, Amer may terminate the agreement, which would have a material adverse

effect on our business and prospects. On June 5, 2011, we entered into an agreement with Amer to acquire all rights, title and interest to VEN 309. If we close on the acquisition, we will own VEN 309 outright. While we will be obligated to pay Amer regulatory and sales-based milestones and royalties, the failure to make those payments will not cause the loss of our rights to VEN 309. We expect the closing of the acquisition to occur by November 15, 2011. Closing is subject to our raising net proceeds of a certain minimum amount, as well as customary closing conditions. Closing is also subject to, in respect of the first pivotal Phase III trial and any recurrence treatment for VEN 309, the absence through November 10, 2011 of any serious severe adverse events that are life threatening with a risk of serious morbidity that have occurred in one or more subjects receiving VEN 309 which are either determined to be at least probably caused by VEN 309 or have been disclosed by us in a public securities filing. If the closing does not occur, the acquisition will not occur and Amer will continue to own the rights to VEN 309 and the current license agreement will remain in effect.

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 March 31, 2011, we had a deficit accumulated during the development stage of $35,906,832. 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 experience negative cash flow and to incur significant operating and capital expenditure for the foreseeable future. We 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.

As a result, we will need to generate significant revenues in order to achieve and maintain profitability. 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 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, any licensing fees and any future securities offerings. We intend to devote substantially all of our resources to the development of VEN 309 and VEN 307. In the event we do not obtain regulatory approval of either of these product candidates, our business will be materially and adversely affected.

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, and 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. Assuming the sale of all shares offered by this prospectus, we expect that our resources will provide us with sufficient capital to fund our operations into 2014 and to develop VEN 309 through two pivotal Phase III trials. 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 the future to support our operations. We anticipate that to complete the clinical trial process to obtain the approval of our product candidates will cost approximately $20 million for VEN 307, $15 million for VEN 308 and $40 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 than if we owned the technology ourselves.

We have determined to not pursue a Special Protocol Assessment, or SPA, for VEN 309 and the FDA may not find the pivotal trials we plan to conduct for VEN 309 to be sufficient to support approval.

In order not to delay the start of our planned Phase III trial for VEN 309 for the treatment of hemorrhoids, we will proceed instead with the trial without an agreement letter on the SPA from the FDA. As a result, none of the recommendations made by the FDA on the major and important elements of the protocol to date and that we have implemented are binding on the FDA, which could result in delays in the start of our first pivotal trial if the FDA materially disagrees with our final protocol, and in the approval of the NDA we plan to file for VEN 309. Further, in addition to our two pivotal Phase III trials for VEN 309, the FDA will also require that we complete various additional clinical trials and non-clinical testing, such as a Phase III recurrence trial and carcinogenicity and toxicology testing, and our discussions with the FDA to date do not cover the detailed design or conduct of these additional trials and testing. As a result, we cannot assure that the pivotal trials and other studies we conduct will be sufficient to support approval of any NDA we file with respect to VEN 309.

The results of our planned Phase III trial for VEN 309 might not be as expected, which expectations are based on our post hoc analysis of an earlier study.

We have modeled the potential performance of the endpoints suggested by the FDA for our planned Phase III trial for VEN 309 using data from a prior double-blind Phase IIb trial of VEN 309 conducted in Germany that was very similar in all major respects to the Phase III trial we intend to conduct. While we believe this post hoc analysis is illustrative information, there are differences related to patient inclusion/exclusion criteria and could be differences related to physician characteristics and study conduct between the studies that could result in different outcomes. In addition, the FDA would not accept such a post hoc analysis in support of an NDA for VEN 309 because of these potential unknown differences. Accordingly, the successful results in the prior study might not be an indicator of success in our planned Phase III trials.

We may not be able to complete the acquisition of VEN 309 from Sam Amer & Co., Inc.

We intend to use approximately $12 million of the proceeds from this offering to acquire all rights, title, and interest in VEN 309 from Sam Amer & Co., Inc. However, we may not be able close the purchase due to, among other things, a failure to meet the closing conditions. Those conditions are the raising by us of a certain amount of net proceeds, as well as customary closing conditions. Closing is also subject to, in respect of the first pivotal Phase III trial and any recurrence treatment for VEN 309, the absence through November 10, 2011 of any serious severe adverse events that are life threatening with a risk of serious morbidity that have occurred in one or more subjects receiving VEN 309 which are either determined to be at least probably caused by VEN 309 or have been disclosed by us in a public securities filing. In addition, either we or Amer can terminate the agreement if the acquisition does not close by November 15, 2011. If this offering closes and the closing conditions to the purchase of VEN 309 are not met or the closing of the purchase of VEN 309 does not occur for any other reason, our management, in its discretion, may allocate proceeds from this offering to other uses with which you might not agree.

We and our auditors have identified material weaknesses in our financial reporting process.

We and our auditors have 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. We and our auditors have 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:

- 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 have taken the following measures to address the material weaknesses identified by us and our auditors and improve our periodic financial statement reporting process:

- hired a Chief Financial Officer in December 2010 (who previously was serving as a consultant) to strengthen our internal staffing and technical expertise in financial accounting and reporting;
- upgraded our accounting software system in the first quarter of 2011;
- limited access to the accounting and information systems and related data to strengthen segregation of duties;
- implemented in the fourth quarter of 2010 procedures and controls in the financial statement close process to improve the accuracy and timeliness of the preparation of quarterly and annual financial statements; and
- hired a controller in April 2011.

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 do not yet have supplies on hand for our planned Phase III clinical trials for VEN 309 for the treatment of hemorrhoids.

We plan to begin our Phase III trial for VEN 309 in the summer of 2011. However, we do not yet have the supplies of VEN 309 or the applicators on hand. While we have identified sources for both and certain supplies have been manufactured, there could be delays in manufacturing and shipping that we cannot foresee. In addition, all of our sources are foreign, which adds shipping and import risks to the receipt of those supplies, such as delays with U.S. Customs. Any delay in the receipt of our supplies would delay the commencement of the Phase III trial, which could delay any NDA filing and any eventual commercialization.

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

While we have contracted with a highly experienced head of manufacturing to oversee the manufacture of our clinical trial supplies, we do not have and do not intend to establish our own manufacturing facilities. Consequently, we lack the physical plant to formulate and manufacture our own product candidates, which are currently being manufactured entirely by commercial third parties, albeit under close supervision by our contractors. 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. 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. 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.

In addition, before any of our collaborators can begin to commercially manufacture our product candidates, each must obtain regulatory approval of the manufacturing facility and process. Manufacturing of drugs for clinical and commercial purposes must comply with the FDA's Current Good Manufacturing Practices, or 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. Our contracted manufacturing facilities 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 any of our collaborators fails to comply with these requirements, it would be subject to possible regulatory action which could limit 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.

Our reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We might be unable to identify manufacturers for commercial supply 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 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 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.
- Currently, our contract manufacturers are all foreign, which increases the risk of shipping delays and adds the risk of import restrictions.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have complete control over third-party manufacturers' compliance with these regulations and standards although we have agents in plant that monitor the production process.
- 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.

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.

We still must complete pharmacological and toxicity testing for VEN 309. In addition, because VEN 309 may be used as a chronic treatment, we are also required to complete long-term carcinogenicity testing. If any of this testing demonstrates meaningful toxicity, it could delay or prevent us from obtaining regulatory approval of VEN 309.

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. For example, although positive results have been observed in earlier clinical trials of each of VEN 309, VEN 307 and VEN 308, there is no assurance that any of our future clinical trials will be successful. Clinical trials might not provide statistically significant data supporting a product candidate's safety and effectiveness to meet the requisite regulatory approvals.

We intend to rely on one or more contract research organizations, or CROs, to conduct our clinical trials for VEN 309 and VEN 307. We will be highly dependent on these CROs to conduct our trials in accordance with the requirements of the FDA and good scientific practice. In the event the CROs fail to perform their duties in such a fashion, we may not obtain regulatory approval for any of our product candidates.

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 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.

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 VEN 309, 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 trials had a genetic reduction of this enzyme and did experience substantially higher levels of VEN 309 in his blood. However, no side effects were observed in this patient. There are several well known drugs that also are dependent on CYP2D6, including several antidepressants as well as tamoxifen. We might restrict the use of VEN 309 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. 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 VEN 307 and VEN 308 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 is currently only one FDA-approved drug for the treatment of anal fissures. Rectiv, a topical nitroglycerin treatment, was approved in late June 2011 by the FDA, and is expected to come to market in the first quarter of 2012. 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, white petrolatum, shark liver oil and/or witch hazel). No data are 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 U.S. 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. Members of the U.S. Congress and some state legislatures are seeking to overturn at least portions of the legislation and we expect they 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 U.S. may not provide reimbursement for our products at rates sufficient for us to achieve profitability, or at all. Like the U.S., 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 Chairman, Chief Executive Officer and acting Chief Medical Officer, Dr. Russell H. Ellison. Our employment agreement with Dr. Ellison does not ensure the retention of Dr. Ellison. This is also true for our other management team members, both present and future.

Furthermore, our future success also depends, in part, on our ability to identify, hire, and retain additional management team members as our operations grow. 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 including Dr. Ellison, that runs during the term of the agreement and for six months after termination. This non-compete provision was also included in employment agreements with our former chief executive officer, chief medical officer and chief scientific officer which have lapsed.

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 June 30, 2011, we had only five employees and three consultants to carry out our business plan. While we believe this will provide us with sufficient staffing to develop VEN 309 through the second quarter of 2012, 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 to commercialize VEN 309 and to develop VEN 307 and VEN 308. 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 in other technologies or businesses. 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 efficiently integrate 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 U.S. Department of Health and Human Services, the U.S. 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 U.S. 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. For example, in late April 2011, the FDA proposed that we include an additional one week treatment arm in our pivotal Phase III trials for VEN 309 to evaluate whether patients could be fully treated within seven days, in addition to the 14-day period we proposed testing. We agreed with the FDA and are adding the third arm, which increased the costs of the pivotal study.

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 could 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 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 prior to beginning the Phase III trial for VEN 309. 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, and those of our contractors, 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 if necessary.

Risks Related to Our Intellectual Property

Our patent for the concentration range of VEN 309 may not issue and our existing composition of matter patent covering VEN 309 could be invalidated.

Different concentrations of a drug are separately patentable under certain circumstances. Because of unexpected differences between concentrations of the product that 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 have not been previously published, on August 23, 2010, we filed method of use patent applications in the U.S. and internationally for VEN 309, claiming a specific concentration range. The patent, if issued, could be considered new art and provide patent protection for 20 additional years. However, if our existing composition of matter patent for VEN 309 is challenged by a third party and invalidated, and the concentration patent is never issued and even if issued is challenged by a third party, we would have only five years of U.S. data exclusivity under the Hatch-Waxman Act from the time VEN 309 is approved.

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 U.S. 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.

Our planned non-compete with Amer, Dr. Sam Amer and his wife may not be enforceable.

A condition to our purchase of VEN 309 from Amer is that each of Amer, Dr. Sam Amer and his wife must enter into a five-year non-compete agreement with us. The non-compete would apply to the U.S. and its territories and anywhere else in the world where a patent has issued for VEN 309 and would prohibit Amer, Dr. Amer and/or his wife, directly or indirectly, from owning an interest in, managing, operating, joining, controlling or participating in the ownership, management, operation or control of any profit or non-profit business or organization that conducts research, develops, formulates, tests, produces, licenses, commercializes, manufactures or distributes a product incorporating VEN 309 or any product which has the function of affecting the $5HT_{2A}$ receptor. The enforceability of non-competes is a matter of state law and courts generally look with disfavor on non-competes that are not narrowly drawn. California is particularly strict with the limitations that may be imposed by non-compete agreements and the geographic scope must be limited to the entity's or individual's "scope of business". While we believe that the non-compete has been drafted to comply with California law, we cannot be certain that it will be enforced. However, Amer, Dr. Amer and his wife could challenge the non-compete in court or choose to violate it in which event we would have to sue to enforce it. Either situation would be costly, might distract the attention of our management and the court might not uphold the non-compete. Further, the milestone and royalty payments we must pay Amer are not contingent on compliance with the non-compete. If Amer, Dr. Amer and/or his wife competed against us in developing a product incorporating VEN 309, it could have a material adverse effect on our business.

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 Our Common Stock

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 June 30, 2011 approximately 13.4% of our issued and outstanding common stock, excluding any shares issuable upon the exercise of warrants. See "Securities Ownership of Certain Beneficial Owners and Management."

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 beneficial ownership of approximately 13% of the common stock of our company, increases Dr. Rosenwald's ability to influence our board of directors and the management of our company. Dr. Rosenwald's rights will terminate upon the earlier to occur of (a) August 30, 2015, (b) the merger, consolidation or sale of all or substantially all of our stock or assets in a transaction or series of transactions immediately after which our stockholders as of immediately prior to the transaction hold less than 50% of the outstanding voting securities of the surviving, acquiring or parent corporation, or (c) Dr. Rosenwald's ownership of our company is less than 5.0% of the outstanding shares of our capital stock.

At March 31, 2011, we had borrowed from Paramount Credit Partners, an entity whose managing member is Dr. Rosenwald, an aggregate principal amount of $1,573,000.

As of March 31, 2011, we owed 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 Dr. Rosenwald, Paramount BioSciences and their 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.

Dr. Rosenwald may exert significant influence on our board of directors and the management of our company.

As of June 30, 2011, Dr. Rosenwald and his affiliates beneficially owned approximately 13.4% of our issued and outstanding capital stock, excluding any shares issuable upon the exercise of warrants. In addition, 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. Accordingly, Dr. Rosenwald and his affiliates can exert significant influence on 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 Dr. Rosenwald and his 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.

We might not be able to maintain the listing of our common stock on the NASDAQ Capital Market.

Our common stock is listed on the NASDAQ Capital Market under the symbol "VTUS." 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.

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

Since we went public on December 22, 2010, the price of our common stock has fluctuated between $6.00 and $21.00. 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:

- results of our clinical trials and other studies;
- availability of capital;
- future sales of our common stock;
- sale of shares of our common stock by our significant stockholders or members of our management;
- additions or departures of key personnel;
- investor perceptions of us and the pharmaceutical industry;
- issuance of new or changed securities analysts' reports or recommendations, or the announcement of any changes to our credit rating;
- success or failure of our product candidates;
- introduction of new products or announcements of significant contracts, acquisitions or capital commitments by us or our competitors;
- threatened or actual litigation and government investigations;
- legislative, political or regulatory developments;
- the overall performance of the equity markets;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- general economic conditions;
- changes in interest rates; and
- changes in accounting standards, policies, guidance, interpretations or principles.

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 adds to our operating costs and might strain our resources and distract our management.

As a public company, we face increased legal, accounting, administrative and other costs and expenses not faced by private companies. We are subject to 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, and 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. These rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. 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 currently has material weaknesses, and failure to achieve and maintain effective internal control over financial reporting could have a material adverse effect on our business and stock price.

As a public company, we must maintain internal control over financial reporting in a manner that meets the standards of publicly traded companies. 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 are in the process of reviewing, documenting and testing our internal control over financial reporting. 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.

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;
- 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; and
- the ability of our board of directors to increase its size and fill vacancies.

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 an aggregate of approximately 2.4 million shares of our outstanding common stock became able to sell those shares beginning on June 14, 2011 when the lock-up agreements to which they were subject expired. These lock-up agreements were put into place when we effected our initial public offering. In addition, our directors and officers and Lindsay A. Rosenwald, our largest stockholder (with respect to an aggregate of 714,996 of his shares), have agreed with the underwriters of this offering to not sell any shares they own or may acquire through the exercise of options or warrants for a period of 90 days after the effective date of the registration statement of which this prospectus is a part. Any substantial sale of common stock after this offering by these holders may have an adverse effect on the market price of our common stock.

Shares eligible for registration for future sale, if and when sold 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 an aggregate of approximately 850,000 shares of our common stock and an aggregate of approximately 912,000 shares of our common stock issuable upon the exercise of warrants are entitled to rights to register the shares held by them under the Securities Act pursuant to registration rights granted to the holders of these securities. These holders had the right to include these shares in the registration statement of which this prospectus is a part. However, the underwriters could exclude these shares from the registration statement and elected to do so. As a result, we intend to file a registration statement covering the resale of these shares as soon as possible after the closing of this offering. Any substantial sale of common stock by these holders after this offering may have an adverse effect on the market price of our common stock.

Risks Related to this Offering

Investors in this offering will experience immediate and substantial dilution.

The public offering of our common stock is expected to be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution in the pro forma net tangible book value per share of common stock from the price per share that you pay for the common stock. For more details, see "Dilution" on page 34. Moreover, 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.

We will need additional financing to fund our activities in the future, which likely will dilute our stockholders.

We anticipate that we will incur operating losses for the foreseeable future. Additionally, we believe we will require substantial funds in the future to support our operations and that the proceeds raised from this public offering will not be sufficient to meet our continuing need for funding. We expect to seek equity or debt financings in the future to fund our operations. The issuance of additional equity securities, or convertible debt or other derivative securities, likely will dilute some if not all of our then existing stockholders, depending on the financing terms.

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains estimates and forward-looking statements, principally in the sections entitled "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:

- the results of our clinical trials and changes to our development plans for our products;
- our anticipated capital expenditures, especially for our drug development activities, 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 ability to obtain FDA approval of our product candidates;
- our products candidates and plans to promote them;
- our expectations regarding our revenues, expenses, effective tax rates and other results of operations;
- 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 $45.0 million, based on the sale of 4,500,000 shares in this offering at the offering price of $10.00 per share.

We estimate that we will receive net proceeds of approximately $41.3 million from the sale of 4,500,000 shares of common stock being offered at the public offering price of $10.00 per share, after deducting an estimated $3.7 million for underwriting discounts and commissions and estimated expenses associated with this offering payable by us, including legal, accounting, printing costs, financial advisory fees and various fees associated with the registration and listing of our shares.

We expect to use the net proceeds of this offering for the following purposes and in the following order (to the extent any proceeds remain):

- the payment of $12,000,000 to acquire all rights, title and interest to VEN 309 from Amer;
- repayment of $1,573,000 in principal of, and all accrued interest ($187,536 as of March 31, 2011) on promissory notes issued to Paramount Credit Partners, LLC, the repayment of which will be triggered by the closing of this offering;
- development of VEN 309 through two pivotal Phase III trials;
- working capital; and
- general corporate and administrative purposes.

The interest rate on the Paramount Credit Partner notes is 10%, which 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, subsequent to our initial public offering, involving the sale of equity securities, sale of assets, licensing, strategic partnership or otherwise, in which we raise at least $5,000,000 in gross cash proceeds. Dr. Lindsay A. Rosenwald, our largest stockholder, is the managing member of Paramount Credit Partners.

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 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, economic, regulatory, competitive or other developments, 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, or take other actions we deem necessary or beneficial to our business, we may apportion proceeds of this offering to such acquisition development or activity. Accordingly, our management team will have significant flexibility in applying the net proceeds of this offering. Pending the use of the net proceeds of this offering, we intend to invest the funds 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.

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the net tangible book value per share of our common stock after this offering. Our net tangible book value as of March 31, 2011 was $12,532,203, or $1.74 per share of common stock. “Net tangible book value” is total assets minus the sum of liabilities and intangible assets. “Net tangible book value per share” is net tangible book value divided by the total number of shares of common stock outstanding.

Net tangible book value dilution per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering, and the net tangible book value per share of our common stock immediately after completion of this offering. After giving effect to the sale of 4,500,000 shares of our common stock in this offering at the public offering price of $10.00, and after deducting the underwriting discount and commissions and estimated offering expenses that we will pay, our net tangible book value as of March 31, 2011 would have been approximately $53,802,203, or $4.60 per share of common stock. This amount represents an immediate increase in net tangible book value of $2.86 per share to existing stockholders and an immediate dilution of $5.40 per share to purchasers of common stock in this offering.

The following table illustrates the dilution:

Public offering price per share	$	10.00
Net tangible book value per share as of March 31, 2011	$	1.74
Increase in net tangible book value per share attributable to this offering	$	2.86
Pro forma net tangible book value per share after this offering	$	4.60
Dilution per share to new investors	$	5.40

This table:

- assumes no exercise of outstanding warrants to purchase 1,004,956 shares of common stock at exercise prices of between $1.24 and $66.46 per share (decreased to 958,902 shares as of June 30, 2011);
- assumes no exercise of outstanding options to purchase 1,777,455 shares of common stock with a weighted average exercise price of $6.14 per share (increased to 1,958,455 shares as of June 30, 2011); and
- 689,745 shares of common stock reserved for future grants under our 2010 Equity Incentive Plan (2,008,745 shares as of June 30, 2011).

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of March 31, 2011 on:

- an actual basis; and
- on a pro forma basis reflecting our receipt of the estimated net proceeds from our sale of 4,500,000 shares of common stock in this offering at the public offering price of $10.00, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and the application of a portion of the net proceeds of this offering to repay outstanding indebtedness under notes payable but not including the issuance of 39,470 shares during the period April 1, 2011 through June 30, 2011 upon the exercise of 46,054 warrants (some of which were exercised utilizing a cashless exercise feature) and the related proceeds of $219,985.

