UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 18, 2011

VENTRUS BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-35005	20-8729264
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer ID Number)

787 7th Avenue, 48th Floor, New York, New York	10019
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (212) 554-4300

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

A copy of a slide presentation that Ventrus Biosciences, Inc. intends to use in industry and investor presentations is hereby furnished as Exhibit 99.1 to this report. The slide presentation will be posted on Ventrus' website at www.ventrusbio.com.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On March 18, 2011, Ventrus issued a press release announcing proposed improved, FDA-recommended endpoints for its Phase III hemorrhoid study for iferanserin (VEN 309). Ventrus will host a conference call at 8:30 a.m. (ET), on Monday, March 21, 2011 to discuss the proposed revised endpoints. A live audio webcast and replay of the conference call will be available on the Company's website at www.ventrusbio.com. A copy of the press release is attached as Exhibit 99.2 to this report and incorporated herein by reference.

By way of background, Ventrus recently had a formal meeting with the U.S. Food and Drug Administration, or FDA, to discuss the feedback received on the last special protocol assessment, or SPA, submitted by Ventrus to the FDA for its proposed pivotal Phase III study for VEN 309 for the treatment of hemorrhoids, in order to resolve remaining issues that would allow an agreement of the protocol between the FDA and Ventrus. Ventrus has received and reviewed the official FDA minutes of that meeting. The primary focus of the meeting was the FDA's recommendations for changes to the definitions of the primary and key secondary efficacy endpoints of the protocol submitted in the SPA. Ventrus viewed the suggestions as improvements to the endpoints as well as enhancing their clinical meaningfulness and readily agreed to the changes.

For the double-blind part of the study, where patients are treated twice daily for two weeks and then followed up on Day 28, the improved, FDA-recommended definitions for the endpoints, which remain subject to FDA agreement with the protocol for the SPA, are:

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

Ventrus has modeled the potential performance of these new endpoints for the Phase III study using data from a prior double-blind Phase IIb study conducted in Germany which randomized 121 patients to iferanserin or placebo ointment. In the German study, using the statistical methodology proposed for the analyses of the primary endpoint in Ventrus' planned Phase III study, the difference between the proportion of patients responding to treatment under the new endpoint definition for cessation of bleeding in the iferanserin arm (57% responders) and the placebo arm (20% responders) was considerable with a p <.0001. This is an improvement over the prior endpoints, which were time-to-bleeding cessation (defined as three consecutive days of no bleeding) as the primary, and proportion of patients who had three days cessation of pain and/or itching as the secondary, due to a more rigorous definition of the endpoint in terms of the duration of effect required for a response. In fact, the difference in proportion of responders between treatment arms in this analysis of the proposed revised primary endpoint is almost twice that seen in an analysis of the previously defined primary endpoint, mostly due to the much lower response in the placebo group as would be expected with a more rigorous definition. Similarly, analyses of the key secondary endpoints of pain and/or itching also showed considerable differences between iferanserin and placebo.

Ventrus believes the new endpoint definitions confirm the projected power of > 90% for the primary endpoint and > 90% for the key secondary endpoints for the proposed Phase III study design of 400 patients randomized 1:1 to iferanserin or placebo ointment. Since the study size and power appear to be re-affirmed by this change, and since all of Ventrus' clinical study sites will be using central Institutional Review Boards (IRBs) with rapid review times, and contracting with sites is already underway, Ventrus believes that its estimated timelines for study start (mid-summer 2011), completion of enrollment (year-end 2012), and availability of data (first quarter 2012), remain unaffected by the proposed new endpoints.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Slide presentation for use in industry and investor presentations.
99.2	Press release dated March 18, 2011.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VENTRUS BIOSCIENCES, INC.

