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): May 2, 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, 5th 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))

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 May 2, 2011, Ventrus issued a press release announcing that it was adding a third treatment arm of shorter duration to its proposed pivotal Phase III study for iferanserin (VEN 309) for the treatment of hemorrhoids. The treatment arm is being added based upon a request from the U.S. Food and Drug Administration, or FDA, in its response to Ventrus' last submission of its special protocol assessment, or SPA, for the Phase III study. A copy of the press release is attached as Exhibit 99.2 to this report and incorporated herein by reference.

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 May 2, 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: May 3, 2011

/s/ David J. Barrett

David J. Barrett, Chief Financial Officer

Exhibit 99.1

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 anticipated capital expenditures and our estimates regarding our capital requirements; our liquidity and working capital requirements; our expectations regarding our revenues, expenses, effective tax rates and other results of operations; 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.

Highlights

- A Phase III company focused exclusively on gastroenterology (GI): ie: anal disorders, a neglected area of drug development
- Our products address large 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

Experienced Management Team

Russell H. Ellison, MD, MSc: ***Chief Executive Officer and Chairman of the Board***

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)
- Prior Board Chairman, **Cormedix Inc**
- Prior board member of **Cougar Biosciences 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)

Experienced Development Team

Monil Shah PharmD: VP Clinical Research

- Novartis, Amgen, Fibrogen, Celgene

Celine Scholl CPM

- Novartis Merck,GSK

Mohan Kabadi PhD: Head of Product Development & Manufacturing

- > 20 years; BMS, Novartis, Faulding, Roche

John Dietrich PhD Preclinical Development (toxicology)

- > 30 years experience

VEN 309: Iferanserin

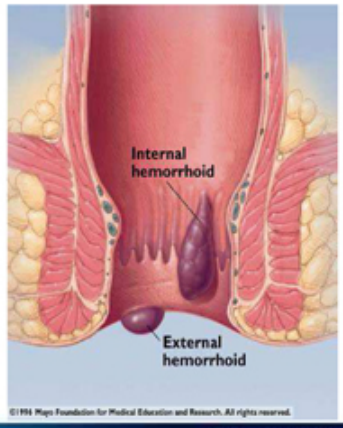
Novel Treatment for Hemorrhoids

ventrus BIOSCIENCES

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 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



VEN 309: Iferanserin

Product Overview

- **Topical rectal ointment: applied intra-anal BID (with applicator)**
- **Mechanism**
  - **NCE – potent 5HT2a antagonist**:
  - **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
  - **Low systemic exposure: < 10% bioavailability (rat)**
- **Indication**
  - Acute treatment of hemorrhoids

- **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
  - **Topical GI product with low bioavailability**: generic substitution potentially difficult

VEN 309: Iferanserin

Ready for Phase III

- **Phase II completed - 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: intermittent chronic recurrent treatment**
  - FDA confirmed PH III status; agreement on primary endpoint
  - **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)
  - Clinical pharmacology program
  - **2 pivotal trials (Phase III) to be done in series**, not on critical path
  - FDA requested that 1st trial will evaluate 7 days in addition to 14 days treatment
  - Primary and secondary endpoints discussed and agreed on with FDA
  - Refiling SPA for 1st protocol for an FDA response approximately end of June

1st Pivotal Phase III Study: Proposed Design

- **Start summer 2011, double blind data available Q1 2012**
  - Approximately 600 patients *(> 99% power for 1^0 and >95% for 2^0 endpoints)*
  - 3 arm study, Double Blind; 0.5% iferanserin vs placebo ointment:
    - Arm 1 Placebo twice daily x 14 days
    - Arm 2 Iferanserin twice daily x 14 days
    - Arm 3 iferanserin twice daily x 7 days then placebo twice daily x 7 days
  - Approximately 80 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: No bleeding day 7 – day 14** (2^{nd} week of treatment)
- **Secondary endpoints: No pain, no itching day 7 - 14**

VEN 309: Iferanserin

Phase III Endpoints Confirmed in Phase IIb (German Study)

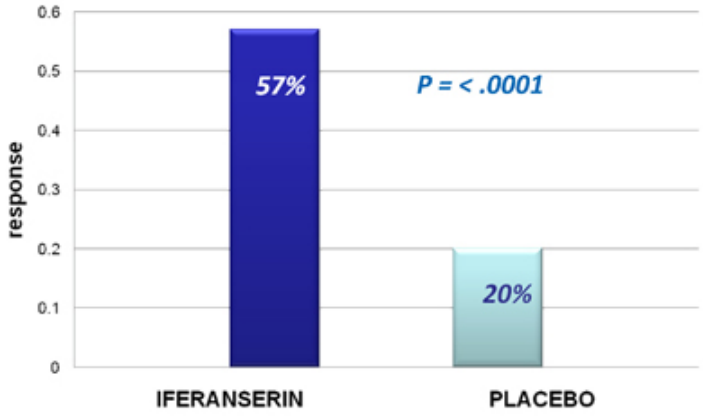
- **6 sites in Germany, conducted 2003/2004**
- **121 patients randomized to iferanserin 0.5% (Phase III dose) BID vs placebo ointment**
- **Baseline and weekly visits for 2 week treatment; follow up at 45 days**
- **Endpoints:** (numeric scales: score 1 = no symptoms)
  - Primary: bleeding scale
  - Secondary: itching and pain scales
  - Other: tenderness, fullness, throbbing, gas, difficulty in defecation and physician's assessment
- **Safety**