	At March 31, 2011 (unaudited)	
	Actual	**Pro Forma**
Cash and cash equivalents	$ 14,000,524	$ 53,697,524
Stockholders' 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: 50,000,000 shares authorized, actual, pro forma and pro forma, as adjusted; 7,189,706 shares issued and outstanding, actual and 11,689,706 shares issued and outstanding, pro forma	7,190	11,690
Additional paid-in capital	48,431,845	89,697,345
Deficit accumulated during the development stage	(35,906,832)	(35,906,832)
Total capitalization	$ 12,532,203	$ 53,802,203

The pro forma number of shares to be outstanding immediately after this offering as shown above is based on 7,189,706 shares outstanding as of March 31, 2011 and excludes:

- 1,777,455 options with a weighted average exercise price of $6.14 per share (increased to 1,958,455 shares as of June 30, 2011);
- 1,004,956 shares of common stock issuable upon the exercise of warrants with exercise prices of between $1.24 and $66.46 per share (decreased to 958,902 shares as of June 30, 2011); and
- 689,745 shares of common stock reserved for future grants under our 2010 Equity Incentive Plan (2,008,745 shares as of June 30, 2010).

MARKET FOR COMMON STOCK

Our common stock is traded under the symbol “VTUS” and is quoted on the NASDAQ Capital Market. The following table sets forth the high and low sales prices for shares of our common stock, as reported by NASDAQ for the periods indicated.

	2010	
	High	Low
First Quarter*	$ —	$ —
Second Quarter*	$	$
Third Quarter*	$	$
Fourth Quarter	$ 7.71	$ 6.00
	2011	
	High	**Low**
First Quarter	$ 11.98	$ 5.75
Second Quarter	$ 21.00	$ 11.02

* Our common stock began trading on the NASDAQ Capital Market on December 17, 2010, on a “when-issued” basis. On December 23, 2010, the first trading day after the distribution, “when-issued” trading with respect to our common stock ended and “regular way” trading began. As a result, our stock was not listed in the first three quarters of 2010 and only listed for 10 trading days in the fourth quarter of 2010.

On July 13, 2011, the closing price for the common stock as reported on the NASDAQ Capital Market was $11.91.

As of June 30, 2011, there were 162 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers. We believe that, when our record holders and stockholders whose shares were held in nominee or street name by brokers are combined, we have an aggregate of approximately 1,000 stockholders.

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 report. 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 report, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a specialty pharmaceutical company currently focused on the development and commercialization of late-stage prescription drugs for 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 and VEN 307. VEN 309, a topical form of iferanserin which blocks a specific serotonin receptor ($5HT_{2A}$), is being developed for the topical treatment of symptomatic hemorrhoids, where it can reduce the bleeding, itchiness, and pain associated with the condition. Approximately 12.5 million people in the U.S. currently suffer from symptomatic hemorrhoids and we are not aware of any FDA-approved prescription drugs for this condition. VEN 307 is a pre-mixed and pre-packaged proprietary topical formulation of the drug diltiazem which we are developing for the treatment of anal fissures. We estimate that over four million people in the U.S. currently suffer from anal fissures and that there are approximately 1.1 million office visits per year and yet, to our knowledge, there is only one drug with FDA approval for this condition.

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 one of two pivotal Phase III clinical trials in the U.S. with VEN 309 beginning in the summer of 2011 and initiate a long-term carcinogenicity study. Depending on our assessment of the data generated by the Phase III trial, which is expected in the first quarter of 2012, 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, and a double blind recurrence trial which, together with the first study, a clinical pharmacology program, one 9-month and one 6-month toxicology study, and the carcinogenicity study (which we plan to complete after the second trial) will comprise the data needed to be able to submit an NDA to the FDA and analogous filings to authorities in Europe and Japan, which we anticipate could occur as early as 2014.

Our development partner for VEN 307, S.L.A. Pharma, began conducting a Phase III clinical trial with VEN 307 in Europe in November 2010 and expects to continue it in 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 Europe 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 trial 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 trial 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 an 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 and our initial public offering. 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 March 31, 2011, we had a deficit accumulated during the development stage of $35,906,832. 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 our existing cash will be sufficient to fund our projected operating requirements until mid-2012, while we anticipate receiving data from the key clinical trials with VEN 309 in the first quarter of 2012 and VEN 307 in the second quarter of 2012. 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 2 to the December 31, 2010 audited 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, measured at grant date, based on the estimated fair value of the award, which 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. The initial non-cash charge to operations for nonemployee 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 service 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 estimate 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 significant 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

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.

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; and (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. Since our inception on October 7, 2005 to March 31, 2011, we incurred $15,222,323 in research and development expenses. 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.

	3 Months ended 3/31/10	3 Months ended 3/31/11	YE 2009	YE 2010	Period from October 7, 2005 (inception) to Mar. 31, 2011
VEN 307	$ 281,600	$ 164,918	$ 155,000	$ 1,309,501	$ 3,966,919
VEN 309	$ 113,776	$ 651,387	$ 2,734,147	$ 379,237	$ 9,091,370
Other[(1)]	$ (114,415)	$ 154,457	$ 53,845	$ 161,928	$ 2,164,034

(1) During the three months ended March 31, 2010, we recorded a credit of $114,415 for stock based compensation (for non-employees, accounted for as variable options) because the fair value of the unvested options including related charges taken in earlier periods for unvested stock options based on expected vesting decreased during the period due to common stock issued at a lower price.

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 $20 million for VEN 307, $15 million for VEN 308 and $40 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 in order to fully complete the development of VEN 307 and VEN 309.

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.

Results of Operations

Comparison of the Three Months Ended March 31, 2011 and March 31, 2010

Research and Development Expense

Research and development expense was $970,762 for the quarter ended March 31, 2011, an increase of $689,801, or 246%, from $280,961 for the quarter ended March 31, 2010. The primary reason for the increase was expenses associated with clinical trial preparation paid to outside consultants and a clinical research

organization. The increase was slightly offset by the reduction of expenses for VEN 308. 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 trial.

General and Administrative Expense

General and administrative expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services and accounting services, insurance and travel expenses, as well as the option expense associated with the grants of options to our employees and directors in 2010. We expect that our general and administrative expenses will increase due to our recent staffing and as we add additional personnel and comply with the reporting obligations applicable to public companies.

General and administrative expense was $1,696,030 for the quarter ended March 31, 2011, an increase of $1,659,486 or approximately 4500%, from $36,544 for the quarter ended March 31, 2010. The increase was primarily due to the fact that we had limited operations and related operating expenses in the first half of 2010 due to the lack of funds and then we began increasing our operating activities in the second half of 2010. The largest G&A expense incurred in the first quarter of 2011 was associated with stock-based compensation expense for employees and directors.

Interest Expense

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 December 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 December 2010, the 8% 2010 senior convertible notes from February 2010 to December 2010, our letter of credit borrowings and interest due on our license fee payments. Additionally, interest expense includes the beneficial conversion feature of conventional convertible debt that was converted below market value as well as amortization of debt discount and deferred financing costs, as well as the debt discount for warrants issued in connection with debt financings.

Interest expense was $69,174 for the quarter ended March 31, 2011, a decrease of $1,500,829, or 95.6%, from $1,570,003 for the quarter ended March 31, 2010. The decrease was primarily due to the decrease in the amount of notes payable and the related debt discount expense since the notes were converted to common stock at the end of 2010. The amortization of debt discount during the three months ended March 31, 2010 was $24,513.

Comparison of the Years Ended December 31, 2010 and December 31, 2009

Research and Development Expense

Research and development expense was $1,850,667 for the year ended December 31, 2010, a decrease of $1,092,325, or 37%, from $2,942,992 for the year ended December 31, 2009. The primary reason for the decrease was the contractual payment of approximately $1,600,000 that was expensed by the Company in 2009. The decrease was offset by the expense from the issuance of a warrant to purchase shares of our common stock issued to S.L.A. Pharma in August 2010 and additional shares of common stock issued to S.L.A. Pharma in December 2010 as a result of our initial public offering share price. These issuances were at a discount to the market price and therefore the warrants had a significant value. 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 consists primarily of salaries, consulting fees and other related costs, professional fees for legal services and accounting services, insurance and travel expenses, as well as the option expense associated with the grants of options to our employees and directors in 2010. We expect that our general and administrative expenses will increase due to our recent staffing and as we add additional personnel and comply with the reporting obligations applicable to public companies.

General and administrative expense was $2,915,590 for the year ended December 31, 2010, an increase of $2,518,352, or 634%, from $397,238 for the year ended December 31, 2009. The increase was primarily

due to $2,298,782 of compensation expense related to options granted to our employees and directors in 2010. In addition, professional fees increased by approximately $210,000, or 98% over 2009 due to the use of consultants to oversee our operations and prepare us for being a public company.

Interest Expense

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 December 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 December 2010, the 8% 2010 senior convertible notes from February 2010 to December 2010, our letter of credit borrowings and interest due on our license fee payments. Additionally, interest expense includes the beneficial conversion feature of conventional convertible debt that was converted below market value as well as amortization of debt discount and deferred financing costs, as well as the debt discount for warrants issued in connection with debt financings.

Interest expense was $10,530,099 for the year ended December 31, 2010, an increase of $9,409,288, or 840%, from $1,120,811 for the year ended December 31, 2009. The increase was primarily due to the $6,001,496 beneficial conversion feature associated with the conversion of the 2007 convertible notes and 2010 convertible notes in December 2010 in connection with our initial public offering as well as $2,484,927 we expensed as amortization of debt discount associated with warrants issued with the 2010 notes. Interest expense paid or payable in cash was $1,329,925 for the year ended December 31, 2010, an increase of $595,773, or 81%, from the $734,152 for the year ended December 31, 2009. In addition, we had higher interest expense in 2010 due to the issuance of the 2010 convertible notes in February, April and May of 2010 and the interest charges from one of our licensors.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-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 March 31, 2011 principally with debt and equity financing, including raising approximately $15.2 million in net proceeds in our initial public offering, which closed on December 22, 2010, and approximately $2.4 million in net proceeds upon the exercise on January 7, 2011 of the over-allotment option granted to the underwriter of our initial public offering. In connection with the initial public offering, all of the convertible notes, and accrued interest thereon, converted into an aggregate of 3,334,085 shares of common stock.

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 were to 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 immediately and automatically converted into shares of our common stock at the close of our initial public offering on December 22, 2010. At the time of conversion, the outstanding balance, including accrued interest, on these notes was $1,131,656.

During 2009, we issued four separate 10% promissory notes, referred to as 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, subsequent to our initial public offering, involving the sale of equity securities, sale of assets, licensing, strategic partnership or otherwise, in which we raise at least $5,000,000 in gross cash proceeds. The closing of this offering will trigger the repayment obligation of the PCP Notes and we will repay the PCP Notes with a portion of the proceeds from this offering. As of March 31, 2011, the principal amount outstanding under these notes was $1,573,000. The PCP Notes are not convertible. 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. As a result of our initial public offering, the PCP warrants are exercisable for an aggregate of 104,867 shares, at a per share exercise price of $6.60.

We 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 and the third and fourth quarters of 2010, we had insufficient funds to pay the quarterly interest amount owed to Paramount Credit Partners, and carried these as accounts payable on our balance sheet. Interest amounts for these three quarterly periods in 2009 and two quarterly periods in 2010 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. In January 2011, we repaid Dr. Rosenwald for all of these quarterly payments with the proceeds from our initial public offering.

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, automatically converted into an aggregate of 1,642,802 shares of our common stock upon the close of our initial public offering, at a conversion price of $4.20, which was equal to 70% of the $6.00 purchase price paid for our stock in the initial public offering.

In connection with the offering of the Bridge Notes, Paramount BioCapital and third party agents received warrants, referred to as the Placement Warrants, to purchase, at an exercise price of 110% of the lowest price paid for securities in a Qualified Financing (as defined in the Placement Warrants), 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 our initial public offering on December 22, 2010, the 2010 Notes plus all accrued but unpaid interest thereon converted automatically into shares of our common stock at a per share price of $4.20, which is 70% of the $6.00 price at which shares of common stock were sold in the initial public offering, referred to as the IPO Price. 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 $6.60, subject to adjustment. Each of these warrants will expire and no longer be exercisable after February 26, 2015.

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 operating activities was $1,814,965 for the three months ended March 31, 2011. The net loss of $2,722,477 for the three months ended March 31, 2011 was higher than cash used in operating activities by $907,512. The primary reasons for the difference is attributed to a stock-based compensation charge of $1,152,785, a decrease in other current assets of $82,616 which consists of insurance premiums during the first quarter of 2011, and a decrease in accounts payable of $189,999 related to payments made during the first quarter of 2011.

Net cash used in operations was $5,214,427 for the year ended December 31, 2010. The net loss for the year ended December 31, 2010 was higher than cash used in operating activities by $10,076,198. The primary reasons for the difference are the $6,001,496 we expensed in beneficial conversion feature associated with the conversion of the notes that converted on December 22, 2010 in connection with our initial public offering, the option expense of $2,298,782 related to the grant of options to our employees and directors in 2010, the expense of $915,118 related to the warrants issued in connection with the conversion of related party notes in 2010 as part of our 2010 convertible note financing, and the $389,532 expense related to the issuance of a warrant in August 2010 and common stock in December 2010 to S.L.A. Pharma, as well as amortization of deferred financing costs and debt discount and interest payable on the 2010 notes.

Net Cash Used in Investing Activities

Net cash used in investing activities was $11,963 for the three months ended March 31, 2011. The cash was used to purchase computer equipment for new employees.

No significant cash was used in investing activities for the years ended December 31, 2010 and 2009.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $1,256,399 for the three months ended March 31, 2011. Net cash provided by financing activities consisted of the sale of common stock pursuant to the exercise of the over-allotment option issued to the underwriters of our IPO, through which we received net proceeds of $2,420,775. Additionally, the Company received approximately $55,000 from the exercise of warrants. Net cash provided by financing activities was reduced by $1,219,380 for the repayment of a promissory note and line of credit due to the Israel Discount Bank.

Net cash provided by financing activities was $19,704,194 for the year ended December 31, 2010. Net cash provided by financing activities consisted primarily of proceeds of approximately $15.2 from our initial public offering that closed in December 22, 2010, proceeds of approximately $3.4 million from the issuance of the 2010 convertible notes in 2010, proceeds of approximately $2.1 million from the conversion of related party debt into 2010 convertible notes, and proceeds of approximately $1.2 million from the notes issued to Israel Discount Bank of New York.

Funding Requirements

We expect to incur losses for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to our recently hired personnel, planned additional clinical trials and planned acquisition of VEN 309 from Amer. 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.

Based on our capital position at March 31, 2011, and our analysis of our development costs as of the date of this prospectus, we estimate our expected future expenditures related to product development, through the date of receipt of data from our planned first pivotal Phase III trial for VEN 309 and the ongoing Phase III trial for VEN 307 in Europe, as follows:

- complete the double blind portion of the Phase III clinical trial of VEN 309 in the treatment of hemorrhoids, carcinogenicity testing and developing new intellectual property: $10,000,000; and
- payment to S.L.A. Pharma of our licensing obligations for VEN 307 of $41,500 per month until the filing of an NDA with the FDA, up to $1,000,000 in milestone payments, payable in four equal installments of $250,000 once specified thresholds of randomized patients have been achieved in the Phase III clinical trial that S.L.A. Pharma is conducting in Europe, and $400,000 in development costs upon receipt of a quality controlled final study report for the Phase III clinical trial.

We believe that our existing cash and cash equivalents, without any proceeds from this offering, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into mid-2012. After giving effect to the sale of all of the shares offered by this prospectus, we believe we would have funds sufficient to enable us to fund our operating expenses and capital expenditure requirements into 2014. We have based these estimates 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. Other than this offering, 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 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

As of December 31, 2010 and as of March 31, 2011, we and our auditors 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. We and our auditors have 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:

- 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 have taken the following measures to address the material weaknesses identified by us and our auditors and improve our periodic financial statement reporting process:

- hired a Chief Financial Officer in December 2010 (who had previously been serving as a consultant) to strengthen our internal staffing and technical expertise in financial accounting and reporting;
- upgraded our accounting software system in the first quarter of 2011;
- limited access to the accounting and information systems and related data to strengthen segregation of duties;
- implemented in the fourth quarter of 2010 procedures and controls in the financial statement close process to improve the accuracy and timeliness of the preparation of quarterly and annual financial statements; and
- hired a controller in April 2011.

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.

Change in Accountants

J.H. Cohn LLP had served as our independent registered public accounting firm since August 31, 2009. J.H. Cohn audited our financial statements for 2008 and 2009 in connection with our 2010 convertible note financing and our initial public offering that we completed on December 22, 2010. On January 13, 2011, our Board of Directors dismissed J.H. Cohn as our independent registered public accounting firm.

J.H. Cohn's reports on our financial statements as of December 31, 2009 and 2008, and for the two years then ended and for the period from October 7, 2005 (inception) to December 31, 2009 did not contain an adverse opinion or a disclaimer of opinion, although the report contained an explanatory paragraph relating to our ability to continue as a going concern, and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the two years ended December 31, 2010 and through January 13, 2011, there were no: (a) disagreements with J.H. Cohn on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to J.H. Cohn's satisfaction, would have caused J.H. Cohn to make reference to the subject matter thereof in connection with its reports on our financial statements as of December 31, 2009 and 2008, and for the two years then ended and for the period from October 7, 2005 (inception) to December 31, 2009; or (b) "reportable events", as defined under Item 304(a)(1)(v) of Regulation S-K. However, J.H. Cohn 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.

J.H. Cohn has indicated to us that it concurs with the foregoing statements contained in the paragraphs above as they relate to J.H. Cohn and has furnished a letter dated January 20, 2011 to the SEC to this effect.

On January 18, 2011, we appointed EisnerAmper LLP as our independent registered public accounting firm for the year ended December 31, 2010. In addition, in March 2011, we engaged EisnerAmper to audit our financial statements for the years ended December 31, 2006 to December 31, 2009 and the period from October 7, 2005 (inception) to December 31, 2005 and for the period from October 7, 2005 (inception) to December 31, 2010 to save expenses on future filings with the SEC.

During the two years ended December 31, 2010 and through January 18, 2011, neither we nor anyone acting on our behalf consulted with EisnerAmper regarding any of the matters or events set forth in Item 304(a)(2)(i) or (ii) of Regulation S-K.

BUSINESS

Overview

We are a development stage specialty pharmaceutical company currently focused on the development of late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoids, anal fissures and fecal incontinence. We are not aware of any prescription drug treatments for hemorrhoids or fecal incontinence that have been approved by the U.S. Food and Drug Administration, or FDA, yet there currently are approximately 12.5 million Americans suffering from symptomatic hemorrhoids and seven million from fecal incontinence. While there are approximately four million Americans currently suffering from anal fissures, we are aware of only one drug that has received FDA approval for the treatment of pain associated with anal fissures; Rectiv received approval in late June 2011, and is expected to come to market in the first quarter of 2012. Rectiv is effective in reducing the pain from anal fissures, but moderate and severe headaches are a frequent side effect of this drug. 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. We are pursuing treatments for three of the 10 most prevalent gastrointestinal disorders in the U.S. We estimate that the patient population of these three disorders exceeds 23 million people in the U.S., based on the data we cite for each indication in this report.

Our lead product VEN 309 (iferanserin) is an in-licensed new chemical entity, or NCE, for the topical treatment of symptomatic 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 had extensive discussions with the FDA under a Special Protocol Assessment, or SPA, process, for our first pivotal trial of VEN 309 for the treatment of symptomatic hemorrhoids. While we have decided not to pursue an agreement letter, we have received many recommendations from the FDA concerning the major and important elements of the trial during this process and we have incorporated these into our protocol. We intend to file the protocol to our existing investigational new drug application, or IND, at the FDA in the summer of 2011.

Our additional product candidate portfolio consists of two in-licensed late-stage drugs. VEN 307 (diltiazem) is intended to treat pain associated with anal fissures and VEN 308 (phenylephrine) is intended to treat fecal incontinence. These candidates are two molecules that were previously approved and are currently marketed for other indications and that have been formulated into our proprietary topical treatments for these new gastrointestinal indications.

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 mg 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) new drug application, or NDA, based on our discussions with the FDA at our pre-IND meeting in August 2007.

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 U.S., 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 VEN 308 as a topical formulation through a Section 505(b)(2) NDA.

In August 2007, we had a pre-IND meeting with the FDA concerning VEN 307 for the treatment of pain from anal fissures where it was established what clinical safety database would be required, and that the 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 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 IIb trial where multiple doses will be assessed and that existing toxicology data are sufficient to support this trial. We have not had further meetings with the FDA on either VEN 307 or VEN 308 since the meetings in 2007. Beginning in February 2009, the development of the three products, VEN 307, VEN 308 and VEN 309, was delayed due to a lack of financial resources prior to the completion of our initial public offering in December 2010. We have used and are using

the proceeds from that offering to continue the development of VEN 309 and VEN 307. We intend to use a portion of the proceeds from this offering to fund the two pivotal Phase III trials for VEN 309.

Our Products and Development Strategy

Our three late-stage product candidates are:

Iferanserin ointment (VEN 309) for the topical treatment of symptomatic 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. VEN 309, an NCE formulated as an ointment for intra-anal application, has highly selective, antagonistic activity against peripheral $5HT_{2A}$ receptors involved in clotting and the contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. By limiting $5HT_{2A}$ receptor activity, VEN 309 improves the flow of blood out of the dilated veins that comprise the hemorrhoid, thereby reducing bleeding, itchiness and pain. As reported by the National Institute of Diabetes and Digestive Kidney Diseases, symptomatic hemorrhoids currently affect approximately 12.5 million people in the U.S. Despite such a high prevalence, 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 drugs in the U.S. for hemorrhoids, such as Anusol®, none have been approved by the FDA or have been designated by the FDA as safe and effective. Various combination products (such as the Preparation H line of products) are available in the U.S. over-the-counter, or OTC, under the FDA's OTC monograph rule. The great majority of these treatments provide only temporary relief from the symptoms of hemorrhoids, but do not address the cause of hemorrhoids. The mechanism of action of these treatments is either generally anti-inflammatory, such as steroids, or acting as a protective coating on the hemorrhoid or acting as local anesthetics, in the case of most of the OTC products, or unknown, in the case of herbal remedies, and we are not aware of any clinical trials published in medical journals on the efficacy or safety of any topical or oral drug 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 currently validated treatment options.

