

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): January 13, 2012

VENTRUS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-35005

(Commission File
Number)

20-8729264

(IRS Employer ID Number)

99 Hudson Street, 5th Floor, New York, New York

(Address of principal executive offices)

10013

(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 January 13, 2012, Ventrus Biosciences, Inc. issued a press release announcing the publication of the prior phase 2b study for iferanserin (VEN 309) for the treatment of hemorrhoid disease, in the peer reviewed journal *Clinical Therapeutics*. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated January 13, 2012.

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: January 13, 2012

By: /s/ David J. Barrett

David J. Barrett, Chief Financial Officer

Ventrus Announces Publication of Prior Phase 2b Study on the Safety and Efficacy of Iferanserin in the Treatment of Hemorrhoid Disease

NEW YORK, January 13, 2011 -- Ventrus Biosciences, Inc. (Nasdaq:VTUS), today announced the online publication of the prior Phase 2b study utilizing iferanserin (VEN 309), its novel investigational drug for the treatment of symptomatic hemorrhoids, in the peer reviewed journal *Clinical Therapeutics*. The article will appear in the February issue of *Clinical Therapeutics* and is currently available online at the following link <http://www.sciencedirect.com/science/journal/aip/01492918>. Data from this trial have been previously disclosed by the company.

The double-blind, placebo-controlled study, conducted between September 2001 and August 2002, randomized 121 patients at five colorectal surgery sites in Germany. The principal investigator and lead author of the paper is Prof. Dr. Alexander Herold of Mannheim, Germany. Compared with placebo, iferanserin significantly reduced patient-reported severity of daily bleeding beginning at day 1 and itching beginning at day 2 ($P < 0.05$). The effects were sustained throughout the 14-day treatment period. There was also a reduction in patient-reported severity of daily pain seen with iferanserin treatment. Adverse events were mild and infrequent and did not differ significantly between treatment groups.

The paper also presents the results from a post hoc analysis of the data using endpoints that Ventrus has adopted for its ongoing Phase 3 pivotal trial being conducted in 600 patients at 70 centers in the US. The primary endpoint in this ongoing Phase 3 study is cessation of bleeding by day 7 through day 14 (second week of treatment). In the German Phase 2b study, it was determined that 57% of iferanserin-treated patients had cessation of bleeding versus only 20% of placebo-controlled patients ($P = 0.0001$). The secondary endpoints of the ongoing Phase 3 study are cessation of itching and pain by day 7 through day 14. In the German Phase 2b study, the data showed that 59% of iferanserin-treated patients versus 32% of placebo-controlled patients ($P = 0.034$) had cessation of itching, while pain ceased at day 7 and did not return by day 14 in 50% of iferanserin-treated patients versus 18% of placebo-treated patients ($P = 0.032$).

“The findings of this Phase 2b German trial were significant in defining the targeted patient population and developing meaningful endpoints for our ongoing pivotal Phase 3 trial for iferanserin. The therapeutic benefits observed in the Phase 2b trial suggest a potential role for iferanserin for the treatment of symptomatic hemorrhoids.” said Dr. Russell Ellison, Chairman and Chief Executive Officer of Ventrus Biosciences, Inc.

Dr. Ellison elaborated, “As recently observed through our omnibus market research, consumers who have suffered from hemorrhoids in the past year constitute approximately 10% of the US adult population, with the vast majority seeking a medical solution.”

Ventrus anticipates reporting the top line data from its ongoing US Phase 3 trial of iferanserin in hemorrhoids in June of 2012, and the data from the European Phase 3 trial of VEN 307 (diltiazem cream) for the treatment of anal fissure in May 2012 (this study completed enrollment in December 2011).

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: Ifersanerin (VEN 309) for the topical treatment of hemorrhoids, for which the first Phase 3 clinical trial began in August 2011 and is ongoing, and topical diltiazem (VEN 307) for the treatment of anal fissures for which the first Phase 3 trial was initiated in November 2010, and is ongoing. Our product candidate portfolio also includes topical phenylephrine (VEN 308) intended to treat fecal incontinence. 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. VEN 309 is a New Chemical Entity (NCE).

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; 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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