UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2013

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

For the Transition Period from _____ to _____

Commission File Number 001-35005

VENTRUS BIOSCIENCES, INC.

(Exact name of registrant specified in its charter)

Delaware	**2834**	**20-8729264**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

99 Hudson Street, 5th Floor
New York, New York 10013
(Address of Principal Executive Offices)

(646) 706-5208
(Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	**Name of Exchange on which Registered**
Common Stock, $0.001 Par Value	Nasdaq Capital Market

Securities Registered Pursuant to Section 12(g) of the Act: None

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2013, was approximately $46.9 million. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the Nasdaq Capital Market on June 28, 2013 (the last trading day before June 30, 2103). For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the voting stock of the registrant as of June 30, 2013.

As of March 24, 2014 there were 23,396,259 shares of the registrant's common stock, $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

VENTRUS BIOSCIENCES, INC.

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This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Item 1A. Risk Factors" and "Cautionary Statement" included in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

PART I

Item 1. Business

Overview

We are a development-stage specialty pharmaceutical company currently focused on the development of late-stage and pre-clinical prescription drugs and biologics, currently for gastrointestinal disorders. 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. Our product portfolio consists of two late stage assets: VEN 307 (topical diltiazem) for relief from pain associated with anal fissures, and VEN 308 (topical phenylephrine) for the treatment of 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.

We also are developing a colonic delivery mechanism (VEN 310), which is a PH sensitive system to deliver bacteria, complex proteins, viral antigens, small molecules and other treatments precisely to the colon.

In addition to VEN 307, VEN 308 and VEN 310, we intend to pursue the in-licensing and acquisition of other development stage as well as pre-clinical assets.

VEN 307 (diltiazem cream) for the relief of pain associated with anal fissures

There are approximately 1.1 million office visits per year for anal fissures in the U.S. In addition, SDI Physician Drug & Diagnostic Audit estimated that in 2010 there were approximately 730,000 unique patients who visited a physician for anal fissures. Despite these figures, we are aware of only one drug that has received U.S. Food and Drug Administration, or FDA, approval for the treatment of pain associated with anal fissures; Rectiv® received approval in late June 2011, and became commercially available 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 topical drug whose active ingredient is nitroglycerin.

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 be approximately 30 mg.

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) than 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, including headaches.

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 VEN 307 for the treatment of pain from anal fissures. Because diltiazem is approved in oral formulations for the treatment of angina and high blood pressure, it is eligible for the FDA's 505(b)2 registration pathway. We intend to develop VEN 307 in a 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. At this meeting, we discussed necessary preclinical testing, and chemistry and manufacturing data necessary to support an investigational new drug product application, or IND, and received guidance on the design of the pivotal Phase III trials.

Our licensor and development partner, S.L.A. Pharma, began enrollment in the first VEN 307 Phase III trial in November 2010 and completed enrollment of 465 patients at 27 sites in 11 countries in Europe in December 2011. Patients were treated for two months and then observed without treatment for one month in a randomized 1:1:1 double-blind study that compared treatments of 2% VEN 307 and 4% VEN 307 to placebo. The primary endpoint was reduction of worst pain with or following defecation averaged across the fourth week of treatment (Week 4), using a validated numerical rating scale (NRS) for pain. Both the 4% and the 2% diltiazem treatment arms demonstrated statistically significant improvement compared to placebo.

Based on these results, in June 2012, to begin our U.S. development of VEN 307, we filed an IND for our pharmacokinetic, or PK, trial in the U.S. for the current formulation of VEN 307. In August 2012, we met with the FDA in a pre-NDA meeting to discuss the Phase III trial, as well as steps to move forward toward an NDA. We were advised that we should submit two provocative skin test trials and a second pivotal study, to, at a minimum, complete the clinical safety data base. In addition, the FDA advised us that it preferred we undertake a more formal standardized definition of healing (similar to that used in wound healing studies) as an endpoint, which would need to be positive in two studies, to support a label claiming improved healing. We determined to not pursue that request, and therefore we do not expect the FDA will allow us to claim improved healing on the product label.

In September 2013, we reported positive results from the two clinical dermal safety studies and one PK study of VEN 307. In the dermal studies, results demonstrated that VEN 307 was safe and well tolerated. The results from our PK study comparing VEN 307 to oral diltiazem in subjects with anal fissure demonstrated that all PK parameters, including AUC, Cmax, Tmax and half-life, were consistent with expectations, and also demonstrated that systemic exposure of VEN 307 was approximately only 10% that of oral diltiazem, in line with prior data from an investigator sponsored trial with this product, and confirming a potentially high safety margin.

We initiated a second pivotal Phase III clinical trial of VEN 307 (three times daily, or t.i.d., formulation) in anal fissures in the fourth quarter of 2012, and reported top line data in the first quarter of 2014. This trial randomized in a 1:1 ratio, 400 subjects to either 2% diltiazem cream applied peri-anally three times daily or a placebo cream, at approximately 120 sites primarily in the U.S. with supplemental sites in Canada and Israel. The treatment and the double blind period duration was four weeks. The primary endpoint was similar to that in the prior Phase III trial conducted by S.L.A. Pharma: worst pain with or following defecation during the fourth week of treatment. The key secondary endpoints were average daily pain and Patients' Global Impression (PGI), also at four weeks. The diltiazem 2% treatment arm demonstrated no significant improvement compared to placebo in the primary endpoint of average of worst anal pain associated with or following defecation.

Based on this data, and inasmuch as a primary purpose of our second Phase III trial was to complete the safety data package for an NDA with the FDA, we have requested a pre-NDA FDA meeting to determine the next steps in the program. Depending on the results of that meeting, we expect to be able to file the NDA in the third quarter of 2014.

We have potential to capture immediate market share if VEN 307 is approved due to the familiarity of gastroenterologists and surgeons 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. VEN 307 is covered by method of use patents that will expire in February 2018. We expect that we will receive a Hatch-Waxman extension of exclusivity for the t.i.d. formulation of VEN 307 to approximately mid-2019. We also have initiated a written request process with the FDA for pediatric studies for VEN 307, which if undertaken, would extend exclusivity for an additional six months.

We have completed the technical development of a different formulation of VEN 307 with new intellectual property in the form of an extended-release, or ER, formulation. There are several proven methodologies for extended-release topical formulations, and we have observed that diltiazem is readily druggable in this regard. We have assessed three to four alternatives preclinically with an external contractor, and we expect to assess in pre-clinical in vivo studies the absorption and the effect on internal anal sphincter, or IAS, pressure with the most promising formulation. Assuming positive outcomes, we plan to file North American patent applications for all formulations that are technically feasible.

VEN 308 (phenylephrine gel) 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 surgical treatment for patients with ulcerative colitis. Fecal incontinence resulting from dysfunctional sphincter tone is a common consequence of this procedure. Patients with 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. 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 7.0 million people, based on 2010 Census Bureau population estimates. The surgery associated with IPAA can weaken sphincters and muscles necessary for continence and therefore can result in incontinence. IPAA-related fecal incontinence is considered an orphan indication by the FDA and the European Medicines Agency, or EMEA. 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. Currently, there are few options available to treat this problem, consisting of over-the-counter, or OTC, bulk laxatives, fiber diets, Imodium, which is a treatment for diarrhea, and invasive surgical procedures. While an injectable inert bulking agent product was approved as a device by the FDA in May 2011 for the treatment of fecal incontinence and a suppository formulation of an alpha adrenergic stimulating agent for the treatment of fecal incontinence is in development, we are not aware of any FDA-approved drugs for fecal incontinence.

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 or used more than 17 million times per year in the U.S., with 99% of the use being for cough/cold oral preparations. The typical oral dosing is 40 mg to 60 mg per day.

In several investigator-initiated 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 potentially 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. Because of the extensive patient exposure to phenylephrine from oral administration as a cough/cold remedy, we intend to develop VEN 308 as a topical formulation through a Section 505(b)(2) NDA. We intend to undertake technical development to create a twice daily patentable formulation of VEN 308 after which we will determine whether to pursue further development of VEN 308. VEN 308 is covered by a patent that will expire in December 2017. 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 expect to conduct a Phase IIb trial in IPAA patients to be followed by one or two Phase III trials (if results are sufficiently positive) in support of the orphan indication of IPAA-related fecal incontinence. 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 for a specific indication.

VEN 310, a pH sensitive system to deliver bacteria, complex proteins, viral antigens and small molecules to the gastro-intestinal tract

In November 2013, we in-licensed from Therabiome, LLC the rights to the oral delivery of pharmaceutical drugs and biologics to specific sites in the intestine, using a pH sensitive controlled release platform technology. We intend to explore the development of the intellectual property for commercialization:

- in the use of bacteria, complex proteins, viral antigens and small molecules by oral delivery in: (i) gastro-intestinal dysbiosis, including but not limited to C. difficile, irritable bowel syndrome-constipation and inflammatory bowel disease, (ii) auto-immune disorders and autism, including but not limited to as controlled by bacteria or virus, and (iii) orally delivered vaccines, including viral and bacterial; and

- any oral delivery of small molecules using the licensed intellectual property.

Since the early 2000's, there has been considerable academic interest in the human microbiome in health and disease, including fecal material transplant, or FMT, in recalcitrant *C. difficile*, and bacterial treatment of vancomycin resistant enterococci colonization, or VRE, inflammatory bowel disease, or IBD, irritable bowel syndrome, or IBS, non-alcoholic Steatohepatitis, or NASH, obesity, and type I and II diabetes. Several privately held companies have initiated programs of bacterial therapy or processed FMT for *C. difficile*, and IBD. Any of these potential treatments, as well as some oral viral vaccines, may require an effective delivery mechanism targeted to the colon or terminal ileum. In addition, there remains a medical need in the use of metronidazole to treat *C. difficile* colonic infections, and in topical steroid treatment of the proximal and transverse colon in ulcerative colitis.

Our Strategy

Our objective is to develop and commercialize highly differentiated products to address critical medical needs, currently for the gastrointestinal tract. We are developing our current product candidates to treat anal fissures (VEN 307) and fecal incontinence (VEN 308). We also are seeking to pursue the development of VEN 310 as a colonic delivery mechanism for agents to treat gastro-intestinal disorders.

While we plan to continue developing VEN 307 and VEN 308 and pursue the development of VEN 310, as part of our growth strategy we are also considering the in-licensing and acquisition of other development stage as well as pre-clinical assets.

To achieve this objective, we intend to:

- have a Section 505(b)(2) pre-NDA meeting with the FDA to determine the next steps to develop VEN 307, based on prior studies and our clinical trial results;
- depending on the results of that meeting, prepare and file an NDA for VEN 307 for the topical treatment of pain associated with anal fissures, which application we anticipate will be filed in the third quarter of 2014;
- do technical development to create a twice daily patentable formulation of VEN 308 after which we will determine whether to pursue further development of VEN 308;
- identify mixtures of human bacterial strains which might be effective in the treatment of CDAD and VRE, and formulate them for oral administration with specific release in the proximal colon for human clinical trials, and we may seek to formulate metronidazole and selected generically available corticosteroids to target colonic release, for Phase I clinical trials to determine systemic and colonic exposure; and
- identify and in-license or acquire development stage as well as pre-clinical compounds and biologics.

Corporate History

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.

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 two 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, which licensed Rectiv to Aptalis Pharma in January 2012; Aptalis Pharma is to be required by Forest Laboratories) 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.

Our clinical program focuses on pain as the primary endpoint. In addition, based on results of previously published trials (such as Kocher et al. 2002; see **Table 1** below) and our two Phase III clinical trials, 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.

Further, to examine the quality of compounded formulations of topical 2% diltiazem, in 2012, we undertook a high-performance liquid chromatography (HPLC) analysis of preparations of topical 2% diltiazem hydrochloride gathered from retail pharmacies in a metropolitan region of the U.S. A participating healthcare professional wrote 12 prescriptions, with two refills allowed per prescription, so that three prescriptions could be filled at each of 12 pharmacies (36 total refills) for compounded 2% diltiazem cream. The analysis included an assessment of potency (percentage of claim) and content uniformity, with sampling from eight different pre-specified locations within the compounded formulation containers. The United States Pharmacopoeia (USP) standard for potency is 90% to 115% of claim. Of the 36 preparations, five (13.89%) were supra-potent and 13 (36.11%) were sub-potent. The supra-potent prescriptions ranged in potency from 117.2% to 128.5% of claim, and the sub-potent prescriptions ranged in potency from 34.8% to 89.8% of claim. Fourteen (38.9%) preparations lacked content uniformity according to the USP standard. These results demonstrate that although compounded drugs might be formulated under professional pharmacy standards, these standards are inherently less rigorous than federal GMP quality standards. We believe that a topical 2% diltiazem cream produced under GMP regulations is needed to avoid the large percentage of substandard compounded formulations of a drug specifically recommended by the practice parameters of a medical society.

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.

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
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

Study	Condition, treatment, dosage	Study design, endpoints	Efficacy	Adverse events
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)

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.

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.

S.L.A. Pharma began enrollment in the VEN 307 Phase III trial in November 2010 and completed enrollment of 465 patients at 27 sites in 11 countries in Europe in December 2011. Patients were treated for two months and then observed without treatment for one month in a randomized 1:1:1 double-blind study that compared treatments of 2% VEN 307 and 4% VEN 307 to placebo. The primary endpoint was reduction of worst pain with or following defecation averaged across the fourth week of treatment (Week 4), using a validated numerical rating scale (NRS) for pain. Patients were required to call into an IVRS daily diary to report their pain during the 8 weeks of treatment, as well as for the one week prior to randomization to ensure sufficient pain prior to randomization. Both the 4% and the 2% diltiazem treatment arms demonstrated statistically significant improvement compared to the placebo arm on the primary endpoint of change from baseline in the Week 4 NRS score for worst anal pain with or following defecation.

Both the 4% and the 2% diltiazem treatment arms demonstrated statistically significant improvement compared to the placebo arm on the primary endpoint of change from baseline in the Week 4 NRS score for worst anal pain with or following defecation. The mean reduction in the NRS pain score was 0.44 ($p = 0.0107$) and 0.43 ($p = 0.0122$) for the subjects receiving 4% and 2% diltiazem, respectively. The secondary endpoint of overall daily anal-fissure-related pain for Week 4 for the 2% diltiazem arm compared to placebo had a reduction in the pain score of 0.42 ($p = 0.0143$), while the 4% diltiazem arm compared to placebo showed a reduction in the pain score of 0.36 ($p = 0.0289$). At Week 8, healing was improved for the 4% diltiazem arm compared to placebo, with 32.7% ($p = 0.0184$) versus 23.9% showing healing. The 2% diltiazem arm showed healing in 31.2% ($p = 0.0426$ versus placebo) of subjects. On the PGI-I measure, there was a difference favoring 2% diltiazem versus placebo at Week 4 ($p = 0.0084$). There were no significant differences between 4% diltiazem and placebo on the PGI-I measure. AEs were approximately similar for the three trial arms. Reports of headaches were similar in the three arms (14.7% for subjects receiving 4% diltiazem, 12.3% for those receiving 2% diltiazem, and 14.2% for patients receiving placebo).

Clinical trial results of diltiazem cream sponsored by us

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. We have employed a two-pronged development strategy for VEN 307, using data from S.L.A. Pharma's Phase III clinical trial in the E.U. and our Phase III clinical trial in the U.S.

Prior to conducting our clinical Phase III trial in the U.S., we had to complete three short-term dermal toxicology studies and file an IND for FDA approval. In September 2013, we reported positive results from the two clinical dermal safety studies and one pharmacokinetic, or PK, study of VEN 307. For the dermal safety studies, we conducted two single-center, randomized, controlled trials to evaluate the irritation and sensitization potential of VEN 307 in healthy volunteers. The studies utilized cumulative as well as repeat insult patch designs, which aim to provide a standard assessment of cutaneous tolerability and safety. In these studies, results demonstrated that VEN 307 was safe and well tolerated. Irritation and sensitization caused by VEN 307 was similar to that seen with both placebo and saline, and was significantly better than that seen with sodium lauryl sulfate (SLS), the positive control. Minimal adverse events and no severe or serious adverse events were reported.

The results from our PK study comparing VEN 307 to oral diltiazem in subjects with anal fissure demonstrated that all PK parameters, including AUC, Cmax, Tmax and half-life, were consistent with expectations, and results demonstrated that systemic exposure of VEN 307 was approximately only 10% that of oral diltiazem, in line with prior data from an investigator sponsored trial with this product, and confirming a potentially high safety margin.

We initiated a second pivotal Phase III clinical trial of VEN 307 (t.i.d. formulation) in anal fissures in the fourth quarter of 2012, and reported top line data in the first quarter of 2014. This trial randomized in a 1:1 ratio, 400 subjects to either 2% diltiazem cream applied peri-anally three times daily or a placebo cream, at approximately 120 sites primarily in the U.S. with supplemental sites in Canada and Israel. The treatment and the double blind period duration was four weeks. The primary endpoint was similar to that in the prior Phase III trial conducted by S.L.A. Pharma: worst pain with or following defecation during the fourth week of treatment. The key secondary endpoints were average daily pain and Patients' Global Impression (PGI), also at four weeks. The diltiazem 2% treatment arm demonstrated no significant improvement compared to placebo in the primary endpoint of average of worst anal pain associated with or following defecation.

The mean of worst AF-related pain score at baseline was 7.09 for diltiazem 2% and 7.18 for placebo, decreasing to 3.81 (-3.28 difference) and 3.72 (-3.46 difference) respectively. Outcomes for the secondary endpoints of overall AF-related pain and PGI-I parallel the primary endpoint. Age, gender, and race were equivalent between arms, and results were not meaningfully different between countries. Adverse events (AEs) were similar for the two treatment arms. Gastrointestinal disorders were the most common with 20.7% of patients in the diltiazem 2% arm versus 21.9% in the placebo arm, substantially less than reported in the first Phase 3 trial. Reports of headaches were 5.1% for diltiazem 2% and 1.9% for placebo. There was one serious adverse event of pregnancy.

Based on this data, and inasmuch as a primary purpose of the second Phase III trial was to complete the safety data package for an NDA with the FDA, we have requested a pre-NDA FDA meeting to determine next steps in the program. Depending on the results of that meeting, we expect to be able to file the NDA in the third quarter of 2014.

We have initiated technical development of what we believe is a superior formulation with potentially new intellectual property in the form of an extended release formulation. There are several proven methodologies for extended release topical formulations, and we have observed that diltiazem is readily druggable in this regard. We have assessed three to four alternatives preclinically with an external contractor, and we expect to assess in pre-clinical in vivo studies the absorption and the effect on IAS pressure with the most promising formulation. Assuming positive outcomes, we plan to file North American patent applications for all formulations that are technically feasible.

Assuming the successful launch of VEN 307 (t.i.d.), we will make the final decision on which twice daily (b.i.d.) formulation to pursue depending on several factors, including whether the new formulation is potentially clinically superior (i.e., the same efficacy, tolerability and systemic diltiazem exposure (the maximum plasma concentration, or Cmax) can be achieved with only b.i.d. administration or less), our available resources, revenue, if any, from VEN 307, the observed market size for anal fissures, and existing and projected reimbursement patterns, 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 comparative manometry studies in volunteers for PK and pharmacodynamic (PD) with two of the new formulations, using our base formulation as the comparator and then launch one to two (depending on FDA requirements) pivotal trials with one of the candidates in parallel in order to complete the NDA for an estimated FDA submission prior to the end of 2017 to allow several years of marketing before loss of exclusivity for the original VEN 307 product. We intend to finance the clinical development of the extended release formulation of VEN 307 from operating profit from the planned commercialization of VEN 307 (t.i.d. formulation). We expect to continue to pursue other lifecycle options, such as combination with other drugs.

Supply of product

We have in place a primary supplier, and have identified and are qualifying back-up suppliers, for the active pharmaceutical ingredient for VEN 307. We have evaluated and selected a supplier of drug product to provide us with our commercial supply of drug product, in the event of FDA approval of 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.

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 to S.L.A. Pharma will not exceed $1,200,000. S.L.A. Pharma has billed us for, and we have paid, $973,500 of services through December 31, 2013. 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

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 (IPAA) 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 Phase II testing. We intend to do technical development to create a twice daily patentable formulation of VEN 308 in the near future after which we will determine whether to pursue further development of VEN 308.

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.

VEN 310

VEN 310 is intended to be a delivery mechanism for bacteria, complex proteins, viral antigens and small molecules to the gastro-intestinal tract.

***C. difficile* associated diarrhea (CDAD)**

CDAD has become more frequent at least partly due to the use of broad spectrum antibiotics which can disrupt the normal gut microbiome, allowing an overgrowth of the vegetative form of *C.difficile* bacteria which leads to a severe, often chronic, and sometimes life-threatening diarrhea (pseudomembranous colitis). Antibiotics such as metronidazole, vancomycin and more recently fidoxamin, are the most commonly used antibiotics to treat CDAD. However a relapse/failure rate of 20-30% is still being observed.

Recently, remarkable efficacy (resolution of symptoms and clearing of *C.difficile* toxin in 1 day) has been reported in relapsed/recalcitrant CDAD patients with the administration of fecal microbial transplantation, or FMT. However the use of human feces as therapy, however efficacious, raises concerns regarding safety, acceptability, manufacturing and reliability. Additionally FMT is normally administered by naso-gastric tube, enema or colonoscopy. A few centers are administering enteric coated capsules, but this method to date requires more than 25 capsules to deliver an effective inoculum. Various proposed mixtures of bacterial strains have been reported in the literature to replicate the effects of FMT in mouse models of CDAD, and there are preliminary data reporting the success of mixtures cultured from human donor stool in patients.

Our strategy is to identify human strains cultured from FMT donors which might replicate the effects of FMT in CDAD, and encapsulate them with our pH sensitive delivery technology for specific release in the proximal colon (reducing inoculum size) for a Phase Ib clinical trial. We may also partner or collaborate with others who may in the future identify effective mixtures of human strains for CDAD, or other diseases, where we would provide the delivery technology.

Metronidazole, a generically available antibiotic, is commonly used orally for the treatment of CDAD, among many other indications. One of the limits to its use in CDAD, at least, is the common occurrence of dose related central nervous system side effects which can limit the doses used, which thereby reduces exposure and possibly effectiveness, as it is absorbed rapidly from the small bowel so that colonic exposure is largely dependent on systemic levels of the drug.

We may seek to formulate metronidazole with our technology for targeted release in the colon, which we believe might thereby considerably increase the colonic exposure of *C.difficile* to the drug, with less systemic exposure, and reduced side effects.

Vancomycin Resistant Enterococci (VRE) colonization

VRE colonization is becoming increasingly prevalent in oncology units and in hospital wards and presents a serious problem as eradication and control is extremely difficult and VRE bacteremia is very hard to treat particularly in an oncology setting. While there are no reports of human FMT used in VRE, there are promising reports in the medical scientific literature of the prevention of colonization in animal models of VRE with single or multiple bacterial strains.

Our strategy is to identify promising mixtures of human strains from testing in in vivo experiments, which we then intend to formulate with our technology for use in a clinical trial in an oncology unit setting where VRE is common and largely intractable.

Inflammatory Bowel Disease (IBD)

IBD, also known as ulcerative colitis, which affects only the colon, and Crohn's disease, which can affect both the colon and the small bowel, still present major therapeutic challenges in the management of acute episodes and in the maintenance of remission. Intravenous and high oral doses of corticosteroids are often used to manage acute episodes, and lower oral doses and enemas of corticosteroids are commonly used to maintain remission or to treat mild relapses. However, the problem of steroid side effects and the impact on the adrenal axis remains as the major limitation of oral steroid use in these settings, and steroid enemas for self-administration can only reach the distal colon, at best.

We may seek to formulate selected generically available corticosteroids which are currently used in this setting, with our technology for targeted proximal and transverse colon delivery, which we believe might allow for higher colonic exposure with lower systemic exposure to the steroid, and therefore may provide better safety and tolerability with equivalent efficacy, much like that seen with the enema corticosteroid formulations in the treatment of distal colon and rectal disease in ulcerative colitis.

License Agreements and 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 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 $4,200,000. From August 2007 through December 31, 2013 we made $4,200,000 of such payments. Additionally, upon receipt in February 2013 of a quality controlled final study report for the Phase III trial for VEN 307 in Europe, the cap on the amount of payments we must make to S.L.A. Pharma in respect of VEN 307 development costs increased to $4,600,000, and we also were required to pay S.L.A. Pharma $400,000, which we paid in February 2013.

We remain obligated to pay S.L.A. Pharma $41,500 a month for project management fees for VEN 307, which we began paying in October 2010, until S.L.A. Pharma is no longer managing the development program for VEN 307. From October 2010 through December 31, 2013, we have paid $1,577,000 in project management fees for VEN 307.

From August 2007 through December 31, 2013, 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.

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 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 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. patents for VEN 307 for topical treatment of pain associated with anal fissures were filed with the United States Patent and Trademark Office on August 12, 1999, now U.S. Patent No. 8,048,875 and July 8, 2011, now U.S. Patent No. 8.318,721. 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 patents were 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 patents were 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.

License Agreement – VEN 310

On November 8, 2013, we entered into a License and Collaboration Agreement with Therabiome, LLC, for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive controlled release platform technology. Under the agreement, Therabiome granted to us the exclusive worldwide license, with rights to sublicense, to develop the intellectual property for commercialization (a) in the use of bacteria, complex proteins, viral antigens and small molecules by oral delivery in (i) gastro-intestinal dysbiosis, including but not limited to C. difficile, irritable bowel syndrome-constipation and inflammatory bowel disease, (ii) auto-immune disorders and autism, including but not limited to as controlled by bacteria or virus, and (iii) orally delivered vaccines, including viral and bacterial, and (b) any oral delivery of small molecules using the licensed intellectual property. We will be solely responsible for all research and development activities with respect to any product we develop under the license.

For the license, we paid Therabiome an upfront non-refundable license fee of $300,000. We must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform, for U.S. regulatory milestones, depending on whether the milestone occurs before the filing of the first new drug application, or NDA, for a product or after the first, second or third NDA filings, as follows:

Regulatory and Clinical Milestones	
Upon the filing of an IND with the FDA:	$100,000 - $130,000
First dose first patient – human Phase I Clinical Trial	$250,000 - $325,000
First dose first patient – human Phase II Clinical Trial	$500,000 - $650,000
First dose first patient – human Phase III Clinical Trial	$750,000 - $975,000
Upon filing of an NDA or BLA with the FDA	$1,000,000 - $1,300,000
Upon marketing approval by the FDA	$3,000,000
Upon approval of a supplemental NDA (sNDA) for a new Indication, in the U.S	$1,000,000

We also must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region, and depend on whether the milestone occurs before the filing of the first NDA filing for a product or after the first, second or third NDA filings, and which will be: one-third of the U.S. milestones paid upon a foreign equivalent of an investigational new drug application, or IND, and marketing approval for each product in the European Union or Japan; 10% of the U.S. milestones paid upon a foreign equivalent of an IND and marketing approval for each product in China; 10% of the U.S. milestone paid upon marketing approval for each product in India and Brazil; and 1% of the U.S. milestone paid upon marketing approval for each product in all other countries. We also must pay Therabiome royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceed two certain thresholds, a one-time cash payment upon reaching each threshold.

If we choose not to develop a product, Therabiome will have the right to request a limited, exclusive sublicense, with the right to sublicense, for developing the intellectual property for the field, subject to our right to reject the request if we, in our sole discretion, determine that the sublicense would negatively impact our products or prospects. If we agree to the sublicense, the terms relating to Ventrus would be the same as under the license agreement applicable to Therabiome products developed under the license agreement. Therabiome also may request to develop with third parties products in the field that are not competing products, which request we can refuse in our sole discretion. If we agree to the request, the terms relating to Ventrus would be the same as under the license agreement applicable to Therabiome products developed under the license agreement. Therabiome must pay us royalties on annual net sales of any product it develops, using the intellectual property, in the low double to mid-double percentages, depending on the level of development or involvement we had in the product.

The term of the license agreement (and the period during which royalties must be paid under the license agreement) will end, on a product-by-product and country-by-country basis, at the later of: (i) the expiration of the last to expire Therabiome patent containing a valid claim covering the sale of a product in a country; or (ii) receipt by a third party of marketing approval for a generic equivalent of the product in that country. We may terminate the license agreement (i) for any reason its entirety or on a product-by-product basis, (ii) on a product-by-product basis for uncured material breach by Therabiome, (iii) on a product-by-product basis in the event Therabiome challenges the validity or enforceability of any issued patent with the licensed intellectual property, or (iv) upon Therabiome's bankruptcy. Therabiome may terminate the license agreement (i) on a product-by-product basis for uncured material breach by us, (ii) on a product-by-product basis in the event we challenge the validity or enforceability of any issued patent with the licensed intellectual property, or (iii) upon our bankruptcy.

If we terminate because of Therabiome's uncured material breach or its bankruptcy, the license of the intellectual property will remain in effect, but the milestones and royalties due Therabiome will be reduced by a certain percentage. If we terminate without cause or Therabiome terminates because of our uncured material breach or bankruptcy, the license granted under the agreement will terminate and we and Therabiome will cooperate to effect the winding down of the activities under the agreement.

Competition

As of the date of this report, we believe that there are no FDA-approved drug products that compete with VEN 308. 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. We are not aware of any other 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. In January 2012, Aptalis Pharma announced that it had signed an exclusive license agreement with ProStrakan Group plc to market Rectiv in the U.S; Rectiv became commercially available in the first quarter of 2012.

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 our two Phase III clinical trials as well as previously published trials (such as Kocher et al. 2002 and Shrivastava 2007, see **Table 1** above under the heading "Diltiazem Cream (VEN 307) 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. 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, in 2011, an Israeli company, RDD Pharma Ltd., completed in Israel a 20 patient single-arm open label study of the effect of coated suppositories of nifedipine, a calcium channel blocker, 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.

Available Information

Our website address is www.ventrusbio.com. Information on our website is not incorporated herein by reference. We make available free of charge through our website our press releases, Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after electronically filed with or furnished to the Securities and Exchange Commission.

Employees

As of February 28, 2014, we had 10 employees and had contracted with six consultants. We use consulting agreements to avoid the costs customarily associated with employees to save resources.

Item 1A. Risk Factors

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report and in any documents incorporated in this report by reference.

If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business

We have no approved products and currently are dependent on the success of VEN 307.

To date, we have no approved product on the market and have generated no product revenues. Our near-term prospects are substantially dependent on our ability to develop and commercialize VEN 307. Unless and until we receive approval from the FDA for VEN 307 and/or approvals from the FDA and other regulatory authorities for our other product candidates, we cannot sell our drugs and will not have product revenues. We will have to fund all of our operations and capital expenditures from cash on hand, any licensing fees and any future securities offerings or debt financings.

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 December 31, 2013, we had a deficit accumulated during the development stage of $111.7 million. We expect to incur substantial additional losses over the next several years as we continue to pursue our in-licensing, research, development and clinical trial activities. 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 VEN 307 or any other product is approved by the FDA for sale, and we 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 significant operating and capital expenditures and resultant substantial losses and negative operating cash flow for the next several years, and beyond if we do not successfully launch and commercialize VEN 307 as planned. We might never achieve or maintain profitability. We anticipate that our expenses will continue to be substantial in the foreseeable future as we:

- seek regulatory approvals for our product candidates, including VEN 307; and
- continue to undertake non-clinical and clinical trials for product candidates.

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:

- obtaining necessary regulatory approvals from the FDA and international regulatory agencies;
- establishing manufacturing, sales, and marketing arrangements with third parties;
- successful completion of research and clinical trials for any product candidates; and
- raising sufficient funds to finance our activities, if and when needed.

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.

