Loxo Oncology Announces Third Quarter 2016 Financial Results

November 2, 2016

– Updated LOXO-101 Phase 1 Clinical Data Accepted for Oral Presentation at ESMO Asia on December 18, 2016 –

– Company to Provide LOXO-101 Program and Pipeline Update During Conference Call and Webcast on Monday, December 19, 2016 at 8:00AM ET –

STAMFORD, Conn., Nov. 02, 2016 (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, 2016. Loxo Oncology will not be conducting a conference call in conjunction with this earnings release.

"Enrollment in the LOXO-101 program and progress in the preclinical pipeline have positioned us well for the remainder of 2016 and 2017," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "In December, we plan to share updated Phase 1 clinical data for LOXO-101 at ESMO Asia. At that time, we will also provide a comprehensive program update that integrates trial enrollment progress with written regulatory feedback to provide increased visibility into the commercial timelines for LOXO-101. Additionally, we look forward to starting Phase 1 studies in 2017 for named candidates LOXO-292 and LOXO-195."

Upcoming Milestones

LOXO-101

- Updated clinical data from the adult Phase 1 trial of LOXO-101 have been accepted for an oral presentation at the European Society for Medical Oncology (ESMO) Asia Congress, taking place December 16-19, 2016 in Singapore. The presentation is titled, "Clinical safety and activity from a phase 1 study of LOXO-101, a selective TRKA/B/C inhibitor, in solid-tumor patients with NTRK gene fusions" and will take place at 4:30PM SGT on Sunday, December 18, 2016.
- In conjunction with ESMO Asia, Loxo Oncology will be hosting a conference call and webcast on December 19, 2016 at 8:00AM ET. Dial-in instructions and webcast information will be posted to the Loxo Oncology website. During this call, Loxo Oncology will review the updated LOXO-101 Phase 1 data and provide an overview of its clinical development plans across the company’s portfolio of investigational medicines. The LOXO-101 program update is expected to include:
  - Current enrollment as “percent to goal”
  - Expected timing of full enrollment relative to goal
  - Expected timing of NDA/MAA filings and label potential
- Preclinical data for LOXO-101 have been accepted for an oral presentation at the 58th American Society of Hematology (ASH) Annual Meeting, taking place December 3-6, 2016 in San Diego. The presentation is titled, “Genetic Modeling and Therapeutic Targeting of ETV6-NTRK3 with LOXO-101 in Acute Lymphoblastic Leukemia” and will take place at 7:45AM PT on Sunday, December 4, 2016.
• Preclinical data for Loxo Oncology’s RET program (LOXO-292) and TRK acquired resistance program (LOXO-195) have been accepted for presentation at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium, taking place November 29 – December 2, 2016 in Munich, Germany.
• Initiation of a Phase 1 study of LOXO-292, Loxo Oncology’s selective RET inhibitor, is expected in early 2017.
• Initiation of a Phase 1 study of next-generation TRK inhibitor LOXO-195, addressing previously treated patients with acquired resistance, is expected in 2017.

Third Quarter 2016 Financial Results

As of September 30, 2016, Loxo Oncology had aggregate cash, cash equivalents and investments of $156.5 million, compared to $153.9 million as of December 31, 2015.

Loxo Oncology continues to expect cash burn of $48 to $52 million in 2016. Based on the current operating plan, the company believes existing capital resources will be sufficient to fund anticipated operations into late 2018.

Research and development expenses were $14.2 million for the third quarter of 2016, compared to $6.3 million for the third quarter of 2015. This increase was primarily due to expanded clinical development activities for LOXO-101, as well as additional expenses related to the preclinical pipeline. Loxo Oncology also recognized research and development-related stock-based compensation expenses of $1.6 million during the third quarter of 2016, compared to $0.5 million for the third quarter of 2015.

Research and development expenses were $34.9 million for the nine months ended September 30, 2016, compared to $15.8 million for the nine months ended September 30, 2015. This increase was primarily due to expanded clinical development activities for LOXO-101, as well as additional expenses related to the preclinical pipeline. Loxo Oncology also recognized research and development-related stock-based compensation expenses of $2.1 million during the nine months ended September 30, 2016, compared to $1.8 million for the nine months ended September 30, 2015.