We have licensed VEN 309 from Sam Amer & Co., Inc., or Amer, who had developed VEN 309 through Phase II trials and up to readiness for Phase III trials 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. On June 5, 2011, we entered into an agreement to acquire all rights, title and interest to VEN 309 from Amer, which we expect to close on or before November 15, 2011, subject to our raising a certain minimum amount of net proceeds, as well as customary closing conditions. Closing is also subject to, in respect of the first pivotal Phase III trial and any recurrence treatment for VEN 309, the absence through November 10, 2011 of any serious severe adverse events that are life threatening with a risk of serious morbidity that have occurred in one or more subjects receiving VEN 309 which are either determined to be at least probably caused by VEN 309 or have been disclosed by us in a public securities filing. For more information, see "— License Agreements & Intellectual Property — License Agreements — VEN 309."

Diltiazem cream (VEN 307), a topical treatment for the relief of pain associated with anal fissures. Anal fissures are 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. In 2010, it was estimated by SDI Health LLC that there were approximately 1.1 million office visits per year for anal fissures. At present, we are aware of only one FDA-approved drugs for the treatment of anal fissures. Rectiv (nitroglycerin) ointment 0.4%, for the treatment of moderate to severe pain associated with chronic anal fissures, received FDA approval in late June 2011, and is expected to come to market in the first quarter of 2012. Topical nitroglycerin, the active ingredient in Rectiv, also has been used to treat anal fissures, but has a substantially higher rate of side effects than topical diltiazem, notably moderate and severe headaches, which also are experienced with Rectiv. We also are aware of limited use of Botox as an injection into the anal sphincter to treat this condition. Several topical forms of nifedipine, a calcium-channel blocker, also are used to treat pain from anal fissures. Diltiazem cream, also a calcium-channel blocker, however, is currently used as the preferred treatment by many gastroenterologists across the U.S. in a version that must be specially mixed, or compounded, for each patient in the pharmacy. Neither compounded diltiazem nor nifedipine, however, is FDA-approved for the relief of pain associated with anal fissures nor is the cost typically reimbursed by Medicare or health insurance plans. We expect that VEN 307 and Rectiv would be reimbursable under

Medicare and 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 nitroglycerin conducted between 1999 and 2002 by various researchers, diltiazem cream significantly reduced the pain associated with anal fissures.

Our product, VEN 307, is a pre-mixed and pre-packaged proprietary formulation of diltiazem that when applied topically yields lower blood levels, at one-tenth the amount of the lowest oral dose used for cardiovascular treatment. We believe these low blood levels improve the safety profile and lower the risk of side effects. We have potential to capture immediate market share if VEN 307 is approved due to the familiarity of gastroenterologists with the current use of diltiazem to treat anal fissures, its ease of prescription as a pre-formulated FDA-approved product with no need for compounding necessary at the pharmacy, and the expected ability for patients to be reimbursed through their health insurance plans 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, our development partner, who has completed early-stage clinical trials, toxicology studies and manufacturing for VEN 307 up to the end of Phase II. We intend to use a portion of our current resources to continue the development of VEN 307.

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 the U.S. population suffer from fecal incontinence, which we estimate to be approximately seven million people, based on 2009 Census Bureau 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, Solesta, an injectable inert bulking agent product, was approved as a device by the FDA in May 2011 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. In addition, Norgine is conducting a European Phase II program with NRL001, a suppository formulation of an alpha adrenergic stimulating agent for the treatment of fecal incontinence. 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. We currently do not expect to spend any time or resources developing VEN 308 until 2012.

The FDA has granted VEN 308 orphan status for the treatment of IPAA-related fecal incontinence. In the U.S., orphan drug designation is given to a drug intended to treat a rare disease of condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Assuming sufficient resources in the future and positive results from a Phase IIb dose ranging trial in the U.S. in support of the orphan indication of IPAA-related fecal incontinence that we intend to undertake, we would expect to submit an orphan NDA for VEN 308 for this indication. Orphan status provides seven years of data exclusivity in the U.S. from the date of approval.

Our Development Efforts

We in-license 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 limited number of employees with the expertise necessary to progress our product candidates down the development path outlined above. This helps us contain our operating costs.

Subsequent to the completion of our initial public offering in late December 2010, we hired five employees and contracted with three individuals or entities to complete our staffing needs for our planned initial Phase III trial of VEN 309. We also have recently contracted with contract research organizations to assist us in our planned Phase III trials for VEN 309. However, we remain dependent on the availability and competency of the third parties with whom we have contracted and with whom we plan to contract for the continued development of our product candidates.

Corporate History

We hired Dr. Russell Ellison, our Chief Executive Officer and Chief Medical Officer, and David Barrett, our Chief Financial Officer, in December 2010 upon the completion of our initial public offering. From June 2010 until they were hired, Dr. Ellison and Mr. Barrett served as consultants because our only business activities during that time consisted of maintaining our licenses with S.L.A. Pharma and Amer and activities connected with our initial public offering. From late December 2010 through February 2011, we completed the staffing for our planned development of VEN 309, by adding a clinician, two clinical project managers, a head of manufacturing, and an executive assistant, on a contract or permanent employment basis. We have used these consultancy arrangements to conserve our resources.

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 and is the chairman of the Business Development Committee of our board of 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 provided 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 when we contracted with Dr. Ellison and Mr. Barrett. In January 2011, we renewed the consulting agreement with Dr. Dietrich.

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 point prevalence of symptomatic hemorrhoids in the U.S. population currently is approximately 4.4%, 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.

According to IMS Health, Inc. (2009), 4.2 million prescriptions are written per year in the U.S. for hemorrhoid prescription products and 22 million units per year are sold in the U.S. for the 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, to our knowledge, lack any clinical trial data 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.

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 could cause exposure of the blood to collagen, which in turn causes platelet clumping with the release of the platelet's artery and vein constricting contents, including serotonin, which via stimulation of the $5HT_2$ receptor causes localized constriction of the exit veins, where most of the vascular smooth muscles are, and, in combination with other factors, causes 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 drugs for hemorrhoids in the U.S., such as Anusol, none have been approved by the FDA nor been designated by the FDA as safe and effective. Various combination products (such as the Preparation H line of products) are available in the U.S. under the FDA's OTC monograph rule. The great majority of these treatments provide only temporary relief from the symptoms of hemorrhoids and do not address the cause of hemorrhoids. The mechanism of action of these treatments is either generally anti-inflammatory, such as steroids, or acting as a protective coating on the hemorrhoid or acting as local anesthetics, in the case of most of the OTC products, or unknown, in the case of herbal remedies, and we are not aware of any clinical trials published in medical journals on the efficacy or safety of any topical or oral drug currently marketed in the U.S. for the treatment of hemorrhoids. 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.

By contrast, our product VEN 309 has highly selective, antagonistic activity against peripheral 5-HT_{2A} receptors ($5HT_{2A}$>$5HT_{2C}$>>$5HT_{2B}$) involved in clotting and the contraction of arteries and veins, two events believed to be associated with hemorrhoid formation. By limiting 5-HT_{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 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 currently validated treatment options.

IFERANSERIN OINTMENT (VEN 309) DEVELOPMENT

Background on Iferanserin

The early proof of concept for the utilization of a 5-HT_{2A} antagonist for the treatment of hemorrhoid was developed by Sam Amer PhD, a former director of research and development at Bristol-Myers Squibb Company. 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 preclinical 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 we believe 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 Phase IIb trial 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 an 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 validated 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 bloodbrain 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 $1/17^{th}$ to $1/88^{th}$ of the exposure that produces toxicity and from $1/45^{th}$ to $1/85^{th}$ of the exposure that produces cardiovascular effects in animal toxicology studies and $1/60^{th}$ – $1/100^{th}$ of the exposure that produces these effects in vitro. In addition, iferanserin exhibits low systemic exposure, with less than 10% bioavailability, based on a pre-clinical rat study.

Clinical trials and patent status

A total of seven clinical trials with iferanserin were completed by Amer (excluding Japan) and Tsumura in Japan between 1993 and 2003. One Phase I trial and one Phase II trial were completed using the racemic mixture of iferanserin. After the successful Phase II proof-of-principle trial, 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 trials — two Phase I trials, two Phase II trials, and one Phase III trial — 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 current 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 under certain circumstances. Because of unexpected differences between concentrations of the product that 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, to our knowledge, have not been previously published, we filed in August 2010 a patent claiming our specific concentration range (among other claims) which, we believe, if issued, could provide patent protection 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 still have five years of U.S. data exclusivity from the date of approval 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, which was transferred to us in April 2008, 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 trial (U.S.)

A double-blind, placebo-controlled trial 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 trial (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 (0.25%) and higher (1.0%) 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 trial (Japan)

A double-blind, placebo-controlled trial was conducted by Tsumura Company with three different concentrations of iferanserin ointment (0.25%, 0.5% and 1.0%) administered twice daily for four weeks for treatment of 104 patients with grade I to III internal hemorrhoids. The trial was completed in July 2002. 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 1.0% of iferanserin showed the most consistent improvements across groups for secondary symptoms, such as bleeding, pain severity and duration, and ease of defecation.

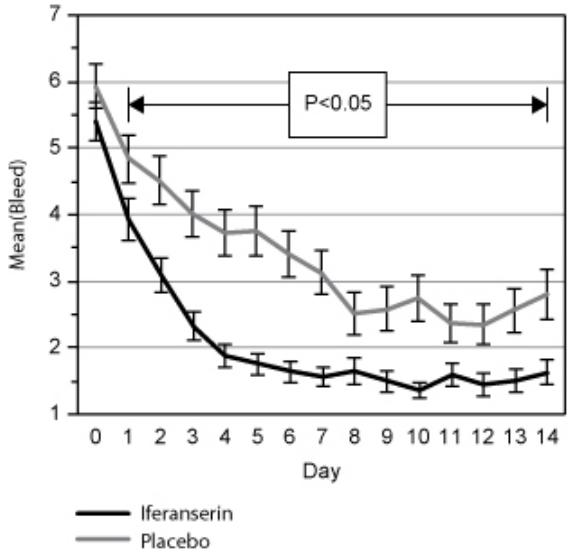
Phase IIb trial (E.U.)

Based on the results of the two Tsumura Phase II trials, a double-blind, randomized, placebo-controlled trial was conducted by Amer at five sites in Germany to evaluate the safety and efficacy of topical iferanserin ointment for the treatment of internal hemorrhoids. Patients with grades I – III internal hemorrhoids with bleeding episodes of at least every other day for two weeks prior to enrollment were eligible for the study. We

refer to this trial as the “German Phase IIb trial.” Participants were instructed to self-administer two grams of either placebo ointment or 0.5% iferanserin ointment into the anal canal twice-a-day (12 hours apart) for 14 days. At the end of each treatment day patients were instructed to complete a patient diary and record the following symptoms: bleeding, itching, pain, tenderness, fullness, throbbing, gas and difficulty of a bowel movement, with bleeding being the primary endpoint for the study. All symptoms were recorded on a scale of 1 – 10, with 1 indicating the absence of the symptom and 10 denoting the worst symptom. The patients were contacted by telephone 45 days after completion of treatment to determine their general health and hemorrhoid status. Adverse events were recorded by the patients. Patients who had complete 14 day diaries for efficacy endpoints and identified to a treatment group were included in the statistical analysis. The patient assessment scores for hemorrhoid bleeding at the end of seven and 14 days of treatment were the primary efficacy endpoints for the study. Secondary endpoints included the effects of treatment on itching, pain, tenderness, feeling of fullness, throbbing, gas and difficulty of defecation. Statistical analysis consisted of two-sided two-sample t-tests, with a p value of p 0.05 being considered statistically significant. Secondary analyses included the difference in assessment score per day. One hundred and eleven patients were evaluable for the primary endpoint of bleeding and 60 patients were evaluable for itching and 40 patients were evaluable for pain.

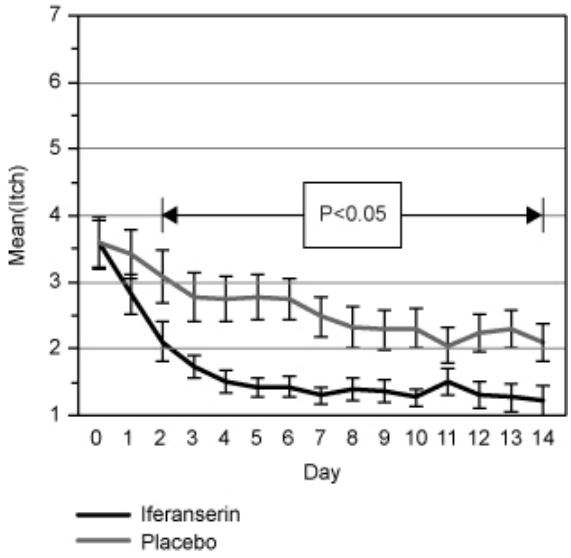
For the primary endpoint of bleeding, the difference in the scores on Day 0 between the two groups was not significant. There was a rapid and substantial decrease in the report of hemorrhoid-associated bleeding in the iferanserin group. The significant difference in bleeding scores between the groups started on Day 1 and remained significant until the end of the treatment period (Day 14) (**Figure 1)**. The primary endpoint of patient assessment scores for hemorrhoid bleeding at the end of seven and 14 days of treatment were significant with p values of $p < 0.0001$ and $p < 0.0075$, respectively.

Figure 1. Mean daily bleeding scores



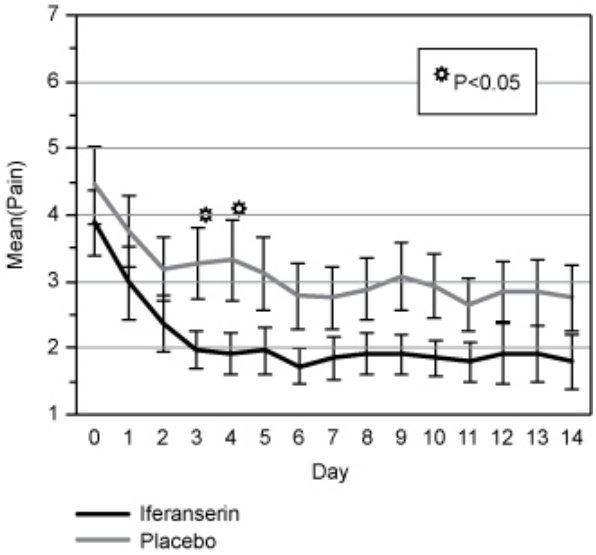
There was no difference in the itching scores on Day 0 between the two groups. As with bleeding, iferanserin produced a rapid, sustained reduction in itching. The significant difference in itching scores between the groups started on Day 2 and remained significant until the end of the treatment period (Day 14 (Figure 2)). The secondary endpoint of patient assessment scores for hemorrhoid itching at the end of seven and 14 days of treatment were significant with p values of $p < 0.0008$ and $p < 0.0207$, respectively.

Figure 2: Mean daily itching score



Finally, compared with placebo, iferanserin ointment significantly reduced pain ($p < 0.05$) by Day 3 (Figure 3). The effect of iferanserin was not significantly different from placebo on either Day 7 or Day 14, possibly due to the low number of patients with pain at baseline. Drug treatment was well tolerated in this trial. The rate of adverse events were similar in both treatment groups, and there were no serious adverse events. The majority of the adverse events were gastrointestinal related.

Figure 3: Mean daily pain scores



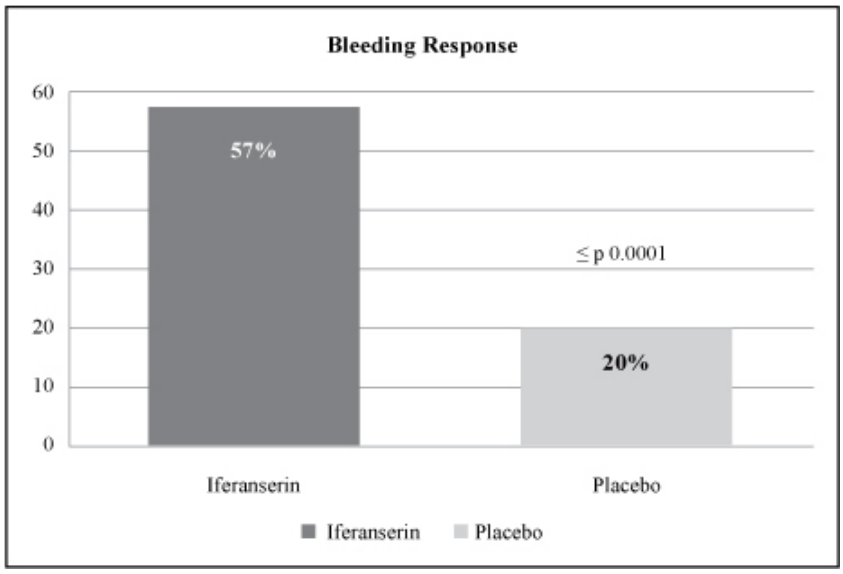
In this Phase IIb double-blind, randomized, placebo-controlled trial of 121 patients with grades I to III internal hemorrhoids, iferanserin provided rapid and sustained improvements of the main symptoms of this disorder: bleeding, itching and pain. Maximal improvements of symptoms, compared to baseline, occurred by Days 3 – 7 and were maintained to Day 14 at the end of the trial.

In order to determine the sample size and statistical power for our planned first pivotal Phase III trial, we have modeled the potential performance of the primary and secondary endpoints which were proposed by the FDA and which we will be using in that trial, using data from the German Phase IIb trial, because the principal elements of the German Phase IIb trial are substantially similar to our planned first Phase III trial. These endpoints are defined as:

- Primary: Proportion of patients with cessation of bleeding by Day 7 that persists for the remainder of the treatment period (through Day 14); and
- Key Secondary: Proportion of patients with cessation of pain and/or itching by Day 7 that persists for the remainder of the treatment period (through Day 14)

Applying the proposed statistical methodology and primary endpoint for our planned Phase III trial to the data from the German Phase IIb trial, the difference between the proportion of patients responding to treatment as defined by the new endpoint definition for cessation of bleeding in the VEN 309 arm (57% responders) and the placebo arm (20% responders) was considerable with $p < 0.0001$ (**Figure 4**). Similarly, analyses of the key secondary endpoints of pain and/or itching also showed considerable differences between VEN 309 and placebo (itching: 59% response to VEN 309 versus 32% response to placebo, $p < 0.034$; pain: 50% response to VEN 309 versus 18% to placebo, $p < 0.032$).

Figure 4. Analysis of the proposed endpoint for the Phase III trial using the data from the German Phase IIb trial.



Iferanserin ointment (VEN 309) development plan

Overview

We had an end-of-Phase II meeting in February 2008 with the FDA and had several interactions with the FDA during an SPA process that we were engaged in with the FDA for several iterations. In these interactions, the FDA has advised us that they consider VEN 309 to be a chronic repeated use product and as such, based on our preclinical and clinical data to date, the FDA has advised us the following elements are required for an NDA submission:

- 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);

- two pivotal Phase III trials, for the treatment of an episode of symptomatic hemorrhoids, and one double blind Phase III trial to determine the safety and efficacy of the treatment of recurrent episodes (which we might be able to combine with one of the pivotal trials depending on the recurrence rate and/or the ability to pre-identify patients who are likely to have recurrence);
- a clinical pharmacology program consisting of a thorough QT study (standard for most drugs), drug-drug interaction studies, and pharmacology in special populations; and
- as is usual for chronic or repeated use drugs, carcinogenicity studies in two species exposed for 104 weeks, preceded by a dose ranging study, and six months toxicology in rats and nine months in dogs.

As the carcinogenicity study (including the prior dose ranging study) can take up to 40 months to complete, we intend to conduct the Phase III trials sequentially as this will not delay the program, will conserve funds, allow an assessment of the recurrence rate, 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 in the summer 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 to initiate the carcinogenicity studies in 2012.

First Pivotal Phase III trial

We originally filed, in June 2008, an SPA with the FDA to ensure its explicit agreement with our first pivotal Phase III protocol for VEN 309, using the 0.5% dose. 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 have made several filings since then based on the responses received from the FDA. In February 2011, we had a Type A meeting with the FDA when we accepted their new proposal for the endpoints in the trial and clarified statistical and other protocol elements. We refiled the protocol under the SPA and received the FDA's response in May 2011 in which they accepted the changes but also proposed the addition of a third arm in the trial to study the safety and efficacy of seven days of treatment, in addition to the 14-day treatment arm and placebo arm that we had proposed in the original protocol. We agreed with the FDA to include the third arm because when we analyzed the Phase IIb German trial that compared iferanserin given twice daily for 14 days with placebo, using the proposed Phase III endpoints, we observed that the majority of iferanserin-treated patients started their response by Day 3. This raises the possibility that iferanserin therapy may require a shorter duration of treatment to show adequate efficacy to stop the bleeding, itching and pain associated with hemorrhoids. We believe that if this regimen proves to be effective, it could be even more acceptable to patients. We do not expect that this modification will materially change the timing to report the top line data, which we still expect will occur in the first quarter of 2012.

In late June 2011, we received a response to our last SPA submission of the revised protocol with the addition of the third arm, which, with the revised statistical plan, appears to be acceptable to the FDA. However, in its response, the FDA requested that additional information be included in the protocol pertaining to some details of the study, and therefore did not issue an agreement letter for the SPA. The FDA's recommendations included adding a standardized methodology to the protocol to assess patients' comprehension of symptoms and symptom terms, such as "anus" or "anal-rectal area"; addressing the possibility that women in menses may not be able to determine whether the source of their bleeding is from hemorrhoids; and adding more clarity to the protocol regarding maintenance of blinding while preserving accurate dosing in the seven-day treatment arm. In addition, the FDA recommended adding a stratification to the efficacy analysis and a rewording for better clarity of the endpoint definition. None of these recommendations affect the previous recommendations from the FDA for the endpoints, overall statistical powering and subject number, and the overall clinical design. Inasmuch as we have now incorporated these latest changes into the protocol, in order to maintain our timelines for the trial, we intend to file the protocol to our existing IND with the FDA, and to not continue to pursue the SPA process.

