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 25, 2013

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 November 25, 2013, Ventrus Biosciences, Inc. issued a press release announcing the completion of enrollment in its second pivotal Phase 3 trial of diltiazem cream (VEN 307) in patients with anal fissure. 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 November 25, 2013.

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 25, 2013

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

EXHIBIT 99.1

VENTRUS BIOSCIENCES COMPLETES ENROLLMENT OF SECOND PIVOTAL PHASE 3 TRIAL OF DILTIAZEM CREAM (VEN 307) IN PATIENTS WITH ANAL FISSURE

Results Expected First Quarter 2014; NDA Filing Expected to Occur in Second Quarter 2014

NEW YORK, November 25, 2013 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS) announced that it has completed patient enrollment and randomization in the second Phase 3 clinical trial of Diltiazem Hydrochloride 2% Cream (VEN 307) in patients with pain related to anal fissure (AF). Ventrus anticipates that data from this Phase 3 study will be available in the first quarter of 2014, and it expects to file a New Drug Application (NDA) for VEN 307 in the second quarter of 2014.

The second pivotal Phase 3 trial, a randomized, double-blind, placebo-controlled, parallel-treatment group, multicenter efficacy and safety study of VEN 307 in subjects with AF, enrolled 434 subjects and is being conducted at 90 global clinical sites, with the majority of sites and patients located in the United States. Enrollment into this trial began in October 2012.

The study’s primary objective is to evaluate the efficacy of VEN 307 on reduction of worst AF-related pain associated with or following defecation when administered three times a day (TID) for 28 days. The secondary objectives are to evaluate the effect of VEN 307 on reduction of overall daily AF-related pain and to evaluate patient global impression of improvement (PGI-I) at Day 29 in subjects with AF-related pain. To be eligible for randomization into the study, all patients had to have sufficient baseline AF-related pain associated with or following defecation of ≥5 on an 11-point numerical rating score (NRS) scale with 0 being no pain and 10 being the worst possible pain.

"This is an important milestone in the clinical development of VEN 307, and marks completion of enrollment in the second of two pivotal clinical trials for the treatment of anal fissures," said Dr. Russell Ellison, Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. "Ventrus is focused on bringing the treatment of anal fissures into the modern medical era by developing the first non-nitroglycerin prescription pharmaceutical treatment for FDA approval, an advancement which could benefit patients who suffer from this extremely painful condition.”

In May 2012, Ventrus reported that its first pivotal Phase 3, randomized, double-blind, placebo-controlled clinical trial of VEN 307 for the treatment of anal fissures met its endpoints. The trial randomized 465 subjects to diltiazem hydrochloride 4% or 2% w/w cream, or placebo, applied topically TID for 8 weeks, followed by a 4 week blinded observation period. At 4 weeks, the 2% diltiazem treatment arms demonstrated improvements compared to placebo in the primary endpoint of average of worst anal pain associated with or following defecation (pain score improvement of 0.43, p=0.0122) and in the secondary endpoints of overall anal-fissure-related pain (pain score of 0.42, p=0.0143). Pain endpoints were assessed using an 11-point numerical pain rating scale (Likert-like scale).

Because diltiazem is approved in oral formulations for the treatment of angina and high blood pressure, VEN 307 is eligible for the FDA's 505(b)2 registration pathway.

About VEN 307: Diltiazem Hydrochloride Cream

Diltiazem hydrochloride is a calcium-channel blocker that has been marketed in oral formulations for the treatment of angina and high blood pressure for over two decades. Diltiazem hydrochloride cream is applied perianally to treat pain related to anal fissure. It has been shown to normalize internal anal sphincter pressure and reduce anal maximal resting pressure, or MRP, and its vasodilator activity has the potential to improve blood supply, thereby decreasing the pain associated with anal fissures.

About Anal Fissures

Anal fissure is a tear in the lining of the anal canal characterized by severe anal pain associated with or after bowel movements. It is a common anal disorder, which we believe is underdiagnosed. The pathogenesis of anal fissure is hypothesized to be initiated by the passage of a hard fecal bolus, resulting in a split in the epithelium of the anal canal. Along with poor vascular supply of the anal epithelium, increased activity (tone) of the internal anal sphincter smooth muscle further compromises the anodermal blood supply and contributes to the pain and ischemia of the anal epithelium, perpetuating ulceration and preventing healing.

In 2010, it was estimated by SDI Health LLC that there were approximately 1.1 million office visits per year for anal fissures. Topical diltiazem, which is not approved by the FDA as a use for anal fissure, is currently listed in the U.S. anal fissure treatment guidelines as a preferred agent prior to attempting surgery, and is available only as a compounded medicine.

About Ventrus

Ventrus is a specialty pharmaceutical company primarily focused on the development and commercialization of prescription drugs addressing gastrointestinal problems. The Company’s lead product, topical diltiazem (VEN 307) for the treatment of anal fissures, reported positive top line results in May 2012. The second Phase 3 trial has now completed enrollment and is expected to report out data in the first quarter of 2014, with a NDA filing expected in the second quarter of 2014. Ventrus’ product candidate portfolio also includes topical phenylephrine (VEN 308) intended to treat fecal incontinence. The Company has also recently licensed intellectual property and know-how relating to the oral delivery of bacteria, viruses and drugs to specific sites in the intestine, using a pH sensitive controlled release platform technology. The potential indication areas include (i) gastro-intestinal, auto-immune and metabolic disorders, (ii) viral and bacterial vaccines, and (iii) optimized colonic delivery of drugs.

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 components, 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; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; our reliance on our lead product candidate, VEN 307; 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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