Date: March 18, 2011

/s/ David J. Barrett
David J. Barrett, Chief Financial Officer


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BIOSCIENCES

This material contains estimates and forward-looking statements, as defined by the Private Securities Litigation Reform Act of 1995. The words "believe," "may," "might," "will," "aim," "estimate," "continue," "would," "anticipate," "intend," "expect," "plan" and similar words are intended to identify estimates and forward-looking statements. Our estimates and forward-looking statements are mainly based on our current expectations and estimates of future events and trends, which affect or might affect our businesses and operations. Although we believe that these estimates and forward-looking statements are based upon reasonable assumptions, they are subject to several risks and uncertainties and are made in light of information currently available to us. Our estimates and forward-looking statements may be influenced by the following factors, among others: 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 expectations regarding our revenues, expenses, effective tax rates and other results of operations; our anticipated capital expenditures and our estimates regarding our capital requirements; our liquidity and working capital requirements; our need to obtain additional funding and our ability to obtain future funding on acceptable terms; our product candidates and plans to promote them; anticipated trends and challenges in our business and in the markets in which we operate; our ability to retain and hire necessary employees and to staff our operations appropriately; our ability to find future acquisition opportunities on favorable terms or at all and to manage any acquisitions; our ability to compete in our industry and innovation by our competitors; our ability to stay abreast of new or modified laws and regulations that currently apply or become applicable to our business; estimates and estimate methodologies used in preparing our financial statements; and the future trading prices of our common stock and the impact of securities analysts' reports on these prices. Estimates and forward-looking statements involve risks and uncertainties and are not guarantees of future performance. As a result of known and unknown risks and uncertainties, including those described above, the estimates and forward-looking statements discussed in this material might not occur and our future results and our performance might differ materially from those expressed in these forward-looking statements due to, including, but not limited to, the factors mentioned above. Estimates and forward-looking statements speak only as of the date they were made, and, except to the extent required by law, we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors.

Experienced Management Team

Russell H. Ellison, MD, MSc: ***Chief Executive Officer and Director***

30 yrs experience in pharmaceutical industry, most recently:

- EVP, Paramount Biosciences (2007-2010)
- VP Clinical Development, **Fibrogen Inc** (2005-2007)
- VP Medical Affairs and CMO, **Sanofi-Synthelabo US** (2002-2005)
- VP Medical Affairs and CMO, **Roche US** (1997-2002)
- Board Chairman, Cormedix Inc
- Prior board member of **Cougar Inc**

David J. Barrett, CPA: ***Chief Financial Officer***

- CFO, NeuroHitech, a public pharma company with development stage and marketed products (2006-2009)
- CFO, Overture Asset Managers & Overture Financial services (hedge fund) (2003-2006)
- Manager Deloitte & Touche (1999-2003)

Investment Highlights

- A Phase III company focused exclusively on gastroenterology (GI): ie: anal disorders, a neglected area of drug development
- Our products address 3 of top 10 GI disorders - markets where there are no FDA approved drugs in the US
- 3 Late stage products:
  - Phase III – Hemorrhoids
  - Phase III initiated – Anal fissures
  - Phase IIb – Fecal incontinence
- Near term milestones with 2 important data read-outs expected in H1 2012
- Multiple scenarios are possible for development and commercialization after H1 data readouts

Product Pipeline

Drug	Indication	Status	US Patient Pop.	Territories
Iferanserin (VEN 309)	Hemorrhoids	Phase III	12.5 mm	Worldwide
Diltiazem (VEN 307)	Anal Fissures	Phase III Initiated	4 mm	North America
Phenylephrine (VEN 308)	Fecal Incontinence	Phase IIb	7 mm	North America

VEN 309: Iferanserin

Novel Treatment for Hemorrhoids

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Hemorrhoid Overview

Symptoms

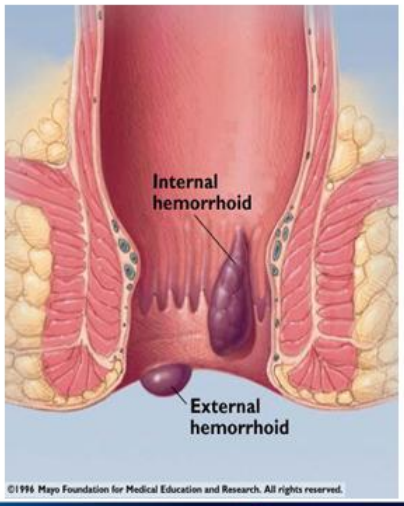
- Bleeding, pain, itch, swelling & tenderness, difficult defecation

Market

- ~12.5 mm patients in US
- Highest prevalence >50 years of age
- No FDA approved products approved in U.S. and current products are not reimbursed
- **4 mm prescriptions written annually in the U.S.** for unapproved use in hemorrhoids
- 22 mm OTC units sold annually in the U.S.
- No other known drugs in development in the U.S.

