Loxo Oncology Reports Fourth Quarter and Year-End 2017 Financial Results

March 1, 2018

– Larotrectinib Rolling NDA Submission on Track for Completion in March –

– LOXO-292 Phase 1 Clinical Data Update Expected in First Half 2018 –

STAMFORD, Conn., March 01, 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 fourth quarter and year-end 2017 financial results.

“2017 was a remarkable year for the company,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “Our TRK franchise partnership with Bayer brings capital and commercial expertise to an NDA-stage opportunity in larotrectinib and an acquired resistance solution in LOXO-195. Continued progress in the Phase 1 trial for LOXO-292, our highly selective RET inhibitor, has positioned the program for a clinical update in the first half of 2018. Finally, our acquisition of LOXO-305, a selective and reversible BTK inhibitor intended for patients with acquired resistance or intolerance to covalent BTK inhibitors, brings a fourth program to our pipeline, with a clinical start planned for the second half of 2018.”

Recent Highlights

TRK Inhibitor Franchise

- **Global Development and Commercialization Partnership with Bayer:** On November 14, 2017, Loxo Oncology announced a global collaboration with Bayer to develop and commercialize larotrectinib and LOXO-195. The company received a $400.0 million upfront payment and is eligible for an additional $1.15 billion in milestones, of which Loxo Oncology believes $425.0 million are achievable in 2018 and 2019. In the U.S., where Loxo Oncology and Bayer will co-promote the products, the parties will share commercial costs and profits on a 50/50 basis. More information on the collaboration can be found here.

Larotrectinib

- ***New England Journal of Medicine (NEJM)* Publication:** On February 22, 2018, the *NEJM* published results for larotrectinib in the treatment of pediatric and adult patients with TRK fusion cancers. The publication included central radiology results and additional patient follow-up from the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting presentation, employing a July 17, 2017 data cutoff. As previously reported, the overall response rate (ORR) was 75% by central assessment and 80% by investigator assessment. As of the July 17, 2017 data cutoff, 86% of responding patients remained on treatment or had undergone surgery with curative intent. The publication can be found here.
- **New Drug Application (NDA) Rolling Submission:** On December 20, 2017, Loxo Oncology announced that the company initiated a rolling NDA submission to the U.S. Food and Drug Administration (FDA) for larotrectinib for the treatment of unresectable or metastatic solid tumors with NTRK-fusion proteins in adult and pediatric patients who require systemic therapy and who have either progressed following prior treatment or who have no acceptable alternative treatments. The company expects to complete the submission by the end of March. More information can be found here.
- **Clinical Data in Thyroid (TC) and Salivary Gland Cancers (SGC):** On February 15, 2018, a poster presentation at the 2018 Multidisciplinary Head and Neck Cancers Symposium outlined data in 19 patients (age 15-75 years) with TRK fusion TC or SGC who were treated in the ongoing larotrectinib clinical trials. In 17 patients with measurable disease (5 TC and 12 SGC), treatment with larotrectinib led to an ORR of 88%, by both central and

investigator assessment. Adverse events were consistent with data previously reported from these trials. The presented poster can be found here.

- **Clinical Data from the Phase 1 SCOUT Clinical Trial:** On December 4, 2017, an oral presentation at the American Association for Cancer Research (AACR) Special Conference on Pediatric Cancer Research outlined data in 17 pediatric patients with TRK fusion cancers who were treated in the larotrectinib pediatric Phase 1 SCOUT clinical trial. Treatment with larotrectinib led to an ORR of 93%, by both central and investigator assessment. An overview of the data can be found here.

Upcoming Milestones

- Larotrectinib (TRK)
  - Completion of the rolling NDA submission is expected in March
  - 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 is expected in the first half of 2018
- LOXO-305 (BTK)
  - Initiation of a Phase 1 clinical trial is expected in the second half of 2018

Fourth Quarter and Full Year 2017 Financial Results

As of December 31, 2017, Loxo Oncology had aggregate cash, cash equivalents and investments of $626.2 million, compared to $141.8 million as of December 31, 2016. Loxo Oncology received $250 million of the $400 million upfront payment related to the Bayer collaboration in the fourth quarter of 2017 and the remaining $150 million is payable in first quarter of 2018.

Revenue from the collaboration agreement was $21.3 million for the fourth quarter and full year of 2017, compared to none for the fourth quarter and full year of 2016. This represents the partial revenue recognition of the $400 million upfront payment from the Bayer collaboration. Loxo Oncology is recognizing revenue 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 will vary from quarter to quarter.

Research and development expenses were $30.7 million for the fourth quarter of 2017 compared to $23.4 million for the fourth quarter of 2016. This increase was primarily due to expanded larotrectinib development activities including clinical costs, as well as additional development expenses related to our other programs. Loxo Oncology also recognized research and development-related stock-based compensation expense of $1.5 million during the fourth quarter of 2017 compared to $1.4 million for the fourth quarter of 2016.

