Loxo Oncology Announces Third Quarter 2015 Financial Results and Provides Program Updates

November 10, 2015

STAMFORD, Conn., Nov. 10, 2015 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers, today reported financial results for the third quarter ended September 30, 2015 and provided an update on its pipeline. Loxo Oncology will not be conducting a conference call in conjunction with this earnings release.

"In the third quarter we made tremendous progress with LOXO-101, executing ahead of plan," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "Our Phase 1 trial continues to mature nicely, and we were able to open our Phase 2 trial approximately six months early. Additionally, we were proud to report that the National Cancer Institute selected LOXO-101 as the preferred and sole TRK inhibitor for relevant patients in the NCI-MATCH trial. I think we can attribute much of this success to the compelling efficacy and tolerability signals seen in Phase 1, and a growing appreciation for the diversity of TRK fusion biology across human cancer in the scientific and molecular diagnostic communities."

**Program Updates**

Loxo Oncology provided the following updates on its development programs:

**LOXO-101: the only potent, oral, selective inhibitor of the tropomyosin receptor kinase (TRK) family of proteins in clinical development**

**LOXO-101 Phase 2 Trial Initiated**

- Loxo Oncology enrolled the first patient in its Phase 2 trial of LOXO-101, a global, multi-center, single-arm, open-label basket trial in approximately up to 150 adult patients with solid tumors that harbor a TRK fusion, as determined by any Clinical Laboratory Improvement Amendments (CLIA) certified or equivalently-accredited test. Patients with TRK fusions will be enrolled into one of eight cohorts: non-small cell lung cancer, thyroid cancer, sarcoma, colorectal cancer, salivary gland cancer, biliary cancer, primary central nervous system tumors and all other solid tumor histologies.

**LOXO-101 Phase 1 Data Presented at EORTC**

- New results from the ongoing dose-escalation Phase 1 study of LOXO-101 in patients with solid tumors refractory to standard therapy were reported in a late-breaking oral presentation at the 27th AACR-NCI-EORTC Symposium on Molecular Targets and Cancer Therapeutics.
- As of the October 20, 2015 data cutoff date, 30 patients had been enrolled and treated, including six patients with cancers harboring TRK fusions. Three of the six patients with TRK fusion cancers had been on study sufficiently long for their first efficacy assessment, and all three had achieved an objective response at the first response assessment, as defined by standard RECIST criteria. All three of these patients remain in response and on study. The other three patients with TRK fusion cancers were recently enrolled and thus had not yet been evaluated for response as of the data cutoff date, though they all remain on study.
- LOXO-101 has been well tolerated, including the 100 mg twice-daily dose, which has been selected for Phase 2 study and has shown efficacy in TRK fusion patients. The majority of adverse events reported by investigators have been mild to moderate. A maximum tolerated dose (MTD) has not been defined, though near-term Phase 1 enrollment will focus on further characterizing the pharmacokinetics and safety of the 100 mg twice-daily dose.
dosing. The data presentation from the meeting can be accessed here https://ir.loxooncology.com/publications.

LOXO-101 Selected for NCI-MATCH Trial

- The independent committee of the National Cancer Institute-Molecular Analysis for Therapy Choice (NCI-MATCH) clinical trial chose LOXO-101 as the sole, dedicated treatment arm for patients with TRK gene fusions.
- The NCI-MATCH trial will initially enroll 3,000 patients with tumor biopsies available for comprehensive genomic profiling and assign these patients to an appropriate targeted therapy arm based on the molecular abnormalities of each tumor. Over 700 trial sites in 48 states in the United States are currently open for enrollment.

LOXO-101 Granted Orphan Drug Designation

- The United States Food and Drug Administration (FDA) granted Loxo Oncology orphan drug designation for LOXO-101 for treatment of patients with soft tissue sarcoma.