Causes

- Increased hydrostatic pressure = AV dilation, slower blood flow
- **Serotonin activation of 5HT2a receptors**
- Efferent vasoconstriction, platelet aggregation, further dilation and symptoms



Product Overview

- **Topical rectal ointment: applied intra-anal BID (with applicator)**

- **Indication**
  - Acute treatment of hemorrhoids: Cessation of bleeding, itch and pain associated with hemorrhoids

- **Mechanism**
  - NCE – **Potent peripheral 5HT2a antagonist:** promotes normalization of blood flow, and cessation of bleeding, pain and itching
  - **Does not cross the blood brain barrier** except at doses much higher than to be used therapeutically
  - **Selective for 5HT2a;** 1/3 affinity for 5HT2c, very low affinity for 5HT2b (antagonist) and 1/1000 affinity for other 5HT receptors

- **Intellectual Property**
  - Licensed from the inventor
  - Patents issued in all major territories
  - US COM patent expires 2015, Hatch-Waxman exclusivity 5 yrs (Rx to OTC switch)
  - **New concentration range patent just filed;** 20 yrs exclusivity: prevents A/B rated generics

Ready for Phase III

- **Phase II completed**
  - Expect SPA with FDA (3rd round) by March 2011
  - FDA confirmed Phase III status
  - Achieved agreement with FDA on primary endpoint
- **CMC ready for scale-up to commercial scale**
- **Excellent safety profile**
  - 7 clinical trials, 220 patients exposed to VEN 309
  - Side effects are local and minor; systemic side effects comparable to placebo
  - No SAE's, no deaths
- **Development plan**
  - 1500 patient safety database; in 2 pivotal trials or 2 pivotals and 1 safety study (TBD)
  - 104 wk 2 species carcinogenicity (no prior findings of concern) is critical path to NDA filing (2014)
  - 2 pivotal trials (Phase III) to be done in series, not on critical path
  - Clinical pharmacology program

1st Pivotal Phase III Study: Proposed Design

- **Start Q2/3 2011, double blind data available Q1 2012**
  - 400 patients
  - Double Blind; 0.5% iferanserin vs placebo ointment
  - 60 sites (North America)
  - 14 days treatment with follow up at 28 days
  - All patients roll to active treatment after 28 days, with 12 month follow up to assess recurrence (open label)

- **Inclusion criteria**
  - Symptomatic grade I to III internal hemorrhoids
  - Bleeding from hemorrhoids 2 consecutive days prior to randomization, with pain or itching accompanying the bleeding for the 2 days

- **Primary endpoint:** time to cessation of bleeding for a minimum of 3 days

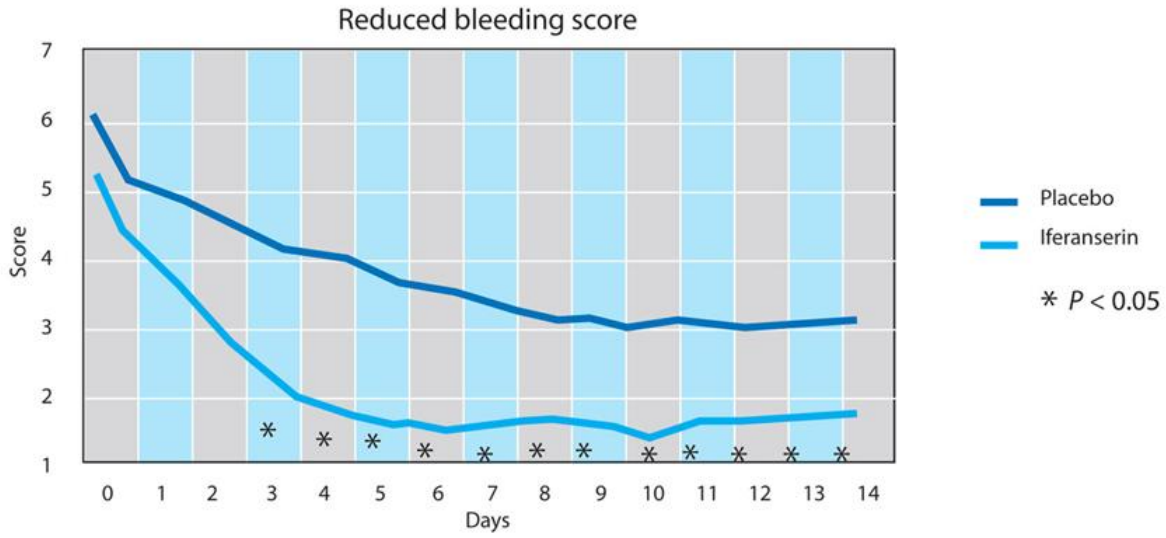
- **Secondary endpoints:** cessation of pain and itching for 3 days