Research and development expenses were $140.0 million for the year ended December 31, 2017, compared to $58.3 million for the year ended December 31, 2016. This increase was primarily due to a non-recurring charge related to the $40.0 million asset acquisition of the BTK inhibitor program from Redx, expanded larotrectinib development activities, as well as additional development expenses related to our other programs. We also had higher employment costs primarily due to increased headcount. Loxo Oncology also recognized research and development-related stock-based compensation expense of $9.5 million during the year ended December 31, 2017, compared to $3.5 million for the year ended December 31, 2016.

General and administrative expenses were $12.7 million for the fourth quarter of 2017 compared to $4.0 million for the fourth quarter of 2016. The increase was primarily due to preparation activities for the potential commercialization of larotrectinib, additional headcount and associated employment costs and general and administrative professional fees. Loxo Oncology also recognized general and administrative-related stock-based compensation expense of $3.3 million during the fourth quarter 2017 compared to $1.2 million for the fourth quarter of 2016.

General and administrative expenses were $33.7 million for the year ended December 31, 2017, compared to $14.9 million

for the year ended December 31, 2016. The increase was primarily due to preparation activities for the potential commercialization of larotrectinib, additional headcount and associated employment costs and general and administrative professional fees. Loxo Oncology also recognized general and administrative-related stock-based compensation expense of $9.9 million during the year ended December 31, 2017, compared to $4.5 million for the year ended December 31, 2016.

Net loss was $20.6 million for the fourth quarter of 2017, compared to $27.2 million for the fourth quarter of 2016. Net loss was $148.9 million for the year ended December 31, 2017, compared to $72.4 million for the year ended December 31, 2016. This increase in net loss is primarily driven by the increases in operating expenses.

Non-GAAP net loss was $37.2 million for the fourth quarter of 2017, compared to $24.6 million for the fourth quarter of 2016. Non-GAAP net loss was $110.8 million for the year ended 2017, compared to $64.4 million for the year ended 2016. This non-GAAP net loss measure, more fully described below under “Non-GAAP Financial Measures,” excludes the recognition of collaboration revenue related to an upfront payment, acquisition of an in-process R&D asset and share-based compensation expenses. A reconciliation of the GAAP financial results to non-GAAP financial results is included with the attached financial statements.

Conference Call Information
Loxo Oncology will host a conference call today at 8:00 a.m. ET to discuss the fourth quarter and full-year 2017 financial results and program updates. To participate in the conference call, please dial (877) 930-8065 (domestic) or (253) 336-8041 (international) and refer to conference ID 7395447. 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. 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, the acquisition of an in process R&D asset 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, acquisition of an in process R&D asset 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)

	December 31, 2017 (Unaudited)	December 31, 2016
Assets		
Cash, cash equivalents and investments	$ 626,200	$ 141,810
Receivable from collaboration partner	150,000	—
Other prepaid expenses and current assets	5,607	2,483
Property and equipment, net	912	248
Other assets	723	771
Total assets	783,442	145,312
Liabilities and stockholders' equity		
Accounts payable	3,996	1,061
Accrued expenses and other current liabilities	22,537	14,083
Deferred revenue	378,699	—
Total liabilities	405,232	15,144
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 125,000,000 shares authorized; 29,991,884 and 21,681,236 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	3	2
Additional paid-in capital	666,891	269,423
Accumulated deficit	(288,112)	(139,236)
Other comprehensive loss	(572)	(21)
Total stockholders' equity	378,210	130,168
Total liabilities and stockholders' equity	$ 783,442	$ 145,312

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Revenue from collaboration agreement	$ 21,300	$ —	$ 21,300	$ —

Operating expenses:				
Research and development	30,718	23,358	140,039	58,275
General and administrative	12,689	4,044	33,657	14,903
Total operating expenses	(43,407)	(27,402)	(173,696)	(73,178)
Loss from operations	(22,107)	(27,402)	(152,396)	(73,178)
Interest income, net	1,479	208	3,520	780
Net loss	$ (20,628)	$ (27,194)	$ (148,876)	$ (72,398)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.69)	$ (1.26)	$ (5.31)	$ (3.46)
Weighted average shares outstanding, basic and diluted	29,948,706	21,634,295	28,035,697	20,905,448

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 December 31,		Year Ended December 31,	
	2017	2016	2017	2016
GAAP net loss	$ (20,628)	$ (27,194)	$ (148,876)	$ (72,398)
Adjustments:				
Revenue from collaboration agreement	(21,300)	—	(21,300)	—
Acquisition of in-process R&D (IPR&D) asset included in R&D expenses	—	—	40,000	—
Share-based compensation expenses included in R&D expenses	1,492	1,369	9,502	3,471
Share-based compensation expenses included in G&A expenses	3,252	1,197	9,920	4,489
Total share-based compensation expenses	4,744	2,566	19,422	7,960
Total adjustments	(16,556)	2,566	38,122	7,960
Non-GAAP net loss	$ (37,184)	$ (24,628)	$ (110,754)	$ (64,438)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.24)	$ (1.14)	$ (3.95)	$ (3.08)
Weighted average shares outstanding, basic and diluted	29,948,706	21,634,295	28,035,697	20,905,448

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