Vitae Pharmaceuticals Reports First Quarter 2016 Operating and Financial Results

May 10, 2016 4:01 PM ET

Proof-of-concept data for VTP-38543 expected in the second half of 2016

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

FORT WASHINGTON, Pa., May 10, 2016 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today reported its operating and financial results for the quarter ended March 31, 2016.

Jeff Hatfield, President and Chief Executive Officer of Vitae, commented, "The highlight of the first quarter was the positive top-line results from Vitae's Phase 2a proof-of-concept clinical trial of VTP-43742, our wholly owned, first-in-class RORγt inhibitor, in psoriatic patients. We believe these results have validated RORγt as a therapeutic target for psoriasis and possibly other autoimmune disorders, and VTP-43742 as a potentially paradigm-changing therapeutic. We now anticipate reporting 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. In addition, Vitae recently completed a follow-on offering, providing us with sufficient resources to continue to develop our proprietary pipeline."

Quarterly and Recent Highlights

Pipeline Updates:

VTP-43742 in Autoimmune Disorders

- **Reported positive top-line results from its Phase 2a proof-of-concept clinical trial of VTP-43742 in psoriatic patients.** VTP-43742 demonstrated a clear signal of efficacy in this randomized, double-blind, placebo-controlled trial that assessed the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral doses of VTP-43742 in patients with moderate to severe psoriasis over a four-week period. While full efficacy in psoriasis is not generally seen until at least 12 weeks of continuous therapy, the PASI (Psoriasis Area Severity Index) score reductions observed for VTP-43742 at four weeks, and the acceleration of rate of PASI reduction between weeks three and four, indicate the potential for greater efficacy with continued oral dosing beyond four weeks. VTP-43742 was shown to be generally well tolerated at all dose levels tested, with no serious adverse events reported. Vitae plans to advance VTP-43742 into a larger-scale, 16-week Phase 2 trial in the fourth quarter of 2016.

VTP-38543 in Atopic Dermatitis

- **Continued enrollment in its Phase 2a proof-of-concept clinical trial of VTP-38543 in atopic dermatitis.** 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 atopic dermatitis. Vitae expects to report top-line efficacy results in the second half of 2016.

Corporate Update:

- **Completed a follow-on public offering in March 2016.** Vitae issued and sold an aggregate of 6.6 million shares of common stock at a price of $6.00 per share. Net proceeds from the offering, including the underwriters' exercise of their option to purchase additional shares and subtracting the underwriting fees and expenses, were approximately $36.9 million.

Financial Results:

- **Operating Expense.** Total operating expenses for the first quarter of 2016 were $10.1 million, compared with $9.6 million for the first quarter of 2015.
    - Research and development expenses were $7.6 million for the first quarter of 2016, compared with $7.5 million for the first quarter of 2015. The slight increase was largely attributable to expenses related to the RORγt program, the atopic dermatitis program, discovery efforts and stock-based compensation, partially offset by reduced drug development and manufacturing expenses related to the RORγt program.
    - General and administrative expenses were $2.5 million for the first quarter of 2016, compared with $2.1 million for the first quarter of 2015. The increase was primarily due to an increase in stock-based compensation expense, legal fees and compensation expenses.
- **Net Loss.** Vitae reported a net loss of $10.0 million, or $0.44 per diluted share, for the first quarter of 2016, compared with a net loss of $9.7 million, or $0.47 per diluted share, for the first quarter of 2015. The increase in net loss was primarily due to the increase in general and administrative expenses.
- **Cash Position.** As of March 31, 2016, Vitae had $86.5 million in cash, cash equivalents and marketable securities, compared with $59.4 million as of December 31, 2015. The increase in cash position was primarily a result of the completion of the follow-on offering in March 2016, partially offset by cash outflows used in operating activities. 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 into the second half of 2018.

Expected Upcoming Events

- **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-43742 in Autoimmune Disorders** – Initiation of a larger-scale, 16-week Phase 2 trial in the fourth quarter of 2016.

Company to Host Conference Call

Vitae will host a conference call today, May 10, 2016, at 4:30 p.m. EDT to discuss the Company's financial results for the quarter ended March 31, 2016, 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 1781961, 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 RORγt 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, 2015, which is on file 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 March 31, 2016 to be filed with the SEC in the second quarter of 2016. 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 March 31,	
	2016	**2015**
Collaborative revenues	$ 51,353	$ 150,239
Operating expenses:		
Research and development	7,636,295	7,505,916
General and administrative	2,497,322	2,111,056
Total operating expenses	10,133,617	9,616,972
Loss from operations	(10,082,264)	(9,466,733)
Other income (expenses):		
Interest income	74,537	74,193
Interest expense	-	(107,864)
Loss on debt extinguishment	-	(206,678)
Total other income (expenses)	74,537	(240,349)
Net loss	$ (10,007,727)	$ (9,707,082)
Per share information:		
Net loss per common share:		
Basic	$ (0.44)	$ (0.47)
Diluted	$ (0.44)	$ (0.47)

Weighted-average number of common shares:		
Basic	22,543,505	20,826,647
Diluted	22,543,505	20,826,647

Vitae Pharmaceuticals, Inc.

Selected Balance Sheet Data

	As of March 31, 2016 (unaudited)	As of December 31, 2015
Cash, cash equivalents and marketable securities	$ 86,471,528	$ 59,369,836
Working capital	81,855,627	53,807,249
Current liabilities	5,802,774	7,329,754
Common stock and APIC	266,453,748	228,463,162
Total stockholder's equity	82,486,920	54,467,750

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