Vitae Pharmaceuticals Reports Second Quarter 2015 Operating and Financial Results

August 4, 2015 4:11 PM ET

Multiple potential milestones in 2H 2015

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

FORT WASHINGTON, Pa., Aug. 4, 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, reported today its operating and financial results for the second quarter ended June 30, 2015.

"During the second quarter of 2015, we initiated a Phase 1 study of VTP-43742, our first-in-class RORγt candidate for the treatment of autoimmune disorders. Initiation of this study was a major accomplishment for the team, as it positions the Company well to deliver expected proof-of-concept efficacy results for the program by the end of 2015," commented Jeff Hatfield, President and Chief Executive Officer of Vitae. "We also made progress in the development of our atopic dermatitis program, which we believe has the potential to address significant unmet medical need. We look forward to announcing multiple data milestones throughout the remainder of the year."

Quarterly and Recent Highlights

Pipeline Updates:

VTP-43742 in Autoimmune Disorders

- **Vitae initiated a Phase 1 single ascending dose clinical trial of VTP-43742, its first-in-class RORγt product candidate for the treatment of autoimmune disorders.** This trial will assess the safety, tolerability, pharmacokinetics and pharmacodynamics of VTP-43742 in approximately 56 healthy human volunteers over several cohorts, with results expected in the second half of 2015. The Company also intends to initiate an overlapping Phase 1 multiple ascending dose, proof-of-concept clinical trial of VTP-43742 in the third quarter of 2015, which will be a double-blind, placebo-controlled trial of approximately 48 healthy volunteers and approximately 60 patients with moderate to severe psoriasis. Top-line clinical efficacy results from the proof-of-concept trial are expected by the end of 2015.

VTP-38543 in Atopic Dermatitis

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

Partnered Programs:

- **Vitae announced top-line clinical efficacy results from the metformin arm of an ongoing Phase 2 proof-of-concept clinical trial of BI187004/VTP-34072 in the treatment of overweight type 2 diabetic patients**. Primary efficacy data (fasting plasma glucose) from the metformin arm did not meet Boehringer Ingelheim's (BI) predefined endpoint criteria. Data from the placebo-controlled monotherapy arm of the trial, which is still ongoing, are expected to be reported later this year. Together, these data sets will be used by BI to determine appropriate next steps for BI187004/VTP-34072.

- **Vitae recently announced the end of the research collaboration and license agreement for beta secretase (BACE) inhibitors.** Termination of the agreement by BI for strategic business reasons will be effective October 21,

2015. In connection with the termination of the agreement, Vitae expects to receive the rights to the BACE program, including BI-1147560/VTP-36951. Under the BACE agreement, no material payments are required to be made by or to the Company in connection with the termination of the agreement. Vitae plans to assess the program and revise its operating plan accordingly after determining the appropriate next steps. The Company will provide an update for the BACE program in the second half of 2015.

Financial Results:

- **Operating Expense.** Total operating expenses for the second quarter of 2015 were $10.0 million, compared with $6.2 million for the second quarter of 2014.
  - Research and development expenses were $7.8 million for the second quarter of 2015, compared with $4.9 million for the same period in 2014. The increase was largely attributable to expenses related to the RORγt program, including VTP-43742, Vitae's atopic dermatitis program and discovery efforts.
  - General and administrative expenses were $2.3 million for the second quarter of 2015, compared with $1.4 million for the same period in 2014. The change was primarily due to increased costs relating to being a public company.

- **Net Loss.** Vitae reported a net loss of $9.8 million for the second quarter of 2015, compared with a net loss of $5.1 million for the second quarter of 2014.

- **Cash Position.** As of June 30, 2015, Vitae had $80.3 million in cash, cash equivalents and marketable securities, compared to $65.3 million as of December 31, 2014. The 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. Based on the Company's current operating plan, which as of now does not include any expenses relating to further development of the BACE program, the Company 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 Milestones

- **VTP-43742 in Autoimmune Disorders** – Initiation of a Phase 1 multiple ascending dose proof-of-concept trial in healthy volunteers and patients with moderate to severe psoriasis.

- **VTP-43742 in Autoimmune Disorders** – Results from the single ascending dose Phase 1 clinical trial assessing safety, tolerability, pharmacokinetics and pharmacodynamics in the second half of 2015.

- **VTP-43742 in Autoimmune Disorders** – Top-line clinical efficacy results from the Phase 1 multiple ascending dose proof-of-concept trial by the end of 2015.

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

- **VTP-34072 in Type 2 Diabetes** – Top-line data from the remaining placebo-controlled monotherapy arm of the Phase 2a proof-of-concept trial in the second half of 2015.

- **VTP-36951 in Alzheimer's Disease –** An update on plans for the program after the BI collaboration and license agreement termination is complete in the second half of 2015.

Company to Host Conference Call

Vitae will host a conference call today, August 4, 2015, at 4:30 p.m. EDT to discuss the company's financial results for the quarter ended June 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 94533069, 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 can potentially address significant unmet medical needs, including disclosed programs in diabetes, Alzheimer's disease, autoimmune disorders, atopic dermatitis and acute coronary syndrome. 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 pre-clinical and clinical development of the product candidates in its portfolio and the use and sufficiency of the Company's cash position. 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 March 31, 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 June 30, 2015 to be filed with the SEC in the third 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 June 30,		**Six Months Ended June 30,**	
	2015	**2014**	**2015**	**2014**

Collaborative revenues	$ 161,588	$ 1,155,496	$ 311,827	$ 2,328,947
Operating expenses:				
Research and development	7,772,822	4,877,246	15,278,738	9,425,258
General and administrative	2,259,358	1,368,394	4,370,414	2,628,291
Total operating expenses	10,032,180	6,245,640	19,649,152	12,053,549
Loss from operations	(9,870,592)	(5,090,144)	(19,337,325)	(9,724,602)
Other income (expenses):				
Other income	1,430	204,399	1,430	217,774
Interest income	107,820	11,256	182,013	28,815
Interest expense	--	(255,675)	(107,864)	(541,037)
Loss on debt extinguishment	--	--	(206,678)	--
Total other income (expenses)	109,250	(40,020)	(131,099)	(294,448)
Net loss	$ (9,761,342)	$ (5,130,164)	$ (19,468,424)	$ (10,019,050)
Per share information:				
Net loss per common share:				
Basic	$ (0.45)	$ (8.50)	$ (0.91)	$ (16.74)
Diluted	$ (0.45)	$ (8.50)	$ (0.91)	$ (16.74)
Weighted-average number of common shares:				
Basic	21,837,676	603,868	21,315,094	598,567
Diluted	21,837,676	603,868	21,315,094	598,567

Vitae Pharmaceuticals, Inc.

Selected Balance Sheet Data

	As of June 30, 2015 (unaudited)	**As of December 31, 2014**
Cash, cash equivalents and marketable securities	$ 80,338,022	$ 65,318,300
Working capital	64,218,894	57,970,386
Current liabilities	7,026,199	8,864,107
Common stock and APIC	225,934,216	188,737,768
Total stockholder's equity	76,433,631	58,718,051

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