Following the progressive feedback from the FDA, the double-blinded randomized trial design of the three arms with a double blind portion and an open label portion will consist of:

Double blind part

- 600 patients (200 patients per arm) recruited at up to 70 sites in the U.S., randomized 1:1:1 to:
  - Arm 1: placebo ointment twice daily intra-anally for two weeks;
  - Arm 2: iferanserin ointment twice daily for two weeks; and
  - Arm 3: iferanserin ointment twice daily for one week followed by placebo ointment twice daily for one week;
- After 14 days treatment, patients will be followed up at Day 28;
- 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; and
- 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.

For the double-blind part of the trial, where patients are treated twice daily for two weeks and then followed up on Day 28, the definitions for the endpoints are:

- Primary: Proportion of patients with cessation of bleeding by Day 7 that persists for the remainder of the treatment period (through Day 14); and
- Key Secondary: Proportion of patients with cessation of pain and/or itching by Day 7 that persists for the remainder of the treatment period (through Day 14).

Open Label part

After the 28 day double blind portion of the trial, patients will be followed quarterly for one year and treated with active drug if they have a recurrence at any time during that period. We will assess time to first recurrence, and the overall recurrence rate over one year, and will be able to observe the unblinded response to treatment of recurrence during this part of the trial.

We believe that our modeling of the endpoint definitions as proposed by the FDA using the German Phase IIb trial data, confirm a projected power of > 99% for the primary endpoint and > 95% for the key secondary endpoints for our proposed Phase III trial. Since all of our clinical study sites will be using central institutional review boards, or IRBs, with rapid review times, and contracting with sites is already underway, we estimate that the study will start in the summer of 2011, complete enrollment approximately January 2012, and that data from the double blind part of the study will be available in the first quarter of 2012.

While we believe that we have addressed all of the FDA's comments, the SPA was not agreed to by the FDA. The recommendations made by the FDA on the protocol to date and that we have implemented will not be binding on the FDA and we will no longer be pursuing the SPA process.

Subsequent Development

After the results of the Phase III trial are available and assuming the results are positive, we intend to use a portion of the proceeds from this offering to:

- continue the carcinogenicity study, conduct the six- and nine-month chronic toxicology studies and conduct a substantially similar Phase III trial and a double blind recurrence trial (or combine this trial with the second pivotal Phase III trial, depending on the early recurrence rate observed in the first pivotal trial) which will also provide adequate numbers of patients exposed for the safety database; and

- 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 the feasibility of lifecycle options for follow-on products such as different formulations, 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 an 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 trial 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.

Supply of clinical trial product

We have identified qualified sources for the active pharmaceutical ingredient, or API, of VEN 309, a qualified source for drug product, and a qualified source for packaging and labeling as well as a source for the applicators for our planned Phase III trials for VEN 309. We currently have an agent-in-plant at the manufacturing sites for the API and drug product to monitor quality and performance. Supplies are being produced to 10% of anticipated commercial lots to ensure that bridging studies will not be necessary for commercial supply and that the specifications are the same as used for the Phase II2b trial in Germany. The suppliers of the API and drug product are foreign, and the packaging and labeling source is in the U.S. Deliveries are planned to allow us to begin the first Phase III trial in the summer of 2011.

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 have been 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. adult population, we estimate that the general prevalence rate is 1.9%, with approximately 4.3 million current cases. In 2010, it was estimated by SDI Health LLC that there were approximately 1.1 million office visits per year for anal fissures.

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

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 to create compounded topical formulations by mixing raw diltiazem, and in some cases nifedipine, another calcium-channel blocker, or nitroglycerin, into a cream, ointment or gel 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, Cellegy Pharmaceuticals, Inc., a drug developer (acquired by ProStrakan Group plc, which is a wholly owned subsidiary of Kyowa Hakko Kirin Co. Ltd.), 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. Cellegy's subsequent multiple 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 Cellegy did not use minimum pain scores as an inclusion criteria, the overall effect was diluted to 22%. In addition, 63% 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. Subsequently Cellegy (now ProStrakan) conducted an additional clinical trial in anal fissures which was filed with the FDA in 2009. ProStrakan received a complete response letter for this new NDA in April 2010, because of issues with statistical significance, according to ProStrakan. However, ProStrakan filed a response to these concerns and, in late June 2011, received approval for the product (Rectiv, a 0.4% concentration of nitroglycerin in ointment) to be applied twice daily for the treatment of pain associated with chronic anal fissures, for up to three weeks duration. This product has been marketed in the U.K. and other European countries and elsewhere since 2007. The professional label in Europe, which is a summary of product characteristics, lists headaches as being very common with a 63% incidence of which 45% were moderate or severe, in three pivotal trials. The U.S. label lists headaches as occurring in 64% of patients, with 938 headaches occurring in 79 patients, in one pivotal trial.

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 these earlier studies. 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 substantially less than those observed with topical nitroglycerin, which primarily were headaches.

DILTIAZEM CREAM (VEN 307) DEVELOPMENT

Background on diltiazem

Diltiazem, a calcium-channel blocker, 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 mg 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. This 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 or route of administration.

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 typically 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.

The use of diltiazem for the treatment of anal fissures was first discovered at St. Mark gastroenterology teaching hospital in London. Professors Kamm and Phillips filed the original method of use patent applications in 1997 in the Great Britain Patent Office. In 1998, a PCT International Application was filed designating the U.S. as National Phase country and which is the current patent application in the U.S. 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.

We have the potential 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 the FDA), with no need for compounding at the pharmacy, and because VEN 307 should 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.

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 us 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 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	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.
Up to $1,000,000	If contingencies are met, payable in four equal installments of $250,000.	Milestone payments due once specified thresholds of randomized patients are achieved in the Phase III trial for VEN 307 in Europe.
$400,000	Upon receipt of a quality controlled final study report of the Phase III trial for VEN 307 in Europe.	Development expense for VEN 307.

On May 26, 2011, the U.S. Patent and Trademark Office, or PTO, found our claims for VEN 307 patentable and issued a notice of allowance for a patent that would cover topical treatment for the relief of pain associated with anal fissures. The patent will expire in February 2018. If approved, VEN 307 will receive three years of data exclusivity in the U.S. under the Hatch-Waxman Act.

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 trial 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
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
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 one, one and a half, two, four and eight 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, including pain, 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 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 trials 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.

S.L.A. Pharma expects to enroll 465 patients at 30 sites in Europe in the Phase III study that it began in November 2010. Patients will be treated for two months in a randomized 1:1:1 double blind study that compares treatments of fiber plus 2% VEN 307 and fiber plus 4% VEN 307 to fiber plus placebo. The primary endpoint is reduction of pain upon defecation at one month, using the validated numerical rating scale for pain. Patients will use daily diaries and will be observed for one week prior to randomization to ensure sufficient pain prior to randomization.

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 trial 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 an NDA submission in 2013. In addition, we intend to compare VEN 307 with Rectiv either in our next Phase III trial(s) as an additional arm or in a separate Phase IV trial to enable a direct comparison of side effects, particularly headache, by physicians.

Supply of clinical trial product

S.L.A. Pharma currently is conducting a Phase III trial in Europe for VEN 307 for the treatment of anal fissures. S.L.A. Pharma has established clinical supply sources for its trials. We would expect to contract with those sources for our planned clinical trials and also plan to identify sources for clinical supplies located in the U.S. prior to conducting clinical trials in the U.S.

Commercial summary for diltiazem cream (VEN 307)

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 two 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 seven million people, based on 2009 Census Bureau 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.

The FDA has granted VEN 308 orphan status for the treatment of IPAA-related fecal incontinence. In the U.S., orphan drug designation is given to a drug intended to treat a rare disease of condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S.

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 is an injectable inert bulking agent product approved as a device by the FDA in May 2011 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. In addition, Norgine plans to conduct a European 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 U.S., 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 of fecal incontinence was first discovered at St. Mark gastroenterology teaching hospital in London. Professors Kamm and Phillips 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 March 31, 2011. 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
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 eight 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 trial in support of the orphan indication of IPAA-related fecal incontinence. Assuming we raise sufficient capital in the future, we plan to start this trial 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.

Supply of clinical trial product

At this time, we are not actively pursuing the development of VEN 308 and have not undertaken any clinical supply activities for VEN 308.

Commercial summary for phenylephrine gel (VEN 308)

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.

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.

License Agreements — VEN 309

In March 2008, we entered into an Exclusive License Agreement with Amer whereby we acquired exclusive patent rights to iferanserin (the Amer Technology) for the topical treatment of any anorectal disorders. Pursuant to the Exclusive License Agreement, we pay Amer a monthly fee of $15,000. If and when we complete our planned Phase III trial for VEN 309, this monthly fee will decrease to $7,500. If and when we file an NDA for VEN 309 with the FDA, this monthly fee will cease. We also 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 Amer Technology is commercialized, we are obligated to pay to Amer annual royalties based upon sales of the product in the U.S. market and outside the U.S.

The Exclusive License Agreement is terminable by either party for cause, upon 30 days' notice and subject to a 60-day cure period (or 30-day cure period for payment default), 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 Exclusive License Agreement upon 30 days' written notice in the event any safety, efficacy or regulatory issues prevent development or commercialization of the Amer Technology.

On June 5, 2011, we entered into an asset purchase agreement with Amer to acquire all rights, title and interest to VEN 309. We paid $500,000 on execution and will pay $12 million for the asset at closing, which is to occur by November 15, 2011. We also paid Amer $50,000 on execution and will pay Amer $5,000 per month for consulting services until closing or the termination of the agreement. Closing is subject to our raising net proceeds of a certain minimum amount as well as customary closing conditions. Closing is also subject to, in respect of the first pivotal Phase III trial and any recurrence treatment for VEN 309, the absence through November 10, 2011 of any serious severe adverse events that are life threatening with a risk of serious morbidity that have occurred in one or more subjects receiving VEN 309 which are either determined to be at least probably caused by VEN 309 or have been disclosed by us in a public securities filing. The purchase agreement contains customary indemnification provisions. We are obligated to pay milestone payments as follows: $1.5 million upon the one year anniversary of FDA approval of our planned NDA for VEN 309; $750,000 upon the attainment of $20 million in cumulative net sales of VEN 309; $1.5 million upon the attainment of $50 million in cumulative net sales; $3.0 million upon the attainment of $75 million in cumulative net sales; and $3.75 million upon regulatory approval for over-the-counter sale of VEN 309. Upon commercialization, we will pay Amer royalties of between 3.0% and 4.0% for net sales in the U.S., depending on the level of net sales in the U.S., and between 1.0% and 1.33% for sales outside of the U.S., depending on the level of gross sales outside the U.S., which, in addition to an approximately 50% reduction in the $20 million aggregate milestone payments under the Exclusive License Agreement, represents an approximately 66% decrease in the royalty fees due to Amer under the Exclusive License Agreement. We will pay Amer a minimum royalty of 50% of the royalties on the forecasted annual net sales in the U.S. and 50% of the royalties on the forecasted annual gross sales outside the U.S. Upon closing Amer, Dr. Amer and his wife will be prohibited for a period of five years after the closing from, directly or indirectly, owning an interest in, managing, operating, joining, controlling or participating in the ownership, management, operation or control of any profit or non-profit business or organization other than Ventrus that conducts research, develops, formulates, tests, produces, licenses, commercializes, manufactures or distributes a product incorporating VEN 309 or any other product which has the function of affecting the $5HT_{2A}$ receptor. The non-compete covers the United Sates and its territories and any other jurisdiction in the world where a patent has issued for iferanserin. Upon the closing of the acquisition, the current Exclusive License Agreement with Amer will terminate. The asset purchase agreement is terminable by either us or Amer if the acquisition does not close by November 15, 2011.

There are four patent filings for VEN 309, all of which, except as noted below, were filed in the name of Dr. Sam Amer as the inventor and Amer as the assignee. The patent filing for the VEN 309 compound that we are developing was filed in the U.S. (No. 5,780,487), Europe (Germany, Great Britain, France, Switzerland and Spain) (No. EP 0973741), Japan (No. 520835/98), Norway (No. 19994181) and Korea (No. 10-997007763). Patents have been granted in the U.S. and Europe, while applications are pending in Norway, Japan and Korea. The U.S. patent will expire on August 7, 2015 and all foreign patents will expire on January 23, 2018, if all maintenance fees are timely paid.

The second patent filing is for the treatment of hemorrhoids with $5\text{-}HT_2$ antagonists and has been filed in the U.S. (No. 5,266,571), Europe (Germany, Great Britain, Austria, Greece, France, Portugal, Luxemburg, Ireland, Spain, Denmark, Switzerland, Belgium, Sweden, and Netherland) (No. EP 0684816), Japan (No. 2807092) and Korea (No. 0278522), in all of which the patent has been granted. The U.S. patent will expire on January 9, 2012 and all foreign patents will expire on February 19, 2013, if all maintenance fees are timely paid.

The third patent filing for VEN 309 is for $5\text{-}HT_2$ receptor antagonist compositions useful in treating venous conditions. This patent has been filed in the U.S. only (No. 5,605,902) and has been granted. The patent will expire on January 9, 2012, if all maintenance fees are timely paid.

The fourth patent filing for VEN is a concentration of range patent for the treatment of internal and external hemorrhoids that was filed in the U.S. (No. 12/860,974) and internationally on August 23, 2010 (No. PCT/US2010/046260). This patent is still pending. If issued, any patent will expire on August 23, 2030.

Finally, we will have data exclusivity for our NDA for VEN 309 in the U.S. for five years from the time of approval under the Hatch-Waxman Act.

Under the current Amer license agreement, we are responsible for the costs of prosecution of the patent, as well as any new patent filings for the licensed product. While we are currently obligated to pay these costs, as long as the license agreement remains in effect Amer will retain ownership of the patents although we will have the rights to license the technology underlying the patents for the duration of the license agreement. If our planned acquisition of VEN 309 closes, the license agreement will terminate and we will own VEN 309 outright and be solely responsible for the prosecution of the patent.

License Agreements — VEN 307 and 308

In March 2007, pursuant to an Exclusive License Agreement, S.L.A. Pharma granted Paramount BioSciences, Inc., or PBS, an exclusive, royalty-bearing license to sell, make, use and import 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, PBS 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, PBS 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 closed an equity financing with gross proceeds of not less than $5,000,000 and the 18,401 shares issued to S.L.A. Pharma did 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 were required to 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 would have a fair market value equal to $500,000 (based on the price per share paid in the financing). As a result, upon the closing of our initial public offering on December 22, 2010, based on the initial offering price of $6.00, we issued S.L.A. Pharma 64,933 shares of our common stock.

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. Pharma to us for $1,087,876. 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 and $50,000 for reimbursement of clinical development costs incurred by S.L.A. Pharma (these amounts 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, 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. From August 2007 through March 31, 2011, we made $3,200,000 of such payments, including $600,000 paid on December 31, 2010, which represented past development costs we had accrued. In addition, we must pay S.L.A. Pharma milestone payments of up to $1,000,000, payable in four equal installments of $250,000 once specified thresholds of randomized patients have been achieved in the Phase III trial for VEN 307 in Europe. Additionally, upon receipt of a quality controlled final study report for the Phase III trial for VEN 307 in Europe (anticipated in the second quarter of 2012), the cap on the amount of payments we must make to S.L.A. Pharma in respect of VEN 307

development costs will be increased to $4,600,000, and we must pay S.L.A. Pharma $400,000. S.L.A. Pharma has not provided the services for this additional work and therefore we have not recorded any additional expenses.

From August 2007 through March 31, 2011, we had paid $973,500 in project management fees to S.L.A. Pharma relating to the development of VEN 308. These project management fees were 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	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.
Up to $1,000,000	If contingencies are met, payable in four equal installments of $250,000.	Milestone payments due once specified thresholds of randomized patients are achieved in the Phase III trial for VEN 307 in Europe.
$400,000	Upon receipt of a quality controlled final study report of the Phase III trial for VEN 307 in Europe.	Development expense for VEN 307.

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 and the cancellation of all future 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 the event that we are not current in our payments under the license agreement, S.L.A. Pharma may terminate the Exclusive License Agreement if we have not brought the payments current within three business days of receipt of notice from S.L.A. Pharma. If the Exclusive License Agreement 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 trial for VEN 307 and we terminate the Exclusive License Agreement within 30 days of the change in control, we must pay the balance of all payments (including the contingent $1,000,000 and $400,000 payments) 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 trial for VEN 307 and we terminate the Exclusive License Agreement within 30 days of the change in control, we must pay the balance of all payments (including the contingent $1,000,000 and $400,000 payments) 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 stockholders 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 U.S. patent for VEN 307 for topical treatment of pain associated with anal fissures was filed with the PTO on August 12, 1999 (No. 09/335,928) and a notice of allowance was issued by the PTO on May 26, 2011. A patent application was filed under the Patent Treaty Cooperation Act on February 23, 1998, entered the national stage in Canada on August 23, 1999 and a patent was issued on November 11, 2006 (No. 2,281,755). The expiration date for the patent in both the U.S. and Canada is February 23, 2018, if all maintenance fees are paid. The patent was filed in the name of Michael A. Kamm and Robin K. S. Phillips as the inventors and S.L.A. Pharma as the assignee.

The U.S. patent expires in February 2018. If approved, VEN 307 will have three years of data exclusivity in the U.S. under the Hatch-Waxman Act.

A patent application for VEN 308 for fecal incontinence was filed under the Patent Treaty Cooperation Act on December 23, 1997, entered the national stage in the U.S. on August 24, 1999 and in Canada on June 18, 1999. A patent was issued in the U.S. on October 21, 2003 (No. 6,635,678) and in Canada on March 18, 2008 (No. 2,275,663). The expiration date for the patent in both the U.S. and Canada is December 23, 2017, if all maintenance fees are paid. The patent was filed in the name of Michael A. Kamm and Robin K. S. Phillips as the inventors and S.L.A. Pharma as the assignee.

Under the S.L.A. Pharma Exclusive License Agreement, we are also responsible for the costs of prosecution of the patents, as well as any new patent filings for the licensed products. While we will pay these costs, S.L.A. Pharma will retain ownership of the patents although we will have the rights to license the technology underlying the patents for the duration of the Exclusive License Agreement.

Competition

As of the date of this prospectus, we believe that there are no FDA-approved products that compete with VEN 309 and VEN 308 nor are we aware of any products that could potentially compete against any of our products for which FDA approval is currently being sought. However, a competing product could be filed for FDA approval in the future. Further, non-FDA-approved products could be introduced in the future that could compete with our planned products.

In late June 2011, ProStrakan Group plc received approval for Rectiv, a 0.4% concentration of nitroglycerin in ointment to be applied intra- and peri-anally twice daily for the treatment of pain associated with chronic anal fissures for a duration of up to three weeks. The U.S. label (professional package insert) for Rectiv lists headache occurring in 64% of patients with 938 headaches occurring in 79 patients, in the one pivotal trial described.

The American Gastroenterology Association, in a technical review of anal fissure management in 2003 (Madoff, R.D. & Fleshman, J.W. (2003) AGA Technical Review on the Diagnosis and Care of Patients With Anal Fissure, *Gastroenterology*, 124, 235–245) states, “Based on the relatively limited data available to date, topical anal fissure therapy with calcium-channel blockers appears to be roughly as effective as treatment with topical nitrates. Moreover, the side effect profile of topical calcium-channel blockers appears superior, specifically with respect to fewer reported headaches.” Rectiv is a topical nitrate.

In the U.S., topical nitroglycerin, compounded in a twice daily ointment has been used for over a decade while diltiazem cream has been in use for approximately five to seven years. Solvay Pharmaceuticals Inc., the original licensee for VEN 307 in the U.S., commissioned in 2003 an extensive quantitative market research study by Eidetics in 206 general practitioners, gastroenterologists and colorectal surgeons. In 2003, compounded topical nitroglycerin had been in use for several years but diltiazem cream had not yet seen appreciable use. The product profile presented to physicians described equivalent efficacy of diltiazem to nitroglycerin for pain relief and healing, but also described meaningful differences in headache incidence, and this is the comparative profile we expect if VEN 307 is approved. In response to this comparative profile, diltiazem was the preferred prescription treatment for anal fissures with 35% overall preference share for topical diltiazem, 23% for topical hydrocortisone and 14% for topical nitroglycerin.

Topical nitroglycerin has also been marketed in the U.K. and other European countries and elsewhere as Rectogesic™ since 2007 while at the same time diltiazem cream, though not approved, has been used on a named patient basis or compounded. The professional label in Europe for Rectiv marketed as “Rectogesic” lists headaches as being very common with a 63% incidence of which 45% were moderate or severe. Indeed,

the Association of Coloproctology of Great Britain and Ireland in their guidelines of 2008 (Cross, K.L.R., et al., (2008), The Management of Anal Fissure: ACPGBI Position Statement, Colorectal Disease, 10 (Suppl. 3), 1-7) states that, " Topical diltiazem has similar efficacy to GTN (nitroglycerin) but with fewer side effects and should be recommended as first line treatment in the management of anal fissure".

