Loxo Oncology Reports Second Quarter 2018 Financial Results

August 9, 2018

- LOXO-292 New Drug Application (NDA) Submission to FDA Expected in Late 2019 -

- Updated Larotrectinib Duration of Response Data to be Reported at ESMO -

- Larotrectinib NDA PDUFA date is November 26, 2018 -

STAMFORD, Conn., Aug. 09, 2018 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company developing highly selective medicines for patients with genomically defined cancers, today reported second quarter 2018 financial results.

“We made significant progress across our pipeline in the second quarter,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “In May, our NDA for larotrectinib was accepted by FDA and granted Priority Review. In June, initial clinical data from the ongoing LIBRETTO-001 Phase 1/2 study of LOXO-292 were presented at ASCO. These data enabled a subsequent FDA meeting, which established a path forward for the program. And lastly, we completed important enabling studies and manufacturing activities for the LOXO-305 IND. In the second half of the year, we are focused on continuing to advance our pipeline, as well as aiding and advising our partners at Bayer in anticipation of a possible larotrectinib regulatory approval. Operationally, we aim to lay the groundwork for the long-term adoption of tumor genomic testing capable of detecting TRK fusions alongside other clinically actionable alterations.”

LOXO-292 Regulatory Update

Loxo Oncology recently conducted a meeting with the U.S. Food and Drug Administration (FDA) for LOXO-292. Based on written minutes from FDA, Loxo Oncology expects to submit a new drug application (NDA) for LOXO-292 in late 2019, utilizing data generated from the ongoing LIBRETTO-001 clinical trial. This timeline integrates standard NDA activities which are ongoing and planned, including clinical pharmacology studies, non-clinical studies, and manufacturing. Loxo Oncology expects to file for separate potential indications for two populations of patients: those with RET fusion-positive solid tumors such as lung and thyroid cancer, and those with RET-mutant medullary thyroid cancer (MTC). In both cases, Loxo Oncology expects that patients will be required to have received systemic therapy, progressed following prior treatment and have no satisfactory alternative treatment options.

Recent Highlights

Larotrectinib

- **Abstract Accepted for Oral Presentation at the European Society for Medical Oncology (ESMO) 2018 Congress:** Clinical data for larotrectinib will be presented at the ESMO 2018 Congress to be held October 19-23, 2018, in Munich, Germany. The presentation will provide updated clinical follow-up for the 55 patients who comprise the primary efficacy analysis population that has supported global regulatory filings. The presentation will also include new data for TRK fusion patients subsequently enrolled.
- **Abstract Accepted for Poster Presentation at the Molecular Analysis for Personalised Therapy 2018 Congress:** On September 15, 2018, Ventana Medical Systems, Inc., a member of the Roche Group, and Loxo Oncology, will present a co-authored poster on the analytical validation of Ventana’s pan-TRK IHC assay at the Molecular Analysis for Personalised Therapy 2018 Congress, to be held September 14-15, 2018 in Paris, France.
- **Acceptance of NDA by FDA:** On May 29, 2018, Loxo Oncology announced FDA acceptance of the larotrectinib NDA and granting of Priority Review for the treatment of adult and pediatric patients with locally advanced or metastatic solid tumors harboring an NTRK gene fusion. The FDA has set a target action date of November 26, 2018

, under the Prescription Drug User Fee Act (PDUFA). More information can be found here.

- **International Symposium on Pediatric Neuro-Oncology (ISPNO) Poster Presentation:** On July 1, 2018, a poster presentation at ISPNO 2018 detailed a case report of a pediatric patient with TRK fusion high-grade glioma treated with larotrectinib on a single patient protocol. The poster can be found here.
- **World Congress on Gastrointestinal Cancer Oral Presentation:** On June 22, 2018, an oral presentation at the ESMO World Congress on Gastrointestinal Cancer detailed larotrectinib data in patients with TRK fusion gastrointestinal (GI) cancers enrolled to the pivotal larotrectinib program. The presentation can be found here.
- ***Journal of Clinical Investigation*** **Publication:** On June 19, 2018, an article was published online in the peer-reviewed *Journal of Clinical Investigation* detailing the occurrence of TRK fusions in hematologic malignancies, including a case report of a patient with TRK fusion acute myeloid leukemia (AML) treated with larotrectinib on a single patient protocol. The publication can be found here.
- ***Pediatric Blood & Cancer*** **Publication:** On June 12, 2018, a case report was published in the online edition of the peer-reviewed journal *Pediatric Blood & Cancer* detailing a pediatric patient with metastatic TRK fusion congenital mesoblastic nephroma (CMN) treated with larotrectinib on the SCOUT trial. The publication can be found here.

