Loxo Oncology Announces Second Quarter 2017 Financial Results

August 8, 2017

– Larotrectinib NDA Submission on Track for Year End 2017 / Early 2018 –

– Larotrectinib, LOXO-195, and LOXO-292 Clinical Trials Actively Enrolling –

– $467.6 million in Cash, Cash Equivalents, and Investments Provides Significant Runway –

STAMFORD, Conn., Aug. 08, 2017 (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 quarter ended June 30, 2017. Loxo Oncology will not be conducting a conference call in conjunction with this earnings release.

“I am very proud of the Loxo Oncology team for delivering a great second quarter,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “The larotrectinib (LOXO-101) presentations at ASCO and the simultaneous LOXO-195 publication in Cancer Discovery illustrate what can be accomplished for patients when a focused management team brings together the disparate disciplines of medicinal chemistry, comprehensive tumor testing and clinical-regulatory execution. In addition, the LOXO-292 IND moves the company into an exciting second target and third clinical-stage program. We look forward to the second half of 2017, when we plan to prepare the larotrectinib NDA submission, advance our TRK fusion diagnostics strategy with third party collaborators, and advance LOXO-292 efficiently through a dose escalation. We hope to be able to share initial clinical data from the LOXO-292 program by the end of the year.”

Recent Highlights

- **Larotrectinib Adult and Pediatric Interim Clinical Data Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting:** In June, interim clinical data from three ongoing larotrectinib trials were reported in two oral presentations at ASCO. The data demonstrated a 76 percent confirmed objective response rate (ORR) in 50 patients for whom follow-up was sufficiently long to include a confirmatory scan. Responses were observed across 17 unique tumor types harboring TRK fusions. The ASCO presentation included adult and pediatric patients with Response Evaluation Criteria In Solid Tumors (RECIST)-evaluable TRK fusion cancers, with an April 14, 2017 data cut-off. See the presented data here.
- **Larotrectinib Regulatory Updates:** In May, the U.S. Food and Drug Administration (FDA) granted orphan drug designation to larotrectinib for the “treatment of solid tumors with NTRK-fusion proteins.” Loxo Oncology remains on track to submit a New Drug Application (NDA) for larotrectinib to the FDA in late 2017 or early 2018. The primary analysis for the NDA will rely upon central, independent radiology review. The company plans to announce these data, which will also include additional patient follow-up from the data set presented at ASCO, before the end of 2017.
- **LOXO-195:** In May, the FDA cleared the IND application for LOXO-195, Loxo Oncology’s next-generation TRK inhibitor. On June 3, 2017, a research brief was published in *Cancer Discovery* outlining the preclinical rationale for LOXO-195 and clinical proof-of-concept data from the first two patients treated. The Phase 1 trial is currently open for enrollment.
- **LOXO-292:** In May, the first patient was enrolled in the Phase 1 clinical trial of LOXO-292, a highly selective RET inhibitor. This first-in-human, global, multi-center Phase 1 trial is evaluating LOXO-292 as a single agent in patients with advanced solid tumors.
- **LOXO-305:** In July, Loxo Oncology announced the acquisition of the Redx Pharma Plc BTK inhibitor program, including lead candidate LOXO-305 (formerly RXC005). Under the terms of the agreement, Loxo Oncology has made a $40 million payment to Redx Pharma Plc. Loxo Oncology is not subject to milestone or royalty obligations. Lead candidate LOXO-305 was designed to reversibly bind BTK and preserve activity in the presence of the C481S acquired resistance mutation. Additionally, it was designed to avoid off-target kinases that have complicated the

development of both covalent and reversible BTK inhibitors. LOXO-305 is expected to enter clinical development in 2018.

- **Equity Financing:** In June, Loxo Oncology announced the closing of an underwritten public offering of 3,622,500 shares of common stock at a public offering price of $72.00 per share, which included the exercise in full by the underwriters of their option to purchase 472,500 additional shares of common stock. Gross proceeds to Loxo Oncology from this offering were approximately $260.8 million.

Second Quarter 2017 Financial Results

As of June 30, 2017, Loxo Oncology had aggregate cash, cash equivalents and investments of $467.6 million, compared to $141.8 million as of December 31, 2016.

Research and development expenses were $24.4 million for the second quarter of 2017 compared to $12.3 million for the second quarter of 2016. This increase was primarily due to expanded larotrectinib development activities including clinical costs and costs related to the companion diagnostics agreement with Roche, as well as additional development expenses related to LOXO-292 and increases in employment costs primarily due to increased headcount. Loxo Oncology also recognized research and development-related stock-based compensation expense of $3.5 million during the second quarter of 2017 compared to $0.2 million for the second quarter of 2016.

Research and development expenses were $44.6 million for the six months ended June 30, 2017, compared to $20.7 million for the six months ended June 30, 2016. This increase was primarily due to expanded larotrectinib development activities including clinical costs and costs related to the companion diagnostics agreement with Roche, as well as additional development expenses related to LOXO-292 and LOXO-195 and increases in employment costs primarily due to increased headcount. Loxo Oncology also recognized research and development-related stock-based compensation expense of $5.9 million during the six months ended June 30, 2017, compared to $0.5 million for the six months ended June 30, 2016.

General and administrative expenses were $6.5 million for the second quarter of 2017 compared to $3.8 million for the second quarter of 2016. The increase was primarily due to increases in preparation activities for the potential commercialization of larotrectinib, headcount and employment costs and general and administrative professional fees. Loxo Oncology also recognized general and administrative-related stock-based compensation expense of $2.0 million during the second quarter 2017 compared to $1.1 million for the second quarter of 2016.

General and administrative expenses were $11.3 million for the six months ended June 30, 2017, compared to $7.2 million for the six months ended June 30, 2016. The increase was primarily due to increases in preparation activities for the potential commercialization of larotrectinib, headcount and employment costs and general and administrative professional fees. Loxo Oncology also recognized general and administrative-related stock-based compensation expense of $3.5 million during the six months ended June 30, 2017, compared to $2.1 million for the six months ended June 30, 2016.

Net loss was $30.4 million and $54.9 million for the three and six months ended June 30, 2017, respectively, compared to $15.9 million and $27.5 million for the three and six months ended June 30, 2016, respectively.

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. 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.

Financials

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

	June 30, 2017	December 31, 2016
Assets	**(Unaudited)**	
Cash, cash equivalents and investments	$ 467,585	$ 141,810
Other prepaid expenses and current assets	3,831	2,483
Property and equipment, net	364	248
Other assets	657	771
Total assets	472,437	145,312
Liabilities and stockholders' equity		
Accounts payable	2,175	1,061
Accrued expenses and other current liabilities	9,008	14,083
Total liabilities	11,183	15,144
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 125,000,000 shares authorized; 29,839,268 and 21,681,236 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	3	2
Additional paid-in capital	655,581	269,423
Accumulated deficit	(194,165)	(139,236)
Other comprehensive loss	(165)	(21)
Total stockholders' equity	461,254	130,168
Total liabilities and stockholders' equity	$ 472,437	$ 145,312

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 24,398	$ 12,331	$ 44,567	$ 20,687
General and administrative	6,515	3,786	11,288	7,180
Total operating expenses and loss from operations	(30,913)	(16,117)	(55,855)	(27,867)
Interest income, net	512	201	926	354
Net loss	$ (30,401)	$ (15,916)	$ (54,929)	$ (27,513)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.14)	$ (0.77)	$ (2.10)	$ (1.36)
Weighted average shares outstanding, basic and diluted	26,586,610	20,587,848	26,129,869	20,177,162

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
1AB Media
973-271-6085
dan@1abmedia.com

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