Loxo Oncology Announces First Quarter 2015 Financial Results

May 14, 2015

STAMFORD, Conn., May 14, 2015 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company focused on the discovery, development, and commercialization of targeted cancer therapies, today reported first quarter 2015 financial results and recent business highlights.

"In the first quarter of 2015 we demonstrated strong progress in our pipeline, including the presentation of initial clinical data for LOXO-101 at AACR and the unveiling of three additional preclinical programs. Our focus on targeted cancer therapies with best-in-class potential reflects our belief that selective, rationally designed drugs can demonstrate clinical benefit and differentiation when tested in patients with the relevant oncogene addicted tumors," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "We are pleased that initial data from our Phase 1a trial of LOXO-101 show that the drug is achieving biologically relevant exposures, while revealing no clear drug-related safety signals. We look forward to moving into exclusively TRK-altered patients in the second half of the year and continuing to advance our pipeline."

Recent Business Highlights

Presented Initial Phase 1a Data for LOXO-101 at the American Association for Cancer Research (AACR) Annual Meeting

In April, the Company presented initial Phase 1a safety and pharmacokinetic data for LOXO-101 in a poster session at the AACR 2015 Annual Meeting in Philadelphia. Key findings from the poster presentation included:

- As of the data cut-off for the poster, March 26, 2015, 15 patients had been enrolled across three dose cohorts: 50mg QD (n=4), 100mg QD (n=5), and 100mg BID (n=6), including one soft tissue sarcoma patient with an NTRK1 fusion enrolled on March 10, 2015
- Pharmacokinetics showed good systemic exposure of LOXO-101 after oral dosing, with higher exposures observed than those predicted in nonclinical studies
- LOXO-101 was generally well tolerated, with the most common adverse events being Grade 1 and 2 fatigue, dizziness and anemia; no study drug related serious adverse events (SAEs) were reported; the maximum tolerated dose (MTD) had not yet been reached.

Updated Program Guidance for 2015

On March 2, 2015, the Company updated its 2015 program guidance, unveiling molecular targets for three of its seven active preclinical programs. The three targets disclosed were Rearranged during Transfection (RET), Fibroblast Growth Factor Receptor (FGFR), and FMS-Like Tyrosine kinase 3 (FLT3). In addition to these three programs, Loxo possesses well-vetted candidates for two other programs, not yet disclosed by target name, which are ready for IND-enabling work. All of the Company's current preclinical pipeline programs are being pursued as part of Loxo's collaboration with Array BioPharma. The Company will provide periodic data updates for its discovery pipeline at medical meetings, beginning in the second half of 2015.

Appointed New Vice President of Finance, Jennifer Burstein, CPA

In early May, Loxo appointed Ms. Jennifer Burstein, CPA, as vice president of finance. Jennifer will be the Company's principal financial officer and principal accounting officer. Prior to Loxo, Ms. Burstein served as vice president of finance at Acorda Therapeutics, Inc., a public biotechnology company, from July 2010 until April 2015, where she held several positions of increasing responsibility in finance from 2006 until being appointed vice president of finance. Prior to joining
Acorda, from 2002 to 2006, she was with Eyetech Pharmaceuticals, Inc., a public biotechnology company, which is currently a subsidiary of Valeant Pharmaceuticals International, Inc., where she held several positions of increasing responsibility in finance until being promoted to senior director, accounting. Before Eyetech, Ms. Burstein worked in the finance departments at several companies and in public accounting. Ms. Burstein received her B.S. in business administration and M.B.A. in accounting from the State University of New York at Buffalo and has a CPA license in New York.

Upcoming Poster Presentations at ASCO Annual Meeting

Loxo today announced it will present two posters at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago, Illinois on May 29-June 2, 2015. Loxo will not be presenting new clinical data at this meeting.

The details of the poster sessions are as follows:

**Poster Session:** Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics

**Date:** Saturday, May 30

**Poster Viewing Session:** 8:00 – 11:30a.m. CDT

**Location:** S Hall A

**Poster Number:** 328b

**Title:** A first-in-human study of LOXO-101, a highly selective inhibitor of the tropomyosin receptor kinase (TRK) family. (Abstract # TPS2624, Trials in Progress)

**Lead Author:** Howard A. Burris, M.D.

**Poster Session:** Cancer Prevention, Genetics, and Epidemiology

**Date:** Monday, June 1

**Poster Viewing Session:** 1:15-4:45p.m. CDT

**Location:** S Hall A

**Poster Number:** 377

**Title:** Identification of tropomyosin kinase receptor (TRK) mutations in cancer. (Abstract # 1553)

**Lead Author:** Nisha Nanda, Ph.D.

First Quarter 2015 Financial Results

As of March 31, 2015 Loxo had aggregate cash, cash equivalents and investments of $107.6 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 $3.8 million for the first quarter of 2015 compared to $2.0 million in the first quarter of 2014. This increase of $1.8 million was primarily due to expanded 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 stock-based compensation expense of $0.5 million during the first quarter of 2015 compared to $40,000 for the first quarter of 2014.
General and administrative expenses were $2.4 million for the first quarter of 2015 compared to $0.9 million in the first quarter of 2014. The increase of $1.5 million was primarily due to increased costs associated with operating as a public company. The Company also recognized stock-based compensation expense of $0.6 million during the first quarter 2015 compared to $20,000 for the first quarter 2014.