LOXO-292

- **Interim Clinical Data Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting:** In June, interim clinical data from the LOXO-292 global LIBRETTO-001 trial were presented in an oral presentation at ASCO. The presentation included 82 patients enrolled across eight dose escalation cohorts and employed an April 2, 2018 data cut-off. The data demonstrated a 77 percent (95% CI: 61-89%) overall response rate (ORR) in RET fusion cancers and a 45 percent (95% CI: 24-68%) ORR in RET mutated MTC as evaluated by RECIST 1.1 criteria. Patients had received a median of three prior treatments with two-thirds having been treated with at least one prior multi-kinase inhibitor. All responding patients across all tumor types remained on therapy as of the data cut-off. LOXO-292 was well tolerated with most treatment-emergent adverse events Grade 1 in severity. The treatment-emergent adverse events observed in ?10% of patients, regardless of relationship to LOXO-292, were fatigue, diarrhea, constipation, dry mouth, nausea, and dyspnea. Phase 2 cohorts are open and enrolling at the 160mg BID dose. See the presented data here.

LOXO-305

- **Presentation Accepted at the Society of Hematologic Oncology (SOHO) Annual Meeting:** In September 2018, Loxo Oncology authors will present LOXO-305 preclinical characterization data in oral and poster presentations at the SOHO Annual Meeting taking place September 12-15 in Houston, Texas.

Upcoming Milestones

- Larotrectinib (TRK)
  - Presentation of updated clinical data at the ESMO Congress
  - Submission of a Marketing Authorisation Application in the European Union, by Bayer, is expected in the second half of 2018
  - NDA PDUFA date of November 26, 2018
- LOXO-195 (next-generation TRK)
  - Updated clinical data is now expected in the first half of 2019
- LOXO-292 (RET)
  - Updated clinical data is expected in the second half of 2018
- LOXO-305 (BTK)
  - Presentation of preclinical data at the SOHO Annual Meeting
  - Initiation of a Phase 1 clinical trial is expected in the fourth quarter of 2018

Second Quarter 2018 Financial Results

As of June 30, 2018, Loxo Oncology had aggregate cash, cash equivalents and investments of $706.4 million, compared to $626.2 million as of December 31, 2017.

Revenue from the collaboration agreement was $42.6 million for the second quarter of 2018, compared to none for the second quarter of 2017. This represents $51.2 million in revenue recognized from the $400 million upfront payment from the Bayer collaboration offset by $8.6 million, Loxo Oncology's share of the joint larotrectinib co-promotion costs.

Revenue from the collaboration agreement was $81.0 million for the six months ended June 30, 2018, compared to none for the six months ended June 30, 2017. This represents $94.1 million in revenue recognized from the $400 million upfront payment from the Bayer collaboration offset by $13.1 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 $41.6 million for the second quarter of 2018 compared to $24.4 million for the second quarter of 2017. This increase was primarily due to expanded development expenses across our LOXO-292 and LOXO-305 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 $5.8 million during the second quarter of 2018 as compared to $3.5 million for the second quarter of 2017.

Research and development expenses were $73.5 million for the six months ended June 30, 2018 compared to $44.6 million for the six months ended June 30, 2017. This increase was primarily due to expanded development expenses across our LOXO-292 and LOXO-305 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 $10.1 million during the six months ended June 30, 2018 as compared to $5.9 million for the six months ended June 30, 2017.

General and administrative expenses were $15.7 million for the second quarter of 2018 compared to $6.5 million for the second 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 $6.5 million during the second quarter of 2018 compared to $2.0 million for the second quarter of 2017.