Phase III Endpoints Confirmed in Phase IIb (German Study)

- 6 sites in Germany, conducted 2003/2004
- 121 patients randomized to iferanserin 0.5% (Phase III dose) BID vs placebo ointment
- Baseline and weekly visits for 2 week treatment; follow up at 45 days
- Endpoints
  - Primary: bleeding scale
  - Secondary: itching and pain scales
  - Other: tenderness, fullness, throbbing, gas, difficulty in defecation and physician's assessment
- Safety

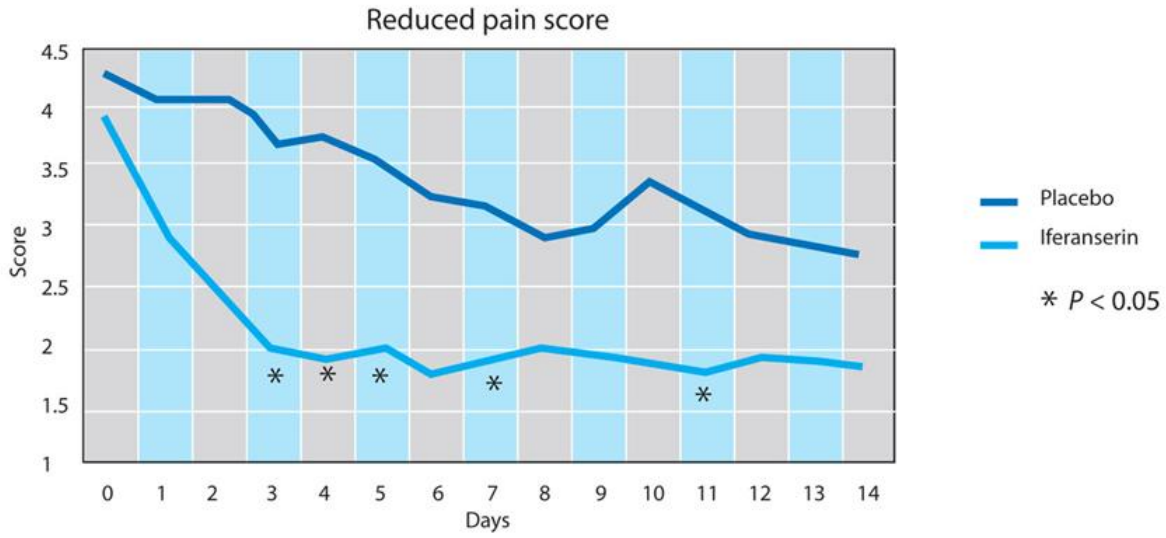
German Phase IIb: Bleeding

Cessation of Bleeding: VEN 309: 89% Placebo: 68%



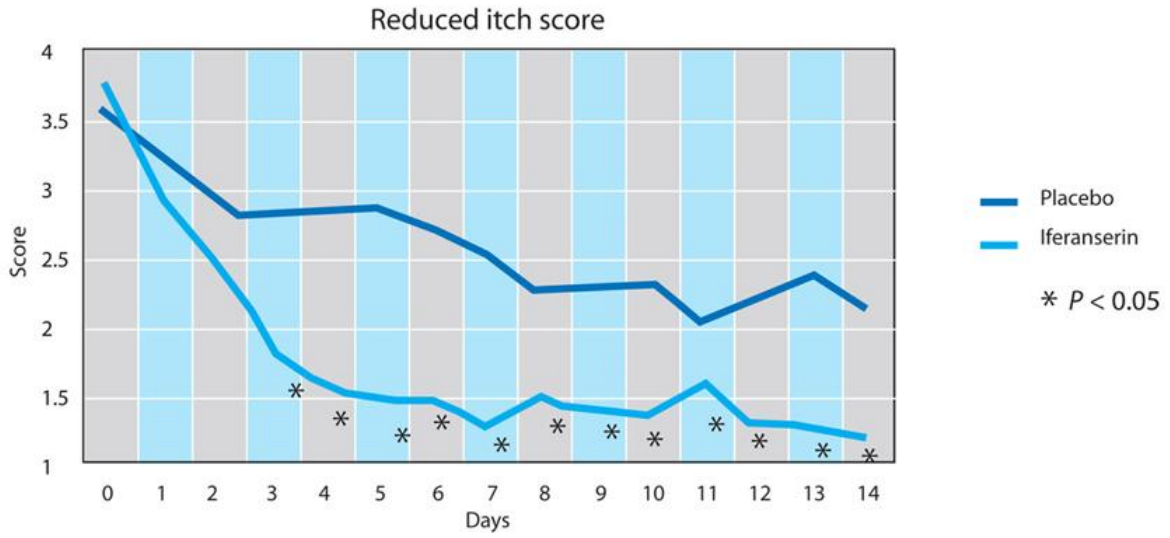
German Phase IIb: Pain

Cessation of Pain: VEN 309: 78% Placebo: 46%

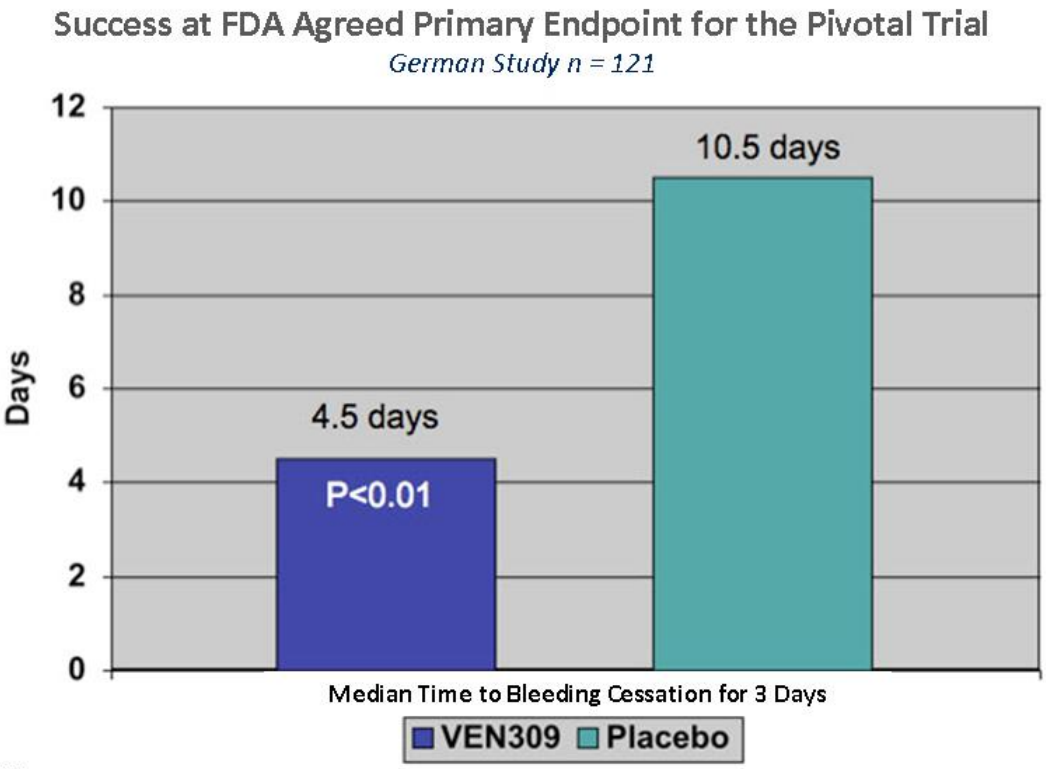


German Phase IIb: Itching

Cessation of Itching: VEN 309: 90% Placebo: 62%



Analysis of German Phase IIb for Phase III Endpoint*