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

Clinical testing is expensive, can take many years to complete and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process due to inadequate performance of a drug or inadequate adherence by patients or investigators to clinical trial protocols. In addition, the results of pre-clinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. For example, in late June 2012, we reported that our Phase III randomized, double-blind, placebo-controlled clinical trial of iferanserin (VEN 309) in patients with hemorrhoidal disease did not meet its endpoints, despite favorable Phase II trial results. We also reported in February 2014 that in our Phase III clinical trial for the treatment of anal fissures VEN 307 demonstrated no significant improvement compared to placebo. While we intend to file an NDA for VEN 307 in the third quarter of 2014, after the review of our planned NDA submission based on the S.L.A. Pharma trial in Europe and our Phase III trial in the U.S., the FDA could require a second U.S. study for approval, which would add to the time and cost of VEN 307's development, which would have a material adverse effect on our business, financial condition, results of operations and prospects. These same risks, apply to our planned development of any other product.

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 research and 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 and sell 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.

The results of additional studies and trials for any of our product candidates might not be positive or as positive as the results any prior studies or trials.

The results of any study or trial for any of our product candidates, including VEN 308 and VEN 310, may not be as positive as the results for any prior studies or trials, if at all. In addition, unforeseen safety issues could emerge in any future study or trial, which could severely hamper the likelihood of FDA or other regulatory approval of any product candidate, including VEN 308 and VEN 310. If any of these events were to occur, the development of any product candidate, including VEN 308 and VEN 310, could be significantly delayed and more expensive than anticipated, and could lead us to abandon our development efforts entirely, any of which would have a significant adverse effect on our business.

We may need additional financing to complete the development of any product candidate, including VEN 307 and VEN 310, and fund our activities in the future.

We anticipate that we will incur operating losses for the next several years as we continue to develop VEN 307 and VEN 310 as well as initiate any development of any other product and will require substantial funds during that time to support our operations. We expect that our current resources will provide us with sufficient capital to fund our operations to develop VEN 307 through to FDA approval and commercial launch and into the second quarter of 2016. However, we might consume our available capital before that time if, for example, we are not efficient in managing our resources or if we encounter unforeseen costs, delays or other issues or if regulatory requirements change. If that happens, we may need additional financing to complete the development of VEN 307 and our other product candidates. Thereafter, if VEN 307 is not approved or the launch is not successful, we will need additional capital to fund our operations in the future. However, there is no assurance that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. If such event or other unforeseen circumstances occurred and we were unable to raise capital, 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 a license relationship for each of VEN 307, VEN 308 and VEN 310.

We have acquired, by license from S.L.A. Pharma, the rights to VEN 307 and VEN 308, and we might enter into additional licenses in the future. VEN 307 is critical to our business. The license with S.L.A. Pharma contains, and we expect that any future licenses will contain, provisions requiring up-front, milestone, and royalty payments to the licensor. In addition, we are obligated to pay S.L.A. Pharma monthly project management fees of $41,500 until S.L.A. Pharma is no longer managing the development program for VEN 307. In the event we breach these obligations to S.L.A. Pharma, 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. Our license with Therabiome also requires us to pay regulatory and clinical milestones as well as royalty payments to Therabiome. If we breach any of these obligations, we could lose our rights to VEN 310. If we fail to comply with similar obligations to any other licensor, it would have the right to terminate the license, 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 licenses will make it less profitable for us to develop our drug candidates than if we owned the technology ourselves.

We have had negative cash flows from operations and might not be able to generate sufficient cash to meet our substantial obligations to S.L.A. Pharma, which could result in the termination of our license or put substantial burdens on our financial position.

We license two of our product candidates, VEN 307 and VEN 308, from S.L.A. Pharma, and have obligations related to VEN 308 and to fund S.L.A. Pharma's development efforts for VEN 307 in the E.U. Under the license, we are obligated to pay S.L.A. Pharma monthly project management fees of $41,500 until S.L.A. Pharma is no longer managing the development program for VEN 307. 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 late 2014 or early 2015 at the earliest.

We expect to experience negative cash flow for at least the next several years as we fund our operating losses and capital expenditures for the development of VEN 307, VEN 308 and VEN 310 and acquire and development other product candidates. 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. 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. Our license with Therabiome also requires us to pay regulatory and clinical milestones as well as royalty payments to Therabiome. If we breach any of these obligations, we could lose our rights to VEN 310.

If we in-license additional product candidates from third parties, any dispute with a licensor or non-performance by us or by our licensor may adversely affect our ability to develop and commercialize that product candidate.

We intend to pursue the in-licensing of other product candidates. Under the terms of any license agreement, the licensor would generally have the right to terminate the agreement in the event of a material breach by us. A license also usually would require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments would depend on our ability to generate cash in the future. Further, a license agreement generally would require us to use diligent and reasonable efforts to develop and commercialize the product candidate.

If there is any conflict, dispute, disagreement or issue of non-performance between us and a licensing partner regarding our rights or obligations under the license agreement, including any conflict, dispute or disagreement arising from our failure to satisfy payment obligations under the agreement, our ability to develop and commercialize the affected product candidate may be adversely affected.

Licensing or acquiring new development stage as well as pre-clinical compounds or biologics may negatively impact our operating results.

Our business strategy contemplates diversification. We are interested in licensing or acquiring new development stage and pre-clinical compounds and biologics. However, we cannot assure you that any such transaction will be successful or that we will realize the anticipated benefits of any such transaction.

Our results of operations may be adversely affected by expenses we incur in making acquisitions. For example, our results of operations may be impacted by expenses, including legal and accounting fees, incurred in connection with the transaction, amortization of acquisition-related intangible assets with definite lives and by additional depreciation expense attributable to acquired assets. Any of the assets we acquire may also involve some issues that we fail to discover before completing the acquisition, such as flaws in the intellectual property rights, which could increase expenses, for which indemnity, if any, may be limited.

We may not be able to manage our anticipated growth, which may in turn adversely impact our business.

We may need to expend funds to improve our infrastructure to address our anticipated growth. The acquisition of one or more assets may place a strain on our management, and our administrative, operational and financial systems. In addition, we may need to hire, train and manage more employees. Management issues associated with acquisitions may require a disproportionate amount of our management’s time and attention and distract our management from running our business.

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

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

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

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

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

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 sufficient 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:

- the lack of effectiveness during clinical trials;
- the emergence of unforeseen safety issues;
- 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;
- delays, suspension, or termination of clinical trials by the institutional review board responsible for overseeing the study at a particular study site; and
- government, institutional review board or other regulatory delays or clinical holds requiring suspension or termination of the trials.

The results from preclinical testing and early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain or have obtained positive results from preclinical or early clinical trials, we might not achieve the same success in future clinical trials. For example, although positive results were observed in earlier clinical trials of each of 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 have used and intend to continue to rely on one or more contract research organizations, or CROs, to conduct our clinical trials. We are 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.

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

Both VEN 307 and VEN 308 have been safely used extensively for decades when given orally at much higher exposures (blood levels) than currently studied in the topical application of VEN 307 and under study in the topical application of 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. We have not yet tested VEN 310 and safety issues could arise during that planned testing or testing of any other product candidates. 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 came to market in the first quarter of 2012. For the treatment of fecal incontinence, Solesta, an injectable therapy developed by Oceana Therapeutics, was approved as a device by the FDA in 2011 and came to market in 2012. To our knowledge, there are no other products approved or in development although there are two non-drug products in development. If our competitors develop effective treatments for anal fissure or fecal incontinence, or any other indication or field we might pursue, 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. Although our employees have extensive experience in the commercialization of drug products, 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 reform legislation, of which the coverage and reimbursement provisions went into effect in late 2013. We cannot predict what impact on federal reimbursement policies and regulatory compliance landscape this legislation will have in general or on our business specifically. We expect continued judicial and legislative review and assessment of this legislation and possibly alternative health care reform proposals. We cannot predict judicial results or 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 could adopt 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 private insurers 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 his retention. 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 or twelve months after termination, depending on the individual. This non-compete provision was also included in employment agreements with former officers, all of 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 business officer, chief medical officer and chief scientific officer remain in effect and are in effect under all of our current consulting agreements.

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 February 28, 2014, we had 10 employees, six consultants and three contract research organizations with whom we have contracted. While we believe this will provide us with sufficient staffing to develop VEN 307 through to FDA approval, we might need to hire or contract with additional qualified personnel with expertise in clinical research and testing, government regulation, formulation and manufacturing and sales and marketing to commercialize VEN 307 or any other product we may seek to develop. 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, although we recently in-licensed the rights to VEN 310 in November 2013. 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 intended 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; untitled letter or 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, the FDA proposed that we include an additional treatment arm in our pivotal Phase III trial for our former product candidate VEN 309, which increased the cost of that trial.

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 approval 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 ongoing FDA oversight 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, among other activities, 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 obtain clinical trial insurance for our product candidates prior to beginning clinical trials. 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 product liability insurance covering 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 business depends on protecting our intellectual property.

If we and our licensors S.L.A. Pharma and Therabiome 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.

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

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 and through February 28, 2014, the price of our common stock has fluctuated between $1.36 and $21.00, with significant volatility after we announced on June 25, 2012 that VEN 309 failed to meet the endpoints of our Phase III trial, and after we announced in February 2014 that VEN 307 demonstrated no significant improvement compared to placabo. Continued 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:

- the receipt or loss of required regulatory approvals for our product candidates, especially VEN 307;
- results of our clinical trials and other studies involving our product candidates;
- 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.

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.

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.

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 securities.

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 securities 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.

If securities analysts downgrade our stock or cease coverage of us, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. Currently, six financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. If any of the analysts who cover us downgrade our stock, our stock price would likely decline rapidly. If these analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Substantial future sales of our common stock in the public market may depress our stock price and make it difficult for you to recover the full value of your investment in our shares of securities.

As of February 28, 2014, we had 23,396,259 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. The market price of our common stock may decline if our common stockholders sell a large number of shares of our common stock in the public market, or the market perceives that such sales may occur. In addition, at February 28, 2014, we had outstanding options and warrants to purchase an aggregate of 2,338,491 shares and 861,046 shares, respectively, of our common stock. If these options or warrants are exercised and the shares issued upon exercise are sold, the market price of our securities may also decline. These factors also could impair our ability to raise needed capital by depressing the price at which we could sell our securities.

Item 1B. Unresolved Staff Comments

None.

Item 2. 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 August 2014. 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. We intend to renew the lease prior to its expiration.

Item 3. Legal Proceedings

On May 9 and May 21, 2013, respectively, two purported class action lawsuits were filed in the U.S. District Court for the Southern District of New York against us, two of our executive officers and the lead underwriter of our initial public offering: Ted Davison, William Gould and Ray Lenci, Individually and on Behalf of All Others Similarly Situated , Plaintiffs v. Ventrus Biosciences, Inc., et al, 13CIV 3119; and Michael Bartley, Individually and on Behalf of All Others Similarly Situated , Plaintiffs v. Ventrus Biosciences, Inc., et al, 13CIV 3429.

The complaints have been brought as purported stockholder class actions, and, in general, include allegations that, during the class period between December 17, 2010 and June 25, 2012, we and our two executive officers violated Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder, and our two executive officers and the lead underwriter of our initial public offering violated Section 20(a) of the Exchange Act in making various statements related to our product, iferanserin (VEN 309), a topical treatment for symptomatic hemorrhoids, including but not limited to, the market for the product, the potential competitors, and the results of clinical trials, thereby inflating the price of our common stock. The complaints seek unspecified damages, interest, attorneys' fees, and other costs.

On July 8, 2013, three prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff, and appoint lead counsel (the "Motions to Consolidate"). The Court took the Motions to Consolidate under submission on July 17, 2013. On July 23, 2013, the Court consolidated the actions and appointed lead plaintiffs and lead counsel. On September 16, 2013, lead plaintiffs filed a consolidated amended complaint. On November 22, 2013, we filed a motion to dismiss the consolidated amended complaint (the "Motion to Dismiss"). The Motion to Dismiss has been fully briefed and the Court has taken the Motion to Dismiss under submission. Due to the early stage of these proceedings, we are unable to predict the outcome or reasonably estimate a range of possible loss relating to these claims.

Other than the above, 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.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

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.

	2012	
	High	**Low**
First Quarter	$ 12.00	$ 7.68
Second Quarter	$ 13.53	$ 4.20
Third Quarter	$ 4.40	$ 3.46
Fourth Quarter	$ 3.81	$ 1.99

	2013	
	High	**Low**
First Quarter	$ 3.92	$ 2.12
Second Quarter	$ 3.09	$ 2.62
Third Quarter	$ 3.75	$ 2.10
Fourth Quarter	$ 3.87	$ 2.67

On March 24, 2014, the closing price for the common stock as reported on the NASDAQ Capital Market was $1.38.

As of March 24, 2014, there were 90 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

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.

Equity Compensation Plans

The information required by Item 4 of Form 10-K regarding equity compensation plans is incorporated herein by reference to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in this report.

Item 6. Selected Financial Data

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the notes thereto included elsewhere in this report.

Statement of Operations Data:

	Year Ended December 31,				
	2013	**2012**	**2011**	**2010**	**2009**
	(in thousands)				
Operating expenses	$ 19,605	$ 24,855	$ 34,002	$ 4,766	$ 3,340
Loss from operations	(19,605)	(24,855)	(34,002)	(4,766)	(3,340)
Interest income	201	65	76	6	-
Interest expense	-	-	(419)	(10,530)	(1,199)
Net loss	(19,404)	(24,790)	(34,345)	(15,291)	(4,539)

Balance Sheet Data:

	As of December 31,				
	2013	2012	2011	2010	2009
	(in thousands)				
Total assets	$ 27,132	$ 20,556	$ 37,046	$ 14,617	$ 166
Deferred financing costs, net	-	-	-	27	69
Total stockholders' equity (deficiency)	24,494	17,810	34,533	11,626	(13,363)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

Overview

We are a development-stage specialty pharmaceutical company currently focused on the development of late-stage and pre-clinical prescription drugs and biologics, currently for gastrointestinal disorders.

We have in-licensed three product candidates, two of which we are actively developing. We are developing VEN 307 for the relief of pain associated with anal fissures. We plan to develop VEN 310 as a colonic delivery mechanism for bacteria, complex proteins, viral antigens and small molecules. We also intend to in-license or acquire other development stage as well as pre-clinical compounds and biologics. We are not actively pursuing the development of VEN 308 at this time. In June 2012, we ceased all activity related to a former product candidate, VEN 309.

Since our inception, we have had no revenue from product sales, and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings since then. 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, maintaining and improving our patent portfolio and raising capital. We have generated significant losses to date, and we expect to continue to generate losses as we continue to develop VEN 307 and VEN 310, and any other product candidate we may acquire. As of December 31, 2013, we had a deficit accumulated during the development stage of $111,723,273. Because we do not generate revenue from any of our product candidates, our losses will continue as we seek regulatory approval and commercialization of our product candidates. We do not anticipate FDA approval and launch of VEN 307 until at least the second half of 2015. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none is approved or successfully launched. 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 through FDA approval of VEN 307 and its initial launch and commercialization and into the second quarter of 2016. Thereafter, we will need revenue from commercial sales of VEN 307, if any, or additional capital to continue operations.

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, 2013 audited financial statements included in this report. 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 and restricted stock 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 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 service period. For the purpose of valuing options and warrants granted to employees and non-employees, we use the Black-Scholes option pricing model. The restricted stock grant was valued using the Monte Carlo simulation 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.

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 December 31, 2013, we incurred $74,072,484 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. Included in research and development expense is the full $12.5 million purchase price we paid in 2011 for VEN 309.

We plan to continue research and development expenses for the at least the next two years in order to complete development of our most advanced product candidate, VEN 307. On June 25, 2012, we reported that a Phase III, randomized, double-blind, placebo-controlled clinical trial of VEN 309 for the treatment of symptomatic hemorrhoids did not meet its endpoints. Based on the disappointing results of that Phase III trial, we determined that our resources would be better allocated toward the planned completion of VEN 307 development program in anal fissures. Consequently, we have no plans to continue development of VEN 309 and ceased all activity related to VEN 309.

The following table summarizes the research and development expenses incurred since inception.

	YE 2011	YE 2012	YE 2013	Period from October 7, 2005 (inception) to December 31, 2013
VEN 307	$ 1,921,922	$ 5,565,280	$ 14,560,539	$ 25,849,742
VEN 309	$ 22,230,856	$ 13,102,375	$ (585,347)	$ 43,187,867
VEN 310	$ -	$ -	$ 358,250	$ 358,250
Other	$ 1,124,904	$ 846,508	$ 695,636	$ 4,676,625

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 clinical data, regulatory conversations with FDA, 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 and regulatory process, we are unable to determine with certainty the duration and completion costs of current or future clinical stages of our product candidate or when, or to what extent, we will generate revenues from the commercialization and sale of our product candidate. Any estimate could change significantly depending on the progress, timing and results of non-clinical and clinical trials associated with any product candidate. We believe we currently have sufficient funds to meet our operating requirements and scheduled regulatory and development activities through FDA approval and initial launch and commercialization of VEN 307 and into the second quarter of 2016. Assuming such approval and launch, thereafter, if we cannot generate significant cash from our operations, we intend to obtain any additional funding we require through strategic relationships, public or private equity or debt financings, or other arrangements, but we cannot assure such funding will be available on reasonable terms, or at all.

Our significant accounting policies are described in more detail in Note 2 to our audited financial statements included in this report.

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.

Contractual Obligations

The following table summarizes our future contractual obligations and commercial commitments at December 31, 2013.

	Less than 1 year	1-2 years
SLA Pharma	$ 249,000	$ -
Regus (office lease)	$ 58,800	$ -
Total contractual obligations	$ 307,800	$ -

Results of Operations

Comparison of the Years Ended December 31, 2013 and December 31, 2012

Research and Development Expense

Research and development expense was $15,029,078 for the year ended December 2013, a decrease of $4,485,085 or 22.98% from $19,514,163 for the same period in 2012. The primary reason for the decrease in 2013 was due to the winding down of our VEN 309 program, which began in late June 2012, offset by increased expense for VEN 307 in both years.

General and Administrative Expense

General and administrative expense was $4,575,701 for the year ended December 2013, a decrease of $765,632 or 14.33% from $5,341,333 for the same period in 2012. The primary reason was a decrease of stock-based compensation expense of $1,300,000, which was offset by additional legal expenses of $370,000 that was primarily due to the class action litigation, Nasdaq fees of $73,000, consulting fees of $57,000 and salaries of $58,000.

Interest Expense and Income

There was no interest expense in 2013 or 2012. Interest income was $201,020 for the year ended 2013 compared to $65,066 from same period in 2012 due to an increase in our cash balance from the sale of common stock and Series A preferred stock.

Liquidity and Capital Resources

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 December 31, 2013 principally with debt (which in connection with the initial public offering, all of the convertible notes, and accrued interest thereon, were converted into common stock) and equity financing, raising an aggregate of $94.8 million in net proceeds from public offerings and private placements from inception to December 31, 2013.

Further, under a shelf registration statement filed with the Securities and Exchange Commission, or SEC, we raised approximately $1.8 million in net proceeds under our at-the-market equity sales program in January 2014. As of December 31, 2013, an aggregate of approximately $75,000,000 worth of securities was available under the shelf registration statement out of which approximately $16,900,000 of common stock was available for the at-the-market common equity sales program.

Net Cash Used in Operating Activities

Net cash used in operating activities was $17,796,088 for the year ended December 31, 2013 and funded our research and development program build out and general and administrative expenses. The net loss of $19,403,759 for the year ended December 31, 2013 was greater than cash used in operating activities by $1,607,671. The primary reason for the difference is attributed to a stock-based compensation charge of $1,712,947.

Net Cash Used in Investing Activities

Net cash used in investing activities was $6,477 for the year ended December 31, 2013.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $24,374,614 for the year ended December 31, 2013. Net cash provided by financing activities during the year ended December 31, 2013 consisted of the sale of common stock and Series A non-voting convertible preferred stock in a registered direct public offering of $20,754,419 and an at-the-market program of $3,620,195.

Funding Requirements

We expect to incur losses for at least the next several years as we develop VEN 307 and thereafter if the FDA does not approve VEN 307 or we do not launch it successfully. We expect to incur increasing research and development expenses for VEN 307 and to begin incurring the same for VEN 310. We expect that our general and administrative expenses will also increase as we add infrastructure for the planned commercialization of VEN 307, and continue to incur costs related to being a public company, including 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 cash position at December 31, 2013, the receipt of approximately $1.8 million in net proceeds in January 2014 from our at-the-market program, and our analysis of our future development costs, we believe that our existing cash and cash equivalents will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through the initial launch and commercialization of VEN 307 and into the second quarter of 2016. 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 may need to raise additional funds to in-license or acquire any other product candidate.

We may need to finance our future cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements, or a bank credit facility or other financing vehicle 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 do not currently have any commitments for future external funding. 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 we need additional capital and 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.

Recent Accounting Pronouncements

None.

Cautionary Statement

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. The following statement highlights some of these risks. For more detail, see “Item 1A. Risk Factors”.

Statements contained in this Form 10-K that are not historical facts, are or might constitute forward-looking statements under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Although we believe the expectations reflected in such forward-looking statements are based on reasonable assumptions, our expectations might not be attained. Forward-looking statements involve known and unknown risks that could cause actual results to differ materially from expected results. Factors that could cause actual results to differ materially from our expectations expressed in the report include, among others: risks related to the costs, timing, regulatory review and results of our studies and clinical trials; our ability to obtain FDA approval of our product candidates; differences between historical studies on which we have based our planned clinical trials and actual results from our trials; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; our liquidity and working capital requirements; our expectations regarding our revenues, expenses and other results of operations; the unpredictability of the size of the markets for, and market acceptance of, any of our products, including VEN 307; our ability to sell any approved products and the price we are able realize; our ability to obtain future funding on acceptable terms; our ability to retain and hire necessary employees and to staff our operations appropriately; our ability to compete in our industry and innovation by our competitors; our ability to stay abreast of and comply with 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; the future trading prices of our common stock and the impact of securities analysts’ reports on these prices; and the risks set out in our filings with the SEC.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates.

We do not believe that our cash and equivalents have significant risk of default or illiquidity. Under our current investment policies, we invest our cash and cash equivalents in money market funds which invest in short-term U.S. Treasury securities with insignificant rates of return. While we believe our cash and equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and equivalents at one or more financial institutions that are in excess of federally insured limits.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during 2012 or 2013.

Our purchases of raw materials and finished goods are denominated in U.S. dollars. Consequently, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e),which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all error and all fraud. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework* issued in 1992 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control-Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2013.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There were no significant changes in our internal control over financial reporting or in other factors that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Our current directors and their respective biographical summaries are as follows.

Name	Age (as of 02/28/14)	Director Since	Business Experience For Last Five Years
Mark Auerbach	75	2010	Mr. Auerbach was elected to our Board in November 2010. Mr. Auerbach is the lead director and chairman of the audit committee of RCS Capital Corporation (NYSE: RCAP), a publicly traded financial services company. Mr. Auerbach previously served as a director and chairman of the audit committee of Optimer Pharmaceuticals, Inc., a public company, from 2005 until its acquisition by Cubist Pharmaceuticals, Inc. in October 2013. 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. Over the last 20 years, Mr. Auerbach also has served as a director for several other companies, including Par Pharmaceutical Companies, Inc., a publicly traded manufacturer and marketer of generic pharmaceuticals and the parent of Par Pharmaceutical, Inc., Collexis Holdings, Inc., a public company which develops knowledge management and discovery software, and RxElite Holdings, Inc., a company which develops, manufactures, and markets generic prescription drug products in specialty generic markets. 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.
Russell H. Ellison, M.D., M.Sc.	66	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. Prior to that, Dr. Ellison served as Vice President of Clinical Development of Fibrogen, Inc., a privately held biotechnology company, Vice President of Medical Affairs and Chief Medical Officer of Sanofi-Synthelabo, USA, a pharmaceutical company, and Vice President, Medical Affairs and Chief Medical Officer of Hoffman-La Roche, Inc., a pharmaceutical company. Dr. Ellison previously served as a director of Cougar Biotechnology, Inc., a publicly traded pharmaceutical company that was acquired by Johnson & Johnson in July 2009, and CorMedix, Inc., a pharmaceutical company that went public in March 2010. He also has served 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 02/28/14)	Director Since	Business Experience For Last Five Years
Joseph Felder, M.D.	53	2008	Dr. Felder joined our Board 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. 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.
Myron Z. Holubiak	74	2010	Mr. Holubiak joined our Board in July 2010. Mr. Holubiak currently serves as President of 1-800-DOCTORS, Inc., a position he has held since May 2007. Mr. Holubiak is the former President of Roche Laboratories, Inc., USA, a major research-based pharmaceutical company, a position he held from December 1998 to August 2001. Prior to that, he held many sales and marketing positions at Roche Laboratories during his 19-year tenure there. Since September 2002, Mr. Holubiak has served on the board of directors of BioScrip, Inc., a publicly traded company and a leading home infusion provider with nationwide pharmacy and nursing capabilities, and is currently chairman of the board. Since October 2012, Mr. Holubiak also has been a member of the board of directors of Intellicell Biosciences, Inc., a publicly traded regenerative medicine company. Mr. Holubiak is a founder and director as well as the chief executive officer of Leonard+Meron Biosciences, Inc., a privately held pharmaceutical company. Mr. Holubiak is also a trustee of the Academy of Managed Care Pharmacy Foundation. Mr. Holubiak received his B.S. in Molecular Biology and Biophysics from the University of Pittsburgh. Among other experience, qualifications, attributes and skills, Mr. Holubiak's 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.
Anthony Altig	58	2012	Mr. Altig joined our Board in January 2012. Since 2008, Mr. Altig has been the Chief Financial Officer of Biotix Holdings, Inc., a company that manufactures microbiological consumables. From 2004 to 2007, Mr. Altig served as the Chief Financial Officer of Diversa Corporation (subsequently Verenium Corporation), a public company developing specialized industrial enzymes. Prior to joining Diversa, Mr. Altig served as the Chief Financial Officer of Maxim Pharmaceuticals, Inc., a public biopharmaceutical company. In addition, Mr. Altig serves as a director and chairman of the audit committee for TearLab Corporation (formerly OccuLogix, Inc.), a publicly traded eyecare technology company, and served as a director of Optimer Pharmaceuticals, Inc., a pharmaceutical company, which was a public company until its acquisition by Cubist Pharmaceuticals, Inc. in October 2013. Among other experience, qualifications, attributes and skills, Mr. Altig's extensive management experience and financial expertise, as well as his experience serving on the boards of directors of several public 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.

Audit Committee

Our Board has established an Audit Committee of which directors Mark Auerbach (Chairman), Myron Holubiak and Anthony Altig are the members. The Board has determined that each of Mr. Altig and Mr. Auerbach qualifies as an "audit committee financial expert" as that term is defined in Item 407(d) of Regulation S-K promulgated by the SEC.

Section 16(a) Beneficial Ownership Reporting Compliance

Pursuant to Section 16(a) of the Securities Exchange Act, our directors and executive officers are required to file reports with the SEC indicating their holdings of and transactions in our equity securities. To our knowledge, based solely on our review of the copies of such reports furnished to us and written representations that no other reports were required, there were no reports required under Section 16(a) of the Exchange Act which were not timely filed during the fiscal year ended December 31, 2013.

Code of Ethics

Our Board has adopted a Code of Ethics for our principal executive officer and all senior financial officers and a Code of Conduct applicable to all of our employees and our directors. Both Codes are available under the Investor Relations-Corporate Governance section of our website at www.ventrusbio.com.

Item 11. Executive Compensation

Director Compensation

The following table shows the compensation earned by each of our non-employee directors for the year ended December 31, 2013.

Non-Employee Director Compensation in Fiscal 2013

Name (1)	Fees Earned or Paid in Cash	Option Awards ($)(2)	All Other Compensation ($)	Total ($)
Anthony E. Altig	$ 40,000	-0-	-0-	$ 40,000
Mark Auerbach	45,000	21,030	-0-	66,030
Joseph Felder	40,000	21,030	-0-	61,030
Myron Holubiak	45,000	21,030	-0-	66,030

(1) As of December 31, 2013, our non-employee directors held options to purchase the following number of shares of our common stock: Mr. Altig, 35,000 shares; Mr. Auerbach, 55,000 shares; Dr. Felder, 57,016 shares; and Mr. Holubiak, 55,000 shares.

(2) The reported amount in the table above of the stock option grants made in 2013 represents the aggregate grant date fair value of the options computed in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 6 of the financial statements included in this Annual Report on Form 10-K.

In September 2011, the Compensation Committee engaged Frederick W. Cook & Co., an independent compensation consultant, to review our non-employee director compensation as compared to that of comparable small public companies in the industry. In November 2011, based on the recommendation of Frederick W. Cook & Co., our Board, with the recommendation of the Compensation Committee, approved our current non-employee director compensation. Directors receive a grant of 10,000 options annually. Upon joining the Board, a new director will be granted 35,000 stock options; in the next calendar year, that director will receive no options; and in the next calendar year he will receive the 10,000 annual grant of options to all directors. Each non-employee director receives an annual cash fee of $40,000, payable quarterly. The chairman of the Audit Committee and the lead independent director each receives an additional annual cash fee of $5,000.

Executive Compensation

Our executive officers are Dr. Russell H. Ellison, our President and Chief Executive Officer, and David J. Barrett, our Chief Financial Officer. Information on Dr. Ellison is provided under Item 10 above. Information on Dr. Barrett is below.

Name	Age (as of 02/28/14)	Business Experience For Last Five Years
David J. Barrett	38	Mr. Barrett joined us as Chief Financial Officer in July 2010. From April 2006 to September 2009, Mr. Barrett served as Chief Financial Officer of Neuro-Hitech, Inc., a public company focused on developing, marketing and distributing branded and generic pharmaceutical products. From September 2003 to April 2006, Mr. Barrett was the Chief Financial Officer /Vice President of Finance of Overture Asset Managers and Overture Financial Services, which, at the time, was a start-up asset management firm that assembled investment products and platforms to distribute turnkey and unbundled investment solutions to financial intermediaries and institutional investors. From July 1999 to September 2003, Mr. Barrett was employed as a Manager at Deloitte & Touche, LLP. Mr. Barrett received his B.S. in Accounting and Economics and his M.S. in Accounting from the University of Florida. He is a certified public accountant.

Executive Compensation

Components of our Executive Compensation Program

The principal components of our executive compensation program are base salary, annual bonus, and long-term incentives. Our Compensation Committee believes that each component of executive compensation must be evaluated and determined with reference to competitive market data, individual and corporate performance, our recruiting and retention goals, internal equity and consistency, and other information we deem relevant. We believe that in the biopharmaceutical industry stock option and/or other equity awards are a primary motivator in attracting and retaining executives, in addition to salary and cash incentive bonuses.

The components of our compensation package are set forth below.

Base Salary

We provide base salaries for our Named Executive Officers to compensate them for their services rendered during the fiscal year. Base salaries for our Named Executive Officers have been established based on their position and scope of responsibilities, their prior experience and training, and competitive market compensation data we review for similar positions in our industry.

Base salaries are reviewed periodically and may be increased for merit reasons based on the executive's performance, for retention reasons or if the base salary is not competitive to salaries paid by comparative companies for similar positions. Additionally, we may adjust base salaries throughout the year for promotions or other changes in the scope or breadth of an executive's role or responsibilities.

