Vitae Pharmaceuticals Reports Third Quarter 2014 Operating and Financial Results

November 12, 2014 4:05 PM ET

Conference Call Scheduled for 4:30 p.m. EST Today

FORT WASHINGTON, Pa., Nov. 12, 2014 (GLOBE NEWSWIRE) -- Vitae Pharmaceuticals, Inc. (Nasdaq:VTAE), a clinical-stage biotechnology company, reported today its operating and financial results for the third quarter ended September 30, 2014.

"The successful completion of our initial public offering in September provides us with additional capital to advance our proprietary pipeline, and, we believe, to achieve a number of key milestones," said Jeffrey Hatfield, President and Chief Executive Officer of Vitae. "In addition, we announced in October positive top-line results from two Phase 1 clinical trials of our BACE inhibitor for Alzheimer's disease that were conducted by our collaboration partner. These positive results are an important first clinical step toward providing to physicians, and ultimately to patients, a novel therapeutic that can potentially prevent or minimize the suffering from this terrible disease."

Quarterly and Recent Highlights

Pipeline Updates:

- **Commenced a Phase 2 clinical trial of VTP-34072 for the treatment of type 2 diabetes as part of Vitae's 11 β HSD1 collaboration with Boehringer Ingelheim (BI).** The trial, which commenced in July 2014 and is being conducted by BI, involves 126 type 2 diabetic patients and is expected to have results in the first half of 2015. Vitae received a milestone payment of $6.0 million from BI as a result of the first patient having been dosed in this trial.
- **Announced positive top-line results for the treatment and prevention of Alzheimer's disease as part of the BACE collaboration with BI.** Two Phase 1 clinical trials of BI1181181 / VTP-37948 were reported as safe and generally well-tolerated across all dose levels tested. BI1181181 / VTP-37948 demonstrated the ability to lower cerebral spinal fluid (CSF) amyloid beta (A β) levels by more than 80%.The results also indicated a half-life of between 16 and 19 hours, supporting a once-daily dosing profile.
- **Continued to advance VTP-43742, our product candidate to treat autoimmune disorders, toward an anticipated filing of an Investigational New Drug Application (IND), with Phase 1 clinical trials commencing thereafter.** Vitae progressed drug manufacturing and other key activities that are expected to enable it to file an IND and initiate Phase 1 clinical trials in the first half of 2015.

Corporate Updates:

- **Successfully completed its initial public offering (IPO)**. Vitae issued and sold an aggregate of approximately 7.9 million shares of common stock, including the shares sold upon the exercise of the underwriter's over-allotment option, at a price of $8.00 per share less underwriting discounts, for aggregate proceeds of approximately $56.3 million, net of offering fees and expenses.
- **Appointed Charles Rowland, Jr. and Gino Santini to its Board of Directors.** Mr. Rowland was formerly Vice President and Chief Financial Officer of ViroPharma Incorporated and currently serves on the Board of Directors of BIND Therapeutics, Inc. and Aurinia Pharmaceuticals Inc. Mr. Santini was formerly Senior Vice President, Corporate Strategy and Business Development at Eli Lilly and Company and currently serves on the Board of Directors of Horizon Pharma, Inc., AMAG Pharmaceuticals Inc., and Sorin S.p.A., as well as a number of private companies.

Financial Results:

- **Revenue.** Collaborative revenues for the third quarter of 2014 were $6.2 million, compared with $5.4 million for the third quarter of 2013. Revenue for the third quarter of 2014 included the $6.0 million milestone payment from BI

related to the first patient being dosed in the Phase 2 clinical trial for VTP-34072, while revenue for the third quarter of 2013 included a $4.0 million milestone payment from BI related to the advancement of a back-up compound related to the BACE collaboration.

