Loxo Oncology Reports First Quarter 2018 Financial Results

May 8, 2018

- LOXO-292 Phase 1 Oral Presentation Upcoming at 2018 ASCO Annual Meeting -

- LOXO-292 Preclinical and Clinical Proof-of-Concept Data Published in Annals of Oncology -

- Rolling Submission for Larotrectinib New Drug Application Completed -

STAMFORD, Conn., May 08, 2018 (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 first quarter 2018 financial results.

“In the first quarter, we delivered against all of our planned corporate goals. We completed the rolling NDA submission for larotrectinib, enrolled well on the LOXO-292 Phase 1 trial and moved LOXO-305 toward a clinical start in the second half of 2018. We also entered into an important collaboration with Illumina to develop a companion diagnostic test for larotrectinib and LOXO-292,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “We look forward to providing a comprehensive update on the Phase 1 study of LOXO-292 at ASCO on June 2nd.”

Recent Highlights

Companion Diagnostic (CDx) Partnership

- **Global Development and Commercialization Partnership with Illumina:** On April 10, 2018, Loxo Oncology announced a global strategic partnership with Illumina to develop and commercialize a CDx version of Illumina’s TruSight Tumor 170 for NTRK fusions and RET fusions/mutations as a Class III FDA-approved companion diagnostic in conjunction with larotrectinib and LOXO-292, respectively. The companies are also planning to broaden the clinical utility of the full panel by seeking approval for the rest of the assay content as a Class II cancer genomic profiling test. More information can be found here.

Larotrectinib

- **Completion of New Drug Application (NDA) Rolling Submission to FDA:** On March 26, 2018, Loxo Oncology completed the rolling submission of an NDA to the U.S. Food and Drug Administration (FDA) for larotrectinib for the treatment of adult and pediatric patients with locally advanced or metastatic solid tumors harboring an NTRK gene fusion. More information can be found here.
- ***The Lancet Oncology* Publication:** On March 29, 2018, *The Lancet Oncology* published results for larotrectinib in the treatment of pediatric patients with TRK fusion cancer. The publication included results from the ongoing pediatric Phase 1/2 trial. In this trial, larotrectinib induced an objective response rate (ORR) of 93 percent in pediatric patients with TRK fusion-positive solid tumors. The publication can be found here.

LOXO-292

- ***Annals of Oncology* Publication:** On April 18, 2018, the *Annals of Oncology* published a manuscript illustrating the preclinical profile of LOXO-292, preclinical work supporting LOXO-292’s selective inhibition of RET, and continued evidence of clinical proof-of-concept. The publication included two patient cases who both presented with RET-altered, multikinase (MKI) inhibitor-resistant cancers. One patient harbored RET M918T-mutant medullary thyroid cancer with an acquired RET V804M gatekeeper resistance mutation, and the other patient harbored KIF5B-RET fusion-positive non-small cell lung cancer with brain metastases. The latter case was previously reported on in October 2017 in a presentation at the International Association for the Study of Lung Cancer 18th World Conference on Lung Cancer. Due to clinical urgency, both were treated with LOXO-292 on intra-patient dose

escalation single patient protocols. Both patients achieved RECIST confirmed partial responses. This represents the first clinical report of the predicted RET V804M gatekeeper mutation arising in a patient previously treated with MKIs, and the first successful treatment of a patient in that setting. In this two-patient dataset, LOXO-292 was well-tolerated with no adverse events attributed to LOXO-292. The publication can be found here.

- **LOXO-292 Oral Presentation Accepted at the American Society of Clinical Oncology (ASCO) Annual Meeting:** On April 4, 2018, Loxo Oncology announced that LOXO-292 interim clinical data from the ongoing Phase 1 clinical trial will be presented in an oral presentation at the ASCO Annual Meeting held June 1 - 5, 2018 in Chicago, Illinois. The presentation is entitled "A Phase 1 Study of LOXO-292, A Potent and Highly Selective RET Inhibitor, in Patients with RET-Altered Cancers." Loxo Oncology will host a conference call and live webcast on Saturday, June 2, 2018 at 4:00 p.m. CT to discuss the clinical data after they are presented at ASCO. Information on how to access the call and webcast can be found below.

