Vitae Pharmaceuticals Reports Third Quarter 2015 Operating and Financial Results

November 5, 2015 4:06 PM ET

Announces psoriasis as lead indication for VTP-43742

Conference call scheduled for 4:30 p.m. EST today

FORT WASHINGTON, Pa., Nov. 5, 2015 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company developing a robust and growing portfolio generated by its proprietary structure-based drug discovery platform, today reported its operating and financial results for the third quarter ended September 30, 2015.

Jeff Hatfield, President and Chief Executive Officer of Vitae, commented, "During the third quarter of 2015, Vitae continued to make meaningful progress with our lead assets, generating positive Phase 1 clinical trial data for VTP-43742, our wholly owned, first-in-class RORgt inhibitor, and advancing it into a Phase 1 clinical trial with psoriasis patients. In addition, we advanced VTP-38543, our wholly owned, potential first-in-class LXRβ selective agonist, towards Phase 1 initiation. After a comprehensive evaluation, we have selected moderate to severe psoriasis as the first autoimmune disorder indication we'll pursue for VTP-43742. We made this decision based on the well-validated clinical benefit achieved with injectable antibodies targeting this disease pathway and our belief in the high probability of technical success. Further, we expect that this indication will represent the fastest timeline to filing a New Drug Application compared to the other indications we evaluated. Most importantly, we believe VTP-43742 has the potential to address a significant unmet medical need and deliver an effective, safe and convenient once-a-day oral therapy option to millions of psoriasis patients worldwide."

Quarterly and Recent Highlights

Pipeline Updates:

VTP-43742 in Autoimmune Disorders

- **Announced positive top-line results from its Phase 1 single ascending dose clinical trial of VTP-43742.** In a double-blind, randomized, placebo-controlled trial that evaluated the safety, tolerability, pharmacokinetic, and pharmacodynamic profile of single oral doses of VTP-43742 in 53 healthy human volunteers, VTP-43742 was shown to be safe and generally well tolerated at all dose levels across a 60-fold dose range with pharmacokinetics consistent with once-a-day dosing. VTP-43742 was also evaluated in an *ex vivo* assay for its ability to inhibit the production of pro-inflammatory cytokine IL-17A in blood obtained from trial subjects. There was a clear dose response, and at multiple doses, subjects who received VTP-43742 showed a suppression of RORγt dependent IL-17A production of more than 90 percent, with the effect largely sustained over the full 24-hour measurement period.

- **Vitae initiated both parts of a Phase 1b multiple ascending dose proof-of-concept clinical trial of VTP-43742, its first-in-class RORγt inhibitor candidate for the treatment of autoimmune disorders.** This trial will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of VTP-43742 in both healthy human volunteers and psoriatic patients. The first part is designed to enroll up to 48 healthy human volunteers over multiple cohorts, with results expected in the fourth quarter of 2015. In the second, proof-of-concept part of the trial, Vitae will evaluate multiple ascending doses of VTP-43742 in patients with moderate to severe psoriasis. The primary endpoint measure will be a percent change from baseline in the PASI (Psoriasis Area and Severity Index) score at four weeks. Due to a slower than projected initial rate of enrollment, top-line proof-of-concept results are now expected in the first quarter of 2016.

VTP-38543 in Atopic Dermatitis

- **Vitae continued to advance VTP-38543, its first-in-class LXR agonist product candidate for the treatment of atopic dermatitis.** Vitae plans to initiate a Phase 1 clinical trial in the fourth quarter of 2015. Phase 1 efficacy proof-of-concept results are expected in 2016.

Financial Results:

- **Operating Expense.** Total operating expenses for the third quarter of 2015 were $13.3 million, compared with $7.9 million for the third quarter of 2014.
  - Research and development expenses were $10.7 million for the third quarter of 2015, compared with $4.8 million for the same period in 2014. The increase was largely attributable to expenses related to the RORγt program, including VTP-43742; the atopic dermatitis program, including VTP-38543; and discovery efforts.
  - General and administrative expenses were $2.7 million for the third quarter of 2015, compared with $3.1 million for the same period in 2014. The decrease was primarily due to reduced stock-based compensation expenses, partially offset by an increase in costs related to being a public company.

- **Net Loss.** Vitae reported a net loss of $13.1 million for the third quarter of 2015, compared with a net loss of $1.8 million for the third quarter of 2014. The increase in net loss was primarily due to the increase in research and development expenses and a $6.0 million milestone payment earned in the third quarter of 2014.

- **Cash Position.** As of September 30, 2015, Vitae had $69.3 million in cash, cash equivalents and marketable securities, compared to $65.3 million as of December 31, 2014. The slight increase in cash position was primarily a result of the completion of the Company's follow-on public offering in the first quarter of 2015, offset by cash outflows used in operating activities. Based on its current operating plan, Vitae believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund its projected operating requirements through the end of 2016.