* *Post hoc*

Near Term Inflection Points

- Expect an SPA approximately end Q1 2011
- 1st patient in hemorrhoid trial in mid-2011
- Potential publications of existing preclinical and clinical data
- Expect PTO action in mid-2011 on new IP
- Completion of enrollment of hemorrhoid trial in Q4 2011
- Data from double blind phase of hemorrhoid trial in Q1 2012

VEN 307: Diltiazem Cream

Novel Treatment for Anal Fissures

Anal Fissures Overview

Symptoms

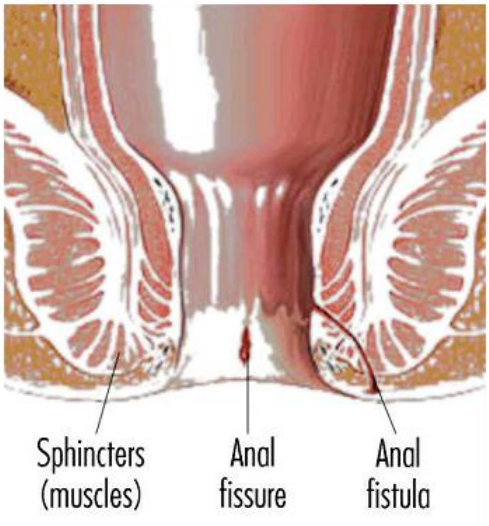
- Ischemic tear in the anus
- **SEVERE** pain

Market

- ~4 million patients in US
- Fiber followed by surgery is standard of care
- No US approved products
- Compounded Diltiazem and some GTN are **already used** by specialists
- 50% of patients referred to specialist
  - Most common outcome is surgery because patients cannot stand the pain

Causes

