Vitae Pharmaceuticals Reports Fourth Quarter and Full Year 2015 Operating and Financial Results

March 3, 2016 4:07 PM ET

Proof-of-concept data for VTP-43742 expected in the first quarter of 2016

Initiated proof-of-concept trial of VTP-38543 in patients with atopic dermatitis

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

FORT WASHINGTON, Pa., March 03, 2016 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today reported its operating and financial results for the fourth quarter and full year ended December 31, 2015.

Jeff Hatfield, President and Chief Executive Officer of Vitae, commented, "Our accomplishments during the fourth quarter and full year of 2015 position Vitae to deliver proof-of-concept data for both of our lead product candidates in 2016. Results for VTP-43742, our wholly owned, first-in-class RORγt inhibitor being developed for moderate to severe psoriasis, are expected to be disclosed in the first quarter of 2016. We anticipate results for VTP-38543, our wholly owned, potential first-in-class LXRβ selective agonist being developed for atopic dermatitis, in the second half of 2016."

Quarterly and Recent Highlights

Pipeline Updates:

VTP-43742 in Autoimmune Disorders

- **Reported positive top-line results from the healthy human volunteer multiple ascending dose clinical trial of VTP-43742.** In this double-blind, randomized, placebo-controlled trial examining the safety, tolerability, pharmacokinetic and pharmacodynamic profile of multiple oral doses of VTP-43742 in 40 healthy human volunteers, VTP-43742 was shown to be safe and generally well tolerated. No serious adverse events were reported, and all study subjects completed the full 10 days of dosing. In an *ex vivo* assay, VTP-43742 suppressed the RORγt dependent production of the pro-inflammatory cytokine IL-17A in blood obtained from study subjects. Those who received VTP-43742 showed a dose-dependent suppression of IL-17A production by more than 90 percent sustained for a full 24 hours in all but the lowest dose cohort.

- **Advanced the second part of a multiple ascending dose, clinical proof-of-concept trial of VTP-43742 in psoriatic patients.** In this study, Vitae is evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and clinical efficacy of multiple ascending doses of VTP-43742 in patients with moderate to severe psoriasis. The primary endpoint measure will be percent change from baseline in the PASI (Psoriasis Area and Severity Index) score at four weeks. The Company has closed enrollment at 34 psoriatic patients and believes that the totality of the data from the 34 psoriatic patients, including clinical efficacy and accelerated biomarker data, will be sufficient to determine next steps in the program. Vitae is currently analyzing the data and expects to announce top-line clinical efficacy and preliminary biomarker results by the end of the first quarter of 2016.

VTP-38543 in Atopic Dermatitis

- **Initiated a Phase 2a proof-of-concept clinical trial of VTP-38543 in atopic dermatitis (AD).** This four-week, randomized, double-blind, placebo controlled Phase 2a trial will assess the safety, tolerability, efficacy, pharmacokinetics and pharmacodynamics of multiple ascending topical doses of VTP-38543 in approximately 100 adult patients with mild to moderate AD. The Company expects to report top-line efficacy results in the second half of 2016.

Corporate Update:

- **Added to the NASDAQ Biotechnology Index (NASDAQ:NBI).**

Financial Results:

- **Operating Expense.** Total operating expenses for the fourth quarter of 2015 were $11.9 million, compared with $7.3 million for the fourth quarter of 2014.
  - Research and development expenses were $9.6 million for the fourth quarter of 2015, compared with $5.1 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 $2.3 million for the fourth quarter of 2015, compared with $2.2 million for the same period in 2014. The slight increase was primarily due to an increase in stock-based compensation expense.

- **Net Loss.** Vitae reported a net loss of $11.4 million, or $0.52 per diluted share, for the fourth quarter of 2015, compared with a net loss of $7.3 million, or $0.40 per diluted share, for the fourth quarter of 2014. The increase in net loss was primarily due to the increase in research and development expenses.

- **Cash Position.** As of December 31, 2015, Vitae had $59.4 million in cash, cash equivalents and marketable securities, compared to $65.3 million as of December 31, 2014. The decrease in cash position was primarily a result of cash outflows used in operating activities, partially offset by the completion of a follow-on public offering in January 2015. Based on its current business 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** – Top-line proof-of-concept results from part two of the multiple ascending dose clinical trial in psoriatic patients in the first quarter of 2016.

- **VTP-38543 in Atopic Dermatitis** – Top-line proof-of-concept results from a clinical trial in mild to moderate atopic dermatitis patients in the second half of 2016.

- **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, March 3, 2016, at 4:30 p.m. EST to discuss the company's financial results for the quarter ended December 31, 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 57209176, 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 developing first-in-class product candidates with potential to transform the treatment paradigm for patients with significant unmet medical needs. Initial indications being pursued include psoriasis, other autoimmune disorders, and atopic dermatitis. Vitae's lead clinical assets include VTP-43742, an oral RORgt inhibitor currently being studied in patients with moderate to severe psoriasis, and VTP-38543, an LXRβ selective agonist being studied in patients with mild to moderate atopic dermatitis.

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 and the company's projected operating expenses. 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 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 September 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 Annual Report on Form 10-K for the year ended December 31, 2015 to be filed with the SEC. 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

	Three Months Ended December 31,		**Twelve Months Ended December 31,**	
	2015	**2014**	**2015**	**2014**
Collaborative revenues	$ 92,091	$ 161,673	$ 579,674	$ 8,668,786
Operating expenses:				
Research and development	9,607,071	5,080,317	35,551,394	19,304,843
General and administrative	2,276,282	2,189,157	9,318,276	7,913,847
Total operating expenses	11,883,353	7,269,474	44,869,670	27,218,690
Loss from operations	(11,791,262)	(7,107,801)	(44,289,996)	(18,549,904)
Other income (expenses):				
Other income	260,573	-	262,003	343,318
Interest income	82,001	27,223	359,981	63,932
Interest expense	-	(194,360)	(107,978)	(960,752)
Loss on debt extinguishment	-	-	(206,678)	-
Total other income (expenses)	342,574	(167,137)	307,328	(553,502)

Net loss	$ (11,448,688)	$ (7,274,938)	$ (43,982,668)	$ (19,103,406)
Per share information:				
Net loss per common share:				
Basic	$ (0.52)	$ (0.40)	$ (2.03)	$ (3.61)
Diluted	$ (0.52)	$ (0.40)	$ (2.03)	$ (3.61)
Weighted-average number of common shares:				
Basic	21,942,901	18,113,997	21,626,151	5,290,534
Diluted	21,942,901	18,113,997	21,626,151	5,290,534

Vitae Pharmaceuticals, Inc.

Selected Balance Sheet Data

	As of December 31, 2015	**As of December 31, 2014**
Cash, cash equivalents and marketable securities	$ 59,369,836	$ 65,318,300
Working capital	53,807,249	57,970,386
Current liabilities	7,329,754	8,864,107
Common stock and APIC	228,463,162	188,737,768
Total stockholder's equity	54,467,750	58,718,051

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