

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 22, 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 June 22, 2011, Ventrus Biosciences, Inc. issued a press release announcing that it had received a response from the U.S. Food and Drug Administration to its last special protocol assessment submission and that it will file the first pivotal trial protocol to its investigational new drug application for iferanserin (VEN 309) for the treatment of hemorrhoids. A copy of the press release is attached as Exhibit 99.1 to this report and 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 June 22, 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: June 22, 2011

/s/ David J. Barrett

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David J. Barrett, Chief Financial Officer

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**VENTRUS RECEIVES SPA RESPONSE FROM FDA AND WILL UPDATE AND FILE THE FIRST PIVOTAL TRIAL PROTOCOL TO ITS IND**

NEW YORK, NY JUNE 22, 2011 – Ventrus BioSciences, Inc. (Nasdaq: VTUS) announced today that it has received a response from the U.S. Food and Drug Administration (FDA) to its last Special Protocol Assessment (SPA) submission for iferanserin (VEN 309) for the treatment of hemorrhoids, and will update the protocol for the company's first pivotal trial for iferanserin and file it to its investigational new drug application (IND), so that the trial can start as planned.

In its response, the FDA requested that additional information be included in the protocol pertaining to certain details of the trial. None of these new recommendations affect the previous recommendations made by the FDA for the endpoints, overall statistical powering and subject number, and the overall clinical design of the trial. Ventrus agrees with all of these new recommendations and will update the protocol accordingly and submit it to the IND.

“The Special Protocol Assessment process for our first pivotal trial with iferanserin (VEN 309) for the treatment of hemorrhoids has been very productive considering that this could be the first new drug application ever filed for a drug in this indication,” said Dr. Russell Ellison, Chief Executive Officer of Ventrus. “This process involved considerable work and thought at the FDA, and though we have not received a final agreement letter, we have implemented all of the suggestions and recommendations of the FDA on the major and important elements of the protocol, including, the definitions of the primary and secondary endpoints, overall design, regimens and doses, basic inclusion and exclusion criteria as well as overall statistical powering and the basic analysis methods. In addition, the definition of the endpoints that the FDA proposed referring to cessation, not just improvement of symptoms, and the addition the FDA proposed of the 7 day treatment arm, are important enhancements to our program. Given the substantial progress that we have made with the FDA in this process, we have decided to proceed with directly implementing our protocol with all FDA recommended changes without further pursuing the SPA,” he said.

**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 pivotal Phase III clinical trial 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.*

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Source: Ventrus Biosciences

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