- **Increased internal anal sphincter pressure** and resultant decreased blood flow
- Usually with constipation



Product Overview

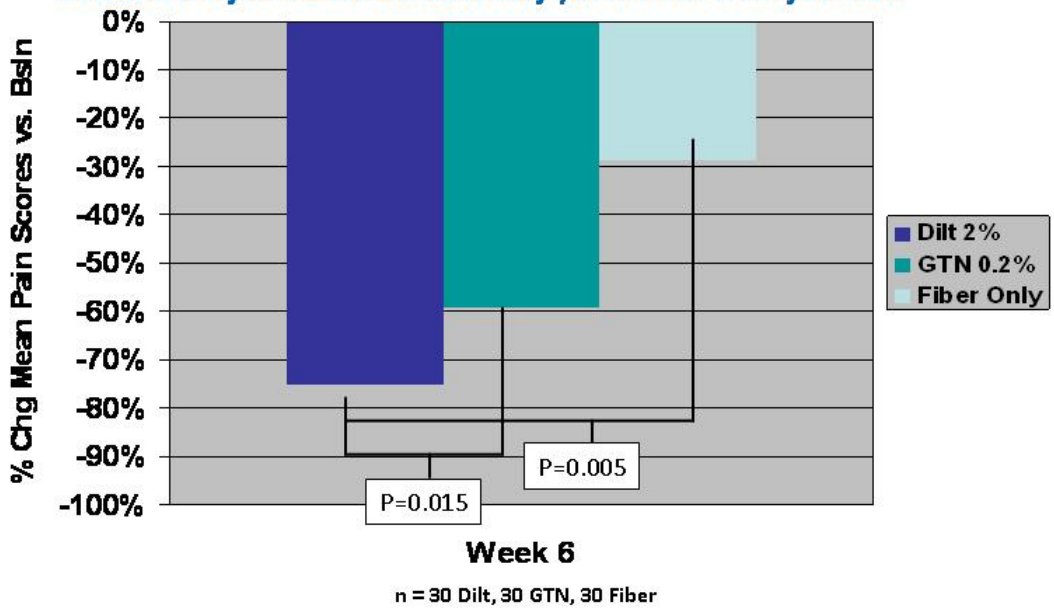
- **Topical Diltiazem Cream: applied peri-anally TID**
  - Originally approved as Cardizem® (Marion Labs) for angina and high blood pressure
- **Indication:** pain associated with anal fissures
- **Approval pathway:** 505(b)(2) – only 2 pivotal trials required
- **Mechanism**
  - Calcium channel blocker - **relaxes the internal anal sphincter**, reducing pain and increases tissue blood flow
- **Intellectual Property**
  - Method of use filed, expires 2017 (+ 3yrs Hatch-Waxman) – not yet issued
  - Multiple possibilities for BID formulations with 20 year IP: final selection Q3 2011
    - Can develop one of these (2 pivotals starting 2012) or original (1 pivotal starting 2012)

