

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): November 14, 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)

99 Hudson Street, 5<sup>th</sup> Floor, New York, New York

10013

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code

(646) 706-5208

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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01. Other Events.**

On November 14, 2011, Ventrus Biosciences, Inc. issued a press release to report top line results of a research study commissioned by Ventrus on the U.S. market for hemorrhoids and iferanserin (VEN-309), as well as give an update on the progress of its ongoing Phase III pivotal trial for VEN-109 for the treatment of asymptomatic hemorrhoids. A copy of the related press release and PowerPoint presentation are attached hereto as Exhibit 99.1 and Exhibit 99.2 respectively and are incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

## (d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 14, 2011.
99.2	Slide presentation of November 14, 2011.

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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: November 14, 2011

By: /s/ David J. Barrett

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David J. Barrett, Chief Financial Officer

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November 14, 2011

**Ventrus Validates Large Patient Potential for VEN 309 with survey data from 10,000 consumers**

*~Expects to Deliver Top Line Results from Two Pivotal Trials in mid-2012 and to complete the acquisition of the global rights and title for VEN 309 from the licensor~*

NEW YORK, November 14, 2011 (GLOBAL NEWSWIRE) -- Ventrus BioSciences, Inc. (Nasdaq:VTUS) announced today an update to the timing for the reporting of the top line results from the ongoing Phase 3 pivotal trial of Iferanserin (VEN 309) in patients with hemorrhoids as well as from the ongoing Phase 3 pivotal trial of Diltiazem (VEN 307) in patients with anal fissures. The company has extended the timing to report the top line results from the hemorrhoid trial by approximately three months, to around June 2012 while top line data for the anal fissure trial is still expected around May 2012.

“Both trials are progressing well with respect to data quality and GCRP (Good Clinical Research Practices). As we expect to report top line Phase 3 results for both products in the second quarter of 2012, these milestones are likely to be close together in time,” said Dr. Russell Ellison, Chairman and Chief Executive Officer of Ventrus. “Our projected NDA filing timelines for both VEN 309 and VEN 307 remain on track, and the new completion timelines for VEN 309 should have no material effect on the balance sheet.”

Additionally, the company commissioned Princeton Brand Econometrics (PBE) to conduct a landmark omnibus survey of consumers and patients. From these data, PBE is developing a predictive model to forecast physician and patient behavior in response to various product profiles and promotional levels.

Initial results from the market research show that the hemorrhoid market is potentially large, patients are seeking solutions, and respond strongly to the VEN 309 product concept. Of the 10,202 adult consumers surveyed, 1,125 patients reported having hemorrhoids within the last two years, which represents approximately 11% of the US adult population (25.8 million of 234 million people). In addition to the 11% two year prevalence, 9%, 6% and 3% reported having hemorrhoids within the past one year (21.7 million people), one month (14 million people) and on the day of survey (6.7 million people) respectively. Of the entire group of hemorrhoid patients surveyed, 85% reported having had treatment at some point; from the treatment subset, 86% reported using OTC and 14% using prescription products as their last treatment. 10% of all hemorrhoid patients surveyed had had an invasive procedure (banding, injection, surgery) at some time, of which 61% had surgery, and 75% of patients who had had an invasive procedure reported a recurrence.

Patients had a strong response to the product concept of VEN 309 as a treatment for their hemorrhoids. Of the 1,125 hemorrhoid patients surveyed, 75% stated that they would request a prescription at their next physician visit. At industry standard promotional levels, the PBE factored modeling calculates that 25% of this large population would actually request the prescription. For those patients experiencing hemorrhoids on the day of the survey, 88% stated they would request a prescription and the PBE factoring model calculates that 80% would actually make the request. In addition, for the entire sample, including all income levels, of those actually receiving a prescription, 66% would fill it with a \$35 out-of-pocket patient co-pay.

The company expects to close the acquisition of the global rights and title for VEN 309 from the licensor, Sam Amer & Co., today as the major conditions required for the close have been met. “Given what we have discovered about the commercial potential of VEN 309, the progress of the development program, and what we have learned about the details of the regulatory pathway and the potential market and data exclusivity, we are very pleased to be able to finalize this transaction,” said Dr. Ellison. “We believe that this could considerably enhance the value of this asset to the company.”