General and administrative expenses were $3.7 million for the third quarter of 2016, compared to $2.6 million for the third quarter of 2015. This increase was primarily due to employment costs and professional fees. Loxo Oncology also recognized general and administrative-related stock-based compensation expense of $1.2 million during the third quarter 2016, compared to $0.7 million for the third quarter 2015.

General and administrative expenses were $10.9 million for the nine months ended September 30, 2016, compared to $7.3 million for the nine months ended September 30, 2015. This increase was primarily due to employment costs and professional fees. Loxo Oncology also recognized general and administrative-related stock-based compensation expenses of $3.3 million during the nine months ended September 30, 2016, compared to $2.0 million for the nine months ended September 30, 2015.

Net loss was $17.7 million and $45.2 million for the three and nine months ended September 30, 2016, respectively, compared to $8.8 million and $23.0 million for the three and nine months ended September 30, 2015, 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 the NAVIGATE global Phase 2 multi-center basket trial in patients with solid tumors that harbor TRK gene fusions, and the SCOUT Phase 1 trial in pediatric patients, including patients with advanced cancer, TRK gene fusions and infantile fibrosarcoma. LOXO-101 has been granted Breakthrough Therapy Designation by the U.S. FDA. For additional information about 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 or visit www.loxooncologytrials.com.

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, the timing and success of our clinical trials, success in our collaborations and the potential therapeutic benefits of our lead product candidate or other product candidates. 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, 2016</th>
<th>December 31, 2015</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>$ 51,929</td>
<td>$ 68,177</td>
</tr>
<tr>
<td>Short-term investments</td>
<td>103,608</td>
<td>85,715</td>
</tr>
<tr>
<td>Prepaid expenses with related party</td>
<td>?</td>
<td>922</td>
</tr>
<tr>
<td>Other prepaid expenses and current assets</td>
<td>4,094</td>
<td>1,830</td>
</tr>
<tr>
<td>Total current assets</td>
<td>159,631</td>
<td>156,644</td>
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<tr>
<td>Long-term investments</td>
<td>1,002</td>
<td>?</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>269</td>
<td>88</td>
</tr>
<tr>
<td>Other assets</td>
<td>726</td>
<td></td>
</tr>
<tr>
<td>Total assets</td>
<td>$ 161,468</td>
<td>$ 157,458</td>
</tr>
</tbody>
</table>

**Liabilities and stockholders’ equity**
Current liabilities:
Accounts payable | $ 1,021 | $ 269 |
Accrued expenses and other current liabilities | 5,633 | 2,584 |
Total liabilities | 6,654 | 2,853 |
Commitments and contingencies | |
Stockholders’ equity: | | |
Common stock, $0.0001 par value; 125,000,000 shares authorized; 21,678,051 and 19,577,707 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively

<table>
<thead>
<tr>
<th>Description</th>
<th>2016</th>
<th>2015</th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional paid-in capital</td>
<td>266,798</td>
<td>221,457</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(112,042)</td>
<td>(66,838)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accumulated other comprehensive income (loss)</td>
<td>56</td>
<td>(16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total stockholders’ equity</td>
<td>154,814</td>
<td>154,605</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total liabilities and stockholders’ equity</td>
<td>$161,468</td>
<td>$157,458</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Description</th>
<th>2016</th>
<th>2015</th>
<th>2016</th>
<th>2015</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>$?</td>
<td>$2,874</td>
<td>$?</td>
<td>$7,711</td>
</tr>
<tr>
<td>Research and development</td>
<td>14,230</td>
<td>3,387</td>
<td>34,917</td>
<td>8,095</td>
</tr>
<tr>
<td>General and administrative</td>
<td>3,679</td>
<td>2,552</td>
<td>10,859</td>
<td>7,331</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>(17,909)</td>
<td>(8,813)</td>
<td>(45,776)</td>
<td>(23,137)</td>
</tr>
<tr>
<td>Interest income, net</td>
<td>218</td>
<td>42</td>
<td>572</td>
<td>128</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (17,691)</td>
<td>$ (8,771)</td>
<td>$ (45,204)</td>
<td>$ (23,009)</td>
</tr>
</tbody>
</table>

Per share information:
Net loss per share of common stock, basic and diluted
$ (0.82) $ (0.53) $ (2.19) $ (1.39)
Weighted average shares outstanding, basic and diluted
21,609,424 16,560,610 20,659,829 16,525,530

Contacts for Loxo Oncology, Inc.
Company:
Jacob S. Van Naarden
Chief Business Officer
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, Inc.