Annual Incentive Bonus

A significant element of the cash compensation of our Named Executive Officers is an annual performance-based cash bonus. A named executive officer's target bonus is generally set as a percentage of base salary to reward strong performance and retain his or her employment in a competitive labor market. In the case of Dr. Ellison and Mr. Barrett, their prior employment agreements, effective through 2013, provided an annual bonus of up to 50% and 25% of their base salary, respectively. Their current employment agreements provide for 50% each. Bonuses are based on the achievement of significant company goals, including research, clinical development, financial, business development and operational milestones, with specific goals tailored to the executive officer's area of responsibility. The performance goals generally are determined by our Compensation Committee in the first quarter of the calendar year but the bonuses are determined at the time bonuses are paid. Additionally, the Board or the Compensation Committee may increase or decrease an executive's bonus payment (above or below the target) based on its assessment of the company's and an executive's individual performance during a given year. For 2013, annual bonuses were based on achievement of company goals related to development of VEN 307, financial operations/investor relations, strategic planning, business development/commercialization, and corporate governance. Each officer's potential bonus was weighted differently for each set of goals, depending on his respective area of responsibility. The business development/commercialization goals for VEN 307 were not met, due to the results of the Phase III trial being no better than placebo as reported in February 2014. The strategic planning goals and corporate governance goals generally were met. The Compensation Committee considered the impact of VEN 307 in adjusting goals and weightings for goals in assessing performance for 2013. The resulting bonuses for Dr. Ellison and Mr. Barrett were $18,750 and $68,750, respectively, which represented 10% and 50% of their respective total possible bonuses for 2013.

Long-term Incentives

Our equity-based long-term incentive program is designed to align our Named Executive Officers' long-term incentives with stockholder value creation. We believe that long-term participation by our executive officers in equity-based awards is a critical factor in the achievement of long-term company goals and business objectives. Our 2010 Plan allows the grant to executive officers of stock options, as well as other forms of equity incentives, as part of our overall compensation program. Grants of options to our executive officers other than our Chief Executive Officer are recommended by the Chief Executive Officer and finalized by the Compensation Committee and/or the Board. Grants of options to our Chief Executive Officer are made by the Compensation Committee and/or the Board.

On April 5, 2013, we granted restricted stock units to Dr. Ellison and Mr. Barrett to more strongly incentivize them to successfully complete the development and to initiate the commercialization of our lead product candidate, VEN 307 (diltiazem), and to continue to strive to grow company value. We approved these grants after considerable deliberation, including consultation with an independent compensation consulting firm, on the best means to retain and incentivize our longer-term employees, all of whom have prior option grants that are significantly underwater. In approving these restricted stock units, the Board's guiding principle was to create a program that is designed to incentivize management to generate a significant increase in total shareholder return as measured by sustained increases in our stock price.

We granted 200,000 restricted stock units to each of Dr. Ellison and Mr. Barrett. Of the units, 25% vested immediately at grant. The remaining 75% will vest in equal 25% tranches if the 20 trading day volume-weighted average price of our common stock as reported on the NASDAQ Capital Market is at least $4.15, $5.15 and $6.15, respectively. The price thresholds were based on $1.00 increases over the 20 trading day volume-weighted average price of our common stock as reported on the NASDAQ Capital Market on April 3, 2013. The performance period for the unvested restricted stock units is June 30, 2016; if one or more of the stock price thresholds are not met by that date the unvested units will expire. As of the date of this report, none of the thresholds has been met.

Both Dr. Ellison and Mr. Barrett elected to defer receipt of all shares issuable under the units, including the immediately vested shares, until the earliest of termination of employment, a change in control of our company, or April 1, 2015.

Other Compensation

We maintain broad-based benefits and perquisites that are provided to all eligible employees, including health insurance, life and disability insurance, dental insurance and paid vacation.

Pension Benefits

We do not maintain any qualified or non-qualified defined benefit plans. As a result, none of our Named Executive Officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our Compensation Committee may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

Nonqualified Deferred Compensation

None of our Named Executive Officers participate in or have account balances in nonqualified defined contribution plans or other non-qualified deferred compensation plans maintained by us. Our Compensation Committee may elect to provide our officers and other employees with non-qualified defined contribution or other non-qualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Summary Compensation Table

The following table sets forth all compensation earned in the fiscal years ended December 31, 2013 and 2012 by our Named Executive Officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock awards ($)	Option awards [1] ($)	Non-equity incentive plan compensation [2] ($)	All other compensation ($)	Total ($)
Russell H. Ellison, M.D.	2013	$ 375,000	$ -	$ 147,500	$ -	$ 18,750	$ -	$ 541,250
President and Chief Executive Officer	2012	375,000	75,000	-	322,739	175,780	-	948,519
David J. Barrett	2013	$ 250,000	$ -	$ 147,500	$ -	$ 68,750	$ -	$ 466,250
Chief Financial Officer	2012	250,000	-	-	215,160	67,500	-	532,660

(1) The reported amounts represent the grant date fair value of the award, computed in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 6 of the financial statements included in this Annual Report on Form 10-K.
(2) Non-equity incentive plan compensation represents amounts paid as annual performance awards.

Outstanding Equity Awards at December 31, 2013

The following table contains certain information concerning unexercised options and unvested restricted stock units for the Named Executive Officers as of December 31, 2013.

	Option Awards					Stock Awards	
Name	Grant date	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Option exercise price ($)	Option expiration date	Number of shares that have not vested (#)	Market Value of shares that have not vested (#)
Russell H. Ellison, M.D.	12/22/10	573,599	-0-	$ 6.00	12/22/20	-	-
	1/15/12[1]	20,000	40,000	$ 8.10	1/15/22	-	-
	4/05/13[2]	-	-	-	-	150,000	$ 573,000
David J. Barrett	12/22/10	305,962	-0-	$ 6.00	12/22/20	-	-
	1/15/12[1]	13,334	26,666	$ 8.10	1/15/22	-	
	4/05/13[2]	-	-	-	-	150,000	$ 573,000

(1) One-third of the options vest on the grant date, one-third vest on the first anniversary of the grant date and one-third vest on the second anniversary of the grant date.

(2) The restricted stock units will vest in equal 25% tranches if the 20 trading day volume-weighted average price of our common stock as reported on the NASDAQ Capital Market is at least $4.15, $5.15 and $6.15, respectively. The price thresholds were based on $1.00 increases over the 20 trading day volume-weighted average price of our common stock as reported on the NASDAQ Capital Market on April 3, 2013. Market value is calculated by multiplying the number of stock units by the closing price of $3.82 for our common stock on December 31, 2013.

Employment Arrangements

Dr. Ellison serves as our Chief Executive Officer and David J. Barrett serves as our Chief Financial Officer, each pursuant to an employment agreement entered into on January 15, 2014, and effective as of December 22, 2013. These employment agreements replaced the prior agreements between us and each of Dr. Ellison and Mr. Barrett that expired on December 22, 2013 in accordance with their terms.

Each new employment agreement has a term of two years and will be automatically extended for additional one-year periods unless we notify the officer at least 180 days prior to the then current expiration date that we intend to not extend the employment agreement. The employment agreements provide for a base salary of $475,000 per year for Dr. Ellison and $300,000 for Mr. Barrett, and an annual discretionary bonus of up to 50% of the officer's base salary based on financial, clinical development and business milestones established by the Board of Directors. Pursuant to the employment agreements, Dr. Ellison and Mr. Barrett received a grant of options to purchase 395,500 shares and 213,000 shares, respectively, of our common stock with a purchase price of $3.81, which was the closing price of the common stock on January 14, 2014. The stock options have a 10-year term and one-third of the options vest on each of the first, second, and third anniversaries of the employment agreement's effective date.

During the term of Dr. Ellison's employment agreement, we will use our best efforts to cause him to be elected as a member and the Chairman of our Board of Directors.

Under the employment agreements, Dr. Ellison and Mr. Barrett are prohibited for 12 months after termination of employment from (i) engaging within the restricted territory (as defined in the agreement) in developing novel prescription drugs for the specific disease treatment of hemorrhoids, anal fissures, and fecal incontinence or any other business in which we are actively engaged at the time of termination of employment, (ii) holding a position in or with responsibility for all or a part of the restricted territory (A) with any person or entity engaged in such a business and for which the officer will perform services that are the same or substantially similar to those performed by him for us within 12 months prior to termination of employment, or (B) in which the officer will use or disclose any of our confidential information, (iii) being employed or engaged by any person or entity that was an agent or customer of ours with whom the officer worked during his employment with us and for whom he will be performing services that are the same or substantially similar to those services he provided to the agent or customer during the officer's employment with us, (iv) soliciting our customers for purposes of marketing or selling similar or competitive products, or interfering with the business relationship between our company and our customers, and (v) inducing any employee or consultant of ours to terminate employment or a contractual relationship with us. In the employment agreement, the term "restricted territory" is defined generally as any country in which we conduct business as of the date of termination of the officer's employment.

If we terminate either Dr. Ellison or Mr. Barrett for cause (as defined in the agreement) or if he terminates without good reason (as defined in the agreement), we will pay his then-current base salary through the date of his termination and any expense reimbursement amounts owed through the date of termination. If Dr. Ellison's or Mr. Barrett's employment is terminated as a result of his death, then we will pay to his estate his then-current base salary for a period of 12 months following such termination.

If either Dr. Ellison's or Mr. Barrett's employment is terminated in connection with or within six months of a change of control (as defined in the agreement), we will provide him the following benefits: (i) a lump-sum payment equal to 18 months of his then-current base salary, (ii) the full annual discretionary bonus as established by the Board, (iii) immediate vesting in full of all equity awards, (iv) extension of the exercise period for all stock options to the end of their term, and (v) reimbursement of COBRA premiums for 18 months or until the officer is eligible for insurance benefits from another employer, whichever is earlier. In the employment 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 all or substantially all of our assets.

If either Dr. Ellison's or Mr. Barrett's employment is terminated as a result of disability, by us without cause (as defined in the agreement), or by the officer for good reason (as defined in the agreement), we will provide him the following benefits: (i) continued payment of his then-base salary for 12 months following date of termination of employment, (ii) immediate vesting in full of all equity awards that would have become vested during the 12 months following termination of employment, (iii) extension of the exercise period for all vested stock options to the end of their term, and (iv) reimbursement of COBRA premiums for 18 months or until the officer is eligible for insurance benefits from another employer, whichever is earlier.

In the employment agreements, the term "cause" is defined generally as (i) willful failure to perform the officer's duties, (ii) willful or intentional misconduct or gross negligence, (iii) indictment of any felony or a misdemeanor involving moral turpitude, (iv) engagement in some form of harassment prohibited by law, (v) intentional misappropriation or embezzlement of our property, (vi) breach by the officer of the non-misappropriation, non-compete and non-solicitation provisions of the agreement, and (vii) uncured breach by the officer of any other provision of the agreement. In the employment agreements, the term "good reason" is defined generally as (i) any material reduction of the officer's duties, responsibilities, or authority, (ii) any material reduction of the officer's compensation or benefits, (iii) relocation of our headquarters or the officer's residence or primary place of employment to a location outside a 30-mile radius of New York, New York. In addition, in the case of Dr. Ellison, "good reason" also is defined as (i) our failure to nominate him for election to our Board and to recommend that stockholders to vote in support of such nomination, (ii) failure of our Board to appoint him as President and Chief Executive Officer, or (iii) removal of him from the Board or as President and Chief Executive Officer, provided that such failure or removal is not in connection with either a termination of Dr. Ellison's employment for cause, or as a result of the failure of our stockholders to elect Dr. Ellison to the Board.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Principal Stockholders

The following table sets forth certain information regarding the ownership of shares of our common stock as of February 28, 2014 by (1) each person known by us to beneficially own more than 5% of the outstanding shares of common stock, (2) each director of our company, (3) each of the Named Executive Officers, as listed in the Summary Compensation Table below, and (4) all directors and executive officers of our company as a group.

This table is based upon information supplied by our Named Executive Officers, directors and principal stockholders and from Schedules 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Share ownership in each case includes shares issuable upon exercise of options and warrants that may be exercised within 60 days after February 28, 2014 for purposes of computing the percentage of common stock owned by such person, but not for purposes of computing the percentage owned by any other person. Unless otherwise noted, the address for each person listed is 99 Hudson Street, 5th Floor, New York, New York 10013. Applicable percentages are based on 23,396,259 shares outstanding on February 28, 2014.

Name of Beneficial Owner	Shares Beneficially Owned	Percentage Owned (%)
5% Stockholders:		
Broadfin Capital, LLC (1) 237 Park Avenue, Suite 900 New York, NY 10017	1,849,839	7.9%
Baker Bros. Advisors, LLC (2) 667 Madison Avenue, 21st Floor New York, NY 10065	2,177,840	9.3%
Visium Asset Management, LP (3) 888 Seventh Avenue New York, NY 10019	1,800,000	7.7%
Directors and Named Executive Officers:		
Anthony Altig (4)	38,334	*
Mark Auerbach (5)	48,340	*
Russell H. Ellison (6)	686,664	2.6%
Joseph Felder (7)	50,356	*
Myron Holubiak (8)	48,340	*
David J. Barrett (9)	382,588	1.6%
All directors and executive officers as a group (6 persons) (10)	1,254,622	5.1%

* Less than 1%.

(1) Based on information contained in Schedule 13G/A filed with the SEC on February 14, 2014 by Broadfin Capital, LLC, Broadfin Healthcare Master Fund, Ltd. and Kevin Kotler. According to the Schedule 13G/A, all three reporting persons hold shared voting and dispositive power over the shares. The principal business address for Broadfin Healthcare Master Fund, Ltd. is 20 Genesis Close, Ansbacher House, Second Floor, Grand Cayman KY1-1108, Cayman Islands.

(2) Based on the information contained in Schedule 13G/A filed with the SEC on February 14, 2014 by Baker Bros. Advisors (GP) LLC, Baker Bros. Advisors LP, Felix J. Baker and Julian C. Baker. The Schedule 13G/A provides that each of the four reporting persons hold sole voting and dispositive power over all of the shares by virtue of their ownership of entities that have the power to control the investment decisions of three limited partnerships: 667, L.P.; Baker Brothers Life Sciences, L.P.; and 14159, L.P. Felix J. Baker and Julian C. Baker are principals of Baker Bros. Advisors, LLC. Felix J. Baker and Julian C. Baker disclaim beneficial ownership of the shares.

(3) Based on the information contained in Schedule 13G/A filed with the SEC on February 14, 2014 by Visium Asset Management, LP ("VAM"), Visium Balanced Master Fund, Ltd., JG Asset, LLC and Jacob Gottlieb. According to the Schedule 13G/A, all three reporting persons hold shared voting and dispositive power over the shares. VAM is investment manager to pooled investment funds and may be deemed to beneficially own the shares that are beneficially owned by the pooled investment funds. JG Asset, LLC is the general partner of VAM and may be deemed to beneficially own the shares that are beneficially owned by VAM. Jacob Gottlieb is the managing member of JG Asset, LLC and and may be deemed to beneficially own the shares that are beneficially owned by JG Asset, LLC.

(4) Includes 23,334 shares that Mr. Altig has the right to acquire from us within 60 days of February 28, 2014 pursuant to the exercise of stock options.

(5) Consists of 48,340 shares that Mr. Auerbach has the right to acquire from us within 60 days of February 28, 2014 pursuant to the exercise of stock options.

(6) Includes (i) 8,065 shares of our common stock issuable upon exercise of a warrant, (ii) 50,000 shares of restricted stock, and (iii) 593,599 shares that Dr. Ellison has the right to acquire from us within 60 days of February 28, 2014 pursuant to the exercise of stock options.

(7) Consists of 50,356 shares that Dr. Felder has the right to acquire from us within 60 days of February 28, 2014 pursuant to the exercise of stock options.

(8) Consists of 48,340 shares that Mr. Holubiak has the right to acquire from us within 60 days of February 28, 2014 pursuant to the exercise of stock options.

(9) Consists of (i) 50,000 shares of restricted stock, and (ii) 332,588 shares that Mr. Barrett has the right to acquire from us within 60 days of February 28, 2014 pursuant to the exercise of stock options.

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

Equity Compensation Plans

The following table sets forth the indicated information as of December 31, 2013 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 Plan	2,016	$	6.00	-0-
2010 Stock Plan:	2,336,475	$	5.87	1,390,485
Equity compensation plans not approved by our shareholders:				
2008 Warrants	9,947	$	66.46	-0-
2009 Placement Agent Warrants	39,657	$	12.40	-0-
2009 PCP Warrants	104,867	$	6.60	-0-
2010 Warrants	342,579	$	6.60	-0-
Consultant Warrants	84,545	$	6.16	-0-
2010 Placement Agent Warrants	82,251	$	7.50	-0-
Underwriter Warrants	197,200	$	7.50	-0-
Total	3,199,537	$	5.51	1,390,485

Our equity compensation plan consists of the 2007 Stock Plan and the 2010 Stock 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 initial public offering.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Independence of Directors

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, Myron Z. Holubiak and Anthony Altig are independent under the NASDAQ Marketplace Rules. Russell 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, Mr. Holubiak and Mr. Altig 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.

Certain Relationships and Related Transactions

The written charter of our Audit Committee authorizes and the NASDAQ Marketplace Rules require our Audit Committee to review and approve related party transactions. In reviewing related party transactions, our Audit Committee applies the basic standard that transactions with affiliates should be made on terms no less favorable to us than could have been obtained from unaffiliated parties. Therefore, the Audit Committee reviews the benefits of the transactions, terms of the transactions and the terms available from unrelated third parties, as applicable. All transactions other than compensatory arrangements between us and our officers, directors, principal stockholders and their affiliates will be approved by our Audit Committee or a majority of the disinterested directors, and will continue to be on terms no less favorable to us than could be obtained from unaffiliated third parties. There were no related party transactions in 2013 and, as of the date of this report, none have been undertaken in 2014.

Item 14. Principal Accounting Fees and Services

Audit Fees. Audit fees include fees billed to us by EisnerAmper in connection with its annual audit of our financial statements and procedures related to our regulatory filings, including regulatory filings and the comfort letter for our 2013 public offering and our 2013 and 2012 at-the-market sales program. The aggregate fees billed to us by EisnerAmper for such audit services rendered for the fiscal years ended December 31, 2013 and 2012 were $177,479 and $198,288, respectively.

Audit-Related Fees. Audit-related services consist solely of routine accounting consultations. During the fiscal years ended December 31, 2013 and 2012, EisnerAmper did not bill us for any audit-related services.

Tax Fees. Tax fees include corporate tax compliance, assistance with an IRS examination as well as advisory services. The aggregate fees billed to us by EisnerAmper for tax-related services in the fiscal years ended December 31, 2013 and December 31, 2012 were $15,500 and $6,000, respectively.

All Other Fees. During the fiscal years ended December 31, 2013 and 2012, EisnerAmper did not bill us for any other fees.

The Audit Committee of the Board considered all of the above activities to be compatible with the maintenance of EisnerAmper's independence. The Audit Committee discussed these services with EisnerAmper and our management to determine that they are permitted under the rules and regulations concerning auditor independence promulgated by the SEC to implement the Sarbanes-Oxley Act of 2002, as well as the American Institute of Certified Public Accountants.

Although the Audit Committee does not have formal pre-approval policies and procedures in place, it pre-approved all of the services performed by EisnerAmper as discussed above, as required by SEC regulation.

Item 15. Exhibits, Financial Statement Schedules

(a) *Exhibits.* The following exhibits are filed as part of this registration statement:

Exhibit No.	Description
1.1	Form of Underwriting Agreement dated December 22, 2010. (1)
1.2	Form of Underwriting Agreement dated July 13, 2011. (10)
1.3	Controlled Equity Offering Sales Agreement, dated January 30, 2012 between Ventrus Biosciences, Inc. and Cantor Fitzgerald & Co. (6)
1.4	Underwriting Agreement, dated January 30, 2013, by and between Ventrus Biosciences, Inc. and William Blair & Company, L.L.C. (9)
1.5	Underwriting Agreement, dated January 30, 2013, by and between Ventrus Biosciences, Inc. and William Blair & Company, L.L.C. (9)
1.6	Amendment No. 1, dated September 13, 2013, to Sales Agreement, dated January 20, 2012, between Ventrus Biosciences, Inc. and Cantor Fitzgerald & Co. (11)
3.1	Amended and Restated Certificate of Incorporation dated November 11, 2010. (2)
3.2	Amended and Restated Bylaws dated July 12, 2010. (5)
3.3	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of Ventrus Biosciences, Inc. filed on January 30, 2013. (8)
4.1	Specimen of Common Stock Certificate. (3)
4.2	Form of Convertible Promissory Note issued to investors between December 2007 and March 2008, as amended in December 14, 2009. (5)
4.3	Form of Warrant issued to investors between June and September 2008. (5)
4.4	Form of Convertible Promissory Note issued to Paramount BioSciences, LLC and Capretti Grandi, LLC in 2008 and 2009, as amended on December 21, 2009. (4)
4.5	Warrants issued to Paramount Credit Partners, LLC on January 23, March 25, June 1 and June 24, 2009. (4)
4.6	Form of Convertible Promissory Note issued to investors and Paramount BioCapital, Inc. in February, March and April 2010. (5)
4.7	Form of Convertible Promissory Note issued to investors in May 2010. (4)
4.8	Form of Warrant issued to investors in February and March, 2010. (4)
4.9	Form of Warrant issued to investors in May 2010. (4)
4.10	Form of Placement Agent Warrant issued to Paramount BioCapital, Inc. on March 11, 2008. (5)
4.11	Placement Agent Warrants issued to National Securities Corporation on February 26, March 31 and May 6, 2010, as amended October 28, 2010 and November 30, 2010. (1)
4.12	Warrant issued to S.L.A. Pharm AG on August 30, 2010. (4)
4.13	Form of underwriters warrant dated December 22, 2010. (1)
10.1*	Exclusive License Agreement dated March 23, 2007 by and between S.L.A. Pharma AG, and Paramount Biosciences, LLC, as amended on July 24, 2008, November 20, 2008, June 1, 2009, December 18, 2009 and June 24, 2010 and letter agreements dated October 27, 2008, November 20, 2008 and January 22, 2009. (2)

Exhibit No.	Description
10.2	Assignment and Assumption Agreement dated August 2, 2007, by and between Paramount Biosciences LLC and Ventrus Biosciences, Inc. (5)
10.3*	License Agreement dated March 10, 2008 by and between Sam Amer & Co., Inc. and Ventrus Biosciences, Inc., as amended on July 31, 2008, September 29, 2008, November 17, 2008, and letter agreements dated March 13, 2009, August 18, 2009, May 13, 2009 and December 15, 2009. (5)
10.4	Amended and Restated Consulting Agreement dated July 19, 2010 between Russell H. Ellison and Ventrus Biosciences, Inc. (5)
10.5	Amended and Restated Employment Agreement dated July 19, 2010 between Russell H. Ellison and Ventrus Biosciences, Inc. (5)
10.6	Amended and Restated Consulting Agreement dated July 19, 2010 between David J. Barrett and Ventrus Biosciences, Inc. (5)
10.7	2007 Stock Incentive Plan. (5)
10.8	Consulting Agreement dated March 1, 2009 between John Dietrich and Ventrus Biosciences, Inc. (4)
10.9	Consulting Agreement dated May 11, 2010 between Timothy Hofer and Ventrus Biosciences, Inc. (4)
10.10	Amendment No. 6, dated August 30, 2010, to Exclusive License Agreement between S.L.A. Pharma AG and Paramount BioSciences, LLC (assigned to Ventrus Biosciences). (4)
10.11	Senior promissory notes issued by Ventrus Biosciences, Inc. to Paramount Credit Partners, LLC on January 23, March 25, June 1 and June 24, 2010 and Waiver Agreement and Amendment dated as of August 30, 2010. (3)
10.12	Employment Agreement dated November 11, 2010 between David J. Barrett and Ventrus Biosciences, Inc. (2)
10.14	2010 Equity Incentive Plan. (4)
10.15	Asset Purchase Agreement dated June 5, 2011 between Ventrus Biosciences, Inc. and Sam Amer & Co., Inc. (5)
10.16	Amendment No. 7, dated June 6, 2011, to Exclusive License Agreement between S.L.A. Pharma AG and Paramount BioSciences, LLC (assigned to Ventrus Biosciences). (5)
10.17	Amendment No. 1, dated August 24, 2011, to Employment Agreement between David J. Barrett and Ventrus Biosciences, Inc. (7)
10.18	Amendment No. 1, dated August 24, 2011, to Amended and Restated Employment Agreement between Russell Ellison and Ventrus Biosciences, Inc. (7)
10.19	Employment Agreement dated September 1, 2011 between Thomas Rowland and Ventrus Biosciences, Inc. (7)
10.20	Employment Agreement dated January 15, 2014 and effective December 22, 2013, by and between Ventrus Biosciences, Inc. and Dr. Russell H. Ellison. (12)
10.21	Employment Agreement dated January 15, 2014 and effective December 22, 2013, by and between Ventrus Biosciences, Inc. and David J. Barrett. (12)

Exhibit No.	Description
10.22**	License and Collaboration Agreement dated November 8, 2013, by and between Ventrus Biosciences, Inc. and Therabiome, LLC.
23.1	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer Pursuant to 18 U.S. C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer Pursuant to 18 U.S. C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definitions Linkbase Document

* Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

** Confidential treatment has been requested with respect to portions of this exhibit. Those portions have been omitted and filed separately with the SEC.

(1) Incorporated by reference to the exhibit filed in the Registrant's Amendment No. 4 to Registration Statement on Form S-1 filed on December 6, 2010.

(2) Incorporated by reference to the exhibit filed in the Registrant's Amendment No. 3 to Registration Statement on Form S-1 filed on November 16, 2010.

(3) Incorporated by reference to the exhibit filed in the Registrant's Amendment No. 2 to Registration Statement on Form S-1 filed on October 29, 2010.

(4) Incorporated by reference to the exhibit filed in the Registrant's Amendment No. 1 to Registration Statement on Form S-1 filed on October 4, 2010.

(5) Incorporated by reference to the exhibit filed in the Registrant's Registration Statement on Form S-1 filed on July 20, 2010.

(6) Incorporated by reference to the exhibit filed in the Registrant's Registration Statement on Form S-3 filed on January 31, 2012.

(7) Incorporated by reference to the exhibit filed in the Registrant's Current Report on Form 8-K filed on August 25, 2011.

(8) Incorporated by reference to the exhibit filed in the Registrant's Current Report on Form 8-K filed on February 4, 2013.

(9) Incorporated by reference to the exhibit filed in the Registrant's Current Report on Form 8-K filed on January 30, 2013.

(10) Incorporated by reference to the exhibit filed in the Registrant's Current Report on Form 8-K filed on July 14, 2011.

(11) Incorporated by reference to the exhibit filed in the Registrant's Current Report on Form 8-K filed on September 13, 2013.

(12) Incorporated by reference to the exhibit in the Registrant's Current Report on Form 8-K filed on January 16, 2014.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

VENTRUS BIOSCIENCES, INC.

Date: March 31, 2014

By: /s/ Russell H. Ellison
Name: Russell H. Ellison
Title: Chief Executive Officer

SIGNATURES

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

Signature	Title	Date
/s/ Russell H. Ellison Russell H. Ellison	Chief Executive Officer (Principal Executive Officer) and Director	March 31, 2014
/s/ David J. Barrett David J. Barrett	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2014
/s/ Anthony E. Altig Anthony E. Altig	Director	March 31, 2014
/s/ Mark Auerbach Mark Auerbach	Director	March 31, 2014
/s/ Joseph Felder Joseph Felder	Director	March 31, 2014
/s/ Myron Z. Holubiak Myron Z. Holubiak	Director	March 31, 2014

FINANCIAL STATEMENTS

VENTRUS BIOSCIENCES, INC.