Based on results of previously published trials (such as Kocher et al. 2002 and Shrivastava 2007, see **Table 1** above under the heading "Diltiazem Cream (VEN 309) Development – Investigator-initiated clinical studies (studies sponsored by individual clinicians)", we believe that the efficacy of diltiazem cream is likely to be similar to Rectiv in the relief of pain from chronic anal fissures while we believe that the side effects, particularly moderate and severe headaches, are likely to be substantially less than those observed with topical nitroglycerin, and we expect to observe this in our subsequent trials some or all of which are expected to have a comparative arm of Rectiv. Consequently, considering existing professional society views in the U.S. and the U.K., even though VEN 307 is not yet approved in those countries, and considering existing data (some of which is directly comparative) on both products, we believe that, if approved, VEN 307 will be highly competitive with Rectiv.

In addition, an Israeli company, RDD Pharma Ltd., has recently completed in Israel a 20 patient single-arm open label study of the effect of coated suppositories of nifedipine on pain and healing in the treatment of chronic anal fissures.

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. We believe that key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price and reimbursement.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the indications we are targeting could render our drugs non-competitive or obsolete.

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 trials are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase I trials 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.

U.S. 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. This 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 or route of administration.

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 — six 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 U.S. 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

We and our 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, we or our 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 we or our 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.

Employees

As of June 30, 2011, we had five employees and had contracted with three consultants on manufacturing, preclinical and clinical aspects of our drug programs. We use these consulting agreements to avoid the costs customarily associated with employees until our financial resources will allow us to hire additional 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, and study start up procedures necessary to allow the first Phase III clinical trial of VEN 309 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.

Properties

We occupy space on the 5th floor at 99 Hudson Street, New York, New York 10013. We rent this space pursuant to a lease that runs until June 2012. 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.

Legal Proceedings

We are not a party to any legal proceedings and we are not aware of any claims or actions pending or threatened against us. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

MANAGEMENT

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 of Directors. Our Board has set the number of directors at five. In the future, the Board might decide to increase the number of directors, within the range, if suitable candidates with desired experience and expertise are found.

Because our common stock is listed on the NASDAQ Capital Market, our Board applies 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. Thomas Rowland is not deemed independent because he was our Chief Executive Officer from April 2007 through February 2009. Russell H. Ellison is not independent because he is our current 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.

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., M.Sc.	63	Director and Chief Executive Officer and Chief Medical Officer
Thomas Rowland	45	Director
Joseph Felder, M.D.	50	Director
Myron Z. Holubiak	64	Director
Mark Auerbach	73	Director
David J. Barrett	35	Chief Financial Officer

Officers & Directors

Name	Age (as of 06/30/11)	Director Since	Business Experience
Mark Auerbach	73	2010	Mr. Auerbach was elected to our Board in November 2010. Over the last 17 years, Mr. Auerbach has served as a director for several companies. Mr. Auerbach currently is a director and chairman of the audit committee of Optimer Pharmaceuticals, Inc. (NASDAQ: OPTR), a publicly traded biopharmaceutical 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 Holdings, Inc., 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 company 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.

Name	Age (as of 06/30/11)	Director Since	Business Experience
Russell H. Ellison, M.D., M.Sc.	63	2010	Dr. Ellison joined us as a director, Chief Executive Officer and Chief Medical Officer in June 2010. He was elected Chairman of our Board in January 2011. From July 2007 to January 2010, Dr. Ellison 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 Roche Laboratories, Inc., USA, a pharmaceutical company. From July 2007 until December 2010, Dr. Ellison served as a director of CorMedix, Inc. (NYSE Amex: CRMD), a pharmaceutical company that went public in March 2010. He currently serves as a director of 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 directors 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.

Name	Age (as of 06/30/11)	Director Since	Business Experience
Joseph Felder, M.D.	50	2008	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 B.S. from the City University of New York and his M.D. 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, especially in the gastroenterology field, led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

Name	Age (as of 06/30/11)	Director Since	Business Experience
Myron Z. Holubiak	64	2010	Mr. Holubiak joined our Board of Directors in July 2010. Mr. Holubiak currently serves as President of 1-800-DOCTORS, Inc., a physician referral service, 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 Marina Biotech, Inc. 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 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.

Name	Age (as of 06/30/11)	Director Since	Business Experience
Thomas Rowland	45	2007	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. He continued these consulting services from March 2009 to January 2010. In February 2010, Mr. Rowland became Vice President of Commercial Development for Alnara Pharmaceuticals, Inc., which was acquired by Eli Lilly and Company. Mr. Rowland currently is a Product Director for Eli Lilly. 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, Mr. Rowland successfully led the turnaround of the gastrointestinal franchise, returning the franchise to positive sales growth, record sales and profitability. Mr. Rowland had the 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, he has contributed to several product, franchise and company turnarounds in senior management roles. 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 our Board of Directors in May 2010, a position he held until January 2011.

Name	Age (as of 06/30/11)	Business Experience
David J. Barrett	35	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. (NHPI.PK), a publicly traded 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 became a director of Coronado BioSciences, Inc., a biopharmaceutical company, in May 2011. 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.

Board Appointment and Observation Rights

In consideration of his guaranteeing an $800,000 promissory note we issued to Israel Discount Bank of New York in September 2010 (that was repaid in January 2011), we entered into a letter agreement with Dr. Lindsay A. Rosenwald, M.D. 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. Dr. Rosenwald's rights terminate upon the earlier to occur of: (a) August 30, 2015, (b) the merger, consolidation or sale of all or substantially all of our stock or assets in a transaction or series of transactions immediately after which our stockholders immediately before the transaction hold less than 50% of the outstanding voting securities of the surviving corporation, or (c) Dr. Rosenwald's ownership of our company is less than 5% of our outstanding shares of capital stock, name of which events has occurred as of the date of this proxy statement.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth all compensation we paid in the fiscal years ended December 31, 2010 and 2009 to our named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	All Other Compensation[2] ($)	Total ($)
Russell H. Ellison, M.D., M.Sc.[3]	2010	—	—	$2,785,384	$ 210,000	$ 2,995,384
President and CEO	2009	—	—	—	—	—
David J. Barrett [4]	2010	—	—	$1,485,541	$ 105,000	$ 1,590,541
Chief Financial Officer	2009	—	—	—	—	—

(1) The reported amount in the table above of the stock option grants made in 2010 represents the aggregate grant date fair value of the options computed in accordance with FASB ASC Topic 718.

(2) Consists of consulting fees. Prior to December 20, 2010, Dr. Ellison and Mr. Barrett served pursuant to consulting contracts and were not employees.

(3) Dr. Ellison entered into a consulting agreement with us in June 2010 and was hired as an employee on December 22, 2010.

(4) Mr. Barrett entered into a consulting agreement with us in June 2010 and was hired as an employee on December 22, 2010.

Option Holdings and Fiscal Year-End Option Values

The following table shows information concerning unexercised options outstanding as of December 31, 2010 for each of our named executive officers.

Outstanding Equity Awards at Fiscal Year-End 2010

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Russell H. Ellison	191,200	382,399	6.00	12/22/20
David J. Barrett	101,973	203,947	6.00	12/22/20

Employment Agreements

Chief Executive Officer

Dr. Ellison serves as our Chief Executive Officer pursuant to an amended and restated employment agreement, which became effective upon the closing of our initial public offering on December 22, 2010. The agreement has a term of three years. 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 based on financial, clinical development and business milestones established by the Board. 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. Pursuant to the agreement, at the completion of our initial public offering, Dr. Ellison received a grant of options to purchase 573,599 shares of our common stock at the initial public offering price of $6.00. This amount was equal to 7.5% of our fully diluted capitalization on that date, 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 2007 Stock Incentive Plan. One third of the options vested 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, provided that these provisions will not apply if we do not renew the agreement.

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 or by Dr. Ellison without Good Reason

If we terminate Dr. Ellison for cause (as defined in the agreement) or if he terminates without good reason (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 by us other than for cause or by Dr. Ellison for good reason (as defined in the agreement), then we must pay Dr. Ellison his then current base salary and all fringe benefits for a period of six months following such termination, any accrued but unpaid bonus, and any expense reimbursement amounts owed through the date of termination. All stock options granted to Dr. Ellison that are scheduled to vest by the end of the term of the employment agreement will be accelerated and deemed to have vested as of the termination date. Stock options that have vested as of Dr. Ellison's termination will remain exercisable for 360 days following his termination.

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 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.

From June 2010 to December 22, 2010, Dr. Ellison served as our Chief Executive Officer pursuant to a consulting agreement, pursuant to which he was paid $30,000 per month.

Chief Financial Officer

Mr. Barrett serves as our Chief Financial Officer pursuant to an amended and restated employment agreement that became effective upon the closing of our initial public offering on December 22, 2010. The agreement has a term of three years. The employment agreement provides for 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. Pursuant to the agreement, Mr. Barrett received a grant of options to purchase our common stock at the initial public offering price of $6.00 in an amount equal to 4.0% of our fully diluted capitalization on the date the employment agreement became 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 options vested 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 or by Mr. Barrett without Good Reason

If we terminate Mr. Barrett for cause (as defined in the agreement) or if he terminates without good reason (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. Stock options that have vested as of Mr. Barrett's termination will remain exercisable for 360 days following his termination.

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.

From June 2010 to December 22, 2010, Mr. Barrett served as our Chief Financial Officer pursuant to a consulting agreement, pursuant to which he was paid $15,000 per month.

Equity Compensation Plan Information

The following table sets forth the indicated information as of December 31, 2010 with respect to our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by our shareholders:			
2007 Stock Incentive Plan	2,016	$ 6.00	-0-
2010 Equity Incentive Plan	1,077,759	$ 6.00	1,389,441
Equity compensation plans not approved by our shareholders:			
2008 Placement Agent Warrants	42,782	$ 12.40	-0-
Licensor Warrants	13,605	$ 1.24	-0-
Consultant Warrants	87,770	$ 6.22	-0-
2010 Placement Agent Warrants	89,000	$ 7.50	-0-
Underwriter Warrants	197,200	$ 7.50	-0-
Total	1,510,132	$ 6.44	1,389,441

Our equity compensation plans consist of the 2007 Stock Incentive Plan and the 2010 Equity Incentive Plan, both of which were approved by our stockholders. Our equity compensation arrangements that have not been approved by our stockholders consist of warrants to purchase shares of our common stock issued to: Paramount BioCapital as placement agent in our 2008 common stock offering; S.L.A. Pharma to whom we issued a warrant for 13,605 shares as part of an amendment to the license agreement between us and S.L.A. Pharma for VEN 307 and VEN 308; three consultants; National Securities Corporation as placement agent in our 2010 convertible note offering; and the underwriters of our IPO.

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 plan reserved up to 483,871 shares of our common stock. 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

Our 2010 Equity Incentive Plan was adopted and approved in July 2010. On adoption, an aggregate of 2,467,200 shares was reserved for issuance thereunder. On May 19, 2011, our stockholders approved an increase in the number of shares reserved for issuance to 3,967,200 shares. As of June 30, 2011, we had issued and outstanding a total of 1,956,439 options under the 2010 Plan, leaving 2,010,761 available for issuance under the 2010 Plan. Of these outstanding grants, 879,519 have been granted to our two executive officers, 302,680 have been granted to other employees, 410,000 to our non-employee directors and 364,240 to consultants.

DIRECTOR COMPENSATION

The following table shows the compensation earned by each of our non-employee directors for the year ended December 31, 2010.

Non-Employee Director Compensation in Fiscal 2010

Name[1]	Fees Earned or Paid in Cash	Option Awards ($)[2]	All Other Compensation ($)	Total ($)
Mark Auerbach	$ -0-	$ 168,653	-0-	$ 168,653
Joseph Felder	-0-	178,739	-0-	178,739
Myron Holubiak	-0-	168,653	-0-	168,653
Thomas Rowland	-0-	168,653	-0-	168,653
Richard Cohen[3]	-0-	96,373	-0-	96,373

(1) As of December 31, 2010, our non-employee directors held options to purchase the following number of shares of our common stock: Mr. Auerbach, 35,000 shares; Dr. Felder, 37,016 shares; Mr. Holubiak, 35,000 shares; and Mr. Rowland, 35,000 shares.

(2) The reported amount in the table above of the stock option grants made in 2010 represents the aggregate grant date fair value of the options computed in accordance with FASB ASC Topic 718.

(3) Mr. Cohen resigned from the Board on November 10, 2010.

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 our 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 our initial public 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 vest in three equal annual installments after the respective vesting commencement date.

SECURITIES 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 June 30, 2011, for:

- each of our named executive officers in the "Summary Compensation Table" on page 88;
- 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.

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 June 30, 2011, 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.

The percentage ownership calculations are based on 7,229,183 shares outstanding on June 30, 2011. 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., 99 Hudson Street, 5th Floor, New York, New York 10013.

Name of Beneficial Owner	Shares Beneficially Owned	Percentage Owned (%)
Mark Auerbach(1)	11,666	*
Russell H. Ellison(2)	199,264	2.7%
Joseph Felder(3)	37,016	*
Myron Holubiak(4)	23,332	*
Thomas Rowland(5)	136,721	1.9%
David J. Barrett(6)	101,973	1.4%
Lindsay A. Rosenwald, M.D.(7) c/o Paramount Biosciences, LLC 787 7th Avenue, 48th Floor New York, New York 10019	1,172,484	15.8%
Elliott Associates, L.P.(8) 712 Fifth Avenue, 36th Floor New York, New York 10019	622,158	8.6%
All directors and executive officers as a group (6 persons)(9)	509,972	6.6%

* Less than 1%.

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

(2) Consists of (i) 8,065 shares of our common stock issuable upon exercise of a warrant and (ii) 191,199 shares of our common stock issuable upon exercise of an option.

(3) Consists of 37,016 shares of our common stock issuable upon exercise of options.

(4) Consists of 23,332 shares of common stock issuable upon exercise of an option.

(5) Includes 118,334 shares of our common stock issuable upon exercise of options.

(6) Consists of 101,973 shares of our common stock issuable upon exercise of an option.

(7) Includes (i) 797,785 shares of common stock and 187,507 shares of common stock underlying warrants held by Paramount BioSciences, LLC, of which Dr. Rosenwald is the sole member, (ii) 51,136 shares held by Capretti Grandi, LLC, an affiliate of Dr. Rosenwald, and (iii) 19,981 shares issuable upon the exercise of warrants held by National Securities Corporation, of which Opus Point Partners, an entity in which Dr. Rosenwald is a general partner. 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 and 28,400 shares issuable upon the exercise of warrants 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) Based on information contained in a Schedule 13G filed with the SEC on December 27, 2010. According to the Schedule 13G, Elliott Associates, L.P. owns the shares through Manchester Securities Corp., which is a wholly owned subsidiary of Elliott Associates, L.P.

(9) Includes the shares described in footnotes (1) through (7).

DESCRIPTION OF CAPITAL STOCK

Common Stock

Our authorized capital stock consists of 50,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of June 30, 2011, we had outstanding 7,229,183 shares of common stock, held of record by 208 stockholders, and no shares of preferred stock. The 208 stockholders of record exclude stockholders whose shares are held in nominee or street name by brokers. We believe that, when our record holders and stockholders whose shares are held in nominee or street name by brokers are combined, we have an aggregate of approximately 1,000 stockholders.

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 does not have the authority to establish the rights and preferences of shares of preferred stock 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 June 30, 2011, we had outstanding options to purchase an aggregate of 1,956,439 shares of common stock and 2,010,761 shares of common stock are available for future issuance under the 2010 Equity Incentive Plan.

Warrants

As of June 30, 2011, we had a warrant outstanding to purchase an aggregate of 8,065 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, for consulting services. This 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, this warrant will expire on November 8, 2014.

As of June 30, 2011, we had warrants outstanding to purchase an aggregate of 39,657 shares of our common stock with an exercise price of $12.40 per share issued to various designees of Paramount BioCapital, Inc. The warrants, in the original amount of 42,782 shares, were originally issued to Paramount BioCapital as part of its compensation for acting as placement agent in our 2008 common stock and warrant financing. 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, this warrant will expire on December 21, 2014.

As of June 30, 2011, we had 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 June 30, 2011, we had warrants outstanding to purchase an aggregate of 104,867 shares of common stock with an exercise price of $6.60 per share issued to the equity holders of 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 $0.001 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 June 30, 2011, we had warrants to purchase an aggregate of 426,454 shares of common stock with an exercise price of $6.60 per share issued to investors in our 2010 senior convertible note financing. Each of these warrants is redeemable at a price of $0.001 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 June 30, 2011, we had a warrant outstanding to purchase 76,480 shares of our common stock with an exercise price of $6.00 issued to a consultant. 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 June 30, 2011, we had warrants outstanding to purchase an aggregate of 82,627 shares of common stock with an exercise price of $7.50 issued to National Securities Corporation and its employees as part of its compensation for acting as placement agent in our 2010 senior convertible note financing. Each of these warrants is redeemable at a price of $0.001 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.

As of June 30, 2011, we had a warrant outstanding to purchase 13,605 shares of our common stock with an exercise price of $1.24 issued to S.L.A. Pharma. Unless earlier exercised, this warrant will expire on August 30, 2013.

As of June 30, 2011, we had warrants outstanding to purchase an aggregate of 197,200 shares of common stock with an exercise price of $7.50 issued to National Securities Corporation and Rodman & Renshaw, or their designees, as part of their underwriting compensation in our initial public offering in December 2010. These warrants are exercisable beginning on December 16, 2012. 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 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, these warrants will expire on December 16, 2016.

Registration Rights

Holders of an aggregate of 850,000 shares of our common stock and an aggregate of approximately 912,000 shares of our common stock issuable upon the exercise of warrants are 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. The underwriters in this offering did not allow any shares to be included in the registration statement of which this prospectus is a part. As a result, we intend to file a registration statement covering the resale of these shares as soon as possible after the closing of this offering.

In addition, if we do not voluntarily file a registration statement as planned, 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.

Lock-up Agreements

In connection with this offering, we, our officers and directors, and our largest stockholder have each entered into a lock-up agreement with the underwriter of this offering that restricts the sale of shares of our common stock by those parties for a period of 90 days after the date of this prospectus, subject to exceptions and 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.”

Transfer Agent and Registrar

Our transfer agent is VStock Transfer, LLC. The transfer agent’s address is 77 Spruce Street, Cedarhurst, New York 11516 and its telephone number is (212) 828-8436.

NASDAQ Capital Market

Our common stock is listed on the NASDAQ Capital Market under the ticker “VTUS.”

Anti-takeover Effects of our Bylaws and Delaware Law

Provisions of our 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. 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 shareholders) will be filled by a majority of our Board then in office.

No Shareholder Action by Written Consent

Our bylaws expressly eliminate the right of our shareholders to act by written consent. Shareholder action must take place at the annual or special meeting of our shareholders.

Special Shareholder Meetings

Our bylaws provide that only our Board or such person or persons designated by our Board may call special meetings of our shareholders.

Requirements for Advance Notification of Shareholder Nominations and Proposals

Our bylaws have advance notice procedures with respect to shareholder 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 shareholder of record who has given timely written notice to our secretary of that shareholder'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 Section 203, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with any interested shareholder for a period of three years following the time that such shareholder became an interested shareholder, unless:

- prior to such time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the shareholder becoming an interested shareholder; or
- upon consummation of the transaction that resulted in the shareholder becoming an interested shareholder, the interested shareholder 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 shareholders, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested shareholder. The shareholders cannot authorize the business combination by written consent.

The application of Section 203 may limit the ability of shareholders 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 shareholder; 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 shareholder; 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 shareholder; 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 shareholder; or
- the receipt by the interested shareholder 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 shareholder" 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 shareholder" to effect various business combinations with a corporation for a three-year period, although the shareholders 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 shareholder 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 shareholder becoming an interested shareholder.

No Cumulative Voting

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

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

As of June 30, 2011, Dr. Lindsay A. Rosenwald beneficially owned approximately 15.8% of our issued and outstanding common stock, including shares issuable upon the exercise of warrants. Dr. Rosenwald is our largest stockholder. 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.

Effective April 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, phenylephrine and iferanserin, and corporate, legal and accounting services. This agreement was terminated as of August 31, 2008, but as of March 31, 2011 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.

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 Dr. Rosenwald, under each of which we could draw funds as approved by the respective noteholder. These notes had identical terms. 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 from whom we license iferanserin (VEN 309). 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 then current principal balance to $811,153. As of December 22, 2010, the aggregate principal amount outstanding under these notes was $1,001,153, all of which, pursuant to the terms of the notes, converted into an aggregate of 269,449 shares of our common stock upon the completion of our initial public offering on December 22, 2010.

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, subsequent to our initial public offering, 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 closing of this offering will trigger the repayment obligation and we will use a portion of the proceeds of this offering to repay this obligation. In addition, PCP received five-year warrants to purchase, at an exercise price of $6.60, which was 110% of the issue price in our initial public offering, 104,867 of shares of our common stock, which was equal to 40% of the principal amount of each PCP Note purchased divided by the issue price in our initial public offering of $6.00.

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 accrued and was 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 was to mature on November 5, 2010, and reduced the aggregate amount available under the line of credit to $1,000,000. 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 Sam Amer & Co., Inc., from whom we license diltiazem cream (VEN 307) and phenylephrine gel (VEN 308), and severance payments to our former

executive officers Thomas Rowland, Terrance Coyne and John Dietrich in the aggregate of $161,459. The amounts borrowed by us under this line of credit totaled $320,000 and were due on November 5, 2010, on which date 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 was guaranteed by Dr. Rosenwald. The interest rate on the note was equal to the interest rate that Israel Discount Bank paid on the cash accounts at the Bank maintained by Dr. Rosenwald and pledged to secure the note, plus 1%. The note was 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. We repaid this note in January 2011.

On November 5, 2010, we borrowed $420,000 under a line of credit from Israel Discount Bank of New York. The line of credit was guaranteed by Dr. Rosenwald. The interest rate on the line of credit was equal to the interest rate that Israel Discount bank paid on the cash accounts at the Bank maintained by Dr. Rosenwald and pledged to secure the line of credit, plus 1%. The line of credit was due on demand or on November 4, 2011. We repaid the amount owed under the line of credit in January 2011.