Upcoming Milestones

- Larotrectinib (TRK)
  - FDA is expected to accept the filing of the New Drug Application in the first half of 2018
  - Marketing Authorisation Application submission by Bayer in the European Union is expected in 2018
  - Presentation of updated TRK fusion clinical data is expected in the second half of 2018
- LOXO-195 (next-generation TRK)
  - Presentation of updated clinical data is expected in the second half of 2018
- LOXO-292 (RET)
  - Presentation of updated clinical data at the ASCO Annual Meeting
- LOXO-305 (BTK)
  - Initiation of a Phase 1 clinical trial is expected in the second half of 2018

First Quarter 2018 Financial Results

As of March 31, 2018, Loxo Oncology had aggregate cash, cash equivalents and investments of $735.6 million, compared to $626.2 million as of December 31, 2017. Loxo Oncology received the remaining $150 million of the $400 million upfront payment related to the Bayer collaboration in the first quarter of 2018.

Revenue from the collaboration agreement was $38.4 million for the first quarter of 2018, compared to none for the first quarter of 2017. This represents $42.9 million in revenue recognized from the $400 million upfront payment from the Bayer collaboration offset by $4.4 million, Loxo Oncology's share of the joint larotrectinib co-promotion costs. Loxo Oncology recognizes revenue from the upfront payment on a proportional performance basis utilizing a calculation based on quarterly research and development spending associated with larotrectinib and LOXO-195, relative to cumulative and forecasted research and development spending on larotrectinib and LOXO-195 over the course of the collaboration agreement. As a result, the quarterly revenue recognized for the upfront payment varies from quarter to quarter. A supporting schedule that shows the different components of revenue from the collaboration agreement is included with the attached financial statements.

Research and development expenses were $32.0 million for the first quarter of 2018 compared to $20.2 million for the first quarter of 2017. This increase was primarily due to expanded larotrectinib development activities including clinical costs, as well as additional development expenses related to our other programs, and higher employment costs primarily due to increased headcount. These numbers are net of 50/50 cost-sharing with Bayer for larotrectinib and LOXO-195 development costs. Loxo Oncology recognized research and development-related stock-based compensation expense of $4.3 million during the first quarter of 2018 as compared to $2.4 million for the first quarter of 2017.

General and administrative expenses were $12.2 million for the first quarter of 2018 compared to $4.8 million for the first quarter of 2017. The increase was primarily due to additional headcount and associated employment costs and general and administrative professional fees. Loxo Oncology recognized general and administrative-related stock-based compensation expense of $5.4 million during the first quarter 2018 compared to $1.6 million for the first quarter of 2017.

Net loss was $3.6 million for the first quarter of 2018, compared to $24.5 million for the first quarter of 2017. This decrease in net loss is primarily driven by the revenue recognized from the $400.0 million upfront payment from the Bayer collaboration, the larotrectinib and LOXO-195 development reimbursement from the Bayer collaboration, offset by increases in operating expenses.

Non-GAAP net loss was $36.8 million for the first quarter of 2018, compared to $20.6 million for the first quarter of 2017. This non-GAAP net loss measure, more fully described below under “Non-GAAP Financial Measures,” excludes the recognition of collaboration revenue related to the Bayer upfront payment and share-based compensation expenses. A reconciliation of the GAAP financial results to non-GAAP financial results is included with the attached financial statements.

Earnings Conference Call Information
Loxo Oncology will host a conference call today at 8:00 a.m. ET to discuss the first quarter 2018 financial results and company updates. To participate in the conference call, please dial (877) 930-8065 (domestic) or (253) 336-8041 (international) and refer to conference ID 1979239. A replay will be available shortly after the conclusion of the call and archived on the company's website for 30 days following the call.

ASCO Conference Call and Webcast Information
Loxo Oncology will be hosting a conference call and live webcast with slides and Q&A on Saturday, June 2, 2018 at 4:00 p.m. CT to discuss the interim LOXO-292 clinical data after they are presented at ASCO. To participate in the conference call, please dial (877) 930-8065 (domestic) or (253) 336-8041 (international) and refer to conference ID 3597058. A live webcast of the presentation will be available at http://ir.loxooncology.com/. A replay will be available shortly after the conclusion of the call and archived on the company's website for 30 days following the call.