(A Development Stage Company)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Ventrus Biosciences, Inc. (a development stage company) (the "Company") as of December 31, 2013 and 2012, and the related statements of operations, stockholders' equity (deficiency), and cash flows for each of the years in the two-year period ended December 31, 2013 and for the period from October 7, 2005 (inception) to December 31, 2013. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit 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, 2013 and 2012, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2013 and for the period from October 7, 2005 (inception) to December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

New York, New York
March 28, 2014

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Balance Sheets

	December 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	**$ 27,061,268**	$ 20,489,219
Other current assets	**63,672**	59,584
Total current assets	**27,124,940**	20,548,803
Computer equipment, net of accumulated depreciation of $39,266 and $33,050	**7,102**	6,841
Total assets	**$ 27,132,042**	$ 20,555,644
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	**$ 2,614,619**	$ 1,847,245
Accrued expenses	**23,435**	898,213
Total liabilities	**$ 2,638,054**	$ 2,745,458
Stockholders' equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized; Series A non-voting convertible preferred stock: 220,000 and 0 issued and outstanding at December 31, 2013 and December 31, 2012, respectively	**220**	-
Common stock, $.001 par value; 50,000,000 shares authorized; 20,733,895 and 12,934,350 issued and outstanding at December 31, 2013 and December 31, 2012, respectively	**20,734**	12,934
Additional paid-in capital	**135,827,557**	110,116,766
Common stock issuable, 125,000 shares at December 31, 2013	**368,750**	-
Deficit accumulated during the development stage	**(111,723,273)**	(92,319,514)
Total stockholders' equity	**24,493,988**	17,810,186
Total liabilities and stockholders' equity	**$ 27,132,042**	$ 20,555,644

The accompanying notes are an integral part of these financial statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statements of Operations

	Year Ended December 31, 2013	Year Ended December 31, 2012	Period from October 7, 2005 (Inception) to December 31, 2013
Operating expenses:			
Research and development	**$ 15,029,078**	$ 19,514,163	**$** 74,072,484
General and administrative	**4,575,701**	5,341,333	24,162,102
Loss from operations	**(19,604,779)**	(24,855,496)	(98,234,586)
Other income (expense):			
Interest income	**201,020**	65,066	362,139
Interest expense:			
Beneficial conversion charge	-	-	(6,001,496)
Amortization of debt discount and warrants	-	-	(2,865,758)
Interest expense	-	-	(4,983,572)
Total other income (expense)	**201,020**	65,066	(13,850,826)
Net loss	**$ (19,403,759)**	$ (24,790,430)	$ (111,723,273)
Basic and diluted net loss per common share	**$ (1.00)**	$ (1.94)	
Weighted average common shares outstanding - basic and diluted	**19,393,486**	12,726,551	

The accompanying notes are an integral part of these financial statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statements of Cash Flows

	Year ended December 31, 2013	Year ended December 31, 2012	Period from October 7, 2005 (Inception) to December 31, 2013
Cash flows from operating activities:			
Net loss	**$ (19,403,759)**	$ (24,790,430)	$ (111,723,273)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	**1,676,789**	2,831,651	10,448,711
Stock-based payments to consultants	**36,158**	339,442	4,366,417
Stock issued in connection with license agreement	-	-	414,825
Charge resulting from beneficial conversion feature	-	-	6,001,496
Stock issued to vendor	-	-	5,000
Warrants issued in connection with related party note conversion	-	-	1,255,978
Amortization of deferred financing costs and debt discount	-	-	3,466,010
Non-cash research and development	-	-	1,087,876
Interest payable - 2007 Senior convertible notes	-	-	1,598,104
Interest payable - 2010 Senior convertible notes	-	-	354,269
Expenses paid on behalf of the Company satisfied through the issuance of notes	-	-	227,910
Interest payable - related parties	-	-	266,279
Interest payable - Paramount Credit Partners, LLC	-	-	187,536
Depreciation	**6,216**	4,618	41,839
Changes in operating assets and liabilities:	-	-	-
Prepaid research and development	-	-	-
Other current assets	**(4,088)**	2,545	(63,672)
Accounts payable and accrued expenses	**(107,404)**	232,384	2,450,518
Net cash used in operating activities	**(17,796,088)**	(21,379,790)	(79,614,177)

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statements of Cash Flows

	Year ended December 31, 2013	Year ended December 31, 2012	Period from October 7, 2005 (Inception) to December 31, 2013
Cash flows from investing activities:			
Purchase of office and computer equipment	**(6,477)**	(3,241)	(48,941)
Net cash used in investing activities	**(6,477)**	(3,241)	(48,941)
Cash flows from financing activities:			
Net proceeds from initial public offering and other offerings	**24,374,614**	4,166,494	93,714,274
Proceeds from private placement	-	-	1,146,024
Proceeds from exercise of warrants and options	-	730,322	1,019,054
Proceeds from 2010 Senior convertible notes	-	-	3,425,000
Proceeds from notes payable to Paramount Credit Partners, LLC	-	-	1,573,000
Repayment of Paramount Credit Partners, LLC Note	-	-	(1,573,000)
Proceeds from notes payable to related parties	-	-	5,041,953
Repayment of notes payable - related party	-	-	(1,500,000)
Proceeds from 2007 Senior convertible notes	-	-	5,305,000
Payment for deferred financing costs	-	-	(1,431,603)
Proceeds from utilization of short-term note and line of credit	-	-	419,380
Repayment of debt facilities	-	-	(419,380)
Proceeds from term note payable	-	-	800,000
Repayment of term note payable	-	-	(800,000)
Proceeds from receipt of subscriptions	-	-	4,684
Net cash provided by financing activities	**24,374,614**	4,896,816	106,724,386
Net (decrease) increase in cash and cash equivalents	**6,572,049**	(16,486,215)	27,061,268
Beginning of period	**20,489,219**	36,975,434	-
End of period	**$ 27,061,268**	$ 20,489,219	$ 27,061,268,

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statements of Cash Flows

	Year ended December 31, 2013	Year ended December 31, 2012	Period from October 7, 2005 (Inception) to December 31, 2013
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
Debt discount on Paramount Credit Partners, LLC notes	-	-	$ 782,376
Debt discount on 2010 senior convertible notes	-	-	$ 1,468,254
Related party notes and accrued interest converted to 2010 Senior convertible notes	-	-	$ 3,995,667
Notes and accrued interest converted to common stock	-	-	$ 14,003,158
Supplemental disclosure - cash paid for interest	-	-	$ 685,397

The accompanying notes are an integral part of these financial statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Statements of Changes in Stockholders' Equity (Deficiency)

Period from October 7, 2005 (Inception) to December 31, 2013

	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
Common stock issued in financing at $60.39 per share in June and September 2008 net of related costs	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

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

	Common Stock				
	Shares	**Amount**	**Additional Paid-in Capital**	**Deficit Accumulated During the Development Stage**	**Total**
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 at $4.20 per share	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 at $6.00 per share 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 at $6.00 per share	64,933	65	389,531	-	389,596
Net loss	-	-	-	(15,290,625)	(15,290,625)
Balance at December 31, 2010	6,746,365	6,746	44,803,724	(33,184,354)	11,626,116
Common Stock issued in January 2011 at $6.00 per share to fulfill over-allotment option from IPO, net of related costs	435,000	435	2,420,341	-	2,420,776
Warrants exercised	50,034	50	288,682	-	288,732
Additional shares issued in January 2011 in connection with the December 22, 2010 conversion of notes into common stock at $4.20 per share	7	-	-	-	-

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

	Common Stock				
	Shares	**Amount**	**Additional Paid-in Capital**	**Deficit Accumulated During the Development Stage**	**Total**
Shares issued in a stock offering in July 2011, at $10.00 per share net of related costs	5,175,000	5,175	47,562,872	-	47,568,047
Stock- based compensation for the period from January 1 to December 31, 2011 to employees and directors	-	-	2,982,949	-	2,982,949
Stock-based payments for the period from January 1 to December 31, 2011 for options issued to consultants	-	-	3,990,817	-	3,990,817
Net loss				(34,344,730)	(34,344,730)
Balance at December 31, 2011	12,406,406	$ 12,406	$ 102,049,385	$ (67,529,084)	$ 34,532,707
Common Stock-issued for options exercised between January and December 2012	68,240	68	427,749	-	427,817
Stock-based compensation for the period from January to December 2012 to employees and directors	-	-	2,831,651	-	2,831,651
Stock-based payments for the period from January 1 to December 31, 2012 for options issued to consultants.	-	-	339,442	-	339,442
Proceeds from common stock sold (at an average $12.45 per share), net of costs	354,700	355	4,166,139	-	4,166,494
Shares issued in cashless exercise of warrants	11,620	11	(11)	-	-
Warrants exercised from January 1, 2012 and December 31, 2012	45,834	46	302,459	-	302,505
Shares issued in a cashless exercise of options	47,550	48	(48)	-	-
Net loss				(24,790,430)	(24,790,430)
Balance at December 31, 2012	12,934,350	$ 12,934	$ 110,116,766	$ (92,319,514)	$ 17,810,186

The accompanying notes are an integral part of these financial statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

	Common	Preferred	Amount	Additional Paid in Capital	Common Stock Issuable	Deficit Accumulated During the Development Stage	Total
Proceeds from common stock sold (at a weighted average $2.62 per share) net of costs	7,799,545	-	7,800	19,196,814	-	-	19,204,614
Proceeds from preferred stock sold (at an average $25.00 per share) net of costs	-	220,000	220	5,169,780	-	-	5,170,000
Stock-based payments for the period from January 1 to December 31, 2013 for options issued to consultants	-	-	-	36,158	-	-	36,158
Stock-based compensation for the period January 1 to December 31, 2013 to employees and directors	-	-	-	1,308,039	-	-	1,308,039
Restricted stock granted to four employees April 2013 expense thru December 2013	-	-	-	-	368,750	-	368,750
Net loss						(19,403,759)	(19,403,759)
Balance at December 31, 2013	20,733,895	220,000	$ 20,954	$ 135,827,557	$ 368,750	$ (111,723,273)	$ 24,493,988

The accompanying notes are an integral part of these financial statements

VENTRUS BIOSCIENCES, INC.
(A Development Stage Company)

Notes to Financial Statements

Note 1 - Organization, Business and Basis of Presentation:

Organization and business:

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

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, conducting clinical and nonclinical trials, 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 U.S. Food and Drug Administration ("FDA") approval and initial launch and commercialization of diltiazem. Assuming such approval and launch, thereafter, continuation of the Company will be dependent on its ability to achieve profitable operations or obtain additional financing. There is no assurance, however, that such financing will be available or that the Company's efforts ultimately will be successful.

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 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 inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. Management believes the Company currently has sufficient funds to meet its operating requirements for the next twelve months. If the Company cannot 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.

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 December 31, 2013, 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.

Additionally, the Company provides a valuation allowance for deferred income tax assets when it is considered more likely than not that all or a portion of such deferred income tax assets will not be realized.

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.

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 stock option and warrant awards, and is recognized as expense over the employee's or director'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 until vested and recognized as consulting expense over the related vesting period. The Company valued the restricted stock grant, 75% of which vests in three equal installments when the 20-day trading volume weighted average price of the Company's common stock is at least $4.15, $5.15 and $6.15, using the Monte Carlo simulation model.

Warrants:

For the purpose of valuing the warrants (See Notes 3 and 8), the Company used the Black-Scholes option pricing model utilizing the following assumptions. 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 warrants based on the full term of the warrant. 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 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.

Warrants, or any other detachable instruments issued in connection with debt financing agreement not required to be recorded at fair value, 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 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 and 8) and has recorded their effects.

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.

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.

The Company has adopted the provisions that tax positions must meet a "more-likely-than-not" recognition threshold to be recognized. The Company has no unrecognized tax benefits recorded for the years ended December 31, 2013 and 2012. When an accrual for interest and penalties is required, interest and penalties will be recognized in tax expense. The Company files income tax returns in the U.S. federal jurisdiction and in New York. There are currently no federal income tax examinations in process. The 2010 through 2013 tax years remain subject to examination by the Internal Revenue Service and other taxing authorities for U.S. federal and state/local tax purposes. The Company does, however, have prior year net operating losses dating back to 2007, which are subject to examination.

Loss per common share:

Basic net 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 net 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 net loss per share is the same. The number of potentially dilutive securities (options, warrants and unvested shares) excluded from the diluted loss per share calculation at December 31, 2013 and 2012 was 3,574,537 and 2,753,126, respectively.

Note 3 - Related Party Transactions:

The following are descriptions of the Company's related party transactions that have been entered into, modified, terminated, or were still in effect in 2013.

Paramount BioSciences, LLC and Affiliates:

Paramount Corporate Development, LLC:

From April 2007 through August 31, 2008, pursuant to a contractual arrangement with Paramount Corporate Development, LLC ("Paramount"), an affiliate of Dr. Lindsay A. Rosenwald, M.D., formerly a significant investor in and stockholder of the Company, the Company incurred $425,000 under this arrangement and as of December 31, 2013 and 2012, owed $100,000, which is included in accounts payable.

Note 4 - Income Taxes:

There was no current or deferred income tax provision for the years ended December 31, 2013 and 2012.

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

	2013	2012
Net operating loss	$ 32,193,000	$ 23,792,000
Stock-based compensation	6,617,000	5,808,000
In-Process Research & Development	6,017,000	5,014,000
Research and development credits	2,149,000	783,000
Totals	46,976,000	35,397,000
Less: valuation allowance	(46,976,000)	(35,397,000)
	$ -	$ -

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, 2013 and 2012 was $11,579,000 and $9,132,000, 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.

At December 31, 2013, the Company had potentially utilizable gross Federal net operating loss carry-forwards of approximately $73,000,000, State net operating loss carry-forwards of approximately $67,000,000 and research and development credit carry forward of approximately $2,149,000, all of which expire between 2027 and 2031.

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.

	2013	2012
Statutory Federal tax rate	(34)%	(34)%
Statutory state and local income taxes (net of Federal)	(11)%	(7)%
Effect of valuation allowance	45%	41%
Effective tax rate	0%	0%

Note 5 - Commitments:

Employment agreements:

The Company's Chief Executive Officer had an employment agreement which provided 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 provided incentive bonuses of $250,000 and $500,000 in the event that the Company's market capitalization exceeded specified levels. The first threshold was met and the $250,000 bonus was paid in the third quarter of 2011. The second threshold, which was to be paid in a combination of cash and shares of common stock, never occurred. The agreement expired on December 21, 2013, in accordance with its terms.

The Chief Financial Officer had an employment agreement which provided for a base salary of $250,000 per year. The agreement also provided incentive bonuses of $250,000 and $500,000 in the event that the Company's market capitalization exceeded specified levels. The first threshold was met and the $250,000 bonus was paid in the third quarter of 2011. The second threshold, which was to be paid in a combination of cash and shares of common stock, never occurred. The agreement expired on December 21, 2013, in accordance with its terms.

On January 15, 2014, the Company entered into employment agreements, with the Chief Executive Officer and the Chief Financial Officer, which were effective as of December 22, 2013 (see Note 10).

Note 6 - Stockholders' Transactions:

Common and Preferred Stock Transactions:

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. Each warrant has a seven-year term and an exercise price of $66.46. The warrants had a fair value of $340,860 and were expensed on issuance since the promissory notes were converted.

The fair value of the warrants granted, mentioned in the preceding paragraph, 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 Paramount BioSciences, Inc. 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 the IPO and raised net proceeds of $2,420,776.

During the twelve months ended December 31, 2011, the Company issued an aggregate of 50,034 shares of common stock pursuant to the exercise of warrants with an average exercise price of $5.77.

On July 19, 2011, the Company issued 5,175,000 shares of its common stock in an underwritten public offering and raised net proceeds of $47,568,047.

The Company filed a shelf registration statement with the Securities and Exchange Commission, which became effective on February 10, 2012, under which it may offer shares of its common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, in one or more offerings, up to a total dollar amount of $100,000,000. As part of the shelf registration statement, the Company included a prospectus for an at-the-market common equity sales program for the sale of up to $20,000,000 of common stock. In May and June 2012, the Company sold an aggregate of 354,700 shares under this program, resulting in net proceeds of approximately $4,166,000, or $11.75 per share. In February 2013, the Company sold an aggregate of 6,670,000 shares of common stock and 220,000 shares of Series A Non-Voting Preferred Stock, which are convertible into 2,200,000 shares of common stock, under the shelf registration statement, resulting in net proceeds of approximately $20,800,000. In September 2013, the Company amended its at-the-market sales agreement to cover the sale of up to $20,521,567 of common stock in addition to what had been sold previously. In September and October 2013, the Company sold an aggregate of 1,129,545 shares of common stock under the amended at-the-market common equity sales program, resulting in net proceeds of approximately $3,600,000, or $3.20 per share. As of December 31, 2013, an aggregate of approximately $75,000,000 worth of securities was available under the shelf registration statement out of which approximately $16,900,000 of common stock was available for the at-the-market common equity sales program.

See Note 10 for transactions subsequent to December 31, 2013.

Common Stock Options and Warrants:

Stock Options:

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.

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.

The Company terminated the 2007 Plan in July 2010, but the 2,016 options granted under the 2007 Plan remain outstanding.

In August 2010, the Company's stockholders approved the 2010 Equity Incentive Plan (the "2010 Plan"). In May 2011, the Company's stockholders approved an amendment to the 2010 Plan to increase the shares reserved for issuance from 2,467,200 to 3,967,200 shares of the Company's common stock. The 2010 Plan authorizes the Company to issue equity incentive awards in the form of shares, options or other awards based on Ventrus common stock as part of an overall compensation package to provide performance-based compensation to attract and retain qualified personnel.

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 under the 2010 plan 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 2011, the Company granted options to purchase 30,000 shares to three of its directors, options to purchase an aggregate of 552,440 shares to four employees and options to purchase an aggregate of 384,240 shares to seven consultants, all pursuant to the 2010 Plan with exercise prices at or greater than the then market value of the Company's common stock ($6.00 - $15.77 per share).

In 2012, the Company granted options to purchase 35,000 shares to a new director and 228,000 options to purchase shares to eight employees which included three new employees. Additionally, the company granted options to purchase an aggregate of 162,740 shares to seven consultants all pursuant to the 2010 Plan. The exercise prices of the options granted were at the then market value of the Company's common stock ($3.60 - $10.62 per share).

In 2013, the Company granted options to purchase 30,000 shares to three directors and 500,000 options to purchase shares to five new employees. The exercise prices of the options granted were at the then market value of the Company's common stock ($2.47 - $3.31 per share).

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

	Year Ended December 31, 2013			Year Ended December 31, 2012		
	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at beginning of period	1,878,475	$ 6.72	$ -	2,046,455	$ 6.40	$ -
Granted	530,000	$ 2.88	$ -	425,740	$ 7.64	$ -
Exercised	-	$ -	-	(168,240)	6.11	-
Forfeited	(69,984)	$ 7.60	$ -	(425,480)	6.64	-
Outstanding at end of year	2,338,491	$ 5.87	$	1,878,475	$ 6.72	$ -
Options exercisable at end of period	2,322,518	$ 6.31	$ -	1,618,820	$ 6.51	$ -
Vested or expected to vest at December 31	2,338,491	-	-	1,878,475	-	-
Shares available on December 31 for options that may be granted	1,390,485	-	-	1,920,485	-	-

Included in the options exercised in 2012 were 100,000 options exercised in a cashless exercise for 47,550 shares of common stock.

The Company expects that all outstanding unvested options will vest. The fair value of the options granted for the year ended December 31, 2013 and 2012, was based on the following assumptions:

	2013	2012
Risk-free interest rate	1.23%-2.34%	1.11%-1.32%
Expected volatility	59.32%-77.34%	76.31%-78.23%
Expected life of options	7 years	7 years
Expected dividend yield	0%	0%

Estimated future stock-based compensation expense relating to unvested stock options (for consultants based on the fair value at December 31, 2013) is as follows:

Years Ending December 31,	Future Stock Option Compensation Expense
2014	682,701
2015	275,820
2016	196,419
2017	20,239
Total estimated future stock-based compensation expense - stock options	$ 1,175,179

The weighted average remaining contractual life of options outstanding at December 31, 2013 is approximately 7.25 years.

Stock-based compensation expensed to research and development expense for the years ended December 31, 2013 and 2012 was $695,636 and $846,508, respectively. Stock-based compensation expensed to general and administrative expense for the years ended December 31, 2013 and 2012 was $1,017,311 and $2,324,585, respectively.

Warrants:

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.

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 Note 8).

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

	Year Ended December 31, 2013		Year Ended December 31, 2012	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	874,651	$ 7.67	956,443	$ 7.61
Granted	-	$ -	-	$ -
Exercised	-	$ -	81,792	$ 7.00
Expired	13,605	$ 1.24	-	-
Outstanding at end of year	861,046	$ 7.77	874,651	$ 7.67
Warrants exercisable at end of period	861,046	$ 7.77	874,651	$ 7.67

Included in the warrants exercised are 35,958 warrants exercised in a cashless exercise for 11,620 shares during the year ended December 2012. All outstanding warrants have vested and no additional expense is expected to be recorded in the future years.

Common Stock Grant:

On April 5, 2013, the Company granted restricted stock units to four employees under the 2010 Plan for an aggregate of 500,000 shares of common stock. Of these units, 25% vested immediately at the grant date. The remaining 75% of the units will vest in equal 25% tranches if the 20 trading day volume-weighted average price of our common stock as reported on the NASDAQ Capital Market is at least $4.15, $5.15 and $6.15, respectively. The performance period for the unvested restricted stock units ends on June 30, 2016; if one or more of the stock price thresholds are not met by that date the unvested units will expire. Each employee elected to defer receipt of all shares issuable under the units, including the immediately vested shares, until the earliest of termination of employment, a change in control of Ventrus, or April 1, 2015. The restricted stock units were issued to employees and officers at a price equal to the market price of the Company's stock at the date of grant. The Company estimated the fair value of the restricted stock units using the Monte Carlo valuation model with the following assumptions; volatility of 56.10% , risk free interest rate of 1.934%, and dividend rate of 0%. The total estimated fair value of the restricted stock units is approximately $1,135,000. Compensation costs for restricted stock award are being recognized on a straight-line basis over the performance period. The first 25% of restricted stock was immediately expensed.

A summary of the status of our restricted stock units as of December 31, 2013 is as follows:

	Year Ended December 31, 2013	
	Shares	Weighted Average Grant Date Fair Value Per Share
Restricted stock units as of January 1, 2013	0	$ -
Granted April 5, 2013	500,000	$ 2.27
Shares vested and issuable	(125,000)	$ 2.95
Restricted stock units as of December 31, 2013	375,000	$ 2.04

Note 7 - License Agreements:

S.L.A. Pharma, AG

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 and use diltiazem for treatment, through topical administration, of anal fissures and phenylepherine for treatment, through topical administration, of fecal incontinence in the United States, Canada and Mexico. Pursuant to the Exclusive License Agreement, PBS was obligated to form a company to develop the technologies referenced in the Exclusive License Agreement and issue a number of shares equal to 5% of such company's outstanding common stock as of the effective date of the Exclusive License Agreement. On August 2, 2007, the Company issued 18,401 shares to S.L.A. 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 each of diltiazem and phenylephrine. Per the agreement, Ventrus' obligation to make these monthly payments until S.L.A. Pharma is no longer managing the development program for diltiazem. Pursuant to amendments to the Exclusive License Agreement, the Company, as of September 30, 2010, was no longer required to make additional payments for phenylephrine. At December 31, 2013, the Company had no amounts due to S.L.A. Pharma.

The Company is also required to reimburse S.L.A. Pharma for clinical development costs associated with the technology development of the diltiazem project. The Company's total payment obligation for the diltiazem project is limited to $4,200,000. The Company made $4,200,000 of payments to S.L.A. Pharma from August 2007 through December 31, 2011.

On June 6, 2011, Ventrus further amended the Exclusive License Agreement with S.L.A. Pharma. The amendment eliminates its potential $800,000 milestone payment to S.L.A. Pharma for the development of diltiazem, 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 Ventrus had failed to make a required payment and a third party wished to enter into a license agreement for diltiazem and phenylephrine, provided the termination would not have been effective if within that one-month period Ventrus paid all the then required payments under the agreement. Pursuant to the amendment, Ventrus 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 diltiazem that S.L.A. Pharma is conducting in Europe. The first two milestones were met and paid in the third quarter of 2011 and the third and fourth milestone was met and paid in the fourth quarter of 2011. Additionally, upon Ventrus' receipt of a quality controlled final study report of the Phase III trial for diltiazem in Europe, Ventrus must pay S.L.A. Pharma $400,000 in development costs for diltiazem. This report was received and the payment was made in February 2013.

The Company is also required to reimburse S.L.A. Pharma for clinical development costs associated with the technology development of the phenylephrine project. S.L.A. Pharma has been paid $600,000 of services for the phenylephrine project through December 31, 2011. S.L.A. Pharma did not provide Ventrus with any services for the phenylephrine project in 2011 or 2012 and management does not expect any services from SLA Pharma for the phenylephrine project in the foreseeable future.

Sam Amer and Company, Inc.

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 for the topical treatment of any anorectal disorders. Through November 14, 2011, the Company made all contractual payments relating to the license agreement. The license agreement terminated in November 2011 upon our acquisition of all rights, title and interest to iferanserin from Amer, discussed below.

On June 5, 2011, the Company entered into an agreement with Amer to acquire all rights, title and interest to iferanserin and on November 14, 2011, closed on this transaction. The Company paid an aggregate of $12.5 million to Amer in the transaction. Because the assets purchased (1) do not meet the definition of a business combination and (2) do not have alternative future use since the assets acquired are contingent on further development and clinical risk, we determined that the entire purchase price of the asset be expensed immediately as in-process research and development.

On June 25, 2012, the Company reported that a Phase III, randomized, double-blind, placebo-controlled clinical trial of VEN 309 for the treatment of symptomatic hemorrhoids did not meet its endpoints. Based on the results of that Phase III trial, the Company ceased all activity related to VEN 309 and ended the program.

Therabiome, LLC

On November 8, 2013, the Company entered into an exclusive worldwide License and Collaboration Agreement with Therabiome, LLC ("Therabiome"), for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive controlled release platform technology. The Company is solely responsible for all research and development activities with respect to any product it develops under the license. For the license, the Company paid Therabiome an upfront non-refundable license fee of $300,000, which was expensed as research and development. The Company must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform, for U.S. regulatory milestones, depending on whether the milestone occurs before the filing of the first new drug application ("NDA") for a product or after the first, second or third NDA filings. The Company also must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region, and depend on whether the milestone occurs before the filing of the first NDA filing for a product or after the first, second or third NDA filings, and which will be: one-third of the U.S. milestones paid upon a foreign equivalent of an investigational new drug application, or IND, and marketing approval for each product in the European Union or Japan; 10% of the U.S. milestones paid upon a foreign equivalent of an IND and marketing approval for each product in China; 10% of the U.S. milestone paid upon marketing approval for each product in India and Brazil; and 1% of the U.S. milestone paid upon marketing approval for each product in all other countries. The Company also must pay Therabiome royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceed two certain thresholds, a one-time cash payment upon reaching each threshold.

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 note holders to an additional extension of the maturity date of the Bridge Notes to September 10, 2010 and again to December 31, 2010. The completion of the Company's IPO triggered the automatic conversion of the Bridge Notes and accrued interest into common stock at 70% conversion price of the IPO price. The Company valued the beneficial conversion feature of the 2007 Notes at $2,957,187, which was recorded as interest expense in 2010. 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.

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 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%

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 matured on September 10, 2010. Upon the closing of a Qualified Financing (as defined below), the 2010 Notes plus any accrued but unpaid interest thereon were to convert 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%

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, 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 9 - Commitments and Contingencies:

Litigation:

In June 2012, the Company announced that is product iferanserin (VEN 309), failed to meet its end point at the completion of its Phase III clinical trial. In May 2013 two purported class action lawsuits alleging violations of the federal securities laws were filed in New York against the Company, two of its executive officers and the lead underwriter of its initial public offering. The lawsuits include allegations that, during the class period between December 17, 2010 and June 25, 2012, the Company and its executive officers and underwriter made various statements related to the Company's product, iferanserin (VEN 309), including but not limited to, the market for the product, the potential competitors, and the results of clinical trials, thereby inflating the price of our common stock. The complaints seek unspecified damages, interest, attorneys' fees, and other costs. On July 23, 2013, the Court consolidated the actions and appointed lead plaintiffs and lead counsel. On September 16, 2013, lead plaintiffs filed a consolidated amended complaint. On September 16, 2013, lead plaintiffs filed a consolidated amended complaint. On November 22, 2013, the Company filed a motion to dismiss the consolidated amended complaint (the "Motion to Dismiss"). The Motion to Dismiss has been fully briefed and the Court has taken the Motion to Dismiss under submission. Due to the early stage of these proceedings, the Company is unable to predict the outcome or reasonably estimate a range of possible loss relating to these claims.

Note 10- Subsequent Event

On January 15, 2014, the Company entered into an employment agreement with its Chief Executive Officer and its Chief Financial Officer, with an effective date of December 22, 2013. Each agreement has a term of two years and will be automatically extended for additional one-year periods unless the Company notifies the officer at least 180 days prior to the then current expiration date that it intends to not extend the employment agreement. The employment agreements provide for a base salary of $475,000 per year for the Chief Executive Officer and $300,000 for the Chief Financial Officer, and an annual discretionary bonus of up to 50% of the officer's base salary based on financial, clinical development and business milestones established by the Board of Directors.

In January 2014, the Company sold an aggregate of 462,364 shares of its common stock in its at-the-market common equity offering program, resulting in net proceeds of approximately $1,763,000 or $3.81 per share.

In February 2014, all 220,000 outstanding shares of the Company's Series A non-voting convertible preferred stock converted into an aggregate of 2,200,000 shares of common stock.

EXHIBIT 10.22

Execution Copy

Portions of this exhibit marked [*] are requested to be treated confidentially.

LICENSE AND COLLABORATION AGREEMENT

This LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), effective as of 8th November 2013 (the "Effective Date"), is by and between Ventrus Biosciences, Inc., a Delaware corporation ("Ventrus") and THERABIOME, LLC, a Delaware limited liability company ("Licensor"). Capitalized terms used but not defined herein shall have the meanings ascribed to them in Exhibit A (Definitions) attached hereto.

RECITALS:

WHEREAS, prior to the Effective Date, DashPharma Consulting, LLC ("Dash") and TheraSyn Sensors, Inc. ("TheraSyn"), both exclusively and perpetually assigned to Licensor certain Intellectual Property (as defined below) of Dash and TheraSyn relating to the oral delivery of pharmaceutical drugs (including, but not limited, to, microbiota, vaccines and small molecules) to specific sites in the intestine, using controlled release platform technology (the "Licensor Technology"); and

WHEREAS, upon the terms and conditions set forth in this Agreement, Ventrus desires to license the Licensor IP for purposes of developing Products and Therapies for Commercialization within the Field (as such terms are defined below).

NOW, THEREFORE, in consideration of the respective representations, warranties, covenants, and agreements contained herein, and for other valuable consideration, the receipt and adequacy of which are hereby acknowledged, Ventrus and Licensor, intending to be legally bound, agree as follows:

ARTICLE I

GOVERNANCE

1.1 Joint Development Committee.

(a) Formation; Representatives. Within thirty (30) days of the Effective Date, the Parties will establish a Joint Development Committee (the "Joint Development Committee" or "JDC"). The JDC shall be comprised of a total of four (4) representatives: [*]. Each such representative shall be of the seniority and experience appropriate for participation therein, in light of the functions, responsibilities and authority of the JDC. Each Party shall make its designation of its representatives not later than thirty (30) days after the Effective Date. Each Party may change any one or more of its representatives at any time upon written notice to the other Parties. If a Party's representative is unable to attend a meeting, such party may designate an alternate to attend such meeting in place of the absent representative. In addition, each Party may, subject to the other Party's consent (not to be unreasonably withheld or delayed), invite non-voting employees, consultants or scientific advisors (provided they are engaged as such under obligations of confidentiality no less protective of the Parties' Confidential Information than as set forth in Article VIII) to attend the meetings of the JDC.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(b) Scope of JDC Authority. The JDC shall be responsible for the overall direction of, and shall facilitate the exchange of information relating to, the research, Development, Manufacturing, and Commercialization activities under this Agreement. The responsibilities of the JDC shall be the following:

(i) Determining Indications and PPILs and when such Indications or PPILs require modification (e.g., between applicable Phases) in respect of Ventrus Products and Ventrus Therapies;

(ii) Reviewing progress and findings of ongoing experiments and studies relating to the Development and Commercialization of Ventrus Products and Ventrus Therapies;

(iii) Promulgating and reviewing Development plans for Ventrus Products and Ventrus Therapies;

(iv) Deciding on the design and execution for each project and each study with respect to Indications for Ventrus Products and Ventrus Therapies;

(v) Determining completions and initiations of each Phase with respect to the Development with respect to an Indication for a Ventrus Product or Ventrus Therapy;

(vi) Reviewing the Development of each Ventrus Product, Ventrus Therapy, and Indication;

(vii) Determining the role of Licensor in activities necessary for the Development and Commercialization with respect to an Indication for any Ventrus Product or Ventrus Therapy;

(viii) Resolving issues escalated from project teams and subcommittees to the JDC;

(ix) Reviewing the prosecution and maintenance of the Licensor Patents; and

(x) Any other responsibilities assigned to the JDC in this Agreement.

(c) Meetings; Project Teams; Subcommittees; Decision-Making.

(i) Meetings. The JDC shall meet to discuss the matters within its function within thirty (30) days after the Effective Date and, thereafter, at least monthly during the first two (2) years after the Effective Date, and at least quarterly thereafter during the Term. In addition, either Party may call a meeting of the JDC upon reasonable notice to the other Party. The JDC shall also meet, unless otherwise agreed to by the Parties, upon the conclusion of each phase of Development under an Indication for any Ventrus Product or Ventrus Therapy. The location of JDC meetings, when in person, shall be at Ventrus's offices unless otherwise agreed by the JDC. The JDC may also meet by means of a telephone or video conference call, and may take action by vote at a meeting or telephone or video conference call, or pursuant to a written vote. Each Party shall bear its own travel and lodging expenses related to participation in and attendance at such meetings by its JDC representatives. At least five (5) Business Days prior to each JDC meeting, Licensor and Ventrus shall inform the other Party in writing of agenda items proposed by such Party for discussion or decision at such meeting, together with appropriate information related thereto. Ventrus shall prepare reasonably detailed written minutes of each JDC meeting, which minutes will reflect, without limitation, material decisions made at such meeting. Meeting minutes will be sent to each member of the JDC for review and approval within five (5) Business Days after the applicable JDC meeting. Minutes will be deemed approved unless a member of the JDC objects to the accuracy of such minutes within ten (10) Business Days of receipt.

(ii) Project Teams; Subcommittees. The JDC shall have the authority to create project teams or subcommittees within its scope of authority, each of which will meet (via telephone or video conference or in person) with such frequency as determined by the JDC and which will report to the JDC on the progress of the activities it has performed no less frequently than quarterly.

(d) Decision-Making.

(i) All decisions of the JDC with respect to matters over which it has decision-making authority in accordance with Section 1.1(b) shall be made by unanimous vote of the JDC's representatives, with each representative member of the JDC having one (1) vote.

(ii) In the case of any matter before the JDC that cannot be resolved within five (5) Business Days of the matter being referred to it, then the resolution and/or course of conduct shall be determined by Ventrus in Ventrus's sole, but reasonable discretion.

(iii) In the event of a disagreement among the members of any project team or subcommittee, the matter shall be referred to the JDC for resolution.

(e) Limited Authority. The JDC shall not have the authority to amend or modify the terms of this Agreement, to expand its scope of authority, or to determine any issue before the JDC in a manner that would conflict with the express terms and conditions of this Agreement.

1.2 Scientific Advisory Board. Within thirty (30) days of the Effective Date, the Parties shall establish a Scientific Advisory Board comprised of members of Ventrus, Licensor, and Third Parties that will function to provide strategic advice and critical assessments of research and development programs under this Agreement (the "Scientific Advisory Board" or "SAB"). Within thirty (30) days of the creation of the JDC, the JDC will determine the composition of the SAB and the specific functions of the SAB. [*]. Compensation of members of the SAB shall be in accordance with Section 6.4(c).

