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Ventrus Biosciences Reports Third Quarter 2012 Financial Results

NEW YORK, Nov. 13, 2012 (GLOBE NEWSWIRE) -- Ventrus Biosciences, Inc. (Nasdaq:VTUS) today reported financial results for the third quarter ended September 30, 2012.

"Following a successful discussion with the FDA and receipt of written feedback from our meeting, we now have a clear path forward toward the submission of a new drug application for VEN 307 as a treatment for anal fissures," said Russell H. Ellison, M.D., M.Sc., Chairman and Chief Executive Officer of Ventrus Biosciences, Inc. "This includes completion of a second Phase 3 trial, which began enrolling patients in November, is expected to be complete by the fourth quarter of 2013 and should serve as confirmation of the positive results we saw in our first Phase 3 study. Anal fissures represent a significant market opportunity, one with no treatment standard and a concentrated prescriber base among gastroenterologist and colorectal surgeons."

For the three months ended September 30, Ventrus's operating loss was $5.4 million which included approximately $735,000 in non-cash stock based compensation expense. Operating loss for the nine months ended September 30, 2012 was approximately $21.0 million which included approximately $2.5 million in non-cash stock based compensation expense. General and administrative expense was $1.1 million for the third quarter of 2012, compared to $1.9 million for the same period in 2011. The decrease was primarily due to a decrease in stock option and warrant expense. Research and development expense was $4.2 million for the third quarter of 2012, compared to $3.7 million for the same period in 2011. The increase was primarily due to the costs associated with closing out the Phase III clinical trial for VEN 309 and manufacturing costs to support future clinical studies for VEN 307.

At September 30, 2012, cash and cash equivalents were approximately $23.6 million, compared to approximately $37.0 million at December 31, 2011. Gross cash spend in the third quarter 2012 was approximately $5.3 million, as compared to approximately $5.6 million in the same period in the prior year. Average monthly gross spend was approximately $1.8 million in the third quarter, as compared to approximately $2.3 million in the second quarter of 2012. Ventrus expects average monthly cash spend to decrease by approximately $1 million per month for the remainder of the year.

About Ventrus

Ventrus is a development stage pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal problems, specifically anal 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. The second Phase 3 trial began enrollment in the fourth quarter of 2012 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.

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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Source: Ventrus Biosciences