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 reporting, timing and success of our clinical trials, and the timing or success of regulatory approvals in the U.S. and in the E.U. Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Annual Report on Form 10-K, 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.

Non-GAAP Financial Measures
This press release includes financial results prepared in accordance with accounting principles generally accepted in the United States (GAAP), and also certain historical non-GAAP financial measures. In particular, we have provided non-GAAP net loss, adjusted to exclude recognized collaboration revenue related to an upfront payment and share-based compensation expenses. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. For a reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measure, see the table below. Non-GAAP financial measures may not be comparable to similarly titled measures reported by other companies, since not all companies may calculate these measures in an identical manner and, therefore, it is not necessarily an accurate measure of comparison between companies. However, we believe the

presentation of non-GAAP net loss, when viewed in conjunction with our GAAP results, provides investors and management with a more complete understanding of our ongoing and projected operating performance because this measure excludes the recognition of collaboration revenue from an upfront payment that is a non-recurring event and non-cash charges that are substantially dependent on changes in the market price of our common stock. We believe our non-GAAP net loss measure helps indicate underlying trends in our business and is important in comparing current results with prior period results.

Financials

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

	March 31, 2018	December 31, 2017
Assets	**(Unaudited)**	
Cash, cash equivalents and investments	$ 735,584	$ 626,200
Receivable from collaboration partner	4,529	150,000
Other prepaid expenses and current assets	5,891	5,607
Property and equipment, net	1,578	912
Other assets	1,027	723
Total assets	748,609	783,442
Liabilities and stockholders' equity		
Accounts payable	5,796	3,996
Accrued expenses and other current liabilities	22,546	22,537
Deferred revenue	335,846	378,699
Total liabilities	364,188	405,232
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 125,000,000 shares authorized; 30,055,380 and 29,991,884 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	3	3
Additional paid-in capital	676,771	666,891
Accumulated deficit	(291,670)	(288,112)
Other comprehensive loss	(683)	(572)
Total stockholders' equity	384,421	378,210
Total liabilities and stockholders' equity	$ 748,609	$ 783,442

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

	Three Months Ended March 31,	
	2018	**2017**

Revenue from collaboration agreement	$	38,429		$	—	
Operating expenses:						
Research and development		31,990			20,169	
General and administrative		12,194			4,773	
Total operating expenses		44,184			24,942	
Loss from operations		(5,755	)		(24,942	)
Interest income, net		2,197			414	
Net loss	$	(3,558	)	$	(24,528	)
Per share information:						
Net loss per share of common stock, basic and diluted	$	(0.12	)	$	(0.96	)
Weighted average shares outstanding, basic and diluted		30,025,461			25,668,052	

LOXO ONCOLOGY, INC.
Reconciliation of GAAP Net Loss to Non-GAAP Net Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,					
	2018			**2017**		
GAAP net loss	$	(3,558	)	$	(24,528	)
Adjustments:						
Revenue from collaboration agreement						
Revenue recognized from $400M upfront payment		(42,853	)		—	
Share-based compensation expenses included in R&D expenses		4,283			2,406	
Share-based compensation expenses included in G&A expenses		5,368			1,568	
Total share-based compensation expenses		9,651			3,974	
Total adjustments		(33,202	)		3,974	
Non-GAAP net loss	$	(36,760	)	$	(20,554	)
Per share information:						
Net loss per share of common stock, basic and diluted	$	(1.22	)	$	(0.80	)
Weighted average shares outstanding, basic and diluted		30,025,461			25,668,052	

LOXO ONCOLOGY, INC.
Calculation of Revenue from Collaboration Agreement
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2018	**2017**
Upfront payment		
Revenue recognized from $400M upfront payment	$ 42,853	$ —
Milestones	—	—
Royalties	—	—
Co-promote		
Product revenue subject to profit sharing (as recorded by Bayer)	—	—
Combined cost of goods sold, distribution, selling, general and administrative expenses	(8,848)	—
Combined collaboration co-promotion profit/(loss)	(8,848)	—
Loxo Oncology's 50/50 share of collaboration co-promotion profit/(loss)	(4,424)	—
Total revenue from collaboration agreement	$ 38,429	$ —

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