VEN 309: Iferanserin

Analysis of German Phase IIb for Phase III Endpoint*

Success with the Primary Endpoint for the Pivotal Trial with 14 days treatment

German Study n = 111 with bleeding at entry



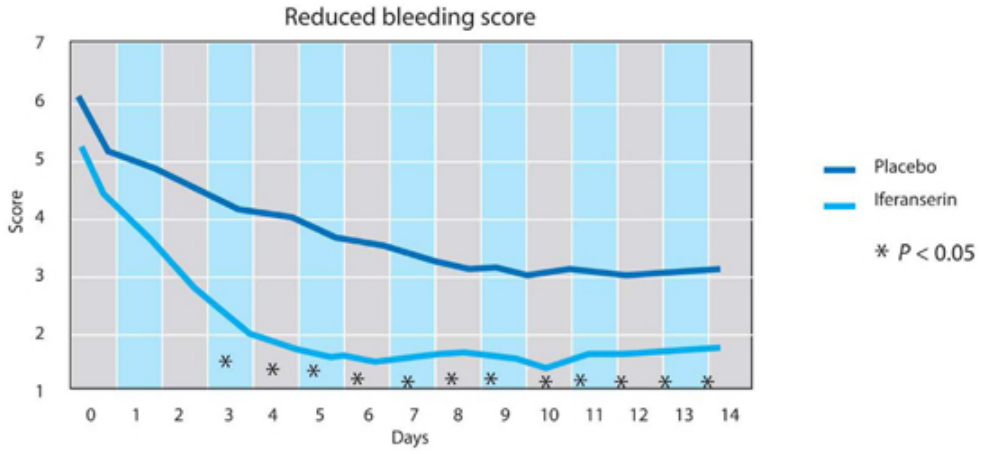
No Bleeding from day 7- day 14 (2nd week of treatment)

Majority of responders in the treatment arm respond by day 3

* *Post hoc*

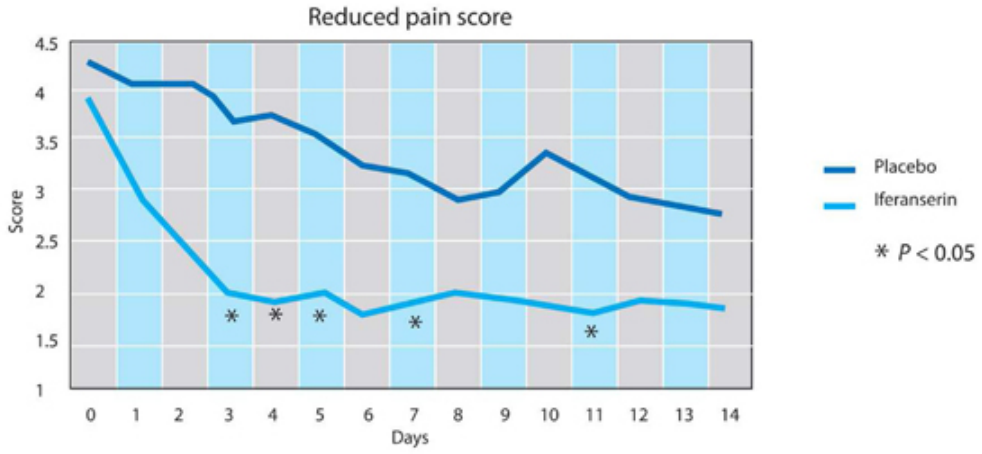
VEN 309: Iferanserin

German Phase IIb endpoints : Bleeding



VEN 309: Iferanserin

German Phase IIb endpoints: Pain



VEN 309: Iferanserin

German Phase IIb endpoints: Itching

VEN 309: Iferanserin

Near Term Inflection Points

- Expect FDA response to new SPA with additional 3rd arm approx. end of June
- 1st patient in hemorrhoid trial in summer 2011: all sites will be enrolled by then
- Potential publications of existing preclinical and clinical data
- Expect PTO action in mid-2011 on new IP
- Completion of enrollment of hemorrhoid trial in Dec 2011 – Jan 2012
- Data from double blind phase of hemorrhoid trial in Q1 2012

