Vitae Pharmaceuticals Reports First Quarter 2015 Operating and Financial Results

May 12, 2015 4:07 PM ET

Multiple impending 2Q inflection points supported by enhanced cash position

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

FORT WASHINGTON, Pa., May 12, 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 first quarter ended March 31, 2015.

"During the first quarter, we continued to execute on our plans to deliver important near-term value drivers for shareholders that we hope will ultimately result in meaningful new treatments for patients suffering from a variety of serious diseases," commented Jeff Hatfield, President and Chief Executive Officer of Vitae. "We made solid progress in the development of our diabetes and autoimmune programs, remained committed to advancing our Alzheimer's program, and extended our expected cash runway through 2016. We look forward to a continued steady stream of activity during the remainder of 2015, including multiple data milestones we expect to achieve this year."

Quarterly and Recent Highlights

Pipeline Updates:

VTP-34072 in Type 2 Diabetes

- **Boehringer Ingelheim (BI) completed the dosing phase of VTP-34072 in the metformin arm of the ongoing Phase 2 proof-of-concept trial; top-line clinical efficacy results for this arm are expected to be announced this quarter.** This trial is a randomized, double-blind, placebo controlled clinical trial with the endpoints being glucose lowering, safety and tolerability. The monotherapy arm of the trial remains ongoing due to slower patient enrollment; the top-line clinical efficacy results for this arm are expected to be announced in the second half of 2015.

BI-1147560 in Alzheimer's Disease

- **BI will advance BI-1147560 for the treatment of Alzheimer's disease; clinical studies expected to begin by year-end.** As disclosed in detail earlier this year, BI placed the previous lead compound, BI-1181181, on a voluntary clinical hold due to skin reactions, and subsequently decided to move forward with the development of BI-1147560. -560 is a structurally different compound that has successfully completed all IND enabling studies. In preclinical studies, -560 was shown to lower amyloid beta levels comparably with -1181. Vitae is eligible to receive a $7 million milestone upon dosing of the first subject in the Phase 1 trial.

VTP-43742 in Autoimmune Disorders

- **Vitae continued to advance VTP-43742, its potential first-in-class product candidate for the treatment of autoimmune disorders.** Vitae has completed the 28-day GLP toxicity studies and expects to initiate a Phase 1 clinical trial during the second quarter.
- **Vitae made several presentations of preclinical data for VTP-43742 at scientific meetings, including the Keystone Symposia on Mechanisms of Pro-Inflammatory Diseases and the AAI's Immunology 2015 conference.** One of the key data sets presented demonstrates that VTP-43742 achieved a superior clinical response in an animal model of multiple sclerosis in comparison to an IL-17A monoclonal antibody.

Other Pipeline Programs

- **Vitae presented preclinical efficacy data for VTP-38543, which is being developed for atopic dermatitis, at the Society for Investigational Dermatology**.
- **Vitae presented preclinical efficacy data for VTP-38443, which is being developed for acute coronary syndrome, at the Arteriosclerosis, Thrombosis and Vascular Biology Meeting.**

Corporate Updates:

- **Vitae completed a follow-on public offering in January 2015**. Vitae issued and sold an aggregate of 3.45 million shares of common stock, including the shares sold upon the exercise of the underwriter's option to purchase additional shares, at a price of $11.90 per share less underwriting fees and expenses, for aggregate net proceeds of approximately $38.0 million.
- **Vitae retired its remaining venture debt facility**. In February 2015, Vitae paid off in full its outstanding venture debt facility of $4.3 million, including applicable prepayment fees.

Financial Results:

- **Operating Expense.** Total operating expenses for the first quarter of 2015 were $9.6 million, compared with $5.8 million for the first quarter of 2014.
  - Research and development expenses were $7.5 million for the first quarter of 2015, compared with $4.5 million for the first quarter of 2014. The increase was largely attributable to expenses related to the RORγt program, including VTP-43742, and the LXRβ program.
  - Selling, general and administrative expenses were $2.1 million for the first quarter of 2015, compared with $1.3 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 $9.7 million for the first quarter of 2015, compared with a net loss of $4.9 million for the first quarter of 2014.
- **Cash Position.** As of March 31, 2015, Vitae had $88.7 million in cash, cash equivalents and marketable securities, compared to $65.3 million as of December 31, 2014. The increase was primarily a result of the completion of the Company's follow-on public offering in the first quarter of 2015.

Expected Milestones

- **VTP-34072 in Type 2 Diabetes** – Top-line clinical efficacy results from the metformin arm of the Phase 2 proof-of-concept trial in type 2 diabetic patients in the second quarter, and top-line clinical efficacy results from the monotherapy arm in the second half of 2015.
- **VTP-43742 in Autoimmune Disorders** – Initiation of a single dose Phase 1 safety and pharmacokinetic (PK) clinical trial in healthy human volunteers in the second quarter of 2015, with completion and results mid-year 2015.
- **VTP-43742 in Autoimmune Disorders** – Initiation and completion of a multiple ascending dose proof-of-concept trial in psoriatic patients, with top-line clinical efficacy results in the second half of 2015.
- **VTP-38543 in Atopic Dermatitis** – Initiation of a Phase 1 safety and PK trial in the second half of 2015.
- **BI-1147560 in Alzheimer's Disease** –Initiation of a Phase 1 clinical trial by the end of 2015, with Vitae eligible to earn a $7 million milestone payment upon first dosing.

Company to Host Conference Call

Vitae will host a conference call today, May 12, 2015, at 4:30 p.m. EDT to discuss the company's financial results for the quarter ended March 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 40302906, 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 novel, small molecule drugs for diseases in which there are 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 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 BI 1181181 and any back up compounds. 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 which has 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 March 31, 2015 to be filed with the SEC in the second 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 December 31,	
	2015	**2014**
Collaborative revenues	$ 150,239	$ 1,173,451
Operating expenses:		
Research and development	7,505,916	4,548,012
General and administrative	2,111,056	1,259,897

Total operating expenses	9,616,972	5,807,909
Loss from operations	(9,466,733)	(4,634,458)
Other (expenses) income:		
Other income	--	13,375
Interest income	74,193	17,559
Interest expense	(107,864)	(285,362)
Loss on debt extinguishment	(206,678)	--
Total other (expenses) income	(240,349)	(254,428)
Net loss	$ (9,707,082)	$ (4,888,886)
Per share information:		
Net loss per common share:		
Basic	$ (0.47)	$ (8.24)
Diluted	$ (0.47)	$ (8.24)
Weighted-average number of common shares:		
Basic	20,826,647	593,206
Diluted	20,826,647	593,206

Vitae Pharmaceuticals, Inc.

Selected Balance Sheet Data (unaudited)

	As of March 31, 2015	**As of December 31, 2014**
Cash, cash equivalents and marketable securities	88,693,190	65,318,300
Working capital	67,800,388	57,970,386
Current liabilities	5,438,036	8,864,107
Common stock and APIC	225,368,097	188,737,768
Total stockholder's equity	85,649,375	58,718,051

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