In December 2010, we entered into an underwriting agreement with National Securities Corporation and Rodman & Renshaw in connection with our initial public offering. Dr. Rosenwald owns, indirectly, through Opus Point Partners, LLC, a controlling interest in National Holdings Corporation, the 100% owner and parent of National Securities Corporation. Pursuant to the underwriting agreement, we paid National and Rodman cash fees of $1,662,400, which included underwriting discounts of $1,261,500 and non-accountable expense reimbursements of $261,000. In addition, we issued to each of National and Rodman five-year warrants to purchase an aggregate of 98,600 shares of common stock with an exercise price of $7.50.

From June 2010 through April 2011, we occupied 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 was no written agreement for this arrangement between us and Paramount BioSciences.

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

UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement dated the date of this prospectus among us and the underwriters named below, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase from us, the number of shares of common stock set forth opposite the underwriter's name in the following table. Leerink Swann LLC and Lazard Capital Markets LLC are acting as joint book-running managers for the offering and as representatives of the underwriters.

Name	Number of Shares
Leerink Swann LLC	2,250,000
Lazard Capital Markets LLC	1,800,000
National Securities Corporation	225,000
Rodman & Renshaw, LLC	225,000
Total	4,500,000

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the shares of common stock covered by the underwriters' over-allotment option described below.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Discounts and Commissions

The underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $0.36 per share. After the initial offering of the shares, the public offering price and other selling terms may be changed by the representatives.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Without Option	With Option
Public offering price	$ 10.00	$ 45,000,000	$51,750,000
Underwriting discounts and commissions	$ 0.60	$ 2,700,000	$ 3,105,000
Proceeds, before expenses, to us	$ 9.40	$ 42,300,000	$48,645,000

The total estimated expenses of the offering, including registration, filing and listing fees, printing fees, the financial advisory fees described below and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately $1.0 million and are payable by us.

Upon the closing of this offering, we will pay to National Securities Corporation a financial advisory fee of $120,000 and to Rodman & Renshaw, LLC a financial advisory fee of $60,000. The financial services provided by Rodman & Renshaw, LLC and National Securities Corporation include assistance in valuation analysis and advice with respect to market conditions, the timing and structure of the offering and execution strategy related to the offering. Both Rodman & Renshaw, LLC and National Securities Corporation are assisting us on a non-exclusive basis in identifying, analyzing, structuring, negotiating and consummating one or several transactions that may include strategic introductions, potential joint venture opportunities and marketing agreements, as well as assisting us in analyzing and reviewing comparative issuer and industry metrics and statistics in order to evaluate market opportunities.

Upon the closing of this offering, we will pay to Torreya Capital, a division of the Financial West Investment Group, member FINRA/SIPC, LLC, or Torreya, a financial advisory fee equal to 1% of the aggregate gross proceeds of this offering. Financial advisory services provided by Torreya include assistance in financial analysis and advice with respect to the offering process and equity capital market alternatives. We are also obligated to reimburse Torreya for out-of-pocket expenses up to a maximum of $5,000. Torreya is not acting as an underwriter in connection with this offering.

Lazard Frères & Co. LLC referred this transaction to Lazard Capital Markets LLC and will receive a referral fee from Lazard Capital Markets LLC in connection therewith.

Over-Allotment Option

We have granted the underwriters an option to purchase up to 675,000 additional shares of common stock at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option for 30 days from the date of this prospectus solely to cover sales of shares of common stock by the underwriters in excess of the total number of shares set forth in the table above. If any shares are purchased pursuant to this over-allotment option, the underwriters will purchase the additional shares in approximately the same proportion as shown in the table above. If any of these additional shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered. We will pay the expenses associated with the exercise of the over-allotment option.

Conflicts of Interest

Dr. Lindsay A. Rosenwald and his affiliates currently beneficially own approximately 15.8% of our issued and outstanding capital stock, including any shares issuable upon the exercise of warrants. 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 pursuant to FINRA Rules. Additionally, we intend to repay certain promissory notes issued to Paramount Credit Partners, LLC using the net proceeds of the offering received by us. Dr. Rosenwald is the sole member of Paramount Credit Partners, LLC, and therefore Paramount Credit Partners, LLC is also deemed to be under "common control" with National Securities Corporation pursuant to FINRA rules.

Because we are under common control with National Securities Corporation, and because we intend to use over 5% of the net proceeds of this offering to repay promissory notes to Paramount Credit Partners, LLC, a "conflict of interest" is deemed to exist under the applicable provisions of Rule 5121 of the FINRA rules. Accordingly, this offering will be made in compliance with the applicable provisions of FINRA Rule 5121. Neither Leerink Swann LLC nor Lazard Capital Markets LLC, who will act as lead underwriters, nor any affiliates of Leerink Swann LLC nor Lazard Capital Markets LLC have a conflict of interest as defined in FINRA Rule 5121. Therefore, a "qualified independent underwriter" will not be necessary for this offering.

Lock-Up Agreements

We, our officers and directors and Dr. Lindsay A. Rosenwald, our largest stockholder, have entered into lock-up agreements with the underwriters. Under these agreements, we and these other individuals have agreed, subject to specified exceptions, not to sell or transfer any common stock or securities convertible into, or exchangeable or exercisable for, common stock, during a period ending 90 days after the date of this prospectus, without first obtaining the written consent of Leerink Swann LLC and Lazard Capital Markets LLC. Specifically, we and these other individuals have agreed not to:

- offer, pledge, sell or contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock (except, in the case of Dr. Rosenwald, the lock-up only applies to an aggregate of 714,996 of his shares); or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described above is to be settled by delivery of common stock or other securities, in cash or otherwise.

The restrictions described above do not apply to:

- with respect to us:
  - the sale of shares of common stock to the underwriters pursuant to the underwriting agreement;
  - the issuance or sale of our common stock or options to purchase our common stock pursuant to our 2007 Stock Incentive Plan or our 2010 Equity Incentive Plan of which the underwriters have been advised in writing or that is described in this prospectus; or
  - the issuance of our common stock issuable upon the exercise of warrants currently outstanding of which the underwriters have been advised in writing or that is described in this prospectus;
- with respect to our directors, officers and Dr. Rosenwald:
  - the transfer, during the restricted period, of shares of our common stock in accordance with the provisions of a plan designed to comply with Rule 10b5-1(c) of the Exchange Act, as currently in effect and without regard to any subsequent amendments or modifications thereto or reinstatements thereof;
  - the exercise of equity awards that expire or are otherwise required to be exercised during the restricted period, but not the sale of the securities acquired through such exercise;
  - the sale of securities to us in connection with cashless exercise of options or the payment of taxes relating to the vesting of restricted stock; or
  - transfers of shares of our common stock or any security convertible into our common stock either during the respective director's or officer's lifetime or upon death by will or intestate succession to the immediate family of the director or officer or to a trust the beneficiaries of which are exclusively the respective director or officer and/or a member or members of his or her immediate family;

provided that in the case of each of any transfer or distribution in the preceding bullet, each transferee or distributee signs and delivers a lock-up agreement agreeing to be subject to the restrictions on transfer described above and no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, is required or is voluntarily made during the restricted period.

The 90-day restricted period is subject to extension if (1) during the last 17 days of the restricted period we issue an earnings release or material news or a material event relating to us occurs or (2) prior to the expiration of the restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the restricted period, in which case the restrictions imposed in the lock-up agreements will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

The NASDAQ Capital Market Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol "VTUS."

Price Stabilization, Short Positions and Penalty Bids

In order to facilitate the offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of common stock in the offering. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares of common stock in the open market. In determining the source of shares of common stock 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. “Naked” short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. 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 our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of our common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

The underwriters make no representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in the offering. The underwriters or selling group members may distribute prospectuses by any electronic means, including but not limited to e-mail distributions.

The underwriters may agree to allocate a number of shares of common stock to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters’ websites and any information contained in any other website maintained by the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part.

Notice to Non-U.S. Investors

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive, each of 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, or the relevant implementation date, an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- To legal entities that 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;
- To any legal entity that has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- To fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of representatives for any such offer; or
- In any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive;

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares of common stock 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 for the shares, as the same may be varied in that member state by any measure implementing the Prospectus Directive in that member state and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

Other Relationships

From time to time, certain of the underwriters and their affiliates have provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions.

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. Ropes & Gray LLP, Boston, Massachusetts, is acting as counsel for the underwriters in connection with this offering.

EXPERTS

The balance sheets of Ventrus Biosciences, Inc. as of December 31, 2010 and 2009 and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2010, and for the period from October 7, 2005 (inception) to December 31, 2010 have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein. Such financial statements have been incorporated herein in reliance on the report of such firm given upon 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

To the Board of Directors and Stockholders of
Ventrus BioSciences, Inc.

We have audited the accompanying balance sheets of Ventrus BioSciences, Inc. (a development stage company) (the "Company") as of December 31, 2010 and 2009, and the related statements of operations, stockholders' equity (deficiency) and cash flows for each of the years then ended and for the period October 7, 2005 (inception) to December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting as of December 31, 2010. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit 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, 2010 and 2009 and the results of its operations and cash flows for each the years then ended and for the period October 7, 2005 (inception) to December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

New York, New York
April 12, 2011

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Balance Sheets

	December 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash	**$ 14,571,055**	**$ 81,288**
Other current assets	**18,915**	**2,519**
Total current assets	**14,589,970**	**83,807**
Computer equipment, net of accumulated depreciation of $27,260 and $14,734	**—**	**12,525**
Deferred financing costs, net	**26,631**	**69,922**
Total assets	**$ 14,616,601**	**$ 166,254**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Borrowings under short-term note and line of credit	**$ 419,380**	**$ 320,000**
Accounts payable	**312,896**	**398,055**
Accrued expenses		
License fees	**—**	**2,919,423**
Other	**—**	**$ 44,982**
2007 Senior convertible notes	**—**	**5,305,000**
Interest payable – 2007 senior convertible notes	**—**	**986,838**
Notes payable – Paramount BioSciences, LLC	**—**	**2,215,591**
Interest payable – Paramount BioSciences, LLC	**—**	**59,719**
Term Note – bank	**800,000**	**—**
Interest payable – related party	**187,536**	**107,840**
Total current liabilities	**1,719,812**	**12,357,448**
Notes payable – Paramount Credit Partners, LLC (net of discount of $302,327 in 2010 and $401,546 in 2009)	**1,270,673**	**1,171,454**
Total liabilities	**2,990,485**	**13,528,902**
Commitments (See Notes 5 and 7)		
Stockholders' equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized, none issued	**—**	**—**
Common stock, $.001 par value; 25,000,000 authorized; 6,746,365 and 447,347 issued and outstanding at December 31, 2010 and 2009 respectively	**6,746**	**447**
Additional paid-in capital	**44,803,724**	**4,530,634**
Deficit accumulated during the development stage	**(33,184,354)**	**(17,893,729)**
Total stockholders' equity (deficiency)	**11,626,116**	**(13,362,648)**
Total liabilities and stockholders' equity (deficiency)	**$ 14,616,601**	**$ 166,254**

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statements of Operations

	Year Ended December 31, 2010	Year Ended December 31, 2009	Period from October 7, 2005 (Inception) to December 31, 2010
Operating expenses:			
Research and development	**$ 1,850,667**	$ 2,942,992	$ 14,251,561
General and administrative	**2,915,590**	397,238	5,520,678
Loss from operations	**(4,766,257)**	(3,340,230)	(19,772,239)
Interest income	**5,730**	140	19,719
Interest expense:			
Beneficial conversion feature	**(6,001,496)**	—	(6,001,496)
Amortization of debt discount and warrants	**(2,484,927)**	(78,504)	(2,563,431)
Interest expense	**(2,043,676)**	(1,120,811)	(4,866,908)
	(10,530,099)	**(1,199,315)**	**(13,431,835)**
Net loss	**(15,290,625)**	**(4,539,405)**	**(33,184,354)**
Basic and diluted net loss per common share	**($24.67)**	**($10.02)**	
Weighted average common shares outstanding – basic and diluted	**619,923**	445,040	

VENTRUS BIOSCIENCES, INC.
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Statement of Cash Flows

	Year ended December 31, 2010	Year ended December 31, 2009	Period from October 7, 2005 (Inception) to December 31, 2010
Cash flows from operating activities:			
Net loss	**(15,290,625)**	(4,539,405)	(33,184,354)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	**2,356,087**	123,758	2,957,322
Stock issued in connection with license agreement	**389,597**	25,000	414,825
Charge resulting from beneficial conversion feature	**6,001,496**	—	6,001,496
Stock issued to vendor	**—**	5,000	5,000
Warrants issued in connection with related party note conversion	**915,118**	—	1,255,978
Amortization of deferred financing costs and debt discount	**2,327,193**	116,952	3,137,052
Non-cash research and development	**—**	—	1,087,876
Interest payable – 2007 Senior convertible notes	**611,266**	573,708	1,598,104
Interest payable – 2010 Senior convertible notes	**354,269**	—	354,269
Expenses paid on behalf of the Company satisfied through the issuance of notes	**—**	—	227,910
Interest payable – related parties	**94,912**	55,841	266,27
Interest payable – Paramount Credit Partners, LLC	**79,696**	107,840	187,53
Depreciation	**12,525**	7,511	27,260
Changes in operating assets and liabilities:			
Prepaid research and development	**—**	800,000	—
Other current assets	**(16,396)**	2,649	(18,915)
Accounts payable and accrued expenses	**(3,049,564)**	(762,773)	312,89
Net cash used in operating activities	**(5,214,427)**	(3,483,919)	(15,369,467)
Cash flows from investing activities:			
Purchase of office and computer equipment	**—**	(2,573)	(27,260)
Cash flows from financing activities:			
Net Proceeds from IPO	**15,184,344**	—	15,184,344
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**	1,905,390	5,041,953
Proceeds from 2007 Senior convertible notes	**—**	—	5,305,000
Proceeds from private placement	**—**	—	1,146,024
Payment for deferred financing costs	**(755,092)**	(76,461)	(1,431,603)
Proceeds from utilization of short-term note and line of credit	**99,380**	150,000	419,38
Proceeds from term note payable	**800,000**	—	800,00
Repayment of notes payable – related party	**—**	—	(1,500,000)
Proceeds from receipt of subscriptions	**—**	—	4,684
Net cash provided by financing activities	19,704,194	3,551,929	29,967,782
Net increase in cash	**14,489,767**	65,437	14,571,055
Beginning of period	**81,288**	15,851	—
End of period	**14,571,055**	81,288	$ 14,571,055
Supplemental schedule of non-cash financing activities:			
Warrants issued to placement agent	**$ —**	**—**	**$ 341,334**
Warrants issued to investors in connection with convertible notes	**$ 1,166,989**	**—**	**$ 1,166,989**
Debt discount on Paramount Credit Partners, LLC notes	**$ —**	**—**	**$ 480,049**
Related party notes and accrued interest converted to 2010 Senior convertible notes	**$ 2,192,433**	**—**	**$ 3,995,667**
Notes and accrued interest converted to common stock	**$ 14,003,158**	**—**	**$ 14,003,158**
Supplemental disclosure – cash paid for interest	**$ 76,899**	**$ 344,974**	**$ 408,073**

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Statements of Changes in Stockholders' Equity (Deficiency)
Period from October 7, 2005 (Inception) to December 31, 2010

	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 founders and 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 for the period from January to December 2007	—	—	16,655	—	16,655
Warrants issued in connection with senior convertible notes in 2007	—	—	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 in January, February and March 2008	—	—	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 in June 2008	29,861	30	1,803,204	—	1,803,234
Warrants issued in connection with related party note conversion in June 2008	—	—	340,860	—	340,860
Stock-based compensation for the period from January to December 2008	—	—	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 for the period from January to December 2009	—	—	123,758	—	123,758
Warrants issued in connection with Paramount Credit Partner LLC notes in January, March and June 2009	—	—	480,049	—	480,049
Common Stock issued to licensor in December 2009 at $12.40 per share	2,016	2	24,998	—	25,000
Common Stock issued 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)
Warrant issued to licensor in connection with amendment to the agreement in August 2010	—	—	161,552	—	161,552
Stock based compensation for the period from January to December 2010	—	—	2,194,535	—	2,194,535
Conversion of notes and accrued interest to common stock in December 2010	3,334,085	3,334	13,999,824	—	14,003,158
Beneficial conversion charge recorded on notes and interest converted to common stock in December 2010	—	—	6,001,496	—	6,001,496
Common stock issued in IPO in December 2010, net of related costs	2,900,000	2,900	15,181,444	—	15,184,344
Fair value of warrants issued with Senior convertible notes in December 2010	—	—	2,344,708	—	2,344,708
Common Stock issued to Licensor for amendment in December 2010	64,933	65	389,532	—	389,597
Net loss	—	—	—	(15,290,625)	(15,290,625)
Balance at December 31, 2010	6,746,365	6,746	44,803,725	(33,184,354)	11,626,116

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)
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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 and commenced operations in April 2007. Ventrus is a specialty pharmaceutical company focused on the late-stage development and commercialization of gastrointestinal products.

On December 22, 2010, the Company issued 2,900,000 shares of its common stock in an initial public offering (the "IPO") and raised net proceeds of $15,184,344. On January 7, 2011, the Company issued an additional 435,000 shares of its common stock to fulfill the over-allotment option that it granted to the underwriters as part of the IPO and raised net proceeds of $2,420,775. On December 22, 2010, in connection with the consummation of the IPO, the Company converted $14,003,158 of convertible notes and accrued interest by issuing an aggregate of 3,334,085 shares to holders of the convertible notes. In addition, the Company issued 64,933 shares of its common stock, valued at $389,597 to S.L.A. Pharma, AG, a Swiss corporation ("S.L.A. Pharma") on December 22, 2010 pursuant to the terms of an amendment to a license agreement.

Basis of presentation:

The accompanying audited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

The Company's primary activities since incorporation have been organizational activities, including recruiting personnel, 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 is in the development stage and has funded its operations primarily through the issuance of equity and debt. The Company expects to continue to expend substantial amounts for continued product research, development, and commercialization activities for the foreseeable future. Management believes the Company's funds are sufficient to continue operations through the second quarter of 2012. Management's plans with respect to funding this development are to secure additional equity, if possible, and to secure additional strategic alliances that will provide available cash funding for operations. Continuation of the Company is dependent on its ability to obtain additional financing and, ultimately, on its ability to achieve profitable operations. There is no assurance, however, that such financing will be available or that the Company's efforts ultimately will be successful.

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 and at December 31, 2010, exceed Federally insured limits.

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 2 — Summary of Significant Accounting Policies: – (continued)

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.

Significant estimates inherent in the preparation of the accompanying financial statements include the fair value of stock options and warrants granted to employees, consultants, directors, investors, licensors, placement agents and underwriters.

Computer equipment:

Computer equipment is stated at cost and depreciated using the straight-line method over the estimated useful life of the related assets of three years. At December 31, 2010, computer equipment was fully depreciated.

Stock based compensation:

The Company's 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 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 issued with convertible notes:

For the purpose of valuing the warrants issued with convertible notes (See Notes 3, 8 and 9), the Company used the Black-Scholes option pricing model utilizing the assumptions noted in those Notes. 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 did not have any trading history for its common stock at the time the grants were issued. 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.

In accordance with ASC Topic 470-20, "*Debt with Conversion and Other Options*," 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 effective interest method.

Beneficial Conversion Feature:

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

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 2 — Summary of Significant Accounting Policies: – (continued)

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 (See Notes 3, 8 and 9) and has recorded their effects.

Research and development:

Research and development expenses include personnel and facility-related expenses, third party contract services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where the Company enters into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities, costs are expensed as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

The Company's accruals for clinical trials are based on estimates of the services received and pursuant to contracts with the respective clinical trial centers and clinical research organizations. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received. As such, expense accruals related to clinical trials are recognized based on the estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

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. 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 loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share reflects 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 unless inclusion of such shares would be anti-dilutive. Since the Company has only incurred losses, basic and diluted loss per share is the same. The number of potentially dilutive securities excluded at December 31, 2010 and 2009 was 2,093,064 and 168,885, 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.

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Notes to Financial Statements

Note 3 — Related Party Transactions:

Consulting services:

Effective April 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 is an affiliate of Dr. Lindsay A. Rosenwald, M.D., a significant investor in and stockholder of the Company. This agreement was terminated as of August 31, 2008. For the period from October 7, 2005 (inception) through August 31, 2008, $425,000 was incurred under this arrangement. As of December 31, 2010 and 2009, the Company had $100,000 outstanding under this arrangement, which is included in accounts payable.