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

ARTICLE II

TECHNOLOGY TRANSFER

2.1 Technology Transfer**.** Licensor agrees to provide to Ventrus or its Affiliate (or a Third Party designated by Ventrus) assistance, training, and/or support as may be requested by Ventrus from time to time during the Term to utilize and leverage the Licensor IP, including, without limitation, by conducting a comprehensive technology and process transfer relating to the Licensor IP, which transfer will commence as soon as feasible after the Effective Date, but in any event, no later than thirty (30) days thereafter, shall be completed no later than ninety (90) days after the Effective Date, and shall be payable by Ventrus in accordance with Section 6.4(d) (the "Technology Transfer").

2.2 Updates. Without limiting the foregoing, on a periodic basis during the Term, promptly following Ventrus's reasonable request from time to time, Licensor shall disclose to Ventrus or its designated Affiliate, for no additional cost, all Licensor IP necessary or useful to (a) the research, Development, Manufacture, and Commercialization of the Products and (b) understanding the Licensor Technology. The information to be delivered pursuant to this Section 2.2 shall include copies of all Patent Rights, Know-How documentation, copyright registrations, and applications thereof, program data, and all other documentation relating to the Intellectual Property embodied in Licensor Technology, whether in human or machine readable form (such form to be reasonably acceptable to Ventrus) not previously provided by Licensor to Ventrus.

2.3 Personnel. Licensor shall make appropriate personnel available to assist Ventrus or its designee during regular business hours as reasonably requested by Ventrus and as agreed by Licensor (such agreement not to be unreasonably withheld), and, subject to Section 6.4(d), below, shall provide the Ventrus or its designee with access to the personnel and operations of Licensor for such periods of time and in such manner as is reasonably necessary to understand and utilize the Licensor Technology and/or to assist Ventrus in connection with the Development or Commercialization of Ventrus Products and Ventrus Therapies under this Agreement. At Ventrus's request, such assistance shall also be furnished at the facilities of Ventrus or its designee.

ARTICLE III

DEVELOPMENT

General. Unless otherwise determined by the JDC, Ventrus shall be solely responsible for all research and Development activities with respect to Ventrus Products and Ventrus Therapies in its sole discretion (collectively, the "Ventrus Development Program"). Ventrus shall use Commercially Reasonable Efforts to Develop Ventrus Products and Ventrus Therapies under the Ventrus Development Program. To the extent requested by Ventrus and agreed by Licensor (such agreement not to be unreasonably withheld), Licensor shall use diligent efforts to assist and support Ventrus in connection with activities pursuant to the Ventrus Development Program. For the avoidance of doubt, any activities performed by Licensor in connection with the Ventrus Development Program shall not confer upon Licensor any decision-making authority with respect to the Ventrus Development Program. To the extent that Licensor is responsible for Development or Commercialization of Ventrus Products or Ventrus Therapies, Ventrus shall use Commercially Reasonable Efforts to assist Licensor with such Development or Commercialization.

Initial Timeline. Ventrus will use Commercially Reasonable Efforts to endeavor to complete the following tasks in accordance with the timeline set forth in the table in this Section 3.2. The Parties acknowledge and agree that the following table is for illustrative purposes only and Ventrus shall not be deemed to be in breach of this Agreement if Ventrus fails to comply herewith. **Task**	**Timeline.**
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

3.1 Development by Licensor.

(a) Ventrus Products and Ventrus Therapies. To the extent that Ventrus elects in its sole discretion not to pursue or otherwise elects to abandon the Development of a Ventrus Product or Ventrus Therapy under an Indication, Ventrus shall provide Licensor with written notice of such election. Within one hundred eighty (180) days from the date of such notice, Licensor may request from Ventrus a limited, exclusive sublicense to the Licensor IP for the purpose of pursuing the Development and Commercialization of a Licensor Product or Licensor Therapy under such Indication in the Field in the Territory, which request shall include proposed Development and Commercialization plans related thereto. Ventrus may elect to grant Licensor such a sublicense, provided that Ventrus in its sole discretion determines that such sublicense would not negatively impact the Ventrus Products, Ventrus Therapies or Ventrus's prospects. In the event Ventrus agrees to grant such a sublicense, (i) those terms set forth in this Agreement applicable to Licensor Products and Licensor Therapies shall apply to such sublicense (including, for the avoidance of doubt and without limitation, Licensor's royalty payment obligations set forth in Section 6.2(d)), and (ii) the Parties agree to use Commercially Reasonable Efforts to memorialize such sublicense in a separate written agreement within one hundred and twenty (120) days of Ventrus's agreement to such sublicense. Further, to the extent that Ventrus agrees to grant such a sublicense, Licensor may further sublicense to one or more Third Parties such sublicensed rights, provided that (x) the terms of such sublicense shall be consistent with and subordinate to the terms of this Agreement, (y) Ventrus shall be named as an intended third party beneficiary under such sublicense, and (z) Licensor promptly provides Ventrus a true and accurate copy of such sublicense following its execution. For the avoidance of doubt, nothing in this Agreement shall prevent Licensor from pursuing the Development and Commercialization of products or therapies utilizing the Licensor IP outside of the Field.

(b) Other Products. During the Term, subject to the restrictions set forth in this Section 3.3(b), Licensor may request of Ventrus that Ventrus permit Licensor to Develop and Commercialize with Third Parties Products and Therapies in the Field in the Territory that are not Competing Products or Therapies. To exercise this right with respect to any Product or Therapy that is not a Competing Product or Therapy, Licensor shall notify Ventrus that it desires to Develop and Commercialize such Product or Therapy, which notice shall (i) identify the pharmaceutically active ingredient(s) of such product or therapy and how the Licensor Technology will be used in conjunction therewith, (ii) include Development and Commercialization plans related thereto, including confirmation that Licensor, in conjunction with a Third Party, has the financial capacity to successfully complete such Development and Commercialization plans, and (iii) request a sublicense hereunder in respect of such Product or Therapy. Ventrus shall have sixty (60) days to review the foregoing to determine whether or not to grant Licensor a sublicense to the Licensor Technology for the purpose of such Development and/or Commercialization. Licensor may not Develop or Commercialize such Product or Therapy without Ventrus's prior written approval in each instance, which may be withheld in Ventrus's sole discretion. In the event Ventrus agrees to grant such a sublicense, (x) those terms set forth in this Agreement applicable to Licensor Products and Licensor Therapies shall apply to such sublicense (including, for the avoidance of doubt and without limitation, Licensor's royalty payment obligations set forth in Section 6.2(d)), and (y) the Parties agree to use Commercially Reasonable Efforts to memorialize such sublicense in a separate written agreement within one hundred and twenty (120) days of Ventrus's agreement to such sublicense. Further, to the extent that Ventrus agrees to grant such a sublicense, Licensor may further sublicense to one or more Third Parties such sublicensed rights, provided that (I) the terms of such sublicense shall be consistent with and subordinate to the terms of this Agreement, (II) Ventrus shall be named as an intended third party beneficiary under such sublicense, and (III) Licensor promptly provides Ventrus a true and accurate copy of such sublicense following its execution.

ARTICLE IV

REGULATORY; COMPLIANCE

4.1 Regulatory Responsibilities. Ventrus or its Affiliates shall be solely responsible for all regulatory activities in respect of the Ventrus Products and Ventrus Therapies including the preparation, submission and maintenance of all IND filings and associated Regulatory Materials worldwide with respect to each Ventrus Product and Ventrus Therapy (and Ventrus shall own all right, title and interest in and to all such Regulatory Materials), including pre-IND correspondence and meetings with Regulatory Authorities, annual reports and amendments as necessary. Upon the request of Ventrus, Licensor shall provide all reasonable assistance to Ventrus with respect to such regulatory activities; provided, however, that respect to such assistance as may be agreed outside of its responsibilities under Sections 1.1 and 2.1, Ventrus shall compensate Licensor in accordance with Section 6.4.

4.2 Regulatory Materials. All Regulatory Approvals for such Ventrus Products or Ventrus Therapies worldwide shall be obtained and held in the name of Ventrus or one of its Affiliates and Ventrus or one of its Affiliates shall own all right, title, and interest in and to all such Regulatory Approvals and all related Regulatory Materials. Licensor agrees to provide such support and assistance to Ventrus or such Affiliate in connection with the foregoing as may be reasonably requested by Ventrus or such Affiliate from time to time.

4.3 Communications.

(a) General**.** Ventrus shall be responsible for communicating with any Regulatory Authority having jurisdiction regarding a Ventrus Product or Ventrus Therapy. Ventrus shall inform Licensor of notification of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority with respect to a Ventrus Product or Ventrus Therapy which: (i) raises any material concerns regarding the safety or efficacy of such Ventrus Product or Ventrus Therapy, or (ii) relates to expedited and periodic reports of adverse events with respect to such Ventrus Product or Ventrus Therapy, and which may have an adverse impact on Regulatory Approval or the Commercialization of a Product or Therapy.

(b) Cooperation. The Parties shall reasonably cooperate with and assist each other in complying with regulatory obligations, including by a Party providing to the other Party such information and documentation which is in such Party's possession as may be reasonably necessary for Ventrus to prepare a response to an inquiry from a Regulatory Authority with respect to a Ventrus Product or Ventrus Therapy in the Territory.

4.4 Pharmacovigilance.

(a) Ventrus and/or one of its Affiliates shall be responsible for the collection, processing, and submission of information related to adverse events associated with a Ventrus Product or Ventrus Therapy (whether or not Regulatory Approval for such Ventrus Product or Ventrus Therapy has been achieved) in accordance with applicable Law and this Agreement (the "Pharmacovigilance Activities"). Licensor shall provide information, as appropriate, to enable Ventrus or such Affiliate to meet its regulatory obligations and Licensor shall be compensated in accordance with Section 6.4(c).

(b) Both Parties shall provide each other with information related to such adverse events as are likely to be reportable to Regulatory Authorities as expedited reports.

4.5 Disclosures. In addition to its obligations under this Agreement, each Party shall promptly disclose to the other Party the following regulatory information: all material notices or demands received from Regulatory Authorities in connection with a Ventrus Product or Ventrus Therapy, including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning a Product, notice of violation letter (*i.e.*, an untitled letter), warning letter, service of process or other inquiry, including that which may affect the overall compliance status of any contract manufacturing organization engaged by a Party in relation to any Ventrus Product or Ventrus Therapy.

4.6 Compliance with Law. Each Party shall be responsible for conducting its activities under this Agreement in accordance with sound and ethical business and scientific practices, and in compliance with all applicable Laws, including GCP, GMP, and GLP.

ARTICLE V

MANUFACTURING AND COMMERCIALIZATION

Unless otherwise agreed to by the Parties in writing, Ventrus will be solely responsible for the Manufacturing of all Ventrus Products. Licensor shall provide Manufacturing-related assistance to Ventrus as reasonably requested by Ventrus and agreed by Licensor (such agreement not to be unreasonably withheld), provided that Ventrus agrees to compensate Licensor in accordance with Section 6.4 with respect to such assistance. Ventrus shall have sole control and final decision-making authority and, together with its Affiliates, responsibility, at its own expense, for the Commercialization of Ventrus Products and Ventrus Therapies in the Territory, including planning and implementation, distribution, booking of sales, pricing, and reimbursement.

ARTICLE VI

FINANCIAL PROVISIONS

6.1 Up-Front Payment. Ventrus shall pay to Licensor Three Hundred Thousand U.S. dollars ($300,000) upon execution of this Agreement.

6.2 Milestone and Royalty Payments.

(a) Ventrus shall promptly notify Licensor after the occurrence of the first PoP for a bacteria, and within five (5) Business Days of such notice, pay Licensor One Hundred Thousand U.S. dollars ($100,000). Ventrus shall also promptly notify Licensor after the occurrence of the first PoP for a virus, and concurrently with such notice, pay Licensor One Hundred Thousand U.S. dollars ($100,000). It is understood and agreed that, in any event, payment of the milestones set forth in this Section 6.2(a) shall be due and payable not later than the date Ventrus initiates formulation studies for the first Ventrus Product or Ventrus Therapy.

(b) Milestone Payments to Licensor. Ventrus shall pay to Licensor the following one-time payments upon the achievement of the milestone events set forth below for each Ventrus Product or Ventrus Therapy on a PPIL basis (as determined by the JDC):

Task	Payment			
	Prior to First NDA Filing	After First NDA Filing	After Second NDA Filing	After Third NDA Filing
Upon the filing of an IND with the FDA:	$ 100,000	$ 110,000	$ 120,000	$ 130,000
Upon the filing of an IND equivalent with the ex-U.S. Regulatory Authorities:	See Exhibit B	110% of amount paid Prior to First NDA Filing	120% of amount paid Prior to First NDA Filing	130% of amount paid Prior to First NDA Filing
First dose first patient – human Phase I Clinical Trial	$ 250,000	$ 275,000	$ 300,000	$ 325,000
First dose first patient – human Phase II Clinical Trial	$ 500,000	$ 550,000	$ 600,000	$ 650,000
First dose first patient – human Phase III Clinical Trial	$ 750,000	$ 825,000	$ 900,000	$ 975,000
Upon filing of an NDA or BLA with the FDA:	$ 1,000,000	$ 1,100,00	$ 1,200,000	$ 1,300,000
Upon marketing approval by the FDA:	$ 3,000,000	$ 3,000,000	$ 3,000,000	$ 3,000,000
Upon marketing approval by the ex-U.S.:	See Exhibit B	See Exhibit B	See Exhibit B	See Exhibit B
Upon approval of a supplemental NDA (sNDA) for a new Indication, in the U.S.:	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000

For purposes of payments under this Section 6.2(b), a "Ventrus Product" shall mean a specific formulation of a specific active ingredient (e.g., a specific selection of bacteria, a specific virus or selection of viruses, a specific small molecule or protein, or combinations of the foregoing), and a "Ventrus Therapy" shall mean a specific therapy based on a specific active ingredient. Each milestone payment under this Section 6.2(b) shall be payable only once per Ventrus Product or Ventrus Therapy, on a PPIL basis, upon the first achievement of such milestone event for such Ventrus Product or Ventrus Therapy in respect of such PPIL. In the event of multiple PPILs for a particular Ventrus Product or Ventrus Therapy, a milestone payment under this Section 6.2(b) shall be payable in respect of each PPIL. The JDC shall determine the specific individual PPILs and claims for each Ventrus Product and Ventrus Therapy at the end of each applicable Phase. For the avoidance of doubt, Indications may change between Phases. After the JDC determines that a milestone has been achieved, Licensor shall submit an invoice to Ventrus with respect to the corresponding milestone payment; *provided*, however, that no such invoice shall be submitted prior to the Effective Date or prior to such JDC determination. It is understood and agreed that, with respect the milestones set forth in this Section 6.2(b), initiation of a subsequent phase of Development shall be determined by the JDC. In each case, Ventrus shall make the corresponding milestone payment within thirty (30) days after its receipt of such invoice from Licensor. Notwithstanding anything to the contrary, for US NDAs or BLAs and for Regulatory Approvals outside of the U.S., one filing shall incur one set of milestone payments even if multiple claims or Indications are made.

(c) Royalties to Licensor. Ventrus shall pay to Licensor the following royalties on Annual Net Sales of each Ventrus Product and Ventrus Therapy on a worldwide basis provided such Ventrus Product or Ventrus Therapy is Covered by a Valid Claim of a Licensor Patent:

Amount	**Royalty Rate/Payment**
Annual Net Sales of applicable Product or Therapy on sales of less than $[*] million	[*]% of such Net Sales
Annual Net Sales of applicable Product or Therapy on sales of $[*] million or more	[*]% of such Net Sales
If Annual Net Sales of applicable Product or Therapy are between $[*] million and less than $[*] million	$[*] million one-time payment with respect the applicable Product or Therapy (in addition to any other of Ventrus's royalty obligations or payments)
If Annual Net Sales Of applicable Product or Therapy are $[*] million or more	$[*] million one-time payment with respect the applicable Product or Therapy (in addition to any other Ventrus's royalty obligations or payments)

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(d) Royalties to Ventrus. Licensor shall pay to Ventrus royalties on aggregate Annual Net Sales of all Licensor Products and Licensor Therapies in the Territory during the Term of this Agreement as follows, based on the level of involvement of Ventrus in the development of the underlying Intellectual Property in the applicable Licensor Product or Licensor Therapy (as determined by the JDC).

Level of Ventrus Development or Involvement With Respect to Applicable Licensor Product or Licensor Therapy	**Royalty on Annual Net Sales of Resulting Licensor Product or Licensor Therapy**
No Development work	0
In Pre-clinical PoC	[*]%
In Phase II Clinical Trial	[*]%
In Phase III Clinical Trial	[*]%
Completed Phase III Clinical Trial	[*]%
Approval obtained in the U.S., irrespective of approvals outside of U.S. territories	[*]%
Approval obtained in any of the following: Germany, France, UK, Sweden, Italy or Japan (but not the U.S.)	[*]%

(e) Duration of Royalty Payments. The royalties payable under Sections 6.2(c) and (d) shall be paid on a country-by-country basis on each Product or Therapy until the expiration or earlier termination of the applicable Royalty Term with respect to such Product or Therapy. "Royalty Term" shall mean, separately with respect to each Product or Therapy in each country, the period commencing on the First Commercial Sale of such Product or Therapy in such country and concluding on the later to occur of (i) expiration of the last to expire Licensor Patent containing a Valid Claim Covering the sale of such Product or Therapy in that country or (ii) receipt by a Third Party of marketing approval of a Generic Product or Therapy in such country. Upon the expiration or earlier termination of the applicable Royalty Term with respect to such Product or Therapy, then, on a Product-by-Product or Therapy-by-Therapy and country-by-country basis, the licenses granted to Ventrus herein will become fully paid-up, royalty-free, transferable, perpetual, and irrevocable.

6.3 Reporting; Invoicing and Payment of Milestone and Royalty Payments.

(a) Royalty Reports; Payments. Within sixty (60) days of the end of any Calendar Quarter during a Royalty Term with respect to any given Product or Therapy, Ventrus or Licensor shall provide the other, as applicable, with a report stating the applicable Net Sales for Products and Therapies sold by the selling Party or its Affiliates in the Territory, on a country-by-country basis, together with the calculation of the royalties due to such other Party. Such report shall accompany any such applicable royalty payments. Any such report shall be deemed the Confidential Information of the Party providing such report. For five (5) years after the sale of a Product or Therapy, Ventrus or Licensor, as the case may be, shall keep (and shall ensure that any sublicensee shall keep) complete and accurate records of such sales in sufficient detail to confirm the accuracy of the royalty calculations hereunder.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(b) Currency.

(i) All payments hereunder shall be made in immediately available funds by wire transfer of U.S. Dollars to the credit of such bank account as may be designated by Ventrus or Licensor in this Agreement or in writing to Ventrus or Licensor.

(ii) All amounts in this Agreement are expressed in U.S. Dollars. All payments under this Agreement shall be made in U.S. Dollars. When conversion of payments from any foreign currency is required to be undertaken by Ventrus, the U.S. Dollar equivalent shall be calculated in the currency of sale, and then such amounts shall be converted into U.S. Dollars using the noon buying rate of the Federal Reserve Bank of New York on the last Business Day of the quarterly period for which such royalties are calculated. If at any time legal restrictions in any country of the Territory prevent the prompt remittance of any payments with respect to sales therein, Ventrus shall have the right and option to make such payments by depositing the payment amount in local currency to Licensor's account in a bank or depository designated by Licensor in the relevant country.

6.4 Other Compensation. Unless as explicitly set forth in this Agreement, Licensor shall not be entitled to any compensation under this Agreement. To the extent Ventrus requests Licensor to perform consulting services that are not contemplated under this Agreement, any terms regarding compensation arising from Licensor's performance of such services shall be set forth in a separate consulting services or similar agreement. To the extent that Ventrus desires to engage an employee or principal of Licensor to perform services on Ventrus's behalf, such engagement shall be set forth in a separate employment or similar agreement. [*].

(a) General. Notwithstanding anything to the contrary in this Agreement, to the extent that Licensor provides an employee or agent of Licensor to Ventrus to be engaged by Ventrus as Ventrus's employee or agent, Ventrus shall not be liable to Licensor for any payments under this Section 6.4 for any work performed by such employee or agent on behalf of Ventrus.

(b) JDC Representation. Members of the JDC shall not be entitled to any compensation for fulfilling their obligations thereunder; provided, however, that to the extent that JDC obligations require more than one (1) day of service per month, each member of the JDC shall be entitled to equal compensation designated by the JDC and approved by Ventrus in writing for each day of service beyond such one (1) day per month.

(c) SAB Representation. Members of the SAB shall be compensated equally in exchange for fulfilling their obligations thereunder; [*]. Compensation for SAB members shall be determined by the JDC.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(d) Technology Transfer and Expenses.

(i) The first one hundred (100) hours of assistance, training, and/or support provided by Licensor to Ventrus or its Affiliate or a Third Party designee under the Technology Transfer shall be at no cost to Ventrus. After such one hundred (100) hour threshold has been achieved, to the extent Ventrus requests in writing additional support with respect to the Technology Transfer, and Licensor agrees in writing to provide such support (such agreement not to be unreasonably withheld), Ventrus agrees to compensate Licensor for such support provided by Licensor at the Standard Hourly Rate then in effect.

(ii) Ventrus agrees to reimburse Licensor for any reasonable, out-of-pocket expenses incurred by Licensor in the performance of its obligations under Section 2.1, provided that such expenses are preapproved by Ventrus in writing. Licensor shall retain proof of such expenses for a period of two (2) years after requesting reimbursement from Ventrus.

(iii) Licensor shall submit an invoice to Ventrus with respect to fees and expenses due and owing with respect to the Technology Transfer that exceed such one hundred (100) hour threshold, and Ventrus shall pay undisputed amounts within thirty (30) days after its receipt of such invoice from Licensor. Any amounts invoiced and paid under this Section 6.4(d) shall be subject to audit by Ventrus in accordance with the audit provisions set forth in Section 6.6, below.

(e) Standard Hourly Rate. The Standard Hourly Rate shall be [*] Dollars per hour ($[*]/hr.) from the Effective Date until [*]. For [*] thereafter, not later than [*], the Parties shall in good faith negotiate the Standard Hourly Rate for [*]. In the event the Parties are unable to agree on a Standard Hourly Rate for [*], notwithstanding anything to the contrary herein, Licensor shall thereafter have no obligation to provide services hereunder, other than to complete such services previously approved by Ventrus and agreed to by Licensor at the Standard Hourly Rate then in effect. Amounts due that are based on the Standard Hourly Rate shall be invoiced by Licensor in six (6) minute increments (i.e., tenths of an hour).

6.5 Tax Matters. The Parties shall use all reasonable and legal efforts to reduce or optimize tax withholding, to the extent permitted by applicable Law, on payments made pursuant to this Agreement. Each Party agrees to cooperate in good faith to provide the other Party with such documents and certifications as are reasonably necessary to enable such other Party to minimize any withholding tax obligations or liabilities. Notwithstanding such efforts, if Ventrus concludes that tax withholdings under the Laws of any country are required with respect to payments to Licensor, Ventrus shall withhold the required amount and pay it to the appropriate governmental authority. The Parties will reasonably cooperate in providing one another with documentation of the payment of any withholding taxes paid pursuant to this Section 6.5 and in completing and filing documents required under the provisions of any applicable tax Laws or under any other applicable Law in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

6.6 Accounting Matters.

(a) Audit Rights. For a period of two (2) years from the end of the calendar year in which a payment was due hereunder, upon thirty (30) days prior notice, each Party (the "**Audited Party**") shall (and shall require that its Affiliates and licensees and sublicensees) make such records relating to such payment available, during regular business hours and not more often than once each calendar year, for examination by an independent certified public accountant selected by the other Party (the "**Auditing Party**") and reasonably acceptable to the Audited Party, for the purposes of verifying the accuracy of the financial reports and/or invoices furnished by the Audited Party pursuant to this Agreement. The results of any such audit shall be shared by the auditor with both Parties and shall be considered Confidential Information of both Parties. Subject to Section 6.6(b), the Auditing Party shall bear the full cost of such audit.

(b) Underpayment. In the event an audit discloses a deficiency in the Audited Party's payments (or invoices), the Audited Party shall promptly rectify such deficiency. If the deficiency is greater than [*] percent ([*]%), the Audited Party shall, in addition to the foregoing, be responsible for the costs incurred by the Auditing Party in conducting such audit. If such deficiency is greater than [*] percent ([*]%), the Audited Party shall, in addition to the foregoing, pay to the Auditing Party interest on any underpayment(s) (or incorrect invoiced amounts) at the monthly rate of [*] percent ([*]%), compounded monthly.

6.7 General Provisions. Except as otherwise set forth herein, all payments hereunder shall be non-refundable and non-creditable and shall be payable in accordance with the terms of this Agreement.

ARTICLE VII

LICENSE GRANTS; EXCLUSIVITY

7.1 License Grant to Ventrus. Licensor hereby grants to Ventrus, and Ventrus hereby accepts, during the Term an exclusive, royalty-bearing license, with the right to freely sublicense under the Licensor IP, to make, use, import, offer for sale, and sell and otherwise fully Develop, Commercialize, and Manufacture Ventrus Products and Ventrus Therapies in the Field in the Territory. Licensor expressly retains for itself the unrestricted right to pursue Development of products and therapies under Licensor IP outside of the Field.

7.2 Exclusivity. During the Term of this Agreement, neither Licensor nor any Affiliate thereof will, directly or indirectly, (a) license, assign or otherwise dispose of any of its rights in the Licensor IP to any Third Party or Affiliate in the Field, or (b) Develop, Manufacture or Commercialize any Competing Product or Therapy in the Field. Licensor represents and warrants that all of its shareholders and that all of its key employees and consultants have executed agreements requiring such Persons to comply with the exclusivity provisions set forth in this Section 7.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

ARTICLE VIII

CONFIDENTIALITY

8.1 Confidential Information. All Confidential Information disclosed by a Party to the other Party in connection with the activities contemplated by this Agreement, shall not be used by the receiving Party except in connection with the activities and licenses contemplated by this Agreement, shall be maintained in confidence by the receiving Party (except to the extent reasonably necessary for Regulatory Approval of a Product or Therapy or for the filing, prosecution and maintenance of Patent Rights), and shall not otherwise be disclosed by the receiving Party to any other Person, without the prior written consent of the disclosing Party, except to the extent that the Confidential Information:

(a) was known by the receiving Party prior to its date of disclosure to the receiving Party, as demonstrated by competent written evidence; or

(b) either before or after the date of the disclosure to the receiving Party, is lawfully disclosed to the receiving Party by sources other than the disclosing Party rightfully in possession of the Confidential Information; or

(c) either before or after the date of the disclosure to the receiving Party, becomes published or generally known to the public (including information known to the public through the sale of products in the ordinary course of business), without the receiving Party or its sublicensees violating this Article VIII; or

(d) is independently developed by or for the receiving Party without reference to or reliance upon the Confidential Information.

Notwithstanding anything set forth herein to the contrary, this Article VIII shall not prohibit Ventrus from disclosing Confidential Information of Licensor (including, without limitation, applicable Licensor IP) (i) to defend or prosecute litigation, (ii) in connection with Regulatory Filings, accepted industry practices, financings, acquisitions, or reorganizations, or (iii) to the extent otherwise required by applicable Law; *provided*, that to the extent practicable under the foregoing subsections (i), (ii), and (iii), Ventrus shall provide prior written notice of such disclosure to Licensor and allow Licensor the opportunity to review such disclosure to the extent practicable under the circumstances (provided that Ventrus is not prejudiced by such review). Notwithstanding the foregoing provisions of this Section 8.1, either Party may only disclose the terms of this Agreement if such Party reasonably determines, based on advice from its counsel, that it is required to make such disclosure by applicable Law, regulation, or legal process (whether in connection with its ongoing disclosure obligations, in connection with a corporate activity, or otherwise), including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or NASDAQ. In which event, the disclosing Party shall provide prior notice of such intended disclosure to the other Party sufficiently in advance to enable the other Party to seek confidential treatment or other protection for such information, unless the disclosing Party was and is prevented by Law or regulation from providing such advance notice, and the disclosing Party shall disclose only such terms of this Agreement as such disclosing Party reasonably determines, based on advice from its counsel, are required by applicable Law, regulation or legal process to be disclosed (whether in connection with its ongoing disclosure obligations, in connection with a corporate activity or otherwise).

With respect to Licensor's activities outside the Field, Licensor may, without the written consent of Ventrus, disclose to Third Parties for the Licensor's good faith pursuit of its legitimate business purposes: (x) the Licensor Know-How that exists as of the Effective Date, or (y) the Licensor Know-How that is not related to the Field that is developed after the Effective Date.

With respect to Licensor's activities within the Field, only if Ventrus has provided written notice to Licensor that Ventrus has elected in its sole discretion not to pursue or Ventrus has otherwise elected to abandon the Development of a Ventrus Product or Ventrus Therapy under an Indication under Section 3.3(a) may Licensor disclose Licensor Know-How to a Third Party, provided that Licensor shall cause such Third Party to agree in writing to binding confidentiality obligations no less protective of the Licensor Know-How on a whole than those set forth herein, including, without limitation, explicit covenants requiring such Third Party not to disclose the Licensor Know-How to any other party for any reason and not to use such Licensor Know-How in the Field under any circumstance.

With respect to Licensor's activities within the Field, only if Ventrus has given Licensor written permission allowing Licensor to disclose Licensor Know-How in order for Licensor to pursue the Development or Commercialization with Third Parties of a Product or Therapy under Section 3.3(b) (which permission, for the avoidance of doubt, shall not be deemed to be approval by Ventrus of any sublicense under Section 3.3(b)) may Licensor disclose Licensor Know-How to such Third Party, provided that Licensor shall (i) cause such Third Party to agree in writing to binding confidentiality obligations no less protective of the Licensor Know-How on a whole than those set forth herein, (ii) name Ventrus as an intended third party beneficiary of such confidentiality obligations in any such written agreement, and (iii) promptly provide Ventrus with a true and accurate copy of any such written agreement following its execution.

8.2 Employee and Advisor Obligations. Each Party agrees that it shall provide Confidential Information received from the other Party only to its and its Affiliates' employees, consultants, advisors, contractors, and permitted sublicensees and proposed sublicensees who have a need to know such information in order for the receiving Party to exercise its rights or perform its obligations under this Agreement and have an obligation restricting disclosure and use of the Confidential Information on terms no less restrictive than those set forth herein. Licensor hereby agrees that all of its employees, consultants, advisors, contractors, and permitted sublicensees who are or will be involved in activities contemplated under this Agreement will have executed, before being involved in any such activities, agreements requiring such Persons to treat all information and other materials to which they thereby receive access as Confidential Information and restricting disclosure and use of the Confidential Information on terms no less restrictive than those set forth herein.

8.3 Publicity. To the extent required by applicable Laws, including regulations promulgated by applicable security exchanges, Ventrus shall have the right to make a press release announcing the achievement of each milestone under this Agreement as it is achieved, and the achievements of Regulatory Approvals in the Territory as they occur or other information relating to Ventrus Products or Ventrus Therapies. Licensor shall make no public disclosures regarding the terms of this Agreement or any of the foregoing without the prior written consent of Ventrus in each instance.

ARTICLE IX

INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION

9.1 Licensor IP. Licensor shall own all right, title, and interest in and to the Licensor IP.

9.2 Improvements.

(a) Licensor Improvements. All Improvements (and all Intellectual Property rights therein) to the Licensor IP (and any Inventions related to the Licensor IP) independently developed by Licensor with no assistance from Ventrus, its Affiliates, or their sublicensee or designees shall be owned by Licensor ("Licensor Improvements"). All such Licensor Improvements shall be deemed to be "Licensor IP" as such term is defined in this Agreement and, for the avoidance of doubt, shall be included in the license granted under Section 7.1.