Pre-clinical Programs

Data on RET and FGFR Programs Presented at AACR-NCI-EORTC

- Loxo presented two preclinical posters at AACR-NCI-EORTC containing the first publicly disclosed data for its Rearranged during Transfection (RET) and Fibroblast Growth Factor Receptor (FGFR) programs.
- Loxo Oncology’s novel, potent and selective RET inhibitor demonstrated potent inhibition of RET in enzyme and cellular assays with minimal activity against highly related kinases in animal models. The company is on track to initiate a Phase 1 study of its RET inhibitor in late 2016 or early 2017.
- Data for the company’s potent and selective FGFR inhibitor show that it spared FGFR1 and other related kinases and possesses high oral bioavailability and favorable PK properties in animal models.

Third Quarter 2015 Financial Results

As of September 30, 2015 Loxo had aggregate cash, cash equivalents and investments of $93.4 million, compared to $112.9 million as of December 31, 2014.

The company continues to expect cash burn of $30-$33 million in 2015, and based on the current operating plan, the company believes existing capital resources will be sufficient to fund anticipated operations into 2017.

Research and development expenses were $6.3 million for the third quarter 2015 compared to $5.1 million for the third quarter 2014. The increase was primarily due to expanded Phase 1 and Phase 2 clinical development activities for LOXO-101 and additional full-time equivalents and other support dedicated to discovery, preclinical, and manufacturing activities at Array BioPharma. The company also recognized R&D-related stock-based compensation expense of $0.5 million during the third quarter of 2015 compared to $1.7 million for the third quarter of 2014.

Research and development expenses were $15.8 million for the nine months ended September 30, 2015 compared to $9.9 million for the nine months ended September 30, 2014. The increase was primarily due to expanded Phase 1 and Phase 2 clinical development activities for LOXO-101 and additional full-time equivalents and other support dedicated to discovery, preclinical, and manufacturing activities at Array BioPharma. The company also recognized R&D-related stock-based compensation expense of $1.8 million during the nine months ended September 30, 2015 compared to $2.0 million for the nine months ended September 30, 2014.

General and administrative expenses were $2.6 million for the third quarter 2015 compared to $1.6 million for the third quarter 2014. The increase was primarily due to additional full-time equivalents, increased compensation costs and increased costs associated with operating as a public company. The company also recognized G&A-related stock-based compensation expense of $0.7 million during the third quarter of 2015 compared to $0.3 million for the third quarter of 2014.

General and administrative expenses were $7.3 million for the nine months ended September 30, 2015 compared to $3.6 million for the nine months ended September 30, 2014. The increase was primarily due to additional full-time equivalents, increased compensation costs and increased costs associated with operating as a public company. The company also recognized G&A-related stock-based compensation expense of $2.0 million during the nine months ended September 30, 2015.
compared to $0.5 million for the nine months ended September 30, 2014.

Net loss attributable to common stockholders was $8.8 million and $23.0 million for the three and nine months ended September 30, 2015, respectively, compared to $6.7 million and $13.6 million for the three and nine months ended September 30, 2014, respectively.

About LOXO-101

LOXO-101 is a potent, oral and selective investigational new drug in clinical development for the treatment of patients with cancers that harbor abnormalities involving the tropomyosin receptor kinases (TRKs). Growing research suggests that the NTRK genes, which encode for TRKs, can become abnormally fused to other genes, resulting in growth signals that can lead to cancer in many sites of the body. In an ongoing Phase 1 clinical trial, LOXO-101 has demonstrated encouraging preliminary efficacy. LOXO-101 is also being evaluated in a global Phase 2 multi-center basket trial in patients with solid tumors that harbor TRK gene fusions. For additional information about both the LOXO-101 clinical trials, please refer to www.clinicaltrials.gov. Interested patients and physicians can contact the Loxo Oncology Physician and Patient Clinical Trial Hotline at 1-855-NTRK-123.