Phase III Initiated

- First Phase II study (2.0% BID vs. Placebo BID) – primary endpoint of healing not met due to high placebo response (similar to GTN studies)
- Numerous investigator initiated studies vs active comparator (GTN 0.2% to 0.5%) and fiber published with favorable results for pain
- FDA pre-IND meeting conducted in August 2007
  - Confirmed Phase III multi-dose plan
  - Achieved clarity on primary endpoint: reduction in **pain**
  - Confirmed safety database
- Phase III trial recently initiated (November) with data in Q2 2012
  - Licensor (SLA) is conducting trial
  - 485 patients in 30 sites in Europe
  - Treated for 2 months: randomized double blind; fiber plus 2%, 4% VEN 307, and placebo
  - **Primary endpoint: reduction in pain using a validated scale**

Phase III Endpoint: Reduction in Pain

Diltiazem Cream more effective than topical nitrate and standard of care in reduction of pain with anal fissures



n = 30 Dilt, 30 GTN, 30 Fiber

Diltiazem vs Topical Nitrate vs Standard of Care

Source: Shrivastava, BK, et al, Randomized clinical trial GTN vs. Diltiazem vs Fiber Only, Surgery Today (2007); 37: 482-485

Near Term Timelines

- Selection of new formulations with extended IP (Q3 2011)
- PTO action on existing patent filing (Q3/4 2011)
- Completion of enrollment of European Phase III (Dec 2011 / Jan 2012)
- Data from Phase III trial (Q2 2012)

Corporate Overview

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Financial Summary

- **IPO in December 2010**
  - 3.335 million shares at $6.00 per share
  - Exchange: Nasdaq ("VTUS")

- **Capital Structure**
  - Cash and Short-term Investments $17.6 million
  - Debt $2.7 mm
  - Common Shares Outstanding 7.2 million (9.3 million fully diluted)
  - Market Cap ~$45 million

Upcoming Milestones and News Flow

	Q2 2011	Q3 2011	Q4 2011	Q1 2012	Q2 2012
VEN309	SPA Granted	Phase III Initiated; German Phase IIB Trial Published		Phase III Data Announced	Ongoing Open Label Recurrence Data
		PTO Action on New IP	Phase III Enrollment Completed		
VEN307		New Formulations Selected with Long IP	Complete Phase III Enrollment		Phase III Data Announced
		PTO Action on Existing Patent Filing			

Multiple Future Scenarios Possible: Iferanaserin and Diltiazem

- **Strategic options: after data readouts in H1 2012**
  - In 2015, 5-6 major pharma companies with primary care and/or GI products and field forces
  - Four with an OTC division
  - 2-3 GI specialty companies

- **Continued development of products by Ventrus: cost/time to approval***
  - After 1st data readout Q1 2012, approx. $20 mm to develop iferanserin to approval; 2015
  - After 1st data readout Q2 2012, approx $15 mm to develop diltiazem cream to approval 2014

- **Commercialization by Ventrus:**
  - Iferanserin: no effective Rx competition: contracted primary care/GI field force (500-600) for 1-2 years plus DTC year 2
  - Diltiazem: compounded version already in use; market is GI surgeons = very low launch costs

** excludes G&A*

The Opportunity

Key Takeaways:

The Products:

- 3 late stage GI drugs with no competing FDA approved products on the market
- VEN 309 will be the first and ONLY FDA approved product for Hemorrhoids, with a market of >12.5 million patients
- VEN 307 will be the first and ONLY FDA approved product for anal fissures, with a market of >4 million patients
- VEN 309 and 307: validated Phase III endpoint that has already demonstrated efficacy in multiple Phase II trials
- Great safety profile – limited side effects from topical administration

The Company:

- 2 high value data read-outs expected over next year
- Significant news flow and multiple milestones between now and data read-outs
- Multiple scenarios are possible for further development and commercialization of the products after the data readouts
- Experienced team with a history of success

Ventrus Announces Improved, FDA-Recommended Endpoints Proposed for Phase III Hemorrhoid Study

Company to Host Conference Call on Monday, March 21 at 8:30 AM ET

NEW YORK, NY, March 18, 2011 (Global Newswire) - Ventrus BioSciences, Inc. (Nasdaq: VTUS) has filed a revised protocol with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) with new, more robust definitions for efficacy endpoints that were recommended by the FDA in a recent meeting with the company for the first pivotal study of the company's iferanserin (VEN 309) ointment, the first prescription product candidate for the treatment of hemorrhoids. Ventrus also announced that it will host a conference call on Monday March 21 at 8:30 AM ET to discuss the proposed revised endpoints.

Russell H. Ellison, MD, Ventrus' CEO said the company is "very pleased with the new endpoint definitions in that they showed considerable differences between active drug and placebo in our analysis of an earlier Phase IIb study in Germany, which has been the cornerstone of our development program."

"In addition, we believe that the new endpoint definitions have the potential to provide a much stronger label which could further serve to encourage faster and broader adoption by physicians and by their patients who suffer the pain and discomfort of hemorrhoids." said Dr. Ellison. There is currently no FDA-approved prescription product for the treatment for hemorrhoids.

Ventrus submitted a new SPA on March 16, 2011, that includes a revised protocol, including the newly defined endpoints, in accordance with the feedback received from that meeting, and expects a response within 45 days, which is the customary FDA review period. The SPA remains subject to FDA agreement.

The pivotal Phase III clinical study for the treatment of hemorrhoids is expected to start on schedule, in mid-summer of this year.

For more detailed information on the endpoints please refer to our current report on Form 8-K filed today with the Securities and Exchange Commission and our website at ventrusbio.com

Conference Call Monday, March 21 at 8:30 AM ET

Ventrus will discuss the proposed revised endpoints in a conference call on Monday, March 21, 2011, at 8:30 AM Eastern Time. Interested investors may participate in the conference call by dialing 1-888-853-9372 (domestic) or 1-720-496-1609 (international), and entering passcode 634075 when prompted. The archived webcast of the conference call will be available for two weeks on Ventrus' web site at www.ventrusbio.com.

About Ventrus

Ventrus is a development stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders. Our lead product, Iferanserin (VEN 309) is a new chemical entity, or NCE, for the topical treatment of hemorrhoids, which targets a specific serotonin receptor (5HT2A) thought to be important in the disease. The first late phase clinical trial (Phase III) with Iferanserin is expected to start mid-year 2011 and we expect data to be available in the first quarter of 2012. Our additional product candidate portfolio consists of two in-licensed late-stage drugs intended to treat anal fissures (VEN 307) and fecal incontinence (VEN 308). The first Phase III clinical trial with VEN 307 has begun in Europe and we expect data to be available in the second quarter of 2012. These candidates are two molecules that were previously approved and marketed for other indications and that have been formulated into our proprietary topical treatments for these new gastrointestinal indications.

Please Note: The information provided herein contains estimates and other forward-looking statements regarding future events. Such statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the unpredictability of the clinical development of our product candidates and of the duration and results of regulatory review of those candidates by the FDA and foreign regulatory authorities; the cost, timing and results of clinical trials and other development activities involving our product candidates; our anticipated capital expenditures and our estimates regarding our capital requirements; our ability to retain and hire necessary employees and to staff our operations appropriately; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. The reader is referred to the documents that we file from time to time with the Securities and Exchange Commission.

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