Vitae Pharmaceuticals Reports Second Quarter 2016 Operating and Financial Results

August 3, 2016 4:06 PM ET

Proof-of-concept data for VTP-38543 expected in the fourth quarter of 2016

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

FORT WASHINGTON, Pa., Aug. 03, 2016 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (NASDAQ:VTAE), a clinical-stage biotechnology company, today reported its operating and financial results for the quarter ended June 30, 2016.

Jeff Hatfield, President and Chief Executive Officer of Vitae, commented, "During the quarter, we made significant progress towards the completion of two key milestones for Vitae. First, we are on track to report top-line results for the ongoing Phase 2a proof-of-concept study for VTP-38543, our wholly owned, potential first-in-class LXRβ selective agonist being developed for atopic dermatitis, in the fourth quarter of 2016. Second, we continue to finalize plans for the next clinical trial, expected to initiate in the fourth quarter of 2016, of VTP-43742, our wholly owned, first-in-class RORγt inhibitor, in psoriasis patients. Previously, VTP-43742 demonstrated results that validated RORγt as a therapeutic target for psoriasis and VTP-43742 as a potentially paradigm-changing therapeutic."

Quarterly and Recent Highlights

Pipeline Updates:

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 fourth quarter of 2016.

VTP-43742 in Autoimmune Disorders

- **Continued preparations for an upcoming Phase 2 clinical trial of VTP-43742 in psoriasis patients.** Vitae plans to advance VTP-43742 into a 16-week Phase 2 trial in the fourth quarter of 2016 with the objectives of: (1) assessing the 16-week efficacy of VTP-43742 in moderate to severe psoriasis patients; (2) assessing the safety of the product candidate in a larger population and over a longer treatment period; and (3) positioning VTP-43742 to begin pivotal trials as soon as practicable after the completion of the Phase 2 clinical trial, if successful. Vitae expects to report top-line data from this trial in the second half of 2017.

VTP-45489 in Autoimmune Disorders

- **Vitae is advancing VTP-45489, its second RORγt inhibitor, into the clinic.** Vitae expects to initiate a Phase 1 single ascending dose clinical trial in normal healthy volunteers during the third quarter of 2016.

New Contour® Program

- **Animal proof-of-principle achieved in a new target program.** Initial lead candidate selected to advance into preclinical development.

Corporate Update:

- **Appointed Carole Sable, M.D., as Chief Medical Officer.** Dr. Sable will oversee the clinical development of Vitae's pipeline, including VTP-43742 and VTP-38543. Dr. Sable brings to Vitae more than 20 years of diverse clinical development and executive management experience, having been involved in all phases of clinical research.

- **Appointed Daniel M. Junius to Vitae's Board of Directors.** Mr. Junius recently retired as President and Chief Executive Officer of ImmunoGen, Inc. and brings both executive and prior board experience to Vitae's Board of Directors.

Financial Results:

- **Operating Expense.** Total operating expenses for the second quarter of 2016 were $10.5 million, compared with $10.0 million for the second quarter of 2015.
  - Research and development expenses were $7.9 million for the second quarter of 2016, compared with $7.8 million for the second quarter of 2015. The slight increase was largely attributable to expenses related to preclinical programs, the atopic dermatitis program, discovery efforts, stock-based compensation and compensation expense, partially offset by reduced manufacturing expenses resulting from the timing of development activities for the RORyt program.
  - General and administrative expenses were $2.7 million for the second quarter of 2016, compared with $2.3 million for the second quarter of 2015. The increase was primarily due to an increase in legal fees, patent related expenses, stock-based compensation expense and compensation expenses.

- **Net Loss.** Vitae reported a net loss of $10.4 million, or $0.36 per diluted share, for the second quarter of 2016, compared with a net loss of $9.8 million, or $0.45 per diluted share, for the second quarter of 2015. The increase in net loss was primarily due to the increase in general and administrative expenses.

- **Cash Position.** As of June 30, 2016, Vitae had $77.4 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 a follow-on public 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 Phase 2a clinical trial in mild to moderate atopic dermatitis patients in the fourth quarter of 2016.

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

- **VTP-45489 in Autoimmune Disorders** – Initiation of a Phase 1 single ascending dose trial in the third quarter of 2016.

Company to Host Conference Call

Vitae will host a conference call with slides today, August 3, 2016, at 4:30 p.m. EDT to discuss the Company's financial results for the quarter ended June 30, 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 56375798, approximately five to 10 minutes ahead of the start of the call.

A live audio webcast of the call and accompanying slides 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 and accompanying slides 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, but not limited to, the development of Vitae's clinical programs. These forward-looking statements are subject to a number of risks, including the risk factors set forth from time to time in Vitae's SEC filings, including, but not limited to, the risks 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 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be set forth in Vitae's Quarterly Report on Form 10-Q for the quarter ending June 30, 2016, to be filed with the SEC in the third 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 June 30,		**Six Months Ended June 30,**	
	2016	**2015**	**2016**	**2015**
Collaborative revenues	$ 3,274	$ 161,588	$ 54,627	$ 311,827
Operating expenses:				
Research and development	7,878,900	7,772,822	15,515,195	15,278,738
General and administrative	2,659,908	2,259,358	5,157,230	4,370,414
Total operating expenses	10,538,808	10,032,180	20,672,425	19,649,152
Loss from operations	(10,535,534)	(9,870,592)	(20,617,798)	(19,337,325)
Other income (expenses):				
Other income	-	1,430	-	1,430
Interest income	125,487	107,820	200,024	182,013
Interest expense	-	-	-	(107,864)
Loss on debt extinguishment	-	-	-	(206,678)
Total other income (expenses)	125,487	109,250	200,024	(131,099)
Net loss	$ (10,410,047)	$ (9,761,342)	$ (20,417,774)	$ (19,468,424)

Per share information:				
Net loss per common share:				
Basic	$ (0.36)	$ (0.45)	$ (0.79)	$ (0.91)
Diluted	$ (0.36)	$ (0.45)	$ (0.79)	$ (0.91)
Weighted-average number of common shares:				
Basic	28,829,553	21,837,676	25,686,529	21,315,094
Diluted	28,829,553	21,837,676	25,686,529	21,315,094

Vitae Pharmaceuticals, Inc.

Selected Balance Sheet Data

	As of June 30, 2016 (unaudited)	**As of December 31, 2015**
Cash, cash equivalents and marketable securities	$ 77,441,692	$ 59,369,836
Working capital	72,373,126	53,807,249
Current liabilities	6,127,981	7,329,754
Common stock and APIC	267,404,963	228,463,162
Total stockholder's equity	73,032,076	54,467,750

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