About Loxo Oncology

Loxo Oncology is a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers. Our pipeline focuses on cancers that are uniquely dependent on single gene abnormalities, such that a single drug has the potential to treat the cancer with dramatic effect. We believe that the most selective, purpose-built medicines have the highest probability of maximally inhibiting the intended target, thereby delivering best-in-class disease control and safety. Our management team seeks out experienced industry partners, world-class scientific advisors and innovative clinical-regulatory approaches to deliver new cancer therapies to patients as quickly and efficiently as possible. For more information, please visit the company's website at www.loxooncology.com.

Forward Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, statements we make regarding the timing and success of our clinical trials and the potential therapeutic benefits and economic value of our lead product candidate. Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Quarterly Report on Form 10-Q, and other reports as filed from time to time with the Securities and Exchange Commission. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Financials

**LOXO ONCOLOGY, INC.**
**Condensed Balance Sheets**
*(in thousands, except share and per share amounts)*

<table>
<thead>
<tr>
<th></th>
<th>September 30, 2015 (unaudited)</th>
<th>December 31, 2014</th>
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<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets:</td>
<td></td>
<td></td>
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<tr>
<td>Cash and cash equivalents</td>
<td>$ 34,409</td>
<td>$ 43,930</td>
</tr>
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</table>
Short-term investments 9,013 62,362  
Prepaid expenses with related party 922 663  
Other prepaid expenses and current assets 2,062 821  
Total current assets 96,406 107,776  
Long-term investments - 6,648  
Property and equipment, net 74 12  
Other assets 222 23  
Total assets $ 96,702 $ 114,459  

Liabilities and Stockholders’ Equity  
Current liabilities:  
Accounts payable $ 731 $ 239  
Accrued expenses and other current liabilities 2,108 1,548  
Total liabilities 2,839 1,787  
Commitments and contingencies  
Stockholders’ equity:  
Common stock, $0.0001 par value; 125,000,000 shares authorized; 
16,687,436 shares issued and outstanding at September 30, 2015; 
16,644,219 shares issued and 16,634,063 shares outstanding at 
December 31, 2014 2 2  
Additional paid-in capital 147,825 143,660  
Accumulated deficit (53,971 ) (30,962 )  
Accumulated other comprehensive income (loss) 7 (28 )  
Total stockholders’ equity 93,863 112,672  
Total liabilities and stockholders’ equity $ 96,702 $ 114,459  

LOXO ONCOLOGY, INC.  
Condensed Statements of Operations  
(unaudited)  
(in thousands, except share and per share amounts)  

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended</th>
<th>Three Months Ended</th>
<th>Nine Months Ended</th>
<th>Nine Months Ended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development with related party</td>
<td>$ 2,874</td>
<td>$ 2,413</td>
<td>$ 7,711</td>
<td>$ 5,395</td>
</tr>
<tr>
<td>Research and development</td>
<td>3,387</td>
<td>2,708</td>
<td>8,095</td>
<td>4,543</td>
</tr>
<tr>
<td>General and administrative</td>
<td>2,552</td>
<td>1,622</td>
<td>7,331</td>
<td>3,612</td>
</tr>
<tr>
<td>Total operating expenses and loss from operations</td>
<td>(8,813 )</td>
<td>(6,743 )</td>
<td>(23,137 )</td>
<td>(13,550 )</td>
</tr>
<tr>
<td>Interest income, net</td>
<td>42</td>
<td>-</td>
<td>128</td>
<td>-</td>
</tr>
<tr>
<td>Net loss</td>
<td>(8,771 )</td>
<td>(6,743 )</td>
<td>(23,009 )</td>
<td>(13,550 )</td>
</tr>
</tbody>
</table>
Accretion of redeemable convertible preferred stock  -  (6)  -  (34)  
Net loss attributable to common stockholders  $ (8,771)  $ (6,749)  $ (23,009)  $ (13,584)  
Share information:  
Net loss per share, basic and diluted  $ (0.53)  $ (0.68)  $ (1.39)  $ (3.87)  
Weighted average shares outstanding, basic and diluted  16,560,610  9,947,321  16,525,530  3,510,170  

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