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): June 25, 2012

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 8.01. Other Events.

On June 25, 2012, Ventrus Biosciences, Inc. issued a press release announcing that its Phase 3, randomized, double-blind, placebo-controlled clinical trial of iferanserin (VEN 309) in patients with hemorrhoidal disease did not meet its endpoints. 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 June 25, 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: June 25, 2012

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

Exhibit 99.1

VENTRUS BIOSCIENCES ANNOUNCES RESULTS FROM PIVOTAL PHASE 3 TRIAL OF IFERANSERIN (VEN 309) IN PATIENTS WITH HEMORRHOIDAL DISEASE

Company to Host Conference Call Today, June 25, at 9:00 a.m. ET

NEW YORK, JUNE 25, 2012 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS) today reported that its Phase 3, randomized, double-blind, placebo-controlled clinical trial of iferanserin (VEN 309) in patients with hemorrhoidal disease did not meet its endpoints.

The Phase 3 trial randomized 603 patients to one of three, twice-daily treatment groups: 7 days of active treatment followed by 7 days of placebo, 14 days of active treatment, or 14 days of placebo treatment. Elimination of bleeding from day 7 through day 14 of treatment was the primary endpoint, with elimination of itching and pain from day 7 through day 14 as the secondary endpoints. Results of this large, well-controlled study failed to demonstrate an improvement for therapy, in either treatment arm, over placebo for the primary and secondary endpoints. Adverse events were similar for the three treatment arms, with 6 severe adverse events reported (3 treatment emergent, one in each group), none of which were deemed to be related to study drug.

While the Company intends to analyze the totality of its Phase 3 data further, it believes that current resources would be better allocated toward the planned completion of its VEN 307 (diltiazem cream) development program in anal fissures and the beginning of further development of VEN 308 (topical phenylephrine) in fecal incontinence. Consequently, Ventrus has no immediate plans to continue development of VEN 309, resulting in a reduction in expenses.

“We would like to thank both investigators and patients for their support and participation in this study and in the VEN 309 program. The outcome of our Phase 3 study comes as a surprise and a disappointment, particularly given the strong evidence of activity in our Phase 2 randomized study,” said Russell H. Ellison, M.D., M.Sc., Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. “Despite this setback, we remain excited about our pipeline and, with a strong cash position, plan to refocus our efforts on taking VEN 307 forward toward registration as a treatment for anal fissures. VEN 307 recently demonstrated a positive outcome in all key measures of efficacy – pain on defecation, overall pain and healing – in this indication in its first Phase 3 study. With the planned elimination of all VEN 309-related expenses, we believe the company is sufficiently capitalized to take VEN 307 through a second Phase 3 study and to approval.”

Ventrus reported in May positive results from its Phase 3, randomized, double-blind, placebo-controlled clinical trial of diltiazem (VEN 307) in patients with anal fissures (AF). The Phase 3 study randomized 465 patients to diltiazem hydrochloride 4% or 2% w/w cream, or placebo, applied topically three times daily (TID) for 8 weeks, followed by a 4 week blinded observation period. Both 4% and 2% diltiazem treatment arms demonstrated significant improvements compared to placebo in the primary endpoint of average of worst anal pain associated with or following defecation and in the secondary endpoints of overall anal-fissure-related pain and anal fissure healing. Adverse events were similar for the three treatment arms. Ventrus plans to meet with the US Food and Drug Administration (FDA) to discuss the Phase 3 diltiazem trial and undertake steps to move forward toward a New Drug Application (NDA). Ventrus is also preparing to initiate a second pivotal Phase 3 trial of VEN 307 in AF, expected to begin in the fourth quarter of 2012. Ventrus holds rights to diltiazem hydrochloride cream in North America.

Dr. Ellison added: “We look forward to meeting with the FDA to discuss VEN 307, and expect to be in a position to communicate the outcome of this meeting in the Fall of this year. We are encouraged that a number of drugs have been approved by the FDA with similar improvements in pain over placebo as those seen in our Phase 3 study of VEN 307.”

The products approved for pain indication with similar differences in treatment over placebo include pregabalin for neuropathic pain; duloxetine for diabetic peripheral neuropathy pain, fibromyalgia, and chronic musculoskeletal pain; and diclofenac sodium topical gel for osteoarthritis pain.

Ventrus’ product candidate portfolio also includes VEN 308, intended to treat fecal incontinence. “In addition to VEN 307, we look forward to beginning the advancement of our VEN 308 program, as we believe an aging population and increase in gastroenterologic procedures has created a heightened demand for new and better options in managing fecal incontinence,” Dr. Ellison added.

Conference Call
The Company is hosting a conference call to discuss results from the Phase 3 iferanserin (VEN 309) study, and its plans for moving the Company forward, today, June 25, at 9:00 a.m. Eastern Time. To participate in the call, interested parties may dial 1-866-428-9517 (Toll-Free/North America) or 1-224-357-2222 (International/Toll) and use Conference ID: 95092830 to register ten minutes before the call is scheduled to begin. The call and presentation will be broadcast live on the internet at http://www.ventrusbio.com.

The call will be archived for replay on June 25 at 12:00 p.m. ET and will remain available until July 2. The replay can be accessed at 1-855-859-2056 (Toll-Free/North America) or 1-404-537-3406 (International/Toll) using Conference ID: 95092830. An audio replay of the call will also be available on the Company's website, http://www.ventrusbio.com, for 30 days after 12:00 p.m. ET, June 25.

About Ventrus
Ventrus is a development stage pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders. Our lead product is topical diltiazem (VEN 307) for the treatment of anal fissures for which the first Phase 3 trial was initiated in November 2010, and reported positive top line results in May 2012. 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.

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; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; the future trading prices of our common stock and the impact of securities analysts' reports on these prices; our reliance on our lead product candidate VEN 307; the unpredictability of the size of the markets for, and market acceptance of, any of our products; 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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