(b) Ventrus Improvements. All Improvements (and all Intellectual Property rights therein) to the Licensor IP (and any Inventions related to the Licensor IP) made by or on behalf of Ventrus or its Affiliates, whether in whole or in part, shall be owned in their entirety by Ventrus.

9.3 Prosecution and Maintenance of Patent Rights.

(a) Prosecution and Maintenance.

(i) Subject to Section 9.3(a)(ii) below, as between the Parties, Ventrus shall have the first right to prepare, file, prosecute, and maintain the Licensor Patents in the Territory, using patent counsel reasonably acceptable to Licensor, and in any event Ventrus agrees to prepare, file, prosecute, and maintain the Licensor Patents in the Major Jurisdictions using Commercailly Reasonable Efforts. The costs of preparation, filing, prosecution, and maintenance of Licensor Patents shall be borne by Ventrus. Ventrus shall provide Licensor with a reasonable opportunity to review and comment on such prosecution efforts regarding the Licensor Patents, as set forth in this Section 9.3(a)(i). Ventrus shall promptly provide Licensor with copies of all material communications from any patent office or similar patent authority regarding the Licensor Patents, and shall provide Licensor with drafts of any material filings or responses to be made to such patent offices or similar patent authorities at least five (5) Business Days prior to any non-extendable deadline for responding or otherwise taking action with respect thereto. Ventrus shall consider in good faith and incorporate any reasonable comments thereto provided by Licensor to the extent applicable to such prosecution and maintenance.

(ii) If Ventrus decides to cease the prosecution or maintenance of any Licensor Patent, it shall notify Licensor in writing sufficiently in advance (but in no event less than twenty (20) Business Days) so that Licensor may, at its discretion, assume the responsibility for the prosecution or maintenance of such Licensor Patent, at Licensor's cost and expense.

(b) **Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provided above in this Section 9.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

9.4 Third Party Infringement.

(a) Notice. Licensor shall promptly, but in no event later than five (5) days after the earlier of receiving written notice or becoming aware of, report in writing to Ventrus any (i) known or suspected infringement of Licensor IP in the Field, including any "patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions; (ii) any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability, or non-infringement of any of the Licensor IP; or (iii) known or suspected unauthorized use in the Field or misappropriation of Licensor IP, of which Licensor becomes aware, and Licensor shall provide Ventrus with all available evidence in its possession supporting such infringement, suspected infringement, unauthorized use, or misappropriation or suspected unauthorized use or misappropriation.

(b) Infringement Action. Ventrus shall have the right to initiate a suit or take other appropriate action that it believes is reasonably required to protect the Licensor IP in the Field, including a defense to a claim of invalidity or unenforceability. Ventrus shall give Licensor advance notice of its intent to file any such suit or take any such action and the reasons therefor, and shall provide Licensor with an opportunity to make suggestions and comments regarding such suit or action, and Licensor shall have the right, at its expense and using counsel of its choice, to participate in any such suit or action; provided, however, that Ventrus (through its counsel) shall, unless otherwise mutually agreed upon by the Parties, at all times be responsible for leading such suit or action and shall be responsible for determining, directing and executing the strategy with respect to such suit or action. Thereafter, Ventrus shall keep Licensor promptly informed, and shall from time to time consult with Licensor regarding the status of any such suit or action and shall promptly provide Licensor with copies *of a*ll material documents (*e.g.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits, and notices of appeal) filed in, or otherwise relating to, such suit or action. In connection with any such proceeding, Ventrus shall not enter into any settlement without the prior written consent of Licensor, such consent not to be unreasonably withheld or delayed. If, after its receipt or delivery of notice thereof under Section 9.4(a), Ventrus (i) notifies Licensor that it will not bring any claim, suit, or action to prevent or abate such Infringement in the Field, or (ii) fails to commence a suit to prevent or abate such Infringement in the Field within one hundred and eighty (180) days, Licensor shall have the right, but not the obligation, to commence a suit or take action to prevent or abate such Infringement under the Licensor Patents, at its own cost and expense.

(c) Conduct of Action; Costs. The Party initiating suit shall have the sole and exclusive right to select counsel for any suit initiated by it under this Section 9.4. If required under applicable Law in order for such Party to initiate or maintain such suit, the other Party shall join as a party to the suit. If requested by the Party initiating suit, the other Party shall provide reasonable assistance to the Party initiating suit in connection therewith at no charge to such Party except for reimbursement of reasonable out-of-pocket expenses incurred in rendering such assistance. The Party initiating suit shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings described in this Section 9.4, including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense.

(d) Recoveries. Any recovery obtained as a result of any proceeding described in this Section 9.4 or from any counterclaim or similar claim asserted in a proceeding described in Section 9.5, by settlement or otherwise, shall be applied in the following order of priority:

(i) first, the Party initiating the suit or action shall be reimbursed for all costs in connection with such proceeding paid by such Party;

(ii) second, the other Party shall be reimbursed for all costs in connection with such proceeding paid by the other Party; and

(iii) third, any remainder that is attributable to lost profits with respect to a Product shall be deemed Net Sales and shall be subject to royalty payments under Article VI.

9.5 Claimed Infringement; Claimed Invalidity.

(a) Notice. In the event that a Third Party at any time asserts a claim, or brings an action, suit, or proceeding against Licensor, or any of its Affiliates or sublicensees, claiming infringement of such Third Party's Patent Rights or unauthorized use or misappropriation of such Third Party's Know-How, based upon an assertion or claim arising out of any of the activities taken in respect of the research, Development, Commercialization or Manufacture of a Product (such a claim, action, suit or proceeding, a "Third Party Infringement Claim"), Licensor shall promptly (not more than ten (10) days after the earlier of receiving written notice or becoming aware of) notify Ventrus in writing of the claim or the commencement of such action, suit, or proceeding, enclosing a copy of the claim and all papers served.

(b) Defense of Third Party Infringement Claims. Subject to Licensor's rights and obligations under Section 11.1, the following provisions shall apply to the conduct of the defense of Third Party Infringement Claims: within thirty (30) days after delivery of the notification required to be delivered under Section 9.5(a), Ventrus shall, upon written notice thereof to Licensor, assume control of the defense of such action, suit, proceeding, or claim. Ventrus shall keep Licensor advised of the status of such action, suit, proceeding, or claim and the defense thereof and shall consider recommendations made by Licensor with respect thereto. Licensor may participate therein at its own expense.

Ventrus shall not agree to any settlement of such action, suit, proceeding, or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of Licensor from all liability with respect thereto, or that imposes any liability or obligation on Licensor, without prior written consent from Licensor.

(c) Patent Invalidity Claim. If a Third Party at any time asserts a claim that any Licensor Patent relating to a Ventrus Product or Ventrus Therapy is invalid or otherwise unenforceable (an "Invalidity Claim"), whether as a defense in an infringement action brought by Licensor or Ventrus pursuant to Section 9.5, in a declaratory judgment action or in a Third Party Infringement Claim brought against Licensor or Ventrus, the Parties shall cooperate with each other in preparing and formulating a response to such Invalidity Claim; provided, however, that Ventrus shall be responsible for responding to and resolving such Invalidity Claim. Ventrus, may elect to settle or compromise any Invalidity Claim involving Patent Rights owned or Controlled by Licensor, subject to Licensor's prior written consent (which shall not be unreasonably withheld).

9.6 Patent Marking. Ventrus shall comply with the patent marking statutes in each country in which a Ventrus Product or Ventrus Therapy is made, offered for sale, sold, or imported by Ventrus, its Affiliates, licensees, and/or sublicensees.

9.7 Trademarks.

(a) Each Party and its Affiliates shall retain all right, title, and interest in and to its and their respective names and logos.

(b) Neither Party shall acquire any rights under this Agreement in any trademark, service mark, or Internet domain name of the other Party.

(c) Ventrus will have sole responsibility, ownership, and decision making power, at its sole expense, for all aspects of naming and branding the Ventrus Products and Ventrus Therapies in the Territory, including creating, selecting, prosecuting, and enforcing trademarks and domain names.

ARTICLE X

REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

(a) Corporate Existence and Power. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business or other activities as they are now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

(b) Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) **Consents.** All consents, approvals, and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

(d) **No Conflict.** It is not a party to any agreement or commitment that would prevent it from granting the rights granted or intended to be granted to the other Party under this Agreement or performing its obligations under this Agreement.

10.2 **Representations and Warranties by Licensor.** Licensor hereby represents and warrants to Ventrus as of the Effective Date as follows:

(a) Exhibit C attached hereto sets forth a complete and accurate list of all Licensor Patents in existence as of the Effective Date, indicating the owner or co-owners thereof if such Licensor Patent is not solely owned by Licensor;

(b) The Licensor Technology does not wrongfully incorporate any Intellectual Property owned or controlled by any Third Party;

(c) The University of Buffalo (and all relevant departments and offices therein, including, without limitation, the University of Buffalo Office of Science, Technology Transfer and Economic Outreach) has waived in writing any and all claims of ownership in Licensor IP. TheraSyn has ownership interests in Licensor and is thereby entitled to royalty payments and other consideration payable by Licensor from Licensor's receipt of payments from Ventrus under this Agreement;

(d) No portion of the Licensor IP was (i) created utilizing any University of Buffalo facility, or (ii) invented during any period of time during which Dr. Schentag was devoted to the normal and assigned functions of teaching, university service, directing or conducting research on the University of Buffalo's premises;

(e) Licensor is the sole and exclusive owner, or exclusive licensee, of all of the Licensor IP free from Encumbrances and is listed in the records of the appropriate governmental authorities as the sole and exclusive owner of record or exclusive licensee for each registration, grant and application included in the Licensor IP;

(f) all of Licensor's and its Affiliates' employees, officers, subcontractors, consultants, and any other Person who has participated in any respect in the invention or authorship of any Licensor IP have assigned to Licensor or its Affiliates, as applicable, all inventions made during the course of and as the result of such Person's association with Licensor and are under written and existing obligations restricting disclosure and use by such Person of Licensor's Confidential Information as well as confidential information of other parties (including Ventrus and its Affiliates) that such Person may receive, to the extent required to support Licensor's obligations under this Agreement;

(g) neither Licensor, nor any Person(s) who have performed work related to the Licensor IP on behalf of Licensor, is or has been debarred under 21 U.S.C. Section 335a or, to Licensor's knowledge, has engaged in any conduct that has resulted, or would reasonably be expected to result, in such debarment under applicable Law, including 21 U.S.C. Section 335a. No actions that would reasonably be expected to result in such debarment are pending or threatened against Licensor or any Person(s) who have performed work related to the Licensor IP on behalf of Licensor and, to Licensor's knowledge, there are no facts that could reasonably give rise to such an action. To the actual knowledge of Licensor, no Person on any of the FDA clinical investigator enforcement lists (including, but not limited to, the (1) Disqualified/Totally Restricted List, (2) Restricted List and (3) Adequate Assurances List) will participate in the performance of any activities hereunder;

(h) Licensor has the right to grant to Ventrus the licenses under the Licensor IP that it purports to grant hereunder and has not granted any Third Party rights that would otherwise interfere or be inconsistent with Ventrus' rights hereunder;

(i) Licensor has the right to use and disclose and to enable Ventrus to use and disclose (in each case under appropriate conditions of confidentiality) the Licensor Know-How free from Encumbrances;

(j) all application, registration, maintenance, and renewal fees in respect of the Licensor Patents have been paid and all necessary documents and certificates have been filed with the relevant agencies for the purpose of maintaining the Licensor Patents;

(k) Licensor has filed and prosecuted the patent applications within the Licensor Patent Rights in good faith and complied with its duties of disclosure with respect thereto and there are and have been no claims, challenges, oppositions, interference, or other proceedings regarding the prosecution of the Licensor Patents;

(l) Licensor has not committed any act, or omitted to commit any act, that may cause the Licensor Patent Rights to expire prematurely or be declared invalid or unenforceable;

(m) the Licensor IP comprises all of the Intellectual Property rights used by Licensor, its Affiliates, consultants, subcontractors, and sublicensees with respect to the Licensor Technology;

(n) to its knowledge, the making, use, sale, offering for sale, importing, exporting, or research, Development, Manufacture, and Commercialization of the Licensor Technology, exclusive of any drug or compound owned or controlled by a Third Party, does not infringe the Patent Rights or misappropriate the Know-How of any Third Party, nor has Licensor received any written notice alleging such infringement or misappropriation;

(o) Licensor has not initiated or been involved in any proceedings, actions, or claims in which it alleges that any Third Party is or was infringing or misappropriating any Licensor IP, nor have any such proceedings, actions or claims been threatened by Licensor, nor does Licensor know of any valid basis for any such proceeding;

(p) there are no pending, and, to Licensor's knowledge, there are no threatened, actions, claims, or proceedings of any nature, civil, criminal, regulatory, or otherwise, in law or in equity, against Licensor or any of its Affiliates or licensees or, to the knowledge of Licensor, pending or threatened actions, claims, or proceedings of any nature, civil, criminal, regulatory, or otherwise, against any Third Party, in each case involving the Licensor IP or relating to the transactions contemplated by this Agreement;

(q) Neither Dr. Schentag nor any employee or consultant of Licensor or its Affiliates involved in the research and Development of the Licensor Technology is subject to any agreement with any other Third Party which requires such employee or consultant to assign any interest in any Licensor IP to any Third Party (including, for the avoidance of doubt, the University of Buffalo);

(r) Licensor has disclosed to Ventrus all government funding relationships to which it is a party that would result in rights to any Product residing in the U.S. Government, National Institutes of Health, National Institute for Drug Abuse or other Regulatory Authority, or other governmental authority;

(s) there are no agreements or arrangements to which Licensor or any of its Affiliates is a party that would limit the rights granted to Ventrus under this Agreement or that restrict or will result in a restriction on the Parties' ability to perform activities contemplated by this Agreement;

(t) the Licensor Know-How has not been used or disclosed by any Person except pursuant to valid and appropriate non-disclosure and/or license agreements that, to Licensor's knowledge, have not been breached. Exhibit E attached hereto sets forth a complete and accurate list of all such non-disclosure and/or license agreements in existence as of Effective Date;

(u) Licensor has not permitted any of the Licensor Know-How to enter the public domain other than those publications listed on Exhibits F-1 and F-2 attached herewith that sets forth a complete and accurate list of all such publications, including publications of patents and patent applications by the relevant patent offices or by WIPO for PCT applications; and

(v) Licensor has disclosed or made available to Ventrus all material scientific and technical information known to it relating to the Licensor Technology, including the safety and efficacy of the Licensor Technology. The materials provided or made available to Ventrus do not contain an untrue statement of material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. Notwithstanding anything to the contrary contained in this Agreement, Licensor has not failed to disclose to Ventrus any fact or circumstance known to Licensor and relating to the Licensor Technology that would be reasonably material to Ventrus in connection with this Agreement or the transactions contemplated herein.

10.3 Representations and Warranties by Ventrus. Ventrus hereby represents and warrants to Licensor as follows:

(a) Ventrus shall not, during the Term, challenge the validity or enforceability of any Licensor IP, provided, however, the foregoing representation and warranty shall not apply to any successor or assign to this Agreement and shall in no way limit the right of such successor or assign to challenge the validity or enforceability of any Licensor IP; and

(b) any subsequent conveyance to or involving sublicensee or other transferee shall be in full compliance with the terms of this Agreement.

10.4 Mutual Covenants. Each Party covenants and agrees that such Party will not employ or engage any Person(s) in connection with this Agreement who, to such Party's knowledge, is or is reasonably likely to be debarred under 21 U.S.C. Section 335a.

10.5 Covenants by Licensor.

(a) No Encumbrances; Maintenance of Rights. Licensor covenants and agrees that from the Effective Date until the expiration of the Term, except as expressly permitted under the terms of this Agreement, neither it nor its Affiliates shall enter into any agreement with any Third Party, whether written or oral, with respect to, or otherwise assign, transfer, license, convey its right, title, or interest in or to or grant any other Encumbrance to or under, the Licensor IP, with respect to the Field.

(b) Debarment. If, at any time after execution of this Agreement, Licensor becomes aware that it or any employee, agent, or subcontractor of Licensor who participated, or is participating, in the performance of any activities hereunder is on, or is being added to the FDA Debarment List or any of the three (3) FDA Clinical Investigator Restriction Lists referenced in Section 10.2(g), it will provide written notice of this to Ventrus within five (5) Business Days of its becoming aware of this fact.

(c) Improvements. Licensor (or Dr. Schentag, as applicable) shall not knowingly make any Improvements to the Licensor IP which are covered in whole or in part by any University of Buffalo Policies, or to which the University of Buffalo or any Third Party could claim any interest. Licensor shall cause Dr. Schentag, to the extent Dr. Schentag performs any services on behalf of Licensor that result in or may result in any Licensor Improvements, to maintain accurate written log records indicating the time and place where Dr. Schentag performs such services, including when he develops such Licensor Improvements.

10.6 DISCLAIMER OF WARRANTIES. NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, EXCEPT AS PROVIDED IN SECTIONS 10.1, 10.2 OR 10.3 OF THIS AGREEMENT, INCLUDING ANY WARRANTY OF ACCURACY, COMPLETENESS, PERFORMANCE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, OR NON-INFRINGEMENT OR TITLE. FURTHER, LICENSOR AND VENTRUS ACKNOWLEDGE AND AGREE THAT NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS REPRESENTING AN ESTIMATE OR PROJECTION OF ANTICIPATED SALES OF ANY PRODUCT, AND THAT THE MILESTONES AND NET SALES LEVELS SET FORTH IN ARTICLE VI OR ELSEWHERE IN THIS AGREEMENT OR THAT HAVE OTHERWISE BEEN DISCUSSED BY THE PARTIES ARE MERELY INTENDED TO DEFINE THE MILESTONE PAYMENTS OR ROYALTY OBLIGATIONS IN THE EVENT SUCH MILESTONES OR NET SALES LEVELS ARE ACHIEVED. NEITHER LICENSOR NOR VENTRUS MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT EITHER PARTY WILL BE ABLE TO SUCCESSFULLY RESEARCH, DEVELOP, MANUFACTURE, OR COMMERCIALIZE ANY PRODUCT, REGARDING THE LIKELIHOOD OF SUCCESS OF ANY APPLICATION FOR REGULATORY APPROVAL RELATING TO ANY PRODUCT, OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH PRODUCT WILL BE ACHIEVED.

ARTICLE XI

INDEMNIFICATION

11.1 Indemnification by Licensor. Subject to the other provisions of this Article XI, Licensor shall defend Ventrus, its Affiliates, and its sublicensees and each of their respective officers, directors, agents, representatives, and employees (collectively, "Ventrus Indemnitees") from and against all charges, allegations, notices, civil, criminal, or administrative claims, demands, complaints, causes of action, proceedings, or investigations of a Third Party (collectively, "Claims"), and indemnify and hold harmless such Ventrus Indemnitees from and against any and all losses, liabilities, obligations, awards, settlements, penalties, fines, sanctions, damages, and reasonable costs (including awards of court costs and reasonable attorneys' fees) (collectively, "Losses") that result from any such Claims, where and to the extent that such Claims are made or brought against any Ventrus Indemnitee by or on behalf of a Third Party, and solely to the extent such Claim is based on or arises out of (a) the breach of any obligation, covenant, warranty, or representation made by Licensor under this Agreement, or (b) Licensor's or its Affiliates' gross negligence or willful misconduct; *provided*, however, that Licensor's obligations except in each case to the extent that such Claim or Loss is attributable to (i) any matter for which Ventrus is obligated to indemnify a Licensor Indemnitee pursuant to Section 11.2, below, or (ii) results from the negligence or willful misconduct of any Ventrus Indemnitees.

11.2 Indemnification by Ventrus. Subject to the other provisions of this Article XI, Ventrus shall defend Licensor, its Affiliates, and its sublicensees and each of their respective officers, directors, agents, representatives, and employees (collectively, "Licensor Indemnitees"), from and against all Claims, and indemnify and hold harmless such Licensor Indemnitees from and against any and all Losses that result from such Claims, where and to the extent that such Claims are made or brought against any Licensor Indemnitee by or on behalf of a Third Party, and solely to the extent such Claim is based on or arises out of:

(a) any violation of applicable Law by Ventrus or its Affiliates in the course of its activities under this Agreement;

(b) the breach of any obligation, covenant, warranty, or representation made by Ventrus under this Agreement;

(c) Ventrus's or its Affiliates' or sublicensee's negligence of willful misconduct; or

(d) are attributable to a Product or Therapy Developed, Commercialized, or Manufactured or supplied by Ventrus (including any successor of Ventrus) or a Third Party authorized by Ventrus to Manufacture and/or supply a Product or Therapy.

provided, however, except in each case to the extent that such Claim or Loss is attributable to any matter for which Licensor is obligated to indemnify a Ventrus Indemnitee pursuant to Section 11.1, above.

11.3 Indemnification Procedures. A Person entitled to indemnification pursuant to either Section 11.1 or Section 11.2 will hereinafter be referred to as an "Indemnitee." A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an "Indemnitor." In the event a Ventrus Indemnitee or Licensor Indemnitee is seeking indemnification under either Section 11.1 or Section 11.2, Ventrus or Licensor, as applicable, will inform the Indemnitor of a Claim as soon as reasonably practicable after it receives notice of the Claim, it being understood and agreed that the failure to give notice of a Claim as provided in this Section 11.3 will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that such Indemnitor is actually and materially prejudiced as a result of such failure to give notice. The Indemnitee will permit the Indemnitor to assume direction and control of the defense of the Claim, and, at the Indemnitor's expense, will cooperate as reasonably requested in the defense of the Claim. The Indemnitee will have the right to retain its own counsel at its own expense. The Indemnitor may not settle such Claim, or otherwise consent to an adverse judgment in such Claim, without the Indemnitee's prior written consent, not to be unreasonably withheld or delayed; *provided*, however, that the Indemnitor shall not require such consent with respect to the settlement of any Claim under which the sole relief provided is for monetary damages that are paid in full by the Indemnitor, which would not materially diminish or limit or otherwise adversely affect the rights, activities, or financial interests of the Indemnitee, and which does not result in any finding or admission of fault by the Indemnitee. If the Indemnitor does not assume direction and control of the defense of the Claim, the Indemnitee may not settle such Claim, or otherwise consent to an adverse judgment in such Claim, without the Indemnitor's prior written consent, not to be unreasonably withheld or delayed.

11.4 Setoff. If and to the extent either Party fails to pay, reimburse, or credit the other Party for any amount owed when due under this Agreement, then the Party to whom such amount is owed may, at its election, without demand, charge and setoff such amount against amounts otherwise due from it or its Affiliates, and the owing Party hereby authorizes all such charges and setoffs.

11.5 Insurance. Ventrus shall, and Ventrus shall require any sublicensee to, at all times procure and maintain, at its (or, in the case of a sublicensee, sublicensee's) cost and expense, product liability insurance in amounts that are necessary, reasonable, and customary to cover any and all of the Development and Commercialization activities in the Field in the Territory.

11.6 LIMITATION OF LIABILITY. NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY, ITS AFFILIATES, SUBLICENSEES, SUCCESSORS OR ASSIGNS, OR ANY THIRD PARTY FOR LOST PROFITS, BUSINESS INTERRUPTION, OR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 OR SECTION 11.2 OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE VIII, OR RELATING TO A PARTY'S BREACH OF REPRESENTATIONS OR WARRANTIES OR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

ARTICLE XII

TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and shall continue, subject to the termination rights set forth in this Article XII, on a Product-by-Product, Therapy-by-Therapy, country-by-country basis in accordance with its terms until, with respect to a Product or Therapy in a particular country, the expiration of such Product's or Therapy's Royalty Term in such country (the "Term").

12.2 Termination by Ventrus Without Cause. Ventrus may terminate this Agreement without cause at any time as an entirety or on a Product-by-Product or Therapy-by-Therapy basis on ninety (90) days' prior written notice to Licensor.

12.3 Termination for Cause.

(a) Termination for Licensor Material Breach. Ventrus may terminate this Agreement on a Product-by-Product or Therapy-by-Therapy basis upon one hundred eighty (180) days prior written notice to Licensor upon the material breach by Licensor of any of its representations, warranties or obligations under this Agreement with respect to such Product or Therapy, other than for payment of undisputed amounts owed under Section 6.2(d), in which event Licensor shall have ninety (90) days to cure such breach; *provided*, however that such termination shall become effective immediately only if Licensor fails to remedy or cure the breach within one hundred eighty (180) days (or ninety (90) days with respect to undisputed amounts due under Section 6.2(d)) of receiving such notice.

(b) Termination for Ventrus Material Breach. Licensor may terminate this Agreement on a Product-by-Product or Therapy-by-Therapy basis upon one hundred eighty (180) days prior written notice to Ventrus upon the material breach by Ventrus of any of its representations, warranties, or obligations under this Agreement with respect to such Product or Therapy, other than for payment of undisputed amounts due under Section 6.1 or 6.2(a), (b) or (c), in which event Ventrus shall have ninety (90) days to cure such breach; *provided*, however that such termination shall become effective immediately only if Ventrus fails to remedy or cure the breach within one hundred eighty (180) days (or ninety (90) days with respect to undisputed amounts due under Section 6.1 or 6.2(a), (b) or (c)) of receiving such notice.

(c) Termination for IP Challenge.

(i) Licensor may terminate this Agreement on a Product-by-Product or Therapy-by-Therapy basis in the event Ventrus (or a successor or a sublicensee of Ventrus) challenges the validity or enforceability of any issued patent within the Licensor IP, provided that Ventrus or such successor or sublicensee does not withdraw such challenge within ninety (90) days of Licensor's written notice of its intent to terminate this Agreement in accordance with this Section 12.3(c)(i).

(ii) Ventrus may terminate this Agreement on a Product-by-Product or Therapy-by-Therapy basis in the event that Licensor (or a sublicensee of Licensor) challenges the validity or enforceability of any issued patent within the Licensor IP which is sublicensed to Licensor by Ventrus under Section 3.3(a) or (b), provided that Licensor or such sublicensee does not withdraw such challenge within ninety (90) days of Ventrus's written notice of its intent to terminate this Agreement in accordance with this Section 12.3(c)(ii). If Ventrus elects to terminate this Agreement with respect to any Licensor Product or Licensor Therapy under this Section 12.3(c)(ii), such sublicense shall be revoked in its entirety and any rights granted to Licensor under such sublicense shall revert to Ventrus.

(d) Product Specific Breach. Notwithstanding the foregoing or any other provision of this Agreement, in no event will any such breach described in Section 12.3(a) or Section 12.3(b) which is specifically related to a particular Product or Therapy be a basis upon which to terminate this Agreement as an entirety or with respect to any other Product, it being understood that any material breach that is related to the Licensor Technology, generally, shall be deemed to relate to all Products and Therapies, and accordingly may constitute the basis for termination of this Agreement as an entirety.

(e) Termination Disputes. If a Party gives notice of termination under this Section 12.3 and the other Party disputes whether such notice was proper, then the issue of whether or not the Agreement was properly terminated shall be resolved in accordance with Section 13.1, and the Agreement shall remain in full force and effect until such dispute is resolved. If as a result of such arbitration it is determined that the notice of termination was proper, then such termination shall be deemed to be effective on the date on which such notice was first provided. On the other hand, if as a result of the arbitration process it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in full force and effect.

12.4 Termination for Bankruptcy. If at any time during the Term of this Agreement, an Event of Bankruptcy (as defined below) relating to a Party (the "Bankrupt Party") occurs, Ventrus (in the case the Bankrupt Party is Licensor) or Licensor (in the case the Bankrupt Party is Ventrus) (the "Non-Bankrupt Party") shall have, in addition to all other legal and equitable rights and remedies available hereunder, the option to terminate this Agreement immediately upon written notice to the Bankrupt Party. The term "Event of Bankruptcy" shall mean, with respect to a Party: (a) filing by such Party in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Bankrupt Party or of its assets; (b) a Person proposing a written agreement of composition or extension of a Bankrupt Party's debts; (c) such Party being served with an involuntary petition against the Bankrupt Party, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof; (d) such Party proposing or being a party to any dissolution or liquidation of such Party; or (e) such Party making a general assignment for the benefit of creditors. If this Agreement is terminated by Ventrus pursuant to this Section 12.4 due to the rejection of this Agreement by or on behalf of Licensor or one or more of its Affiliates under Section 365 of Title 11, United States Code (the "Bankruptcy Code"), all licenses and rights to licenses granted under or pursuant to this Agreement by Licensor or its Affiliates to Ventrus are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that Ventrus, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, and that upon commencement of a bankruptcy proceeding by or against any Licensor or one or more of its Affiliates under the Bankruptcy Code, Ventrus shall be entitled to a complete duplicate of or complete access to (as Ventrus deems appropriate) any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Ventrus (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by Ventrus, unless Licensor elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of Licensor upon written request therefor by Ventrus. The foregoing provisions of this Section 12.4 are without prejudice to any rights Ventrus may have arising under the Bankruptcy Code or other applicable Law.

12.5 Effect of Termination.

(a) If Ventrus terminates this Agreement pursuant to Section 12.3(a) or Section 12.4:

(i) The licenses and other rights granted by Licensor to Ventrus under the Licensor IP will remain in effect in accordance with their respective terms; *provided*, *however*, that the amount of any milestone payments and royalties applicable to Licensor under Article VI shall be reduced by [*] percent ([*]%);

(ii) Section 7.2 shall survive in accordance with its terms for the duration of the Royalty Term; and

(iii) Except as set forth in this Section 12.5(a) and in Section 12.5(d), the rights and obligations of the Parties hereunder shall terminate as of the date of such termination.

(b) If Ventrus terminates this Agreement pursuant to Section 12.2 or Licensor terminates this Agreement pursuant to Section 12.3(b) or (c) or 12.4:

(i) all licenses granted by a Party to the other Party hereunder will terminate and revert to the Party terminating the Agreement;

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(ii) The Parties shall cooperate to effect an orderly wind down of activities hereunder, including in the case of a termination of this Agreement with respect to the Licensor Technology; and

(iii) Except as set forth in Section 12.5(d), the rights and obligations of the Parties hereunder shall terminate as of the date of such termination.

(c) Notwithstanding the foregoing, if either Party terminates this Agreement with respect to a Product or Therapy, then the Parties' other rights and obligations hereunder, including all rights and obligations with respect to any other Product or Therapy, shall continue and remain in full force and effect.

(d) Survival. The expiration or termination of any right or obligation under this Agreement for any reason will not affect obligations, including the payment of any royalties and milestones, that have accrued as of the date of such expiration or termination, as the case may be, and the provisions set forth in Sections 6.2(c), 6.2(d), 6.2(e), 6.3, 6.5, 6.6, 6.7, 12.5 and 12.6, and Articles VIII, IX, X, XI, and XIII shall survive such expiration or termination.

12.6 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein.