Net loss attributable to common shareholders was $6.2 million and $2.9 million for the first quarters of 2015 and 2014, respectively.

The Company will not be conducting a conference call in conjunction with this earnings release. Loxo plans to continue its tradition of conducting an earnings conference call in conjunction with its fourth quarter earnings releases.

**About Loxo Oncology**

Loxo Oncology is committed to the discovery, development, and commercialization of targeted cancer therapies with best-in-class potential. Our diverse pipeline reflects the convergence of proven therapeutic technologies with emerging insights into the underlying susceptibilities of cancer and drug resistance. We leverage the expertise of our partners in academia and industry and our management team’s deep clinical-regulatory experience to deploy focused clinical development strategies in well-defined patient populations. Our goal is to create important new cancer therapies as efficiently as possible to substantially benefit patients. [www.loxooncology.com](http://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 our future financial performance, business plans and objectives, partnerships, timing and success of our clinical trials, our ability to obtain regulatory approval, the potential therapeutic benefits and economic value of our lead product candidate or pipeline candidates, potential growth opportunities, financing plans, competitive position, industry environment and potential market opportunities. Further information on potential risk factors that could affect our business and its financial results are detailed in our Annual Report on Form 10-K for the period ended December 31, 2014, filed with the Securities and Exchange Commission on March 27, 2015, 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>March 31, 2015 (unaudited)</th>
<th>December 31, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$37,255</td>
<td>$43,930</td>
</tr>
<tr>
<td>Short-term investments</td>
<td>60,697</td>
<td>62,362</td>
</tr>
<tr>
<td>Prepaid expenses with related party</td>
<td>658</td>
<td>663</td>
</tr>
</tbody>
</table>
### Liabilities and stockholders’ equity

**Current liabilities:**
- Accounts payable: $285,000 (2015) vs. $239,000 (2014)
- Accrued expenses and other current liabilities: $1,024,000 (2015) vs. $1,548,000 (2014)

**Total liabilities:** $1,309,000 (2015) vs. $1,787,000 (2014)

**Commitments and contingencies**

**Stockholders’ equity:**
- Common stock, $0.0001 par value; 125,000,000 shares authorized; 16,644,219 shares issued and 16,634,063 outstanding:
  - March 31, 2015: 2 shares
  - March 31, 2014: 2 shares

- Additional paid-in capital: $144,709,000 (2015) vs. $143,660,000 (2014)
- Accumulated deficit: $(37,144,000) (2015) vs. $(30,962,000) (2014)
- Accumulated other comprehensive loss: $(7,000) (2015) vs. $(28,000) (2014)

**Total stockholders’ equity:** $107,560,000 (2015) vs. $112,672,000 (2014)

**Total liabilities and stockholders’ equity:** $108,869,000 (2015) vs. $114,459,000 (2014)

---

**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 March 31, 2015</th>
<th>Three Months Ended March 31, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>$ 1,918</td>
<td>$ 1,275</td>
</tr>
<tr>
<td>Research and development</td>
<td>1,915</td>
<td>767</td>
</tr>
<tr>
<td>General and administrative</td>
<td>2,392</td>
<td>860</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>(6,225)</td>
<td>(2,902)</td>
</tr>
<tr>
<td>Interest income, net</td>
<td>43</td>
<td>—</td>
</tr>
<tr>
<td>Net loss</td>
<td>(6,182)</td>
<td>(2,902)</td>
</tr>
<tr>
<td>Accretion of redeemable</td>
<td>—</td>
<td>(11)</td>
</tr>
<tr>
<td>convertible preferred stock</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss attributable to</td>
<td>$ (6,182)</td>
<td>$ (2,913)</td>
</tr>
<tr>
<td>common stockholders</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Per share information:
Net loss per share of common stock, basic and diluted $ (0.38)  $ (14.22)
Weighted average shares outstanding, basic and diluted 16,474,269  204,807

Contacts:
Company:
Jacob S. Van Naarden
Vice President, Corporate Development and Strategy
jake@loxooncology.com

Investors:
Peter Rahmer
The Trout Group, LLC
646-378-2973
prahmer@troutgroup.com

Media:
Dan Budwick
Pure Communications, Inc.
973-271-6085
dan@purecommunicationsinc.com
Loxo Oncology