Notes payable:

On October 7, 2005, the Company issued a 5% promissory note payable to Paramount BioSciences, LLC ("PBS"), an affiliate of Dr. Rosenwald, to borrow funds as needed. 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 units consisting of one share of common stock and one warrant to purchase common stock 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 a BCF 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 Dr. Rosenwald, to borrow funds as needed. This note and all accrued interest were to mature on July 12, 2010, or earlier if certain events occurred. On June 16, 2008, this note was voluntarily converted into units consisting of one share of common stock and one warrant to purchase common stock 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 1,346 shares of the Company's common stock for which the Company recorded a BCF 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 and April 24, 2009, the Company issued an 8% promissory note to PBS and an 8% promissory note to Capretti Grandi, LLC, another entity related to Dr. Rosenwald, to borrow funds as needed. Originally, all amounts outstanding under these notes matured and were payable on July 23, 2010 and April 24, 2012. On December 21, 2009, these notes were amended to provide that all loans (including principal and accrued interest thereon) made by PBS and Capretti Grandi, LLC 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. These notes were further amended to provide that all remaining amounts outstanding under the notes will automatically convert

VENTRUS BIOSCIENCES, INC.
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Notes to Financial Statements

Note 3 — Related Party Transactions: – (continued)

into the Company's equity securities issued in the Company's next equity 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. As of December 31, 2009, the aggregate principal amount outstanding under these notes was $2,215,591 and the accrued interest due was $59,719. On February 1, 2010, the Company received an additional $950,000 in loan proceeds from PBS. On February 26, 2010, a portion of the PBS notes outstanding ($2,192,433) was converted into 2010 convertible notes (the "2010 Notes"). The Company valued the beneficial conversion feature of the 2010 Notes at $939,614, which was recorded as interest expense after the Qualified Financing was completed. The Company computed the conversion feature to be $939,614 by dividing the amount of debt and interest ($2,192,433), which is convertible into common stock by the conversion rate (70%). From this amount ($3,132,047) the amount of debt and interest ($2,192,433) was subtracted to determine the amount by which the instrument if-converted exceeds the conversion amount ($939,614). On December 22, 2010, in connection with the IPO, the remaining principal amount of $1,001,153 and accrued interest of $130,533 were converted into 269,449 shares of common stock at a price of $4.20, a conversion price equal to 70% of the lowest per unit price paid for such securities in cash by investors. The Company valued the beneficial conversion feature of the remaining notes at $485,008, which was recorded as interest expense. The Company computed the conversion feature to be $485,008 by dividing the amount of debt and interest ($1,131,686), which is convertible into common stock by the conversion rate (70%). From this amount ($1,616,694) the amount of debt and interest ($1,131,686) was subtracted to determine the amount by which the instrument if-converted exceeds the conversion amount ($485,008). Upon conversion, these notes were automatically cancelled.

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 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 are 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, subsequent to the Company's IPO, 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. 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, 2010, 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 December 22, 2010, in connection with the completion of the IPO, the amount and exercise price of the PCP Warrants was fixed at 104,867 shares of the Company's common stock with an exercise price of $6.60 per share. During 2010, PCP transferred the rights to an aggregate of $1,147,000 in principal amount of the PCP Notes and an aggregate of 76,553 of PCP Warrants to various employees of affiliates of PCP, none of

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Notes to Financial Statements

Note 3 — Related Party Transactions: – (continued)

whom are related parties. As a result, at December 31, 2010, PCP owned only $426,000 in principal amount of the PCP Notes and only 28,314 PCP Warrants.

On December 22, 2010, in connection with the completion of the IPO and pursuant to the terms of the warrants held by the purchasers of the 2010 Notes, the above related party holders of 2010 Notes were issued 182,703 warrants with a per share exercise price of $6.60. Each of these warrants will expire and no longer be exercisable after February 26, 2015. The Company valued these warrants at $915,118 using the Black-Scholes option pricing model, and the Company expensed the entire amount as interest expense in 2010. 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%

Line of Credit and Term Note:

On December 3, 2008, the Company, PBS 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. PBS pledged collateral consisting of personal assets 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 was accrued and was 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 was to mature 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 was several, not joint, with respect to the payment of all obligations thereunder. As of December 31, 2009, the amount borrowed by the Company under the Bank of America, N.A. line of credit was $320,000. In November 2010, the Company paid off the Bank of America, N.A. line of credit with proceeds from a promissory note issued to Israel Discount Bank.

On September 23, 2010, the Company borrowed $800,000 from Israel Discount Bank of New York ("Israel Discount Bank"). The promissory note the Company issued to Israel Discount Bank to evidence the loan is guaranteed by Dr. Rosenwald. The interest rate on the note is equal to the interest rate that Israel Discount Bank will pay on the cash accounts at Israel Discount Bank maintained by Dr. Rosenwald and pledged to secure the note, plus 1%. At December 31, 2010 the interest rate was 1.45%. The note is due on September 22, 2011. As of December 31, 2010, the amount borrowed by the Company that was outstanding under the Israel Discount Bank promissory note was $800,000. In consideration of his guaranteeing the $800,000 promissory note the Company issued to Israel Discount Bank, the Company entered into a letter agreement with Dr. Rosenwald whereby Dr. Rosenwald has the right to attend meetings of the Company's board of directors and to appoint two directors to the 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. The rights granted to Dr. Rosenwald in connection with his guarantee continue until specified termination conditions.

On November 5, 2010, the Company borrowed an additional $420,000 from Israel Discount Bank of New York. The promissory note issued to Israel Discount Bank to evidence the loan is guaranteed by Dr. Rosenwald. The interest rate on the note is equal to the interest rate that Israel Discount bank will pay on the cash accounts at Israel Discount Bank maintained by Dr. Rosenwald and pledged to secure the note, plus

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Notes to Financial Statements

Note 3 — Related Party Transactions: – (continued)

1%. At December 31, 2010 the interest rate was 1.45%. The note is due on demand or on November 4, 2011. The Company used the proceeds from the note to pay off the Bank of America, N.A. line of credit.

The Company repaid the Israel Discount Bank promissory notes in full in January 2011, using proceeds received upon the exercise by the underwriters of the Company's IPO of their over-allotment option, which closed on January 7, 2011**.**

Placement Agent:

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 these agreements 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 of 89,000 shares of common stock, with an exercise price of $7.50. In addition, the Company paid National's outside counsel $32,500 for its services as placement agent counsel. Dr. Lindsay A. Rosenwald beneficially owns, indirectly, a controlling interest in the parent holding company of National.

In connection with the Company's IPO, National, Rodman & Renshaw ("Rodman") and the Company entered into an underwriting agreement dated December 16, 2010, pursuant to which at closing on December 22, 2010, the Company paid National and Rodman cash fees of $1,662,400, which consisted of underwriting discounts of $1,261,500 and non-accountable expense reimbursements of $261,000. In addition, the Company issued to each of National and Rodman warrants to purchase an aggregate of 98,600 shares of common stock with an exercise price of $7.50.

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. The IPO satisfied this obligation.

Note 4 — Income Taxes:

There was no current or deferred income tax provision for the years ended December 31, 2010 and 2009.

The Company's deferred tax assets as of December 31 consist of the following:

	2010	2009
Net operating loss	$ 8,255,000	$ 6,248,000
Stock-based compensation	1,291,000	267,000
Research and development credits	245,000	229,000
	9,791,000	6,744,000
Less: valuation allowance	(9,791,000)	(6,744,000)
	$ —	$ —

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 increase in the total valuation allowance for the years ended December 31, 2010 and 2009 was $3,047,000 and $2,215,000, respectively. The tax benefit assumed the Federal statutory tax rate of 34% and a state and local tax rate of 11% and has been fully offset by the aforementioned valuation allowance.

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Note 4 — Income Taxes: – (continued)

At December 31, 2010, the Company had potentially utilizable Federal and state net operating loss tax carryforwards of approximately $18,500,000, expiring through 2030.

An ownership change under Internal Revenue Code ("IRC") Section 382 is likely to have occurred due to common stock issued in the IPO and debt conversions in December 2010. Due to the change in ownership provisions of the IRC, the availability of the Company's net operating loss carry forwards may be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carry forwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carry forward is subject to any IRC Section 382 limitation. To the extent there is a limitation, there would be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance.

	2010	2009
Statutory Federal tax rate	(34)%	(34)%
Statutory income tax rate (net of Federal)	(7)%	(7)%
Warrant amortization and beneficial conversion charges	19%	9%
Effect of valuation allowance	22%	32%
Effective tax rate	—%	—%

Management believes that the Company does not have any uncertain tax positions that will result in a material impact on the Company's financial statements. The Company files income tax returns in the U.S. federal and applicable state jurisdictions. There are currently no federal or state income tax examinations and therefore all years are statutorally open and subject to examination. If and when applicable, the Company will recognize interest and penalties as income tax expense.

Note 5 — Commitments:

Employment agreements:

Dr. Ellison serves as the Company's Chief Executive Officer pursuant to an employment agreement entered into in June 2010, and amended and restated in July 2010, that became effective on December 22, 2010, upon the closing of the IPO. 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 incentive bonuses of $250,000 and $500,000 in the event that the Company's market capitalization exceeds specified levels, which has not yet occurred. On December 22, 2010, Dr. Ellison received a grant of options to purchase 573,599 shares of the Company's common stock at $6.00 per share, which amount was equal to 7.5% of the Company's fully diluted capitalization at that date. One-third of these options vested at grant and the remaining options vest in equal amounts on the first and second anniversaries of the grant. Consequently, 382,398 options were unvested at December 31, 2010. The options expire on December 22, 2020. The Company recognized $951,355 as compensation expense related to these options as of December 31, 2010.

Mr. Barrett currently serves as our Chief Financial Officer pursuant to an employment agreement entered into in June 2010, and amended and restated in July 2010, that became effective upon December 22, 2010, upon the closing of the IPO. The employment agreement provides for a base salary of $250,000 per year. The agreement also provides incentive bonuses of $250,000 and $500,000 in the event that the Company's market capitalization exceeds specified levels, which has not yet occurred. On December 22, 2010, Mr. Barrett received a grant of options to purchase 305,920 shares of the Company's common stock at $6.00 per share, which amount was equal to 4.0% of the Company's fully diluted capitalization at that date. One-third of these options vested at grant and the remaining options vest in equal amounts on the first and second anniversaries

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Notes to Financial Statements

Note 5 — Commitments: – (continued)

of the grant. Consequently, 203,947 options were unvested at December 31, 2010. The options expire on December 22, 2020. The Company recognized $507,390 as compensation expense related to these options as of December 31, 2010.

Debt repayments:

The scheduled payments based on maturities of current and long-term debt as of December 31, 2010 are as follows:

Year:	
2011	$ 1,219,380
2012	—
2013	1,573,000
Total Debt Outstanding	$ 2,792,380

Consulting Agreements

Effective May 11, 2010, the Company entered into a consulting agreement with Timothy Hofer, pursuant to which Mr. Hofer provides the Company with consulting services focused on general business and company development. Mr. Hofer is also a former employee of PBS, 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 fully vested ten-year warrant to purchase 76,480 shares of the Company's common stock, at an exercise price of $6.00 per share. The Company recognized $372,103 of consulting expense as of December 31, 2010 because the warrants were fully vested on that date.

Note 6 — Stockholders' Transactions:

Common Stock Transactions:

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 a 1-for-12.4 reverse stock split. All shares and per share amounts reflect the effects of the reverse split.

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. During August 2007, the Company issued 18,401 shares of common stock at $0.0124 per share in accordance with the license agreement between the Company and S.L.A. Pharma (see note 7). During 2007, the Company recorded $228 of stock-based research and development expense in connection with this license.

During June through September 2008, the Company issued 18,977 shares of common stock and 3,796 warrants at $60.39 per unit (consisting of a share of common stock with 20% warrant coverage) in connection with a private placement financing at $60.39 per unit. Each warrant has a seven-year term and an exercise price of $66.46. The Company raised $929,457 of net proceeds.

During July 2008, the Company issued 29,861 shares of common stock and 6,151 warrants at $60.39 per unit (consisting of a share of common stock with 20% warrant coverage) 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.

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Notes to Financial Statements

Note 6 — Stockholders' Transactions: – (continued)

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 S.L.A. Pharma pursuant to an amendment to the license agreement between the Company and S.L.A. Pharma, and 403 shares of common stock to a vendor, each at a value of $12.40 per share, recording an expense of $25,000 and $5,000 to research and development expense, respectively.

In connection with the Company's IPO, all of the issued and outstanding convertible notes issued in 2007 and 2010 converted into shares of common stock pursuant to the terms of those notes. All principal and accrued interest on the 2007 and 2010 convertible notes converted at per share price of $4.20, which was 70% of the public offering price of $6.00 per share in the IPO, resulting in an aggregate of 1,642,802 shares of common stock issued upon conversion of the 2007 convertible notes and an aggregate of 1,421,834 shares of common stock issued upon conversion of the 2010 convertible notes. Also in connection with the IPO, and pursuant to their terms, the promissory notes issued to PBS and Capretti Grandi LLC, were converted at a per share price of $4.20, which was 70% of the public offering price of $6.00 per share in the IPO, resulting in an aggregate of 269,449 shares of common stock issued upon conversion of these notes.

On December 22, 2010, the Company issued 2,900,000 shares of its common stock in an IPO at $6.00 per share and received net proceeds of $15,184,344, after deduction of underwriting discounts, commissions and other expenses related to the IPO.

Pursuant to the terms of the license agreement between the Company and S.L.A Pharma, the Company was obligated to issue to S.L.A. Pharma that number of additional shares of common stock so that, when added to the 18,401 shares initially issued, the new and old shares had an estimated fair market value equal to $500,000 (based on the price per share paid in the financing). The closing of the Company's IPO triggered this obligation. As a result, the Company issued 64,933 shares of its common stock to S.L.A. Pharma on December 22, 2010. The Company valued the stock issuance to S.L.A. Parma at $389,597 and expensed the full amount to research and development expense as of December 31, 2010.

On January 7, 2011, the Company issued 435,000 shares of its common stock to fulfill the over-allotment option that it granted to the underwriters as part of its IPO at a price of $6.00 per share and received net proceeds of $2,420,775, after deduction of underwriting discounts and commissions. Including the over-allotment shares, a total of 3,335,000 shares were sold in the IPO, resulting in gross proceeds of approximately $20 million.

Common stock options and warrants:

In 2007, the Company established a stock incentive plan (the "2007 Plan") under which incentive stock and/or options could 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 could 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.

There were no options issued under the 2007 Plan in 2008 or 2009.

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Notes to Financial Statements

Note 6 — Stockholders' Transactions: – (continued)

On May 11, 2010, the Company granted options to purchase 2,016 shares of its common stock to a director under the 2007 Plan with an exercise price of $6.00. The Company valued these options at $9,714 and expensed the full amount on the grant date since the options were fully vested.

All outstanding options under the 2007 Plan have fully vested by the end of 2010. The Company terminated the 2007 Plan in July 2010, but the 2,016 options granted under the 2007 Plan remain outstanding.

During 2007, the Company granted 12,903 warrants 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. During 2008, 1,613 of these warrants were forfeited due to the consultant's relationship with the Company ending prior to the vesting period. All of the warrants that remain outstanding were fully vested at December 31, 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 (see Note 7) pursuant to an amendment to the license agreement between the Company and S.L.A. Pharma. The warrant was fully vested at issuance and the Company recognized the full amount of $161,552 of stock-based research and development expense as of December 31, 2010. 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	2010
Risk-free interest rate	4.00%	1.55% – 3.61%	1.67% – 2.69%	0.75%
Expected volatility	65.55%	104.78% – 219.91%	128.96% – 163.74%	113.31%
Expected life of warrants (in years)	7 years	7 years	7 years	3 years
Expected dividend yield	0%	0%	0%	0%

In August 2010, the Company's stockholders approved the 2010 Equity Incentive Plan (the "2010 Plan"). The 2010 Plan authorizes the Company 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 2010 Plan reserves up to 2,467,200 shares of the Company's common stock. In November 2010, the Company granted options to non-employee directors to purchase an aggregate of 160,000 shares under the 2010 Plan. In addition, under Dr. Ellison's and Mr. Barrett's respective employment agreements, in connection with the closing of the Company's IPO, the Company granted to Dr. Ellison and Mr. Barrett options to purchase shares of the Company's common stock with an exercise price of $6.00, which was equal to the initial public offering price per share, in an amount equal to 7.5% (573,599 shares) and 4.0% (305,920 shares), respectively, of the Company's fully diluted capitalization on that date.

In addition to the options and warrants discussed above, in connection with the Company's financings in 2007, 2008, 2009 and 2010, the Company issued warrants to investors and/or placement agents to purchase shares of common stock as well as certain consulting warrants (See Notes 3, 8 and 9).

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Notes to Financial Statements

Note 6 — Stockholders' Transactions: – (continued)

A summary of the Company's warrant activity and related information is as follows:

	Year Ended December 31, 2009		Year Ended December 31, 2010	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	64,018	$ 33.86	168,885	$ 11.67
Granted	104,867	$ 6.60	767,924	$ 6.84
Outstanding at end of year	168,885	$ 11.43	936,809	$ 7.71
Warrants exercisable at end of period	168,885	$ 11.43	936,809	$ 7.71

All outstanding warrants have vested and no additional expense is expected to be recorded in future years.

A summary of the Company's option activity and related information is as follows:

	Year Ended December 31, 2010		
	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at beginning of period	0	—	
Granted	1,156,255	$ 6.01	$ 705,406
Outstanding at end of year	1,156,255	$ 6.01	$ 705,406
Options exercisable at end of period	473,991	$ 6.00	$ 293,874
Vested or expected to vest at December 31	1,156,255		
Shares available on December 31 for options that may be granted	1,389,441		

Estimated future stock-based compensation expense relating to stock options is as follows:

Calendar Years Ending December 31,	Future Stock Option Compensation Expense
2011	$ 1,573,110
2012	1,491,158
2013	60,680
Total estimated future stock-based compensation expense – stock options	$ 3,124,947

The weighted average remaining contractual life of options outstanding at December 31, 2010 is approximately 18 months.

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Notes to Financial Statements

Note 7 — License Agreements:

In March 2007, pursuant to an Exclusive License Agreement, S.L.A. Pharma granted PBS a royalty-bearing license to sell, make, use and import 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. Pharma to satisfy this obligation. In addition, the Company was obligated to issue to S.L.A. Pharma that number of additional shares of common stock so that the number of shares following specific transactions would have a fair market value equal to $500,000. On December 22, 2010, the Company issued S.L.A Pharma an additional 64,933 shares valued at $389,597 to satisfy this obligation. See Note 6.

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. Pharma 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. Pharma and $50,000 for reimbursement of clinical development costs incurred by S.L.A. Pharma (these amounts were paid by PBS and were included in the consideration paid by the Company 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. Pharma annual royalties, based upon net sales of the product. In addition, the Company is 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 the Company make any improvements regarding the Compound Technology, the Company is required to grant S.L.A. Pharma licenses to use such improvements.

As compensation for S.L.A. Pharma's participation in the management and the development of the technologies, Ventrus is required to make two separate payments to S.L.A. Pharma equal to $41,500 per month each (aggregate $83,000 per month) ("Monthly Payments") for diltiazem and phenylephrine. Per the agreement, Ventrus' obligation to make these monthly payments was to terminate upon a new drug application ("NDA") filing. Pursuant to certain amendments to the Exclusive License Agreement, the Company had been accruing the monthly payments ($41,500) for phenylephrine under the Exclusive License Agreement. From January 31, 2010 until September 30, 2010, the date of ending the development efforts on phenylephrine. The Company continued to pay S.L.A. Pharma the monthly payments of $41,500 per month for diltiazem and has been current in such payments. At December 31, 2010, the Company had paid all contractual payments relating to the license agreement.

Ventrus is also required to reimburse S.L.A. Pharma 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 $3,200,000 and $1,650,000 of payments to S.L.A. Pharma through December 31, 2010 and December 31, 2009 and expects to make the payments upon completion of recruitment into the Phase III trial in Europe, of $800,000. S.L.A. Pharma has not completed the recruitment of patients into the Phase III trial and therefore Ventrus has not accrued the $800,000 expense at December 31, 2010. In addition, both Ventrus and S.L.A. Pharma have agreed to add additional services outside the scope of the agreement for $400,000. The services have not yet been provided by S.L.A. Pharma. Ventrus' total payment obligation for the phenylephrine project shall not exceed $1,200,000. S.L.A. Pharma has provided and billed Ventrus for $600,000 of services for the phenylephrine project through December 31,

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Notes to Financial Statements

Note 7 — License Agreements: – (continued)

2009. S.L.A. Pharma did not provide or bill the Company for any services for the phenylephrine project in 2010 and management does not expect to be billed for any services for the phenylephrine project in the foreseeable future.

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 and royalty payments totaling up to $20 million upon the achievement of various milestones related to regulatory or commercial events. The license agreement is terminable by either party for cause and, upon 30 days notice in the event any safety, efficacy or regulatory issues prevent development or commercialization of the technology. At December 31, 2010, the Company had made all contractual payments relating to the license agreement.

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 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 and again to December 31, 2010. The Bridge Notes, plus all accrued interest thereon, would 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. The completion of the Company's IPO triggered the automatic conversion of the Bridge Notes. Upon conversion, the Bridge Notes were automatically cancelled. The Company valued the beneficial conversion feature of the 2007 Notes at $2,957,187, which was recorded as interest expense after the Qualified Financing was completed. The Company computed the conversion feature to be $2,957,187 by dividing the amount of debt and interest ($6,899,770), which is convertible into common stock by the conversion rate (70%). From this amount ($9,856,957) the amount of debt and interest ($6,899,770) was subtracted to determine the amount by which the instrument if-converted exceeds the conversion amount ($2,957,187).

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 agreed to additional services by PCI during the 18-month period subsequent to March 11, 2008 which expired without any further amounts being paid. PCI is a related party to the Company since it is wholly-owned by Dr. Rosenwald.

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Notes to Financial Statements

Note 8 — Private Placements: – (continued)

In addition, PCI and third party agents received seven-year warrants (the "Placement Warrants"). The amount of shares and the exercise price were to be determined based on whether a qualified financing occurred on or before December 21, 2009. The qualified financing did not occur by such date and as a result the number of shares subject to the Placement Warrants is 42,782 shares, an amount equal to 10% of the principal amount of the Bridge Notes purchased, divided by $12.40, with an exercise price equal to $12.40. PCI subsequently transferred the Placement Warrants among various of its employees. The Company estimated the value of the Placement 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 Bridge Notes. The fair value of the Placement 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%

Note 9 — 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 would 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"). The completion of the Company's IPO triggered the automatic conversion of the 2010 Notes. Upon conversion, the 2010 Notes were automatically cancelled. The Company valued the beneficial conversion feature of the 2010 Notes at $1,619,687, which was recorded as interest expense after the Qualified Financing was completed. The Company computed the conversion feature to be $1,619,687 by dividing the amount of debt and interest ($3,779,269), which is convertible into common stock by the conversion rate (70%). From this amount ($5,398,956) the amount of debt and interest ($3,779,269) was subtracted to determine the amount by which the instrument if-converted exceeds the conversion amount ($1,619,687).