Expected Upcoming Events

- **VTP-43742 in Autoimmune Disorders** – Results from the first part of the multiple ascending dose Phase 1b trial in healthy human volunteers in the fourth quarter of 2015.

- **VTP-43742 in Autoimmune Disorders** – Top-line proof-of-concept results from part two of the multiple ascending dose Phase 1b clinical trial in psoriatic patients in the first quarter of 2016.

- **VTP-38543 in Atopic Dermatitis** – Initiation of a Phase 1 clinical trial in the fourth quarter of 2015.

- **BI187004 in Type 2 Diabetes** – Top-line data from the remaining placebo-controlled monotherapy arm of the Phase 2a proof-of-concept trial in the fourth quarter of 2015.

- **VTP-36951 in Alzheimer's Disease** – Vitae is continuing to assess the BACE program to determine appropriate next steps and expects to provide an update on its plans in the first half of 2016.

Company to Host Conference Call

Vitae will host a conference call today, November 5, 2015, at 4:30 p.m. EST to discuss the company's financial results for the quarter ended September 30, 2015, and recent operational highlights. A question and answer session will follow Vitae's remarks. To participate on the live call, please dial 844-423-9893 (domestic) or +1-716-247-5808 (international), and provide the conference ID 70141193, approximately five to 10 minutes ahead of the start of the call.

A live audio webcast of the call will be available via the "Investor Relations" page of the Vitae website, www.vitaepharma.com. Please log on through Vitae's website approximately 10 minutes prior to the scheduled start time.

A replay of the webcast will be archived on Vitae's website for 90 days following the call.

About Vitae Pharmaceuticals

Vitae Pharmaceuticals is a clinical-stage biotechnology company focused on discovering and developing first-in-class, small molecule drugs for difficult-to-drug disease targets that address significant unmet medical needs, including programs in autoimmune disorders, atopic dermatitis, Alzheimer's disease and diabetes. This robust and growing portfolio of novel product candidates is generated internally by Contour®, Vitae's proprietary structure-based drug discovery platform.

For additional information, please visit the company's website at www.vitaepharma.com.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended including statements regarding the clinical development of VTP-43742 and VTP-38543. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan," "impending" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Vitae is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in Vitae's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Vitae's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Vitae and its collaborative partners; the ability to obtain and maintain regulatory approval of Vitae's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Vitae's product candidates; the size and growth of the potential markets for Vitae's product candidates and the ability to serve those markets; Vitae's expectations regarding Vitae's expenses and revenue, the sufficiency of Vitae's cash resources and needs for additional financing; Vitae's ability to attract or retain key personnel; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vitae's Annual Report on Form 10-K for the year ended December 31, 2014 and Vitae's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 which have been filed with the Securities and Exchange Commission (SEC). Additional factors may also be set forth in those sections of Vitae's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 to be filed with the SEC in the fourth quarter of 2015. In addition to the risks described above and in Vitae's other filings with the SEC, other unknown or unpredictable factors also could affect Vitae's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Vitae undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

Vitae Pharmaceuticals, Inc.

Statement of Operations (unaudited)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2015	**2014**	**2015**	**2014**
Collaborative revenues	$ 175,756	$ 6,178,166	$ 487,583	$ 8,507,113
Operating expenses:				

Research and development	10,665,585	4,799,268	25,944,323	14,224,526
General and administrative	2,671,580	3,096,399	7,041,994	5,724,690
Total operating expenses	13,337,165	7,895,667	32,986,317	19,949,216
Loss from operations	(13,161,409)	(1,717,501)	(32,498,734)	(11,442,103)
Other income (expenses):				
Other income	--	125,544	1,430	343,318
Interest income	95,967	7,894	277,980	36,709
Interest expense	(114)	(225,355)	(107,978)	(766,392)
Loss on debt extinguishment	--	--	(206,678)	--
Total other income (expenses)	95,853	(91,917)	(35,246)	(386,365)
Net loss	$ (13,065,556)	$ (1,809,418)	$ (32,533,980)	$ (11,828,468)
Per share information:				
Net loss per common share:				
Basic	$ (0.60)	$ (1.06)	$ (1.51)	$ (12.18)
Diluted	$ (0.60)	$ (1.06)	$ (1.51)	$ (12.18)
Weighted-average number of common shares:				
Basic	21,853,530	1,711,969	21,483,233	971,439
Diluted	21,853,530	1,711,969	21,483,233	971,439

Vitae Pharmaceuticals, Inc.

Selected Balance Sheet Data

	As of September 30, 2015 (unaudited)	**As of December 31, 2014**
Cash, cash equivalents and marketable securities	$ 69,326,306	$ 65,318,300
Working capital	63,705,808	57,970,386
Current liabilities	7,641,791	8,864,107
Common stock and APIC	226,898,892	188,737,768
Total stockholder's equity	64,374,050	58,718,051

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