ARTICLE XIII

MISCELLANEOUS

13.1 Arbitration. In the event of any dispute or disagreement arising from or relating to this Agreement, the Parties shall use their best efforts to settle such dispute or disagreement through informal negotiations. If the Parties are unable to mutually agree upon a solution within (30) days of commencing any such negotiation efforts, such dispute or disagreement shall be subject to binding arbitration in New York, NY, under the expedited rules of the American Arbitration Association ("AAA") then in effect. The Parties agree that any arbitration will be administered by the AAA and that there shall be one, sole arbitrator who shall be mutually agreed upon by the Parties and who shall be an attorney with experience in and knowledge of the biopharma industry. In the event the Parties fail to agree upon an arbitrator within the time period prescribed under AAA rules or within such other time frame as the Parties may agree in writing, upon request of either Party the arbitrator shall instead be appointed in accordance with AAA rules. The Parties agree that the arbitrator shall have the authority to permit full and complete discovery, both written and oral, by deposition, to establish reasonable additional procedures to facilitate and complete any such arbitration within one hundred eighty (180) days of the arbitrator's appointment, and to decide any motions brought by any party to the arbitration, including motions for summary judgment and/or adjudication and motion to dismiss, prior to any arbitration hearing. Any administrative or hearing fees payable for any arbitration brought by a Party under this Agreement shall be shared equally by Licensor and Ventrus. Notwithstanding the foregoing, the Parties agree that the arbitrator shall have the power to award any remedies, including attorneys' fees and costs, available under applicable law. Arbitration shall be the sole, exclusive, final, and binding remedy for any dispute between the Parties, and judgment may be entered by a court having jurisdiction thereof. The proceedings, including any outcome, shall be confidential. Notwithstanding the foregoing, by agreeing to arbitration the Parties do not intend to deprive any court of competent jurisdiction of its ability to issue any form of provisional remedy, including, but not limited to, a preliminary injunction or attachment in aid of the arbitration, or to order any interim or conservatory measure, with respect to any dispute or disagreement arising between the Parties under Article 8 or Article 9. A request for such provisional remedy or interim or conservatory measure by a Party to a court or other government entity shall not be deemed a breach of this Agreement or a waiver of this Section 13.1.

13.2 Governing Law and Jurisdiction. This Agreement shall be governed by and construed under the laws of New York, without giving effect to the conflicts of laws provision thereof. The United Nations Convention on Contracts for the International Sale of Goods (1980) shall not apply to the interpretation of this Agreement.

13.3 Notices. Any notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and shall be deemed to have been delivered upon personal delivery or (a) in the case of notices provided between Parties in the continental United States, four (4) days after deposit in the mail or the next Business Day following deposit with a reputable overnight courier and (b) in the case of notices provided by telecopy (which notice shall be followed immediately by an additional notice pursuant to clause (a) above if the notice is of a default hereunder), upon completion of transmissions to the addressee's telecopier (to be followed the same say as the transmission with an email copy), as follows (or at such other addresses or facsimile numbers or email addresses as may have been furnished in writing by one of the Parties to the other as provided in this Section 13.3):

If to Licensor:

TheraBiome, LLC
[*]
[*]
Attention: Managing Member
Fax: [*]
Email: [*]

With a required copy (which shall not constitute notice) to:

Acuity Law Group, PC
12707 High Bluff Drive, Suite 200
San Diego, California 92130
Attention: [*]
Fax: [*]
Email: [*]

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

If to Ventrus (2 copies):
Ventrus Biosciences, Inc.
99 Hudson Street, 5th Floor
New York, NY 10013
Attention: CEO and CFO
Fax: [*]
Email: [*]

With a required copy (which shall not constitute notice) to:

Proskauer Rose LLP
11 Times Square
New York, NY 10026
Attn: [*]
Fax: [*]
Email: [*]

13.4 Severability. If any provision of this Agreement is found by an arbitrator or a court of competent jurisdiction to be unenforceable, then such provision shall be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it shall be severed from the remainder of this Agreement. The remainder of this Agreement shall remain in full force and effect, unless the severed provision is essential and material to the rights or benefits received by either Party. In such event, the Parties shall negotiate, in good faith, and substitute a valid and enforceable provision or agreement that most nearly implements the Parties' intent in entering into this Agreement.

13.5 Interpretation. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation." The word "will" shall be construed to have the same meaning and effect as the word "shall." The word "or" shall be construed to have the same meaning and effect as "and/or." Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and assigns, (d) the words "herein", "hereof' and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (e) all references herein to Articles, Sections, or Exhibits shall be construed to refer to Articles, Sections, and Exhibits of this Agreement. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

13.6 Entire Agreement; Amendments. This Agreement, including all Exhibits attached hereto, constitutes the entire agreement between the Parties with respect to the within subject matter and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter. The Summary of Non-Binding Key License Agreement Terms, entered into by the Parties on August 14, 2013, is hereby terminated in its entirety and superceded by this Agreement, and for the avoidance of doubt, no terms thereunder shall be enforceable by any Party. This Agreement may be amended only in writing signed by properly authorized representatives of each of the Parties. In the event of any conflict between a substantive provision of this Agreement and any Exhibit hereto, the substantive provisions of this Agreement shall prevail.

13.7 Independent Contractors; No Agency. Neither Party shall have any responsibility for the hiring, firing, or compensation of the other Party's employees or for any employee benefits. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party shall be that of independent contractor. The Parties agree and acknowledge that neither owes any fiduciary duties to the other.

13.8 Subcontracting; Assignment; Successors. Ventrus may perform its obligations and exercise its rights under this Agreement through its Affiliates or Third Parties. Licensor may not assign this Agreement in whole or in part without the prior written consent of Ventrus, which consent shall not unreasonably withheld, and such attempted assignment shall be deemed null and void. This Agreement shall be binding upon, and shall inure to the benefit of, all permitted successors and assigns.

13.9 Execution in Counterparts; Electronic Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or by electronic delivery in *.pdf* format shall be deemed to be original signatures.

13.10 Waivers. No failure on the part of Ventrus or Licensor to exercise and no delay in exercising any right, power, remedy, or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice, or constitute a waiver of any such right, power, remedy, or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy, or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy, or privilege.

13.11 Actions of Affiliates. Each Party shall be liable for any failure by its Affiliates to comply with the restrictions, limitations, and obligations set forth in this Agreement. Each Party may perform its obligations hereunder personally or through one or more Affiliates, although each Party shall nonetheless be solely responsible for the performance of its Affiliates. Neither Party shall permit any of its Affiliates to commit any act (including any act of omission) that such Party is prohibited hereunder from committing directly. To the extent that the rights granted to a Party hereunder may be and are exercised by an Affiliate of such Party, such Affiliate shall be bound by the corresponding obligations of such Party.

13.12 Expenses. Except as otherwise expressly set forth in this Agreement, each Party shall bear its own costs and expenses (including attorney's fees and costs) incurred by such Party in connection with the negotiation, preparation, execution, and delivery of this Agreement and such Party's performance of the activities contemplated by this Agreement.

13.13 Anti-Bribery; Anti-Corruption. Each Party and their respective Affiliates shall comply fully at all times with all applicable Laws and regulations, including but not limited to the U.S. Foreign Corrupt Practices Act and all other applicable anti-bribery and/or anti-corruption Laws of each jurisdiction in which such Party conducts business under this Agreement or otherwise in connection with this Agreement.

13.14 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm, or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced Person engaged in the same type of undertaking under the same or similar circumstances). If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

13.15 Export Clause. Each Party acknowledges that the Laws and regulations of the U.S. restrict the export and re-export of commodities and technical data of U.S. origin. Each Party agrees that it shall not export or re-export restricted commodities or the technical data of the other Party in any form without the appropriate U.S. and foreign government licenses.

[Signature Page Follows]

IN WITNESS WHEREOF, Licensor and Ventrus have caused this License and Collaboration Agreement to be duly executed by their authorized representatives, as of the date first written above.

Ventrus Biosciences, Inc.

By: /s/ Russell H. Ellison
Name: Russell H. Ellison
Title: CEO
Date: November 8, 2013

THERABIOME LLC

By: /s/ Mohan Kabadi
Name: Mohan Kabadi
Title: Partner/Member/President
Date: November 8, 2013

THERABIOME LLC

By: /s/ Jerome J. Schentag
Name: Jerome J. Schentag
Title: Partner/Member/Chairman
Date: November 8, 2013

Exhibit A

DEFINITIONS

For the purpose of the Agreement, the following terms, whether used in singular or plural form, shall have the respective meanings set forth below:

1. "AAA" shall have the meaning set forth in Section 13.1.

2. "Affiliate" shall mean, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control", "controls", or "controlled" means, direct or indirect, ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors in the case of a corporation or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity; status as a general partner in any partnership; or any other arrangement whereby the Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity or the ability to cause the direction of the management or policies of a corporation or other entity.

3. "Agreement" shall have the meaning set forth in the Preamble, and shall include, for the avoidance of doubt, all Exhibits attached hereto.

4. "Annual Net Sales" shall mean, with respect to a Product or Therapy, the Net Sales of such Product or Therapy during a Calendar Year.

5. "Audited Party" shall have the meaning in Section 6.6(a).

6. "Auditing Party" shall have the meaning in Section 6.6(a).

7. "Bankrupt Party" shall have the meaning set forth in Section 12.4.

8. "Bankruptcy Code" shall have the meaning set forth in Section 12.4.

9. "Business Day" shall mean a day on which banking institutions in New York, New York, are open for business.

10. "Calendar Quarter" shall mean each calendar quarter of a Calendar Year ending on March 31st, June 30th, September 30th, and December 31st.

11. "Calendar Year" shall mean each calendar year starting on January 1st and ending on December 31st.

12. "Claims" shall have the meaning set forth in Section 11.1.

13. "CPI-U" shall mean the "Consumer Price Index – All Urban Consumers", as published by the U.S. Bureau of Labor Statistics (or its successor agency).

14. "Commercialization" or "Commercialize" shall mean any and all activities directed to marketing, promoting, detailing, distributing, importing, having imported, exporting, having exported, selling, or offering to sell a Product or Therapy.

15. "Commercially Reasonable Efforts" shall mean, with respect to Ventrus's obligations under this Agreement, including to undertake research, Development, Manufacturing or Commercialization activities, as applicable, those efforts and resources consistent with the usual practices of Ventrus in pursuing the research, Development, Manufacturing, or Commercialization of a similarly situated pharmaceutical product, or therapy at a similar stage of research, Development, or Commercialization, taking into account efficacy, safety, proprietary position of the product or therapy, including patent and regulatory exclusivity, regulatory structure involved, including anticipated or approved labeling and anticipated or approved post-approval requirements, present and future market and commercial potential, including competitive market conditions and probability of the profitability of the product or therapy in light of pricing and reimbursement issues, and all other relevant factors including technical, legal, scientific, or medical factors.

16. "Competing Product or Therapy" shall mean any product or therapy, other than a Product or Therapy, that is a pharmaceutical preparation for use in the Field that contains Licensor Technology and an active pharmaceutical ingredient (including, without limitation, small molecules, bacteria, viruses and proteins) that is used in a Product or Therapy.

17. "Confidential Information" shall mean all information disclosed by a Party or its Affiliates to the other Party or its Affiliates, including proprietary information and materials (whether or not patentable) regarding the disclosing Party's technology, products, business information or objectives, including any technical information, formulae, processes, techniques, preclinical information, toxicology information, clinical, non-clinical, or pre-clinical information, regulatory information, manufacturing information, formulation information, packaging information, dosing information, dose regimen information, target patient information, marketing information, sales information, pricing information, reimbursement information, Know-How, trade secrets, or inventions (whether patentable or not), that is treated as confidential by the disclosing Party in the regular course of business. The terms of this Agreement shall constitute the "Confidential Information" of the Parties.

18. "Control" or "Controlled" shall mean, with respect to rights in any Intellectual Property or other intangible property, the possession by a Party (whether by ownership, license or "control" (as defined in the definition of "Affiliate" above) over an Affiliate having possession by ownership or license) of the ability to grant access to, or a license or sublicense of, such rights.

19. "Cover", "Covered", or "Covering" shall mean, with respect to a Patent, that, in the absence of a license granted to a Person under an issued Valid Claim included in such Patent, the manufacture, use, importation, distribution, or sale of a Product, Therapy, or other product or therapy, as applicable, by such Person would infringe such Valid Claim.

20. "Develop" or "Development" shall mean any and all preclinical and clinical drug development activities including test method development and stability testing, toxicology, animal efficacy studies, formulation, quality assurance/quality control development, statistical analysis, clinical studies, clinical trials and testing, regulatory affairs, product approval and registration, chemical, or biological development and development manufacturing, process development, upscaling, validation, packaging development and manufacturing, and development documentation efforts in support of development activities anywhere in the world.

21. "Dr. Kabadi" shall mean Dr. Mohan Kabadi.

22. "Dr. Schentag" shall mean Dr. Jerome Schentag.

23. "Effective Date" shall have the meaning set forth in the Preamble.

24. "EMA" shall mean the European Medicines Agency or any successor agency thereto.

25. "Encumbrance" shall mean any claim, charge, equitable interest, hypothecation, lien, mortgage, pledge, option, license, assignment, power of sale, retention of title, right of pre-emption, right of first refusal, or security interest of any kind, including the overriding obligations to the U.S. government as set forth in Public Law 96-517 (35 U.S.C. §§200-204), as amended, and any similar obligations under the Laws of any other country or jurisdiction.

26. "Event of Bankruptcy" shall have the meaning set forth in Section 12.4.

27. "FDA" shall mean the U.S. Food and Drug Administration or any successor agency thereto.

28. "Field" shall mean the following:

(a) Use of bacteria, viruses, proteins, and small molecules in the following therapeutic areas by oral delivery utilizing the Licensor IP:

(i) Gastro-intestinal dysbiosis including but not limited to the following Indications:

I. *Clostridium difficile*-Associated Disease;

II. Other antibiotic induced diarrheas and gastro-intestinal dysfunction (e.g. amoxicillin);

III. Irritable bowel syndrome–constipation (IBS-c) and irritable bowel syndrome-diarrhea (IBS-d) as controlled or resolved by administration of living bacteria alone or in combination with marketed and developmental drugs; or

IV. Inflammatory bowel disease (IBD)(e.g., Crohn's disease and ulcerative colitis) and maintenance and induction of remission thereof, as controlled or resolved by administration of living bacteria alone or in combination with marketed and developmental drugs; or Metabolic syndrome, type 2 diabetes, obesity, and hypertension as controlled by bacteria.

(ii) Auto-immune disorders and autism, including, but not limited to, as controlled by bacteria or virus.

(iii) Orally delivered vaccines (including viral and bacterial).

(b) Any oral delivery of small molecules using the Licensor IP.

For the avoidance of doubt, "Field" does not include Alzheimer's disease, other neurodegenerative diseases, therapeutic oncological vaccines, GERD (gastroesophageal reflux disease), or route of delivery other than oral delivery.

29. "First Commercial Sale" shall mean the first sale of a Product or Therapy by Ventrus or an Affiliate or sublicensee of Ventrus, or by Licensor or an Affiliate or sublicensee of Licensor, as applicable, to a Third Party in a country following Regulatory Approval of such Product or Therapy in that country. Sales or transfers of reasonable quantities of a Product or Therapy for research, PoC studies, or other clinical trial purposes, or for compassionate or similar use, shall not be considered a First Commercial Sale.

30. "Generic Product or Therapy" shall mean, with respect a country, state, or other jurisdiction, any approved product or therapy, other than a Product or Therapy, marketed in such jurisdiction that is a pharmaceutical preparation for use in the Field that (i) contains the same active pharmaceutical ingredient(s) (including, without limitation, small molecules, bacteria, viruses, and proteins) then used in a Product or Therapy Commercialized by or on behalf of Ventrus in such jurisdiction and (ii) with respect to pharmacodynamic and pharmacokinetic properties is identical to or within an acceptable bioequivalent range of the Product or Therapy approved for sale by all applicable regulatory authorities within such jurisdiction.

31. "Good Clinical Practices" or "GCP" shall mean the then-current standards, practices and procedures promulgated or endorsed by (a) the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the EU, (b) the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA, and (c) the equivalent Laws in any relevant country, in each case, including all applicable rules, regulations, orders, and guidance applicable thereto, and as each may be amended from time to time, and any successor thereto.

32. "Good Laboratory Practices" or "GLP" shall mean the then-current standards, practices and procedures promulgated or endorsed by (a) the European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices as well as "The rules governing medicinal products in the European Union," Volume 3, Scientific guidelines for medicinal products for human use (ex - OECD principles of GLP), (b) the then current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and (c) the equivalent Laws in any relevant country, in each case, including all applicable rules, regulations, orders, and guidance applicable thereto, and as each may be amended from time to time, and any successor thereto.

33. "Good Manufacturing Practices" or "GMP" shall mean the then-current good manufacturing practices required by (a) the FDA and the provisions of 21 C.F.R. Parts 210 and 211, (b) European Commission Directive 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively, as well as "The rules governing medicinal products in the European Union," Volume 4, Guidelines for good manufacturing practices for medicinal products for human and veterinary use, and (c) the principles detailed in the ICH Q7A guidelines, in each case, including all applicable rules, regulations, orders, and guidance applicable thereto, and as each may be amended from time to time, and any successor thereto.

34. "Improvements" shall mean all discoveries, developments, modifications, innovations, updates, enhancements, or improvements (whether or not proprietary or protectable under patent, trademark, copyright, or similar Law and whether stored or transmitted in oral, documentary, electronic, or other form) made with respect to the Licensor Technology.

35. "IND" shall mean an application submitted to a Regulatory Authority to initiate human clinical trials, including (a) an Investigational New Drug application or any successor application or procedure filed with the FDA, or any foreign equivalent thereof, and (b) all supplements and amendments that may be filed with respect to the foregoing.

36. "Indemnitee" shall have the meaning set forth in Section 11.3.

37. "Indemnitor" shall have the meaning set forth in Section 11.3.

38. "Indication" shall mean a specific disease or condition.

39. "Intellectual Property" shall mean all Patent Rights, Know-How, trademarks (whether registered or unregistered), trademark applications, service marks, tradenames, trade dress, trade logos, slogans, symbols, graphics and the like, copyrights, copyright applications, copyrightable works, confidential or proprietary information, trade secrets, licenses, domain names, mask works, information and proprietary rights and processes, and any other intellectual property and all good will associated therewith Controlled by a Party or its Affiliates.

40. "Invalidity Claim" shall have the meaning set forth in Section 9.6(c).

41. "Inventions" shall mean any Know-How or other subject matter invented in the performance of activities under this Agreement.

42. "Joint Development Committee" or "JDC" shall have the meaning set forth in Section 1.1(a).

43. "Know-How" shall mean any data, information, inventions, proprietary information, trade secrets, or technology (whether or not proprietary or protectable under patent, copyright, or similar Law and whether stored or transmitted in oral, documentary, electronic, or other form). Know-How shall include ideas, concepts, formulas, methods, procedures, designs, compositions, plans, documents, discoveries, developments, techniques, protocols, specifications, works of authorship, biological materials, and any information relating to research and development plans, experiments, results, compounds, therapeutic leads, candidates and products, clinical and preclinical data, clinical trial results, and manufacturing information, plans and standard operating procedures, including any scientific, regulatory, pre-clinical or clinical information or data regarding specific Indications, and any marketing, financial, commercial, personnel, and other business information and plans.

44. "Law" shall mean any law, statute, rule, regulation, ordinance, or other pronouncement having the effect of law of any federal, national, multinational, state, provincial, county, city, or other political subdivision, domestic or foreign.

45. "Licensor" shall have the meaning set forth in the Preamble.

46. "Licensor Improvements" shall have the meaning set forth in Section 9.2(a).

47. "Licensor Indemnitees" shall have the meaning set forth in Section 11.2.

48. "Licensor IP" shall mean all Intellectual Property Controlled by Licensor or its Affiliates as of the Effective Date or thereafter during the Term that relates to and/or may be useful for the Licensor Technology and/or Products and Therapies (including, without limitation, Licensor Technology and any Licensor Improvements).

49. "Licensor Know-How" shall mean any Know-How Controlled by Licensor or its Affiliates and constituting Licensor IP.

50. "Licensor Patents" shall mean any Patent Rights Controlled by Licensor or its Affiliates and included within Licensor IP.

51. "Licensor Product" shall mean any pharmaceutical preparation containing the Licensor Technology Developed or Commercialized by Licensor within the Field.

52. "Licensor Technology" shall have the meaning set forth in the Recitals.

53. "Licensor Therapy" shall mean any pharmaceutical therapy containing the Licensor Technology Developed or Commercialized by Licensor within the Field.

54. "Losses" shall have the meaning set forth in Section 11.1.

55. "Major Jurisdictions" shall mean the United States, the European Union (as represented by the European Patent Office ("EPO") with respect to patent prosecution, and each EPO member state with respect to patent validation and annuities), Australia, Canada, China, Japan, Russia (as represented by the Eurasian Patent Office with respect to patent prosecution, and Russia with respect to patent validation and annuities), and South Korea.

56. "Manufacture" or "Manufacturing" shall mean any and all activities and operations involved in or relating to the manufacturing, quality control testing (including in-process, release and stability testing), releasing or packaging, for pre-clinical, clinical or commercial purposes.

57. "Net Sales" shall mean the net sales recorded by a Party or any of its Affiliates or sublicensees, excluding distributors and wholesalers, for any Product or Therapy sold to Third Parties other than sublicensees as determined in accordance with U.S. GAAP as consistently applied, less a deduction of [*] percent ([*]%) for direct expenses related to the sales of the Product or Therapy, distribution and warehousing expenses and uncollectible amounts on previously sold Products or Therapies. The deductions booked on an accrual basis by a Party and its Affiliates under U.S. GAAP to calculate the recorded net sales from gross sales shall be limited to the following:

(i) normal trade and cash discounts granted or allowed from the invoiced amount;

(ii) amounts repaid or credited by reasons of defects, rejections, recalls or returns;

(iii) rebates and chargebacks paid to customers and Third Parties (including, without limitation, Medicare, Medicaid, Managed Healthcare and similar types of rebates);

(iv) amounts provided or credited to customers through coupons and other discount programs;

(v) delayed ship order credits, discounts or payments given related to the impact of price increases between purchase and shipping dates; and

(vi) fee for service payments made to customers for any non-separable services (including compensation for maintaining agreed inventory levels and providing information).

With respect to the calculation of Net Sales:

(i) Net Sales only include the value charged or invoiced on the first arm's length sale to a Third Party and sales between or among the applicable Party and its Affiliates and sublicensees shall be disregarded for purposes of calculating Net Sales; and

(ii) If a Product or Therapy is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under U.S. GAAP are met.

58. "Non-Bankrupt Party" shall have the meaning set forth in Section 12.4.

59. "Party" shall mean Ventrus or Licensor, as context requires; "Parties" shall mean Ventrus and Licensor.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

60. "Patent Rights" shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations, and extensions thereof and supplemental protection certificates relating thereto, any confirmation patents or registration patents or patents of addition based on any such patents, and all counterparts thereof or substantial equivalents in any country, including utility models and industrial designs (collectively, "Patents") and any applications or provisional applications for any of the foregoing ("Patent Applications").

61. "Person" shall mean any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau, or agency, any other entity or body, or an individual.

62. "Phase" shall mean either Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial with respect to an Indication.

63. "Phase I Clinical Trial" shall mean a human clinical trial conducted on a limited number of study subjects for the purpose of gaining evidence of the safety and tolerability of, and information regarding potential pharmacological and biological activity for, a product or technology, as described in 21 C.F.R. § 312.21(a) (including any such clinical study in any country other than the United States), performed in human patients.

64. "Phase II Clinical Trial" shall mean a human clinical trial for which a primary endpoint is a preliminary determination of efficacy in patients with the disease being studied as required in 21 C.F.R. §312.21(b), or a similar clinical study prescribed by the Regulatory Authorities in a country other than the United States.

65. "Phase III Clinical Trial" shall mean a controlled clinical study that is performed after preliminary evidence suggesting effectiveness of a Product or Therapy has been obtained, and is intended to demonstrate or confirm the therapeutic benefit of the Product and to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the Product and to provide an adequate basis for Regulatory Approval and for the Product's or Therapy's labeling and summary of Product or Therapy characteristics, or any clinical trial that would otherwise meet the criteria of 21 C.F.R. § 312.21(c) or any foreign equivalent thereof.

66. "PoC" shall mean pre-clinical proof-of-concept as determined by Ventrus, using criteria similarly applied to Ventrus internal programs. Specifically, (a) with respect to a bacteria, PoC shall mean in vivo survival of I anaerobe and 1 aerobe species demonstrated in an animal model agreed on by the JDC and precise release at the designated site in the bowel as mimicked in vitro in experiments agreed on by the JDC, and (b) with respect to viruses, PoC shall mean Immunogenic in vivo in an animal model to be agreed on by the JDC and precise release at the designated site in the bowel as mimicked in in vitro in experiments agreed on by the JDC.

67. "PoP" shall mean (a) with respect to bacteria, the proof-of-principle demonstration of the release mechanism of the Licensor Technology, in separate in vitro experiments each simulating conditions of the human colon, of (i) a viable anaerobic bacterial species, and (ii) a viable aerobic bacterial species, as determined by Ventrus, using criteria similarly applied to Ventrus internal programs; and (B) with respect to a virus, the proof-of-principle demonstration that a virus delivered using the Licensor Technology to the colon of mice results in a detectable antibody response to such virus.

68. "Product" shall mean, as context requires, a Ventrus Product or a Licensor Product.

69. "Professional Package Insert Labeling" or "PPIL" shall mean an Indication for a Ventrus Product or Ventrus Therapy that is described in the professional package insert or prescribing information that is included along with such Ventrus Product or Ventrus Therapy, as required by the applicable Regulatory Authority.

70. "Regulatory Approval" shall mean, with respect to a Product or Therapy in any country or jurisdiction, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization from a Regulatory Authority in a country or other jurisdiction that is necessary to market and sell such Product or Therapy in such country or jurisdiction.

71. "Regulatory Authority" shall mean any federal, national, multinational, state, provincial, or local regulatory agency, department, bureau, or other governmental entity with authority over the marketing, pricing, or sale of a pharmaceutical product or therapy in a country, including the FDA, EMA and any corresponding national or regional regulatory authorities.

72. "Regulatory Filings" shall mean with respect to a Product, any submission to a Regulatory Authority of any appropriate regulatory application, and shall include, without limitation, any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings shall include any IND, NDA, or the corresponding application in any other country or group of countries.

73. "Regulatory Materials" shall mean, with respect to a Product or Therapy, regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary or advisable in order to obtain Regulatory Approval for or to research, Develop, Manufacture or Commercialize such Product for or in a particular country or regulatory jurisdiction. Regulatory Materials include Regulatory Approvals, presentations, responses, and applications for Regulatory Approvals.

74. "Royalty Term" shall have the meaning set forth in Section 6.2(e).

75. "Scientific Advisory Board" or "SAB" shall have the meaning ascribed to it in Section 1.2.

76. "Standard Hourly Rate" shall mean the rate at which Licensor may invoice Ventrus for performing certain services under this Agreement, to the extent such services preapproved by Ventrus in writing.

77. "Technology Transfer" shall have the meaning set forth in Section 2.1.

78. "Term" shall have the meaning set forth in Section 12.1.

79. "Territory" shall mean the world.

80. "Therapy" shall mean, as context requires, a Ventrus Therapy or a Licensor Therapy.

81. "Third Party" shall mean any Person other than Licensor or Ventrus and their respective Affiliates.

82. "Third Party Infringement Claim" shall have the meaning set forth in Section 9.6(a).

83. "United States" or "U.S." shall mean the United States of America, its territories and possessions.

84. "U.S. GAAP" shall mean "Generally Accepted Accounting Principles" (United States).

85. "University of Buffalo" shall mean the University of Buffalo (The State University of New York).

86. "University of Buffalo Policies" shall mean the following documents promulgated by the University of Buffalo: (a) the Royalty Distribution Policy (established September 1, 2009), attached to the Agreement as Exhibit D-1, (b) the UB Office of Science, Technology Transfer and Economic Outreach, Intellectual Property Ownership Determination, Hospital Affiliations (revised January 24, 2005), attached to the Agreement as Exhibit D-2, and (c) the Patents and Inventions Policy (as approved by the Board of Trustees on September 19, 1979 and amended on November 16, 1988), attached to the Agreement as Exhibit D-3.

87. "Valid Claim" with respect to any country, provided there is no Generic Product or Therapy present in such country's market, shall mean a claim of (i) a patent application within the Licensor Patents that has been pending for not more than seven (7) years from the date of filing of such patent application, or (ii) an issued and unexpired Licensor Patent in such country which has not been revoked, held unenforceable, unpatentable, or invalid by an administrative agency, court, or other governmental agency of a competent jurisdiction in a final and non-appealable decision (or decision unappealed within the time allowed for appeal), and which has not been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise.

88. "Ventrus" shall have the meaning set forth in the Preamble.

89. "Ventrus Development Program" shall have the meaning set forth in Section 3.1.

90. "Ventrus Indemnitees" shall have the meaning set forth in Section 11.1.

91. "Ventrus Product" shall mean any pharmaceutical preparation containing the Licensor Technology that is Developed or Commercialized by Ventrus (expressly excluding any Licensor Product). For the avoidance of doubt, a Product may be in the form of, or include, bacteria, viruses, small molecules, or proteins.

92. "Ventrus Therapy" shall mean any therapy containing the Licensor Technology that is Developed or Commercialized by Ventrus (expressly excluding any Licensor Therapy).

Exhibit B

Milestone Proportions for ex-U.S.

EU:
1/3 IND/CTA clearance
either
1. [*] or
2. [*]

Japan:
1/3 for IND and NDA approval

China: (PRC)
10% IND/NDA approval

India:
10% NDA approval only

Brazil:
10% NDA approval only

All other countries:
1% NDA approval only

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

Exhibit C

Licensor Patents

PCT application no. PCT/US13/31483, filed 14 March 2013

[*]

[*]

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

Exhibit D-1

University of Buffalo Royalty Distribution Policy

University at Buffalo
The State University of New York

Policy Library

ROYALTY DISTRIBUTION POLICY

Category: Research
Responsible Office: Office of the Provost
Responsible Executive: Provost

Date Established: 9/01/09
Date Last Revised: -
Date Posted to Library: 9/16/09

Summary

The University at Buffalo uses a single uniform structure to distribute proceeds derived from the commercialization of inventors' intellectual property and technology.

Policy

POLICY STATEMENT

The University at Buffalo (UB, University) encourages innovation by its faculty, staff, and students. When those innovations are licensed and generate royalty income for the University, that royalty income is shared with those who made the innovation.

This revised policy supersedes all prior policies and will be applied to any royalty income received on or after the Date Established listed above.

Royalty Income Distribution Schedule

All royalty income will be distributed as follows:

Distribution to	Percent	Limitations
Inventor(s)	40%	Royalty income distribution checks are made payable only to the inventor and are non-assignable.
Inventor's Department(s)	5%	Royalty income received by the department must be utilized for the support of scientific research or education.
Inventor's School(s)	5%	Royalty income received by the school must be utilized for the support of scientific research or education.
University Support of Research	50%	Royalty income must be utilized for the support of scientific research or education.

Notes:

1) If royalty payments are received via wire transfer, processing fees associated with the wire transfer will be deducted from the campus 60% share before distributions are made.
2) The Departmental share of royalties will be capped at $1 Million per Fiscal year, and the Schools share at $5 Million. Royalties in excess of the caps will be distributed to the University in Support of Research.

Inventors' Share

In accordance with the State University of New York Patents and Inventions Policy, 40% of royalty income is shared with the inventors.

- When there is more than one inventor, each inventor's share of royalty income is decided among the inventors and documented in the Inventors' Agreement. The Office of Science, Technology Transfer and Economic Outreach (STOR) prepares the Inventors' Agreement and upon request, provides guidance regarding inventor sharing. All inventors must sign the Inventors' Agreement.
- Royalty income distribution checks will be made payable only to the inventor and either mailed to the inventor's residence or deposited directly to the inventor's personal account.
  - All inventor royalty income distribution checks are non-assignable. If the inventor chooses to further distribute their funds, they must do so personally after cashing the check.
- It is the inventor's responsibility to provide STOR with a current address and accurate contact information.
- The inventor will continue to receive their share of royalty income regardless of their UB employment status. Payments to deceased inventors will be forwarded to the inventor's heirs or legatees.