Each 2010 Noteholder holds a warrant to purchase that 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. Each of these warrants will expire and no longer be exercisable after February 26, 2015. In connection with the Company's IPO, the number of shares of common stock issuable pursuant to these warrants is an aggregate of 285,417 shares with an exercise price of $6.60 per share. The Company valued these warrants at $1,429,590 using the Black-Scholes option pricing model and has expensed such amount as of December 31, 2010. The fair value of the warrants granted was based on the following assumptions:

Risk-free interest rate	2.02%
Expected volatility	124%
Expected life of warrants	5 years
Expected dividend yield	0%

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Notes to Financial Statements

Note 9 — 2010 Senior convertible notes: – (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 was $5,617,433. In connection with the Company's IPO, these 2010 Notes converted into an aggregate of 1,421,834 shares of common stock. Upon conversion, these 2010 Notes were automatically cancelled.

Note 10 — Subsequent Events:

Common Stock Options:

In January and February 2011, the Company granted options to purchase 250,000 shares to one of its directors, options to purchase an aggregate of 286,800 shares to three employees and options to purchase an aggregate of 364,240 shares to five consultants, all pursuant to the 2010 Plan with exercise prices at or greater than the then market value of our common stock ($6.24 – $14.63).

VENTRUS BIOSCIENCES, INC.
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Condensed Balance Sheets

	March 31, 2011 (Unaudited)	December 31, 2010 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	**$ 14,000,524**	**$ 14,571,055**
Other current assets	**101,531**	**18,915**
Total current assets	**14,102,055**	**14,589,970**
Computer equipment, net	**11,209**	**—**
Deferred financing costs, net	**24,557**	**26,631**
Total assets	**$ 14,137,821**	**$ 14,616,601**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	**$ 122,896**	**$ 312,896**
Borrowings under line of credit	**—**	**419,380**
Term Note – bank	**—**	**800,000**
Interest payable – Paramount Credit Partners, LLC	**187,536**	**187,536**
Total current liabilities	**310,432**	**1,719,812**
Notes payable – Paramount Credit Partners, LLC (net of discount of $277,814 and $302,327)	**1,295,186**	**1,270,673**
Total liabilities	**1,605,618**	**2,990,485**
Commitments		
Stockholders' equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized, none issued	**—**	**—**
Common stock, $.001 par value; 25,000,000 shares authorized; 7,189,699 and 6,746,365 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	**7,190**	**6,746**
Additional paid-in capital	**48,431,845**	**44,803,724**
Deficit accumulated during the development stage	**(35,906,832)**	**(33,184,354)**
Total stockholders' equity	**12,532,203**	**11,626,116**
Total liabilities and stockholders' equity	**$ 14,137,821**	**$ 14,616,601**

See Notes to Condensed Financial Statements

VENTRUS BIOSCIENCES, INC.
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Condensed Statements of Operations

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010	Period from October 7, 2005 (Inception) to March 31, 2011
Operating expenses:			
Research and development	$ 970,762	$ 280,961	$ 15,222,323
General and administrative	1,696,030	36,544	7,216,707
Loss from operations	(2,666,792)	(317,505)	(22,439,031)
Interest income	13,490	6	33,209
Interest expense:			
Beneficial conversion feature	—	—	(6,001,496)
Amortization of debt discount and deferred financing costs	(24,513)	(1,119,924)	(2,587,944)
Interest expense	(44,663)	(450,079)	(4,911,569)
	(69,176)	(1,570,003)	(13,501,009)
Net loss	$(2,722,478)	$(1,887,502)	$(35,906,832)
Basic and diluted net loss per common share	**($0.38)**	**($4.20)**	
Weighted average common shares outstanding – basic and diluted	7,147,624	447,347	

See Notes to Condensed Financial Statements

VENTRUS BIOSCIENCES, INC.
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Condensed Statement of Changes in Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Balance at January 1, 2011	6,746,365	$ 6,746	$44,803,724	$ (33,184,354)	$11,626,116
Common Stock issued on January 7, 2011 at $6.00 per share to fulfill over-allotment option from IPO, net of related costs	435,000	435	2,420,340	—	2,420,775
Warrants exercised on March 31, 2011 at $6.60 per share	8,334	9	54,995	—	55,004
Stock-based compensation	—	—	1,152,786	—	1,152,786
Additional shares issued in connection with the December 22, 2010 conversion of notes into common stock	7	—	—	—	—
Net Loss				(2,722,478)	(2,722,478)
Balance at March 31, 2011	**7,189,706**	**$ 7,190**	**$48,431,845**	**$(35,906,832)**	**$12,532,203**

See Notes to Condensed Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Condensed Statements of Cash Flows

	Three Months ended March 31, 2011	Three Months ended March 31, 2010	Period from October 7, 2005 (Inception) to March 31, 2011
Cash flows from operating activities:			
Net loss	**$ (2,722,478)**	**$ (1,887,502)**	$ (35,906,832)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	**1,152,786**	**(114,415)**	4,110,108
Depreciation	**755**	**1,233**	28,016
Stock issued in connection with license agreement	**—**		414,825
Charge resulting from beneficial note conversion	**—**		6,001,496
Stock issued to vendor	**—**		5,000
Warrants issued in connection with related party note conversion	**—**	**941,966**	1,255,978
Amortization of deferred financing costs and debt discount	**26,587**	**225,604**	3,163,639
Non-cash research and development	**—**		1,087,876
Interest payable – 2007 Senior convertible notes	**—**	**153,293**	1,598,104
Interest payable – 2010 Senior convertible notes	**—**	**33,902**	354,269
Expenses paid on behalf of the Company satisfied through the issuance of notes	**—**		227,910
Interest payable – related parties	**—**	**40,158**	266,279
Interest payable – Paramount Credit Partners, LLC	**—**	**39,325**	187,536
Changes in operating assets and liabilities:			
Other current assets	**(82,618)**	**1,506**	(101,533)
Accounts payable and accrued expenses	**(189,999)**	**(1,226,249)**	122,897
Net cash used in operating activities	**(1,814,967)**	**(1,791,179)**	(17,184,434)
Cash flows from investing activities:			
Purchase of office and computer equipment	(11,963)	—	(39,223)
Cash flows from financing activities:			
Net Proceeds from IPO and the over-allotment option exercise	**2,420,775**	**—**	17,605,119
Proceeds from 2010 Senior convertible notes	**—**	**2,150,000**	3,425,000
Proceeds from notes payable to Paramount Credit Partners, LLC	**—**	**—**	1,573,000
Proceeds from notes payable to related parties	**—**	**950,562**	5,041,953
Proceeds from 2007 Senior convertible notes	**—**		5,305,000
Proceeds from private placement	**—**		1,146,024
Payment for deferred financing costs	**—**	**(322,884)**	(1,431,603)
Proceeds from utilization of line of credit	**—**		419,380
Proceeds from term note payable	**—**		800,000
Repayment of term note	**(800,000)**		(800,000)
Repayment of notes payable – related party	**—**		(1,500,000)
Repayment of debt facilities	**(419,380)**		(419,380)
Proceeds from exercise of warrants	**55,004**		55,004
Proceeds from receipt of subscriptions	**—**		4,684
Net cash provided by financing activities	**1,256,399**	**2,777,678**	**31,224,181**
Net (decrease) increase in cash	**(570,531)**	**986,499**	14,000,524
Beginning of period	**14,571,055**	**81,288**	
End of period	**$ 14,000,524**	**$ 1,067,787**	$ 14,000,524
Supplemental schedule of non-cash financing activities:			
Warrants issued to placement agent	**$ —**		**$ 341,334**
Warrants issued to investors in connection with convertible notes	**$ —**	**$ 1,166,989**	**$ 1,166,989**
Debt discount on Paramount Credit Partners, LLC notes	**$ —**		**$ 480,049**
Related party notes and accrued interest converted to 2010 Senior convertible notes	**$ —**	**$ 2,192,433**	**$ 3,995,667**
Notes and accrued interest converted to common stock	**$ —**		**$ 14,003,158**
Supplemental disclosure – cash paid for interest	**$ 39,325**	$ 135,755	$ 408,073

See Notes to Condensed Financial Statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Condensed Financial Statements
(March 31, 2011)

Note 1 — Organization, Business and Basis of Presentation:

Organization and business:

Ventrus BioSciences, Inc. (a development stage company), formerly known as South Island BioSciences, Inc. ("Ventrus" or the "Company") was incorporated in the State of Delaware on October 7, 2005 and commenced operations in April 2007. Ventrus is a specialty pharmaceutical company focused on the late-stage development and commercialization of gastrointestinal products.

On December 22, 2010, the Company issued 2,900,000 shares of its common stock in an initial public offering (the "IPO") and raised net proceeds of $15,184,344. On January 7, 2011, the Company issued an additional 435,000 shares of its common stock to fulfill the over-allotment option that it granted to the underwriters as part of the IPO and raised net proceeds of $2,420,775. In addition, on December 22, 2010, in connection with the consummation of the IPO, the Company converted $14,003,158 of convertible notes and accrued interest by issuing an aggregate of 3,334,085 shares to holders of the convertible notes.

Basis of presentation:

The accompanying condensed balance sheet as of December 31, 2010, which has been derived from the Company's audited financial statements, and the unaudited interim condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles and the rules and regulations of the Securities and Exchange Commission ("SEC") related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosures made are adequate to make the information presented not misleading. The unaudited interim condensed financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. These unaudited condensed financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. The operating results presented in these unaudited condensed financial statements are not necessarily indicative of the results that may be expected for any future periods.

Capital Resources:

The Company has not derived any revenue from product sales to date as our products have not been approved for sale by the U.S. Food and Drug Administration ("FDA") or any foreign regulatory agency. Since inception, the Company's operations have been financed primarily through the sale of equity securities, the proceeds from the exercise of warrants and stock options and issuance of debt. The Company has incurred losses from operations and negative cash flows since the inception of the Company, and expects to continue to incur substantial losses for the foreseeable future as it continues product development. As a result, the Company may need to obtain additional funds to finance its operations in the future. Until the Company can generate significant cash from its operations, it intends to obtain any additional funding it requires through strategic relationships, public or private equity or debt financings, or other arrangements and it cannot assure such funding will be available on reasonable terms, or at all. If the Company is unsuccessful in raising additional required funds, it may be required to delay, curtail or eliminate plans or programs relating to its business.

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Condensed Financial Statements
(March 31, 2011)

Note 2 — Summary of Significant Accounting Policies:

Cash and Cash Equivalents:

All highly liquid investments with maturities of three months or less at the time of purchase are considered to be cash equivalents. All of the Company's cash equivalents have liquid markets and high credit ratings. The Company maintains its cash in bank deposit and other accounts, the balances of which, at times and at March 31, 2011, 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.

Significant estimates inherent in the preparation of the accompanying financial statements include the fair value of stock options and warrants granted to employees, consultants, directors, investors, licensors, placement agents and underwriters.

Stock-based compensation:

The Company's share-based compensation cost is measured at grant date, using the Black-Scholes option pricing model to estimate the 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 which is estimated 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.

Research and development:

Research and development expenses include personnel and facility-related expenses, third party contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where the Company enters into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities, costs are expensed as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

The Company's accruals for clinical trials are based on estimates of the services received and pursuant to contracts with the respective clinical trial centers and clinical research organizations. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received. As such, expense accruals related to clinical trials are recognized based on the estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Condensed Financial Statements
(March 31, 2011)

Note 2 — Summary of Significant Accounting Policies: – (continued)

Income taxes:

The Company's income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. 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. 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 loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share reflects 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 unless inclusion of such shares would be anti-dilutive. Since the Company has only incurred losses, basic and diluted loss per share is the same. The number of potentially dilutive securities excluded at March 31, 2011 and 2010 was 2,782,412 and 436,322, respectively.

Fair value measurements:

The carrying value of the Paramount Credit Partners, LLC notes approximate fair value due to the short-term nature of the notes and the related interest rates approximate market rates.

Note 3 — Related Party Transactions:

The Company has entered into various related party transactions as more fully described in Note 3 to the Company's financial statements in its Annual Report on Form 10-K for the year ended December 31, 2010. The following are descriptions of the Company's related party transactions that have been entered into, modified, terminated, or are still in effect in 2011.

Consulting services:

Effective April 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 is an affiliate of Dr. Lindsay A. Rosenwald, M.D., a significant investor in and stockholder of the Company. This agreement was terminated as of August 31, 2008. For the period from October 7, 2005 (inception) through August 31, 2008, $425,000 was incurred under this arrangement. As of March 31, 2011 and December 31, 2010, the Company had $100,000 outstanding under this arrangement, which is included in accounts payable.

Notes payable:

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 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 are 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, subsequent to the Company's IPO, including an

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Condensed Financial Statements
(March 31, 2011)

Note 3 — Related Party Transactions: – (continued)

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 104,867 shares of common stock at an exercise price of $6.60. 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 March 31, 2011, the principal amount outstanding under these notes is $1,573,000.

Line of Credit:

On September 23, 2010, the Company borrowed $800,000 from Israel Discount Bank of New York ("Israel Discount Bank"). The promissory note the Company issued to Israel Discount Bank to evidence the loan was guaranteed by Dr. Rosenwald. In consideration of his guaranteeing the $800,000 promissory note, the Company entered into a letter agreement with Dr. Rosenwald whereby Dr. Rosenwald has the right to attend meetings of the Company's board of directors and to appoint two directors to the 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. The rights granted to Dr. Rosenwald in connection with his guarantee continue until specified termination conditions. On November 5, 2010, the Company borrowed an additional $420,000 under a line of credit from Israel Discount Bank of New York. The promissory note issued to Israel Discount Bank to evidence the loan was guaranteed by Dr. Rosenwald. The Company used the proceeds from the note to pay off a line of credit with Bank of America, N.A. in November 2010. The Company repaid the Israel Discount Bank promissory note and the amount owed under the line of credit in full in January 2011.

Note 4 — Commitments:

Employment agreements:

Dr. Russell Ellison serves as the Company's Chief Executive Officer pursuant to an employment agreement entered into in June 2010, and amended and restated in July 2010 that became effective on December 22, 2010, upon the closing of the IPO. 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 incentive bonuses of $250,000 and $500,000 in the event that the Company's market capitalization exceeds specified levels, which has not yet occurred.

Mr. David Barrett currently serves as our Chief Financial Officer pursuant to an employment agreement entered into in June 2010, and amended and restated in July 2010 that became effective upon December 22, 2010, upon the closing of the IPO. The employment agreement provides for a base salary of $250,000 per year. The agreement also provides incentive bonuses of $250,000 and $500,000 in the event that the Company's market capitalization exceeds specified levels, which has not yet occurred.

Consulting Agreements:

Effective May 11, 2010, the Company entered into a consulting agreement with Timothy Hofer, pursuant to which Mr. Hofer provides the Company with consulting services focused on general business and company development. Mr. Hofer is also a former employee of Paramount BioSciences, LLC ("PBS"), 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.

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Condensed Financial Statements
(March 31, 2011)

Note 5 — License Agreements:

In March 2007, pursuant to an Exclusive License Agreement, S.L.A. Pharma, AG ("S.L.A. Pharma") granted PBS a royalty-bearing license to sell, make, use and import 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. Pharma to satisfy this obligation. In addition, the Company was obligated to issue to S.L.A. Pharma that number of additional shares of common stock so that the number of shares following specific transactions would have a fair market value equal to $500,000. On December 22, 2010, the Company issued S.L.A Pharma an additional 64,933 shares to satisfy this obligation.

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. Pharma 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. Pharma and $50,000 for reimbursement of clinical development costs incurred by S.L.A. Pharma (these amounts were paid by PBS and were included in the consideration paid by the Company 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. Pharma annual royalties, based upon net sales of the product. In addition, the Company is 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 the Company make any improvements regarding the Compound Technology, the Company is required to grant S.L.A. Pharma licenses to use such improvements.

As compensation for S.L.A. Pharma's participation in the management and the development of the technologies, Ventrus is required to make separate payments to S.L.A. Pharma 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 a new drug application ("NDA") filing. Pursuant to certain amendments to the Exclusive License Agreement, the Company, as of September 30, 2010, was no longer required to make additional payments for phenylephrine. At March 31, 2011, the Company had no monies outstanding to S.L.A. Pharma.

Ventrus is also required to reimburse S.L.A. Pharma 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 $3,200,000 of payments to S.L.A. Pharma from August 2007 through March 31, 2011 and expects to make the payments upon completion of recruitment into the Phase III trial in Europe, of $800,000. S.L.A. Pharma has not completed the recruitment of patients into the Phase III trial and therefore Ventrus has not accrued the $800,000 expense at March 31, 2011. In addition, both Ventrus and S.L.A. Pharma have agreed to add additional services outside the scope of the agreement for $400,000. The services have not yet been provided by S.L.A. Pharma. Ventrus' total payment obligation for the phenylephrine project shall not exceed $1,200,000. S.L.A. Pharma has been paid $600,000 of services for the phenylephrine project through March 31, 2011. S.L.A. Pharma did not provide or bill the Company for any services for the phenylephrine project in 2010 and the first quarter to 2011 and management does not expect to be billed for any services for the phenylephrine project in the foreseeable future.

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Condensed Financial Statements
(March 31, 2011)

Note 5 — License Agreements: – (continued)

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 as an NDA was not submitted by September 2010. In addition, Ventrus may be required to make future milestone and royalty payments totaling up to $20 million upon the achievement of various milestones related to regulatory or commercial events. The license agreement is terminable by either party for cause and, upon 30 days notice in the event any safety, efficacy or regulatory issues prevent development or commercialization of the technology. At March 31, 2011, the Company had made all contractual payments relating to the license agreement.

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 — Stockholder's Transactions:

Common Stock Transactions:

On January 7, 2011, the Company issued 435,000 shares of its common stock to fulfill the over-allotment option that it granted to the underwriters as part of the IPO and raised net proceeds of $2,420,775.

On March 31, 2011, the Company issued an aggregate of 8,334 shares of common stock pursuant to the exercise of warrants with an exercise price of $6.60.

Common Stock Options and Warrants:

In August 2010, the Company's stockholders approved the 2010 Equity Incentive Plan (the "2010 Plan"). The 2010 Plan authorizes the Company 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 2010 Plan reserves up to 2,467,200 shares of the Company's common stock. In November 2010, the Company granted options to non-employee directors to purchase an aggregate of 160,000 shares under the 2010 Plan. In addition, under Dr. Ellison's and Mr. Barrett's respective employment agreements, in connection with the closing of the Company's IPO, the Company granted to Dr. Ellison and Mr. Barrett options to purchase shares of the Company's common stock with an exercise price of $6.00, which was equal to the initial public offering price per share, in an amount equal to 7.5% (573,599 shares) and 4.0% (305,920 shares), respectively, of the Company's fully diluted capitalization on that date.

In January and February 2011, the Company granted options to purchase 250,000 shares to one of its directors, options to purchase an aggregate of 229,440 shares to one employee and options to purchase an aggregate of 218,240 shares to five consultants, all pursuant to the 2010 Plan with exercise prices at or greater than the then market value of the Company's common stock ($6.24 – $14.63).

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Condensed Financial Statements
(March 31, 2011)

Note 6 — Stockholder's Transactions: – (continued)

A summary of the Company's warrant activity and related information is as follows:

	Period Ended March 31, 2011	
	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	936,809	$ 7.71
Granted	0	—
Exercised	(8,334)	$ 6.60
Outstanding at end of period	928,475	$ 7.71
Warrants exercisable at end of period	928,475	$ 7.71

A summary of the Company's option activity and related information is as follows:

	Period Ended March 31, 2011		
	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2011	1,156,255	$ 6.01	
Granted	697,680	$ 6.34	
Outstanding at March 31, 2011	1,853,935	$ 6.14	$ 10,593,924
Options exercisable at end of period	704,036	$ 6.08	$ 4,062,682

The fair value of the options granted for the three-month period ended March 31, 2011, was based on the following assumptions:

Risk-free interest rate	1.84% – 3.03%
Expected volatility	92.48% – 94.74%
Expected life of Options	7 years
Expected dividend yield	0%

Estimated future stock-based compensation expense relating to stock options is as follows:

Calendar Years Ending December 31,	Future Stock Option Compensation Expense
2011 (9 months)	$ 2,796,543
2012	2,313,287
2013	795,381
2014	52,625
Total estimated future stock-based compensation expense – stock options	$ 5,907,830

The weighted average remaining contractual life of options outstanding at March 31, 2011 is approximately 9.75 years.

Stock-based compensation expensed to research and development expense for the three months ended March 31, 2011 and 2010 was $154,457 and $(114,415), respectively. During the three months ended March 31, 2010, the Company recorded a credit of $114,415 for stock-based compensation (for non-employees and accounted for as variable options) because the fair value of the unvested stock options, including related charges taken in earlier periods for the unvested stock options based on expected vesting, decreased during this period due to common stock issued at a lower price. Stock-based compensation expensed to general and administrative expense for the three months ended March 31, 2011 and 2010 was $998,328 and $0, respectively.

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4,500,000 Shares
Common Stock
$10.00 per share

Leerink Swann
Lazard Capital Markets
National Securities Corporation
Rodman & Renshaw, LLC

PROSPECTUS