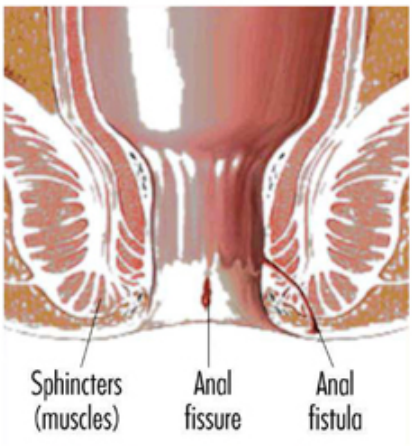
VEN 307: Diltiazem Cream

Novel Treatment for Anal Fissures

VEN 307: Diltiazem Cream

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



VEN 307: Diltiazem Cream

Product Overview

- **Topical Diltiazem Cream: applied peri-anally TID**
  - Originally approved as Cardizem® (Marion Labs) for angina and high blood pressure
- **Mechanism**
  - Calcium channel blocker - **relaxes the internal anal sphincter**, reducing pain and increases tissue blood flow
- **Indication:** pain associated with anal fissures
- **Approval pathway:** 505(b)(2) – only 2 pivotal trials required
- **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)

VEN 307: Diltiazem Cream

Phase III Initiated

- **Numerous investigator initiated studies vs active comparator (GTN 0.2% to 0.5%) and fiber published with favorable results for pain**
- **NDA program for GTN (Cellegesic) had multiple failures:** small trials, endpoint problem, and excess analgesic use in treatment arm due to headaches
- **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
  - Addressed weaknesses in GTN studies in our protocol
- **Phase III trial recently initiated (November) with data in Q2 2012**
  - Licensor (SLA) is conducting trial
  - 465 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 on defecation using a validated scale**

VEN 307: Diltiazem Cream

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

ventrus BIOSCIENCES

Financial Summary

- **IPO in December 2010 (Over allotment in January 2011)**
  - Raised $20 million gross proceeds
    - 3.335 million shares purchased at $6.00
  - 3.420 million shares converted at IPO
  - Common Shares Outstanding after IPO 7.2 million (9.3 fully diluted)
  - Exchange: Nasdaq ("VTUS")

- **Capital (as of 12/31/2011)**
  - Cash and Short-term Investments $14.5 million
  - Over allotment (1/7/2011) $2.61 million
  - Debt $2.7 mm

Multiple Future Scenarios Possible: Iferanaserin and Diltiazem

- **Strategic options: after data readouts in H1 2012**
  - In 2012, 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:

- 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

Exhibit 99.2

Ventrus Adds Third Treatment Arm of Shorter Treatment Duration to Its Phase III Study of Iferanserin in Hemorrhoids

NEW YORK, NY MAY 2, 2011 –Ventrus BioSciences, Inc. (Nasdaq: VTUS-News) announced today that it has added a third treatment arm to its first pivotal Phase III study of Iferanserin (VEN 309), the first prescription product candidate for the treatment of hemorrhoids. The treatment arm has been added based upon a request from the U.S. Food and Drug Administration (FDA) in their response to the company's March 16, 2011 submission of the protocol for the study, made under a Special Protocol Assessment (SPA), and upon a new analysis of a prior Phase IIB study.

In its response, the FDA proposed that the company include an additional one week treatment arm in the pivotal study to evaluate whether patients could be fully treated within 7 days.

"When we analyzed our Phase IIb German study that compared Iferanserin given twice daily for 14 days, with placebo, using these endpoints, we observed that the majority of Iferanserin treated patients started their response by Day 3. This raises the possibility that Iferanserin therapy may require a shorter duration of treatment to show adequate efficacy to stop the bleeding, itching and pain associated with hemorrhoids," said Russell H. Ellison MD, CEO of Ventrus Biosciences. "It's not only good development practice to explore the possibility of a shorter treatment period as proposed by FDA's feedback, but should this regimen prove to be effective, it could be even more acceptable to patients" Dr. Ellison noted.

Following the feedback from the FDA, the double-blinded randomized trial design of the three arms would consist of:

Arm 1: placebo ointment twice daily intra-anally for 2 weeks;
Arm 2: Iferanserin ointment twice daily for 2 weeks; and
Arm 3: Iferanserin ointment twice daily for 1 week followed by placebo ointment twice daily for 1 week.

In its response to the SPA submission the FDA agreed with the definition of the primary and secondary endpoints that had been proposed and with the basic design elements of the study. The primary endpoint for all three arms will therefore be the proportion of patients who have no bleeding from the beginning of the 7^{th} day of treatment to the end of the 14^{th} and last day of treatment as previously announced. The secondary endpoints of pain and itching are similarly defined.

"We will go forward with the FDA proposal and submit a revised protocol under the SPA with the additional treatment arm in a timely fashion. We do not expect that this modification will materially change the timing to report the top line data, which we still expect will occur in the first quarter of 2012, in accordance with previous guidance," said Dr. Ellison.

About Iferanserin (VEN 309)

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 in the summer of 2011 and we expect data to be available in the first quarter of 2012.

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 is Iferanserin (VEN 309) for the topical treatment of hemorrhoids. 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.

CONTACT: Ventrus Biosciences, Inc.

David Barrett

646-706-5208

dbarrett@ventrusbio.com

Source: Ventrus Biosciences