- **Operating Expense.** Total operating expenses for the third quarter of 2014 were $7.9 million, compared with $4.8 million for the third quarter of 2013. This included non-cash stock compensation expense of $2.0 million and $29 thousand in the third quarter of 2014 and 2013, respectively.
    - Research and development expenses were $4.8 million for the third quarter of 2014, compared with $3.5 million for the third quarter of 2013. The increase was largely attributable to expenses related to the RORγt program, including VTP-43742.
    - Selling, general and administrative expenses were $3.1 million for the third quarter of 2014, compared with $1.3 million for the same period in 2013. The increase was largely attributable to expenses related to stock-based compensation of $1.7 million.
- **Net Loss/Income.** Vitae reported a net loss of $1.8 million for the third quarter of 2014, compared with net income of $0.2 million for the third quarter of 2013.
- **Cash position.** As of September 30, 2014, Vitae had $67.8 million in cash, restricted cash and marketable securities, compared to $32.5 million as of December 31, 2013. The increase was primarily a result of the completion of the company's IPO which raised $48.7 million, net of underwriting discounts and offering expenses, in the third quarter of 2014. Subsequent to the quarter end, the underwriters exercised their over-allotment option for approximately 1 million additional shares, which were purchased at $8.00 per share less underwriting discounts and raised an additional $7.6 million, net of expenses.

Upcoming Milestones:

Vitae reaffirmed the following previously disclosed potential development milestones for its programs in the first half of 2015:

- **VTP-34072 -** (11 β HSD1) - Top-line results from the Phase 2 proof of concept trial in type 2 diabetic patients.
- **VTP37948 / BI1181181** - (BACE) - Completion of additional Phase 1 clinical trials, including a multiple rising dose trial.
- **VTP-43742 -** (ROR γ t) - Initiation and completion of a single dose Phase 1 safety and PK clinical trial in healthy human volunteers.

Company to Host Conference Call

Vitae will host a conference call today, November 12, 2014, at 4:30 p.m. EST to discuss the company's financial results for the quarter ended September 30, 2014, 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 32241442, 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. The company is developing a robust and growing portfolio of novel product candidates generated by Contour®, its 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 Vitae's and its partner's plans for its product candidates. 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" 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 final prospectus filed under Rule 424(b)(4) with the Securities and Exchange Commission (SEC) in connection with Vitae's initial public offering. Additional factors may also be set forth in those sections of Vitae's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 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 (unaudited)

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2014	**2013**	**2014**	**2013**
Collaborative revenues	$ 6,178,166	$ 5,352,230	$ 8,507,113	$ 7,314,528
Operating expenses:				
Research and development	4 ,799,268	3,527,624	14,224,526	11,112,251
General and administrative	3,096,399	1,316,695	5,724,690	3,996,478
Total operating expenses	7,895,667	4,844,319	19,949,216	15,108,729
(Loss) / income from operations	(1,717,501)	507,911	(11,442,103)	(7,794,201)
Other (expenses) income:				
Other income	125,544	—	343,318	303,891
Interest income	7,894	14,335	36,709	57,441
Interest expense	(225,355)	(342,763)	(766,392)	(1,110,978)
Total other (expenses) income	(91,917)	(328,428)	(386,365)	(749,646)
Net (loss) income	$ (1,809,418)	$ 179,483	$ (11,828,468)	$ (8,543,847)
Per share information:				

Net (loss) income per common share:				
Basic	$ (1.06)	$ 0.00	$ (12.18)	$ (15.36)
Diluted	$ (1.06)	$ 0.00	$ (12.18)	$ (15.36)
Weighted-average number of common shares:				
Basic	1,711,969	564,702	971,439	556,220
Diluted	1,711,969	564,702	971,439	556,220

Vitae Pharmaceuticals, Inc.

Selected Balance Sheet Data (unaudited)

	As of September 30, 2014	**As of December 31, 2013**
Cash, Cash Equivalents and Marketable securities	$ 67,806,843	$ 32,454,453
Working Capital	58,362,135	23,905,376
Current Liabilities	10,898,413	9,517,419
Convertible Preferred Stock	0	125,869,931
Common Stock and APIC	180,864,663	3,983,281
Total Stockholder's equity / (deficit)	58,154,269	(106,894,151)

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