Inventor's Department Share

- The inventor's department share will continue regardless of the inventor's UB employment status.
- When there are multiple inventors, the distribution among departments will be proportional to the inventor's share documented in the Inventors' Agreement.
- If the department chairs agree to a department share distribution different than the one documented in the Inventors' Agreement, the revision must be on file with STOR. If the revision is not on file, STOR will distribute the inventor's department share according to the Inventors' Agreement.
- The department share does not move when an inventor leaves one department for another at UB.

Inventor's School Share

- The inventor's school share will continue regardless of the inventor's UB employment status.
- When there are multiple inventors, the distribution among schools will be proportional to the inventor's share documented in the Inventors' Agreement.
- If deans agree to a school share distribution different than the one documented in the Inventors' Agreement, the revision must be on file with STOR. If the revision is not on file, STOR will distribute the inventor's school share according to the Inventors' Agreement.
- The school share does not move when an inventor leaves one school for another at UB.

Inventor's Center/Institute

- In the event inventors are employees of a center or institute and not otherwise affiliated with a department and school, the Vice President for Research, Provost or other responsible administrative authorities will determine an appropriate allocation to supporting centers, institutes, departments, or schools. A signed agreement specifying the division of royalty income must be on file with STOR.

BACKGROUND

The State University of New York Patents and Inventions Policy stipulates that

> All net proceeds after payment of the inventor's share as defined in subdivision (c), and other appropriate costs associated with the university technology transfer program, realized from the marketing of State University inventions shall be used for the support of State University research programs.

The Bayh-Dole Act of 1980 further states that such balance after payment to inventors and expenses "will be utilized for the support of scientific research or education."

APPLICABILITY

The policy applies to all royalty revenues received, regardless of when the disclosure was first made.

DEFINITIONS

Invention - A novel creation, discovery, and/or idea that may be protected by patent or similar United States or international intellectual property rights. "Invention" may also be used herein with respect to making royalty distributions under the Computer Software Policy.

Inventor - UB individual (faculty, staff, or student) who has made an intellectual contribution to the invention as claimed in a pending or issued patent. Inventor includes a non-affiliated individual who works with a UB inventor and assigns the invention to SUNY or The Research Foundation and a UB inventor who later goes to work at a company. Inventor does not include a joint inventor employed by a company.

Royalty Income - gross royalty paid as proceeds from the licensing of an invention.

RESPONSIBILITY

Inventor

- Disclose inventions to the STOR Office as soon as possible and whenever practical before publication, as required under SUNY Patents and Inventions Policy, and in the case of federally funded research in accordance with 37 CR 401 (otherwise known as the Bayh-Dole Act).
- Work with STOR and outside patent counsel to make applications for patents and complete assignments and other related documents as required.
- Sign and return the Inventors' Agreement prepared by STOR.
- Ensure that STOR always has a current address and contact information.

Department Chairs

- Notify STOR of any agreement to divide the department share differently than the one documented in the Inventors' Agreement.
- Ensure that all royalty income received by the department is utilized for the support of scientific research or education.

Deans and Vice Presidents

- Notify STOR of any agreement to divide the school's share differently than the one documented in the Inventors' Agreement.
- Ensure that all royalty income received by the school is utilized for the support of scientific research or education.

STOR

- Conduct all operations necessary to manage, process, protect, license, and report inventions.
- Negotiate licenses to inventions and related property rights.
- Provide guidance regarding inventor sharing.
- Prepare the Inventors' Agreement.
- Provide the Inventors, Deans, and Chairs with copies of completed Inventors' Agreements.
- Maintain inventor current address and contact information.
- Administer the distribution of royalty income.
- Make reasonable efforts to locate inventors who have changed address without notifying STOR.

Contact Information

Office of Science, Technology Transfer and Economic Outreach
1576 Sweet Home Road, Suite 111
Amherst, NY 14228
Phone: (716) 645-5500
Fax: (716) 645-3436
http://www.research.buffalo.edu/stor/default.cfm

Related Information

University Documents:

Patents and Inventions Policy
http://www.research.buffalo.edu/ovpr/policies/patents.cfm
Intellectual Property Ownership Determination Hospital Affiliations
http://www.research.buffalo.edu/stor/pdf/STOR-Hospital%20Affiliation01.05.pdf

Other Documents:

SUNY Computer Software Policy
http://www.research.buffalo.edu/ovpr/policies/computer_software_policy.cfm
Software Policy Clarification and Web Wizard
http://www.research.buffalo.edu/ovpr/policies/computer_clarification.cfm
SUNY Copyright Policy
http://www.suny.edu/SUNYPP/pdf.cfm?doc_id=88#page=3

Related Links:

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Research Foundation Patents and Inventions Policy:
http://portal.sfnuny.org/portal/page/portal/Intellectual_property/rto/POLICIES/rtupol001.htm
SUNY Patent & Invention Policy: Patents and Inventions Policy of State University of New York
The Bayh-Dole Act: http://www.cogr.edu/docs/Bayh_Dole.pdf

Presidential Approval

John B. Simpson — *9/1/09*

John B. Simpson, President — Date

Exhibit D-2
UB Office of Science, Technology Transfer and Economic Outreach, Intellectual Property Ownership Determination, Hospital Affiliations

stor UB Office of Science, Technology Transfer and Economic Outreach Revised 1/24/05

UB Office of Science, Technology Transfer and Economic Outreach
Intellectual Property Ownership Determination
Hospital Affiliations

BACKGROUND:

From time to time, the University at Buffalo Office of Science, Technology Transfer and Economic Outreach (STOR) Intellectual Property Division receives disclosures from inventors working at the various affiliated hospitals. The question of intellectual property ownership arises with respect to the nature of the inventor's employment and facilities used in making the invention. Similar intellectual property ownership issues arise in establishing sponsored research contracts, including clinical trial agreements.

The following guidelines should be used in determining intellectual property ownership with respect to research conducted in affiliated hospitals. Note that this process will apply to all hospital affiliations with the exception of the Veteran Administration Medical Center, which is the subject of a separate agreement. Relevant portions of the contract with Kaleida, and the Patents and Inventions Policy of SUNY are presented at the end of this document to illustrate the nature of the contract language defining this ownership determination process.

IP OWNERSHIP DETERMINATION

1) Does the inventor(s) have a UB faculty appointment?
   a) YES, proceed to 2
   b) NO - proceed to 4

2) What is the nature of the UB appointment?
   a) Full-Time Faculty (FTF) (1.0 FTE), or Part-Time Faculty (less than 1.0 FTE), proceed to 3
   b) Geographic Full Time (GFT) faculty, proceed to 3
   c) Volunteer faculty, then volunteer owns
      i) unless conducted at UB or a UB-leased facility, or by prior agreement with UB to the contrary – then proceed to 3

3) Was the research conducted as part of the faculty member's professional obligation to conduct University research?
   a) YES, proceed to 4
   b) if NO, faculty must provide proof (see *i-iv* below) satisfactory to UB that research was not conducted under the faculty member's research obligation

i) adequate proof (including but not limited to time and place verification) must document dissociation from University or University-leased facilities and professional responsibilities
ii) if funding to support the research was from a non-UB source and not managed by UB, then this must be documented
iii) UB credentials must not have been used in obtaining support for or performing the research
iv) Would the research have been permitted if the researcher did not have a UB faculty appointment?
A) If the answer to *iv* is NO – then proceed to 4
B) If *i-iii* can be documented, then Researcher owns

4) Were Hospital facilities that are under a UB lease used in making the invention?
NOTE 1: Facilities leased solely by a practice plan corporation is not a University leased facility.
NOTE 2: Contact Suzanne Laychock for University-leased facilities under SUNY contracts for research.
a) YES, then UB owns
b) NO, proceed to 5, except:
i) would the hospital space be available to the researcher if the researcher did not have a UB faculty appointment?
A) NO – then UB owns
B) YES – then proceed to 5

5) Was the research associated with the invention sponsored by UB (e.g. research funding was managed by the Research Foundation, UB Foundation, or State; or, privately funded or unfunded research)?
a) YES, UB owns
b) No, Researcher owns

RELEVANT PORTIONS OF KALEIDA CONTRACT

B. Role of Faculty Members.

All research undertaken by Faculty Members utilizing the University-leased space at KALEIDA shall be considered University sponsored research. All sponsored programs and other funding associated with such research shall be processed through either UB Foundation Services, Inc., acting on behalf of the Research Foundation of State University of New York (Research Foundation), or through the Research Foundation.

H. Intellectual Property Rights.

All intellectual property rights associated with research conducted at KALEIDA shall accrue to the party sponsoring such research, except for rights arising out of research conducted within the University's leased space, in which case all rights accrue to the University. KALEIDA acknowledges and agrees that the University's policies (including, but not limited to, the regulations set forth in 8 NYCRR Section 335.28, as amended from time to time) shall govern the extent to which the University or its Faculty Members have any intellectual property rights or financial interest in University-sponsored research conducted at KALEIDA. Except as otherwise set forth herein, the parties agree that the economic benefit derived from research and technology development activities jointly sponsored by KALEIDA and the University shall be shared according to the pro rata share of each institution's investment. The University agrees that no part of any facility of KALEIDA shall be considered "university facilities" for purposes of SUNY Patent Policy unless the specific portion of such facility in question is, as of the time the invention is discovered, leased by the University for its exclusive use. The parties further agree that any research grants, contract agreement or patents that are initiated by KALEIDA or its related entities which are not University-sponsored (including, by not limited to, pharmaceutical contracts, community service grants, demonstration projects and joint ventures with entities other than SUNY) shall be administered by KALEIDA and shall not be governed by the Agreement. The terms "SUNY Patent Policy" shall mean the policy set forth in 8 N.Y.C.R.R. Section 335.28, or any successor policy.

Patents and Inventions Policy of State University of New York

The patents and inventions policy of the State University of New York as approved by the Board of Trustees on September 19,1979 and amended on November 16, 1988, reads as follows:

Title 8, Chapter V, Subchapter B, Section 335.28 of the Official Compilation of Codes, Rules and Regulations of the State of New York.
(Article XI, Title J, Section 1. of the Policies of the Board of trustees.)

335.28 Patents and inventions policy.

(a) - Purpose.

(1) State University recognizes that the three primary missions of an educational institution are teaching, research, and public service. While carrying out its research mission, State University further recognizes that inventions of value to the public will be made by persons working in its facilities. It is the policy of State University to encourage such inventors and inventions and to take appropriate steps to aid the inventor and ensure that the public receives the benefit. Appropriate steps include securing research support, identifying inventions, securing appropriate patents, marketing inventions through licensing and other arrangements, and managing royalties and other invention-related income. These activities are undertaken in a spirit of cooperation with governmental agencies and private industry as part of State University's contribution to the economic well-being of the State of New York and of the nation.

(2) In implementing its policies State University will take appropriate steps to ensure that its faculty may freely publish the results of scholarly research pursuant to the State University board of trustees policy on unrestricted disclosure of research activities as set forth in trustees' resolution number 66-258. In conformance with this principle, all concerned shall cooperate so that essential rights to inventions shall not be lost.

(3) All net proceeds after payment of the inventor's share as defined in subdivision (c), and other appropriate costs associated with the university technology transfer program, realized from the marketing of State University inventions shall be used for the support of State University research programs.

(b) All inventions made by faculty members, employees, students, and all others utilizing university facilities at any of the State-operated institutions of State University shall belong to State University and should be voluntarily disclosed, or shall be disclosed to State University upon request of the university. The inventor or inventors shall make application for patents thereon as directed by State University and shall assign such applications or any patents resulting therefrom to or as directed by State University. However, non-university organizations and individuals who utilize university research facilities under the trustees' policy on cooperative use of research equipment, or policy and guidelines on use of State University facilities by emerging technology enterprises, will retain ownership of all patentable inventions. Also, an invention made by an individual wholly on such individual's own time, and without the use of such university facilities, shall belong to the individual even though it falls within the field of competence relating to the individual's university position. For purposes of this provision, an individual's "own time" shall mean time other than that devoted to normal and assigned functions in teaching, university service, direction and conduct of research on university premises and utilizing university facilities. The term "university facilities" shall mean any facility available to the inventor as a direct result of the inventor's affiliation with State University, or any facility available under the trustees' policy on cooperative use of research equipment, or policy on use of facilities by emerging technology enterprises, and which would not otherwise be available to a non-State University-affiliated individual. Where any question is raised as to ownership of an invention or patent under these provisions, the matter shall be referred to a committee of five members to be named by the chancellor of State University. At least three of such members shall be members of the academic staff of the university. Such committee shall make a careful investigation of

the circumstances under which the invention was made and shall transmit its findings and conclusions to the chancellor for review. If the committee determines that the invention has been made without the use of university facilities and not in the course of the inventor's employment by or for the university, and the chancellor concurs in such determination, the university will assert no claim to the invention or to any patent obtained thereon.

(c) With respect to any invention obtained by or through State University or assigned to or as directed by it in accordance with the foregoing provisions, the university, in recognition of the meritorious services of the inventor and in consideration of the inventor's agreement that the invention shall belong to the university, will make provision entitling the inventor and the inventor's heirs or legatees to a nonassignable share in any proceeds from the management and licensing of such invention to the extent of 40 percent of the gross royalty paid, unless this exceeds the limits fixed by applicable regulations of the relevant sponsoring agency, which will control in such cases. State University may make suitable arrangements with non-profit patent management agencies for the purpose of obtaining services and advice with respect to the patentability of inventions, the obtaining of patents thereon and the management and licensing of inventions. Such arrangements may provide for division of the net income from any invention after payment of the inventor's share between the management agency and State University.

(d) Upon recommendation of the patents and inventions policy board, the chancellor may grant exclusive licenses for a fixed period for the marketing of inventions, since it is recognized that in the absence of such a condition some inventions may not reach the marketplace for the public benefit. Granting of exclusive licenses for a fixed period may be accepted by the chancellor as a condition for industrial sponsorship of research programs, within guidelines recommended by the patents and inventions policy board.

(e) Grants made available to State University by or through The Research Foundation of State University of New York shall be subject to the policy herein stated except in special instances as hereinafter provided. Nothing in the policy herein stated shall prevent the acceptance of research grants from, or the conduct of research for, agencies of the United States, either directly or through the Research Foundation, upon terms and conditions under applicable provisions of Federal law or regulations which require a different disposition of inventions or patent rights, nor shall anything herein contained prevent cooperative arrangements with other agencies of the State of New York for research.

(f) The chancellor, acting with the advice of the patents and inventions policy board or State University's designated patent management agent, may determine not to file a patent application in the case of any specific invention or continue efforts at marketing. The university's decision shall be arrived at, in consultation with the inventor, within a period not to exceed six months from the date of first submission of the inventor's properly executed statement of disclosure of invention to the university or its designee. In every instance in which the university determines not to file a patent application or continue efforts at marketing, or fails to elect to do so within six months from the date of submission of said disclosure statement, all of the university's rights to the invention shall be released to the inventor, who may then file for a patent, subject only to those restrictions that may be required by an external sponsor, if any. In every instance in which the university determines to file a patent application or continue efforts at marketing, the inventor may, at any subsequent time, request the patents and inventions policy board to recommend such release. For any invention so released to an inventor, State University, at its option, shall receive 10 percent of the net proceeds, in recognition of the contribution of the State and people of New York to the support of the research which resulted in said invention. For purposes of this provision, the term "net proceeds" shall mean earnings to the inventor from the invention over and beyond reasonable costs incurred in the process of patent application and management.

(g) In all cases, any person is entitled to request an exception or waiver to the provisions of this patents and inventions policy. The person requesting an exception or waiver shall have the right to appear, accompanied by representatives of the person's choice, before the patents and inventions policy board for consideration of the request for an exception or waiver. The patents and inventions policy board shall

prepare a report of its findings and an advisory recommendation to the chancellor for review. The decision of the chancellor on the findings and recommendations of the patents and inventions policy board shall be final.

(h) The chancellor shall establish and appoint a patents and inventions policy board of the State University of New York and designate the chair thereof in accordance with the following:

(1) The patents and inventions policy board shall have no more than 10 members, and shall include one representative of the central administration, two from the university centers, one from the health sciences centers, one from another major research institution of the university, one from the colleges of arts and sciences, one from the agriculture and technology colleges, one from The Research Foundation of State University of New York, and two representatives from business and industry.

(2) The patents and inventions policy board shall have full powers of organization.

(3) The members of the patents and inventions policy board shall serve without extra compensation and at the pleasure of the chancellor. The normal term of appointment shall be for three years.

(4) The patents and inventions policy board shall meet at least once annually.

(5) The patents and inventions policy board shall advise the chancellor in the following matters:

(i) guidelines and procedures for the implementation of these policies;

(ii) exceptions to these policies in unusual circumstances;

(iii) determining the extent of the university's interest in inventions;

(iv) determining whether or not to grant exclusive licenses or to commit the university to the future granting of exclusive licenses as a condition of sponsorship for particular research projects; and

(v) such other matters as the chancellor may deem appropriate.

(6) The patents and inventions policy board shall undertake continual review of these policies and advise the chancellor and the board of trustees thereto.

(7) The patents and inventions policy board shall maintain current information concerning patent and invention activities within the university, disseminate information to the faculty of State University concerning such activities, and encourage general awareness of and interest concerning patents within the university community.

(8) The patents and inventions policy board, through the chancellor, shall report annually to the board of trustees concerning its activities and recommendations during the preceding year.

Exhibit D-3

University of Buffalo Patents and Inventions Policy

Patents and Inventions Policy

The patents and inventions policy of the State University of New York as approved by the Board of Trustees on September 19, 1979 and amended on November 16, 1988, reads as follows:

Title 8, Chapter V, Subchapter B, Section 335.28 of the Official Compilation of Codes, Rules and Regulations of the State of New York. (Article XI, Title J, Section 1, of the Policies of the Board of Trustees.)

335.28 Patents and inventions policy.

(a) Purpose.

1. State University recognizes that the three primary missions of an educational institution are teaching, research, and public service. While carrying out its research mission, State University further recognizes that inventions of value to the public will be made by persons working in its facilities. It is the policy of State University to encourage such inventors and inventions and to take appropriate steps to aid the inventor and ensure that the public receives the benefit. Appropriate steps include securing research support, identifying inventions, securing appropriate patents, marketing inventions through licensing and other arrangements, and managing royalties and other invention-related income. These activities are undertaken in a spirit of cooperation with governmental agencies and private industry as part of State University's contribution to the economic well-being of the State of New York and of the nation.
2. In implementing its policies State University will take appropriate steps to ensure that its faculty may freely publish the results of scholarly research pursuant to the State University board of trustees policy on unrestricted disclosure of research activities as set forth in the trustees' resolution number 6-258. In conformance with this principle, all concerned shall cooperate so that essential rights to inventions shall not be lost.
3. All net proceeds after payment of the inventor's share as defined in subdivision (c), and other appropriate costs associated with the university technology transfer program, realized from marketing of State University inventions shall be used for the support of State University research programs.

(b) All inventions made by faculty members, employees, students, and all others utilizing university facilities at any of the State-operated institutions of State University shall belong to State University and should be voluntarily disclosed, or shall be disclosed to State University upon request of the university. The inventor or inventors shall make application for patents thereon as directed by State University and shall assign such applications or any patents resulting therefrom to or as directed by State University. However, non-university organizations and individuals who utilize university research facilities under the trustees' policy on cooperative use of research equipment, or policy and guidelines on use of State University facilities by emerging technology enterprises, will retain ownership of all patentable inventions. Also, an invention made by an individual wholly on such individual's own time, and without the use of such university facilities, shall belong to the individual even though it falls within the field of competence relating to the individual's university position. For purposes of this provision, an individual's "own time" shall mean other than that devoted to normal and assigned functions in teaching, university service, direction and conduct of research on university premises and utilizing university facilities. The term "university facilities" shall mean any facility available to the inventor as a direct result of the inventor's affiliation with State University, or any facility available under the trustees' policy on cooperative use of research equipment, or policy on use of facilities by emerging technology enterprises, and which would not otherwise be available to a non-State University-affiliated individual. Where any question is raised as to ownership of an invention or patent under these provisions, the matter shall be referred to a committee of five members to be named by the chancellor of State University. At least three of such members shall be members of the academic staff of the university. Such committee shall make a careful investigation of the circumstances under which the invention was made and shall transmit its findings and conclusions to the chancellor for review. If the committee determines that the invention has been made without the use of university facilities and not in the course of the inventor's employment by or for the university, and the chancellor concurs in such determination, the university will assert no claim to the invention or to

any patent obtained thereon.

(c) With respect to any invention obtained by or through State University or assigned to or as directed by it in accordance with the foregoing provisions, the university, in recognition of the meritorious services of the inventor and in consideration of the inventor's agreement that the inventions shall belong to the university, will make provision entitling the inventor and the inventor's heirs or legatees to a nonassignable share in any proceeds from the management and licensing of such invention to the extent of 40 percent of the gross royalty paid, unless this exceeds the limits fixed by applicable regulations of the relevant sponsoring agency, which will control in such cases. State University may make suitable arrangements with non-profit patent and management agencies for the purpose of obtaining services and advice with respect to the patentability of the inventions, the obtaining of patents thereon and the management and licensing of inventions. Such arrangements may provide for division of the net income from any invention after payment of the inventor's share between the management agency and State University.

(d) Upon recommendation of the patents and inventions policy board, the chancellor may grant exclusive licenses for a fixed period for the marketing of inventions, since it is recognized that in the absence of such condition some inventions may not reach the marketplace for the public benefit. Granting of exclusive licenses for a fixed period may be accepted by the chancellor as a condition for industrial sponsorship of research programs, within guidelines recommended by the patents and inventions policy board.

(e) Grants made available to State University by or through The Research Foundation of State University of New York shall be subject to the policy herein stated except in special instances as hereinafter provided. Nothing in the policy herein stated shall prevent the acceptance of research grants from, or the conduct of research for, agencies of the United States, either directly or through the Research Foundation, upon terms and conditions under applicable provisions of Federal law or regulations which require a different disposition of inventions or patent rights, nor shall anything herein contained prevent cooperative arrangements with other agencies of the State of New York for research.

(f) The chancellor, acting with the advice of the patents and inventions policy board or State University's designated patent management agent, may determine not to file a patent application in the case of any specific invention or continue efforts at marketing. The university's decision shall be arrived at, in consultation with the inventor, within a period not to exceed six months from the date of the first submission of the inventor's properly executed statement of disclosure of invention to the university or its designee. In every instance in which the university determines not to file a patent application or continue efforts at marketing, or fails to elect to do so within six months from the date of submission of said disclosure statement, all of the university's rights to the invention shall be released to the inventor, who may then file for a patent, subject only to those restrictions that may be required by an external sponsor, if any. In every instance in which the university determines to file a patent application or continue efforts at marketing, the inventor may, at any subsequent time, request the patents and inventions policy board to recommend such release. For any invention so released to an inventor, State University, at its option, shall receive 10 percent of the net proceeds, in recognition of the contribution of the State and people of New York to the support of the research which resulted in said invention. For purposes of this provision, the term "net proceeds" shall mean earnings to the inventor from the invention over and beyond reasonable costs incurred in the process of patent application and management.

(g) In all cases, any person is entitled to request an exception or waiver to the provisions of this patents and inventions policy. The person requesting an exception or waiver shall have the right to appear, accompanied by representatives of the person's choice, before the patents and inventions policy board for consideration of the request for an exception or waiver. The patents and inventions policy board shall prepare a report of its findings and an advisory recommendation to the chancellor for review. The decision of the chancellor on the findings and recommendations of the patents and inventions policy board shall be final.

(h) The chancellor shall establish and appoint a patents and inventions policy board of the State University of New York and designate the chair thereof in accordance with the following:

1. The patents and inventions policy board shall have no more than 10 members, and shall include one representative of the central administration, two from the university centers, one from the health sciences centers, one from another major research institution of the university, one from the colleges of arts and sciences, one from the agriculture and technology colleges, one from the Research Foundation of State University of New York, and two representatives

from business and industry.

2. The patents and inventions policy board shall have full powers of organization.
3. The members of the patents and inventions policy board shall serve without extra compensation and at the pleasure of the chancellor. The normal term of appointment shall be for three years.
4. The patents and inventions policy board shall meet at least once annually.
5. The patents and inventions policy board shall advise the chancellor in the following matters:
    1. Guidelines and procedures for the implementation of these policies;
    2. Exceptions to these policies in unusual circumstances;
    3. Determining the extent of the university's interest in inventions;
    4. Determining whether or not to grant exclusive licenses or to commit the university to the future granting of exclusive licenses as a condition of a sponsorship for particular research projects; and
    5. Such other matters as the chancellor may deem appropriate.
6. The patents and inventions policy board shall undertake continual review of these policies and advise the chancellor and the board of trustees thereto.
7. The patents and inventions policy board shall maintain current information concerning patent and invention activities within the university, disseminate information to the faculty of State University concerning such activities, and encourage general awareness of and interest concerning patents within the university community.
8. The patents and inventions policy board, through the chancellor, shall report annually to the board of trustees concerning its activities and recommendations during the preceding year.

Exhibit E

Licensor Non-Disclosure and License Agreements

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[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

Exhibit F-1

Licensor Publications

Jerome J Schentag PharmD

1976-1987 (1-130)
1988-1999 (131-281)
2000-2013 (282-356)

1. Koup JR, Schentag JJ, Vance JW, Kuritzky PM, Pyszczynski DR, Jusko WJ. System for clinical pharmacokinetic monitoring of theophylline therapy. Am J Hosp Pharm. 1976;33(9):949-56.

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4. Schentag JJ, Jusko WJ. Renal clearance and tissue accumulation of gentamicin. Clin Pharmacol Ther. 1977;22(3):364-70.

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16. Chairmonte DA, Schentag JJ. A specific and sensitive high pressure liquid chromatographic procedure for cimetidine and creatinine. Ther Drug Monit. 1979;1:545-54.

17. Haughey DB, Lanse S, Imhoff T, Tobin M, Schentag JJ. Allopurinol sensitivity: report of two cases. Am J Hosp Pharm. 1979;36(10):1377-80.

18. Jusko WJ, Gardner MJ, Mangione A, Schentag JJ, Koup JR, Vance JW. Factors affecting theophylline clearances: age, tobacco, marijuana, cirrhosis, congestive heart failure, obesity, oral contraceptives, benzodiazepines, barbiturates, and ethanol. J Pharm Sci. 1979;68(11):1358-66.

19. Schentag JJ, Cerra FB, Calleri G, DeGlopper E, Rose JQ, Bernhard H. Pharmacokinetic and clinical studies in patients with cimetidine-associated mental confusion. Lancet. 1979;1(8109):177-81.

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Mohan Kabadi:

1. Rajen Shah. Mohan B. Kabadi, David G. Pope and L. Augsburger: Physico-Mechanical Characterization of the Extrusion-Spheronization Process. Part-II: Rheological Determinants for successful Extrusion and Spheronization. Pharmaceutical Research, 12, 496-507 (1995)

2. Rajen Shah, Mohan B. Kabadi, David G. Pope and L. Augsburger: Physico-Mechanical Characterization of the Extrusion-Spheronization Process. Part-1: Instrumentation of the Extruder. Pharmaceutical Research, 11, 355-360 (1994)

3. Mohan B. Kabadi and Yie W. Chien, "Intra-vaginal Controlled Administration of Flurogestone Acetate (IV): In Vitro-In Vivo Correlation for Intra-vaginal Drug Delivery from Rate Control Vaginal Pessary". Drug Development and Industrial Pharmacy, 11 (6 & 7), 1333-1361 (1985).

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5. Acetate (III): Development of Rate-Control Vaginal Devices". Drug Development and Industrial Pharmacy, 11 (6 & 7), 1271-1312 (1985).

6. Kakuji Tojo, Mohan B. Kabadi and Yie W. Chien, "Effect of Diffusional Boundary Layer on the Rate of Controlled Drug Release. (Submitted for publication).

7. Mohan B. Kabadi and Yie W. Chien, "Intra-vaginal Controlled Administration of Flurogestone Acetate (II): Development of In Vitro System for Intra-vaginal Release and Permeation of Flurogestone Acetate. J. Pharm. Sci., 73, 1464 (1984).

8. Mohan B. Kabadi, Kirti H. Valia and Yie W. Chien, "Intra-vaginal Controlled Administration of Flurogestone Acetate (I): Development of Stability-indicating HPLC method and Stability Kinetics of Flurogestone Acetate". J. Pharm. Sci., 73, 1461 (1984)

Exhibit F-2

Non-Licensor Patent disclosures – Jerome J Schentag and Co-inventors

Oral Proteins: US Provisional 61/783,003 filed March 14, 2013: Inventors are: Schentag, J. McCourt, M, Mielnicki, L, Hughes J

Oral RYGB mimetic: US 61/551,638 October 26th, 2011; Published Nov 3, 2011 as US2011/0268795A1; Published May 2, 2013 as WO 2013/063527A1; Inventors Fayad J, Monte S, Schentag J

HepatitisC: US 12/26561 Feb 24, 2012; Published Sept 7, 2012 as WO 2012/118712 and PCT 2012/026561; Inventors are Schentag, J, Fayad J.

Regeneration: US Provisional 61/750,042 filed Jan 8, 2013; Inventors are Fayad, J., Schentag J
Diabetes: US provisional 61/254,373 filed Oct 23, 2009; Non Provisional as US 12/911,497 filed Oct 25, 2010; Published as US 2011/097807A1 on April 28, 2011; Issued Patent 8,367,418 on February 5, 2013. Inventors are Monte S, Bright F, Schentag J.

Smart Pills: 5,279,607; 5,395,366; Smarter Pills; 2012/006454; 2012/024034; Inventors are Schentag J, D'Andrea D, Bright F

Ocular Delivery: 2008/0318843 Inventors are Schultz, C. Schentag J.

Non-Licensor Patent disclosures – Mohan Kabadi and Co-inventors

1. Mohan B. Kabadi, et al. Tetracycline Stabilizing Formulations, U.S. Patent Number (Pending).

2. Mohan B. Kabadi and R. Vivilecchia, Stabilized Pharmaceutical Compositions Comprising an HMG-COA Reductase Inhibitor Compound. U.S. Patent Number 5,356,896 (October 18, 1994). European Patent Pending.

3. Mohan B. Kabadi, Niranjan M. Patel and Susan Moniot, "Transdermal Delivery System". U.S. Patent number 4,788,064 (November 29, 1988).

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Ventrus Biosciences, Inc. (a development stage company) on Form S-3 (No. 333-179259) and Form S-8 (No. 333-173613) of our report dated March 28, 2014, on our audit of the financial statements as of December 31 2013 and 2012, and for each of the years in the two-year period ended December 31, 2013 and for the period from October 7, 2005 (inception) to December 31, 2013, which report is included in this Annual Report on Form 10-K to be filed on or about March 31, 2014. We also consent to the reference to our firm under the caption "Experts" in the Registration Statement on Form S-3.

/s/ EisnerAmper LLP

New York, New York
March 28, 2014

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Russell H. Ellison, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended December 31, 2013 of Ventrus Biosciences, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 31, 2014
/s/ Russell H. Ellison

Russell H. Ellison
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David J. Barrett, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended December 31, 2013 of Ventrus Biosciences, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 31, 2014
/s/ David J. Barrett

David J. Barrett
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S. C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Ventrus Biosciences, Inc. (the "Company") for the fiscal year ended December 31, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Russell H. Ellison, Chief Executive Officer (Principal Executive Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 31, 2014
/s/ Russell H. Ellison

Russell H. Ellison
Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S. C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Ventrus Biosciences, Inc. (the "Company") for the fiscal year ended December 31, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Barrett, Chief Financial Officer (Principal Financial and Accounting Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 31, 2014
/s/ David J. Barrett

David J. Barrett
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)