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The Company will conduct a conference call and webcast today, November 14, at 8:00 A.M. EST, to discuss the financial results, clinical program updates, and the third party market research survey. The call and webcast are open to any interested party. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (877) 293-5456 (U.S.); (707) 287-9357 (international), passcode 26472909. A live, audio-only webcast is also available on the Company's website at <http://investor.ventrusbio.com/events.cfm>. The audio webcast of the conference call will be accessible following the live broadcast through December 5, 2011. Additional information is also available on the company's website at [ventrusbio.com](http://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 products are: Iferanserin (VEN 309) for the topical treatment of hemorrhoids, for which the first Phase III clinical trial began in August 2011 and is ongoing, and topical Diltiazem for the treatment of anal fissures for which the first Phase III trial was initiated November 2010, and is ongoing. Our product candidate portfolio also includes topical phenylephrine intended to treat fecal incontinence (VEN 308). VEN-307 and VEN-308 are two molecules that were previously approved and marketed for other indications and that have been formulated into our in-licensed proprietary topical treatments for these new gastrointestinal indications, and VEN 309 is a New Chemical Entity (NCE)

## **About Princeton Brand Econometrics**

Princeton Brand Econometrics (PBE) is a marketing engineering consultancy headquartered in Princeton, NJ, that builds models which simulate the cause and effect dynamics of market environments of interest, based on extensive and rigorous quantitative research. PBE's average forecast error across 31 published validations is  $\pm 2.68\%$  of actual in-market outcomes, and its forecasting methodology has been utilized by 9 of the 10 top pharmaceutical companies.

*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 timing, cost and results of clinical trials and other development activities involving our product candidates; 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 unpredictability of the size of the markets for, and market acceptance of, any of our products, including VEN 309; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; the risks of not closing the acquisition of VEN 309 from Sam Amer & C.; 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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## Forward Looking Statements

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This material contains estimates and forward-looking statements. 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 many 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: 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; the risks of not closing the acquisition of VEN 309 from Sam Amer & Co.; 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 309; our ability to sell any approved products and the price we are able realize; our need to obtain additional funding and 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, including our Annual Report on Form 10-K. 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.

## Summary of Update

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- **\$ 53 mil cash end Q3 2011; no debt**
- **Programs: Ventrus is on track to deliver Ph 3 data on two significant GI drug development candidates by mid 2012**
  - **VEN 309: topical Ifeanserin for the treatment of hemorrhoids**
    - Top line data from pivotal trial and PK data now expected at end of Q2 2012
    - NDA filing timelines are unchanged
    - Data quality favorable; no serious severe adverse events related to drug, to date
  - **VEN 307 topical Diltiazem for the treatment of anal fissure**
    - Topline data still expected in Q2 2012 (most likely May);
- **Market Research – Third party Omnibus survey on hemorrhoids**
  - Confirms hemorrhoid prevalence is high and exceeds previous estimates: patients are taking action
  - Patient response to hemorrhoid product concept is strong
- **Completion of acquisition of VEN 309 expected Nov 14, 2011**



## Q3-2011 Financial Update

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### ➤ Cash balance

■ Cash and cash equivalents at Sept 30, 2011	\$ 53.3 Mil
■ Expected cash burn next 12 months*	\$ 12 -\$ 16 Mil
■ Cash and cash equivalents YE 2011 end guidance	\$ 34-\$ 36 Mil

### ➤ Stock data

■ Fully diluted shares outstanding	15.3 Mil
■ Shares outstanding	12.4 Mil

### ➤ Sources of funding 2007 to present

■ Funding pre-IPO	\$ 10 Mil
■ IPO December 2010	\$ 18 Mil
■ Secondary public offering July 2011	\$ 47.5 Mil

- \* Excludes payment to acquire rights to Amer: estimates - our operation expenditures could change

## VEN309 (Iferanserin) for the Treatment of Hemorrhoids

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### ➤ Ongoing Phase III trial: Iferanserin 0.5% ointment b.i.d.

#### ■ Design

- 3 arms, 200 patients per arm (placebo, 14 day treatment, 7 day treatment), total 600 patients, 70 sites
- 2 week treatment followed by 2 week observation, double-blind
- 1 year open-label extension (treatment for recurrence of symptoms)
- Primary endpoint, cessation of bleeding day 7–14; secondary endpoints, cessation of pain, itching day 7-14. Endpoints collected daily using Interactive Voice Response System (IVRS)
  - ▶ Patients need 2 consecutive days of bleeding and either pain or itching at randomization: *meaningful symptoms to get meaningful improvement*
- Due to 1 year open-label extension
  - ▶ Colonoscopy required pre-randomization if > 3 yrs ago
  - ▶ No DDI data re CYP2D6: exclude history of and current depression, SSRI's
  - ▶ Exclude history of heart disease, BMI > 36, other chronic diseases

#### ■ Progress

- Initiated early August with 65 sites; currently all 70 sites screening
- Enrolling correct patients, minimal loss of key outcome data on IVRS, continuous data review
- Large number of patients entering screening as expected

## **VEN309 (Iferanserin) for the Treatment of Hemorrhoids**

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- **Estimated timelines**
  - **Previous guidance**
    - ▶ Enrollment complete: Early 2012
    - ▶ Double blind data and open label recurrence data to date: **Q1 2012**
  
  - **Updated guidance based on 3 months of enrollment**
    - ▶ Enrollment complete: April 2012
    - ▶ Double-blind data and available open-label recurrence data: **around June 2012**
      - Screen failure rate higher than expected: need for symptoms x 2 days and exclusion criteria
  