General and administrative expenses were $27.9 million for the six months ended June 30, 2018 compared to $11.3 million for the six months ended June 30, 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 $11.9 million during the six months ended June 30, 2018 compared to $3.5 million for the six months ended June 30, 2017.

Net loss was $11.7 million and $15.3 million for the three and six months ended June 30, 2018, respectively, compared to $30.4 million and $54.9 million for the three and six months ended June 30, 2017, respectively. 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 $50.6 million and $87.4 million for the three and six months ended June 30, 2018, respectively, compared to $25.0 million and $45.5 million for the three and six months ended June 30, 2017, respectively. 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 and Webcast Information

Loxo Oncology will host a conference call today at 8:00 a.m. ET to discuss the second quarter 2018 financial results and

company updates. A live webcast can be accessed under "Events & Presentations" in the Investors & Media section of the company's website at www.loxooncology.com. The conference call can be accessed by dialing (877) 930-8065 (domestic) or (253) 336-8041 (international) and referring to conference ID 7291605. The webcast will be archived and made available for replay on the company's website beginning approximately two hours after the event.

About Loxo Oncology

Loxo Oncology is a biopharmaceutical company developing highly selective medicines for patients with genomically 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, with the intention of 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, the success of our efforts to commercialize larotrectinib, 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)

	June 30, 2018 (Unaudited)	December 31, 2017
Assets		
Cash, cash equivalents and investments	$ 706,401	$ 626,200

Receivable from collaboration partner	—	150,000
Other prepaid expenses and current assets	5,749	5,607
Property and equipment, net	3,333	912
Other assets	1,027	723
Total assets	716,510	783,442
Liabilities and stockholders' equity		
Accounts payable	4,789	3,996
Payable due to collaboration partner	593	—
Accrued expenses and other current liabilities	34,386	22,537
Deferred revenue	284,618	378,699
Total liabilities	324,386	405,232
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 125,000,000 shares authorized; 30,426,546 and 29,991,884 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	3	3
Additional paid-in capital	695,996	666,891
Accumulated deficit	(303,396)	(288,112)
Other comprehensive loss	(479)	(572)
Total stockholders' equity	392,124	378,210
Total liabilities and stockholders' equity	$ 716,510	$ 783,442

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenue from collaboration agreement	$ 42,601	$ —	$ 81,030	$ —
Operating expenses:				
Research and development	41,555	24,398	73,545	44,567
General and administrative	15,742	6,515	27,936	11,288
Total operating expenses	57,297	30,913	101,481	55,855
Loss from operations	(14,696)	(30,913)	(20,451)	(55,855)
Interest income, net	2,970	512	5,167	926
Net loss	$ (11,726)	$ (30,401)	$ (15,284)	$ (54,929)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.39)	$ (1.14)	$ (0.51)	$ (2.10)
Weighted average shares outstanding, basic and diluted	30,156,986	26,586,610	30,091,587	26,129,869

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
GAAP net loss	$ (11,726)	$ (30,401)	$ (15,284)	$ (54,929)
Adjustments:				
Revenue from collaboration agreement				
Revenue recognized from $400M upfront payment	(51,228)	—	(94,081)	—
Share-based compensation expenses included in R&D expenses	5,825	3,456	10,108	5,862
Share-based compensation expenses included in G&A expenses	6,521	1,979	11,889	3,548
Total share-based compensation expenses	12,346	5,435	21,997	9,410
Total adjustments	(38,882)	5,435	(72,084)	9,410
Non-GAAP net loss	$ (50,608)	$ (24,966)	$ (87,368)	$ (45,519)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.68)	$ (0.94)	$ (2.90)	$ (1.74)
Weighted average shares outstanding, basic and diluted	30,156,986	26,586,610	30,091,587	26,129,869

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Upfront payment				
Revenue recognized from $400M upfront payment	$ 51,228	$ —	$ 94,081	$ —
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	(17,254)		(26,102)	
Combined collaboration co-promotion profit/(loss)	(17,254)		(26,102)	
Loxo Oncology's 50/50 share of collaboration co-promotion profit/(loss)	(8,627)		(13,051)	
Total revenue from collaboration agreement	$ 42,601	$	$ 81,030	$

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