  - **Impact On Future studies** (2<sup>nd</sup> pivotal and double-blind recurrence trial)
    - ▶ Screen failure rate expected to decrease due to less restrictive exclusion criteria
      - Neither trial has open-label extension; DDI studies will be available
  
  - **No effect on NDA filing timelines; no material effect on the balance sheet**

# ***VEN309 (Iferanserin) for the Treatment of Hemorrhoids***

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## ➤ **Pharmacology program: CYP2D6 metabolism**

- Iferanserin is dependant on CYP2D6 for metabolism and inhibits CYP2D6 in the liver (Prozac)
  - Advantage: GI topical drug with low systemic exposure
- Program designed to generate the following data
  - Poor metabolizers (missing genes): safety and exposure, needed for QT study
    - ▶ One poor metabolizer (2 genes missing) in Ph I had no adverse events
  - Drug interaction with CYP2D6 dependant/inhibiting drugs (Cymbalta [duloxetine], dextromethorphan)
- **Data expected Q2 2012 (with pivotal trial data expected)**
  - Allow less restrictions in exclusion criteria for the next studies
  - Provide high dose arm for QT study
  - De-risk safety profile

## **VEN307 (Diltiazem Cream) for Anal Fissures**

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### ➤ **Ongoing Phase III study in Europe**

#### ■ **Design**

- 3 arms (2%, 4%, placebo) 155 patients each (465 total); 31 sites in Europe
- 3 months double-blind (2 months treatment, 1 month follow-up)
- Primary endpoint: reduction in pain on defecation at 1 month; Secondary endpoint: reduction in pain on defecation at 2 months
- Patients need to have pain 2 days per week for 4 weeks prior to entry; moderate to severe pain at randomization

#### ■ **Progress**

- Ventrus did detailed review of blinded data and study operations 10/2011: Correct patients enrolled, IVRS compliance good to date, data being reviewed continuously

#### ■ **Expected timelines**

- Enrollment expected to be complete: January 2012
- Unblinded data expected to be available: around May 2012

## Hemorrhoid Rx Commercial Potential Study

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- **Ventrus commissioned an omnibus survey and predictive modeling market research in September 2011 of 800 physicians and 1,125 hemorrhoid patients**
  - Physician project is beginning the analysis stage
  - Consumer project is in analysis stage and initial results are available
  
- **Study Approach**
  - Each respondent sees only one profile
  - PBE *factors* (discounts) the self-stated survey responses regarding VEN 309 adoption to accurately reflect real world behavior, based on extensively validated in-market models
  
- **Princeton Brand Econometrics**
  - Founded in 1991 and has worked for 9 of the top 10 pharmaceutical companies
  - Chosen based on their track record of accurately predicting physician and consumer behavior given a range of product profiles and promotional levels
  - Mean absolute percentage error over 31 validated forecasts is 2.68%



## Study Results

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- 10,202 adult consumers were screened (designed to match US demographics)
- 1,125 (11%) consumers reported suffering from hemorrhoids within the last two years...ie: *hemorrhoid patients*
  - 2010 US Adult population – 234,564,000 (2010 US census)
- **Period prevalence:**
  - 2 years: 11% - 25.8 million
  - 1 year: 9.3% - 21.7 million
  - 1 month: 6.0% - 14.0 million
  - Day of survey: 2.9% - 6.7 million
- **Treatments**
  - 15% report never using OTC or Rx treatment
  - Of those treating, 86% reported using an OTC preparation or 14% Rx as their last treatment
  - 10% reported having an invasive procedure (61% surgery) with 75% reporting recurrence of symptoms after surgery

## Patient response to VEN 309 DTC/PR concept

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### ➤ Strong willingness to ask their doctor for VEN 309 at the next visit

- In the entire sample: (complete range of current satisfaction, severity frequency of hemorrhoids, time of last episode, and income):
  - 75% stated\* that they would request a prescription at the next visit
  - 25% would actually request a prescription (75% factored by PBE algorithm)
  - 66% receiving a prescription would fill the Rx at a \$35 out-of-pocket co-pay\*\*
    - ▶ 78% with household income above \$50k/year would fill the Rx at a \$35 copay\*\*
  
- For patients who are having symptoms now, (estimated at 6.7 mm)
  - 88% stated\* they would request a prescription and
  - 80% would actually request it\*\*

\*Stated includes "Definitely, Probably and Might"

\*\* PBE factored



## ***Completion of Purchase of VEN 309 rights***

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### ➤ Deal to close Nov 14, 2012

- Purchase of global rights and title to all aspects
- US royalties decrease from double digits to 4%
- ROW royalties decrease from mid single digits to 1%
- Milestones decreased by \$10 million
- \$500,000 paid on execution of contract (June 2011)
- \$12 million to be paid on closure
- Transaction closing conditions were met:
  - No serious severe adverse events possibly related to drug by Nov 11 2011
  - Sufficient capital raised in follow-on