

# Loxo Oncology, Inc. (LOXO)

LOXO Announces 2015 Program Guidance and Unveils Selected Preclinical Programs

## MARKET DATA

Price	\$13.13
52-Week Range:	\$9.90 - \$16.45
Shares Out. (M):	16.6
Market Cap (\$M):	\$218.0
Average Daily Vol. (000):	19.0
Cash (M):	\$119
Cash/Share:	\$7.13
Enterprise Value (M):	\$212
Float (M):	16.2
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

FY DEC	2014E	2015E	2016E
Revenue (\$M) 1Q	\$0.0A	--	--
2Q	\$0.0A	--	--
3Q	\$0.0A	--	--
4Q	\$0.0	--	--
FY	\$0.0	\$0.0	\$0.0
EPS 1Q	(\$0.68)A	--	--
2Q	(\$14.39)A	--	--
3Q	(\$0.68)A	--	--
4Q	(\$0.30)	--	--
FY	(\$1.48)	(\$1.93)	(\$3.74)

Source: Company reports and JMP Securities LLC

## STOCK PRICE PERFORMANCE



**MARKET OUTPERFORM** | Price: \$13.13 | Target Price: \$23.00

## INVESTMENT HIGHLIGHTS

**Loxo Oncology outlined company updates for 2015; reiterate our Market Outperform rating and \$23 price target through a synthesis of discounted cash flow, sum-of-the-parts, and compound annual growth valuation methodologies.**

On this morning's call, LOXO provided an update on its leading clinical asset (LOXO-101) as well as disclosed several new targets that the company plans to pursue in preclinical, IND-enabling, programs. Of importance, upcoming LOXO catalysts that should attract investor interest include an initial pharmacokinetic and safety Phase Ia readout that will be presented at the American Association for Cancer Research (AACR) to be held in Philadelphia on April 18-22; and an expected clinical update in 2H15 at a future medical meeting, if the data support proof of concept for LOXO-101 in TRK-positive patients. We look forward to these updates as the preliminary clinical data could provide a glimpse into the activity of LOXO-101 (Figure 1).

**Quick refresher on TRK and LOXO-101.** Recall that the TRK family of neurotrophin receptors, exemplified by TRKA, TRKB and TRKC, function primarily in the growth, differentiation and survival of neurons. NTRK1 fusions have been described in a subset of lung adenocarcinoma patients; and more recently, TRK fusions were found in many more tumor types than previously elucidated (see our note on LOXO dated November 24, 2014), suggesting a broader market potential for LOXO-101. The compound binds all three subtypes of the TRK receptors, i.e., TRKA, B, and C. LOXO-101 is being developed under license from Array Biopharma (ARRY, NC), and is undergoing clinical development in patients with advanced solid tumors. The Phase 1a study, being run at four sites (Sarah Cannon Research Institute, U Penn, MGH and University of Colorado), is presently in the midst of the dose-escalation portion of the trial to determine the maximum tolerated dose (MTD), and is proceeding well, according to management. LOXO-101 is expected to advance into clinical development in lung cancer patients wherein a TRK fusion protein is the key "driver" of the cancer, although the overarching goal is to also identify one or more areas of TRK biology to rapidly advance into a Phase 2 study. LOXO-101 will be evaluated in patients with TRK fusions, splice variants, mutations or in conditions where TRKs are overexpressed. Although the space appears to be populated with drugs in various stages of development (Figure 2), we believe LOXO-101 is a superior candidate given its high specificity to the isoforms, with limited exposure to the CNS (it should strike the intended target, limiting off-target toxicities and CNS side effects). We currently model uptake of LOXO-101 in non-small cell lung cancer (NSCLC), metastatic colorectal cancer (mCRC) and papillary thyroid cancer. Recall, as we wrote in November, 23 NTRK1, NTRK2, and NTRK3 fusions across nine tumor types (vs. three in our model) were recently reported (such as in head and neck squamous cell carcinoma), which could offer additional areas of development for TRK inhibitors.

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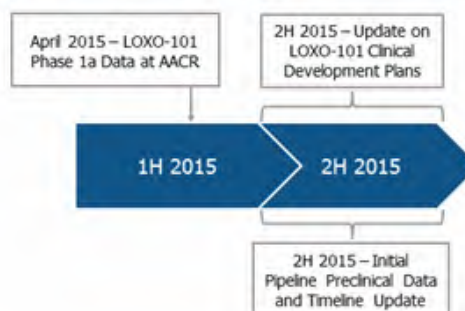
FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO JMP FACTS AND DISCLOSURES SECTION.

**Not just about TRK anymore.** This morning, LOXO unveiled three new receptor tyrosine kinase targets as part of its preclinical program, in addition to its two undisclosed targets: RET (rearranged during transfection), FGFR (fibroblast growth factor receptor), and FLT3 (fms-like tyrosine kinase). As with LOXO-101, these candidates are a part of collaborations that the company has secured with Array BioPharm. Even though the exclusivity targets that LOXO holds with ARRY has been pared down from 12 (exclusive of LOXO-101) to four, with a potential for a fifth candidate (providing ARRY an additional milestone), we view this attrition as a greater focus by LOXO upon the validity of the targets and thus the company's most promising programs.

**We believe an investment in LOXO represents an investment in a modern model of the oncology drug development company of the future.** More concretely, we believe LOXO-101 represents a compound with a high likelihood of clinical benefit and, ultimately, regulatory and commercial success. In our view, LOXO-101 should generate \$1 billion-plus worldwide revenues, divided amongst three separate indications. Longer term, we believe the management team, with guidance and input from its scientific advisory board, possesses the necessary skill set to repeat the success that we expect to be achieved with LOXO-101 with future pipeline candidates.

**FIGURE 1. Upcoming Catalysts**

### Program Guidance and Milestones



Source: Company Presentations

**FIGURE 2. Ongoing Trials**

Agent	Company	Stage of Development	Clinical Trials Identifier
TSR-011	Tesaro	Phase I/II - solid tumors with confirmation of either ALK or TRK positive status	NCT02048488
Entrectinib/RXDX-101	Ignity	Phase I/II in different tumor types with molecular alterations in TRKA, TRKb, TRKC, ROS1, and ALK	NCT02097810
PLX7486	Plexikon	Phases I/II in advanced solid tumors; in part lic in patients with activating TRK point or NTRK fusion mutations	NCT01804530
Dovitinib/TKI258	Novartis	Phase II with pathway activated tumors with mutations of FGFR, PDGFR, VEGF, cKIT, FLT3, CSFR1, TRK and RET	NCT01831726
MGCD516	Mirati Therapeutics	Phase I with tumors for activating MET, NTRK2, NTRK3 or DDR2 mutations, MET or KIT/PDGFR/KDR gene amplifications	NCT02219711
Cabozantinib/XL184	Exelixis	Phase II win NSCLC with ROS1 or NTRK fusions or increased MET or AXL activity	NCT01639508

Source: JMP Securities LLC and Company Reports

FIGURE 3. Income Statement

Income Statement (\$MM)	Incep. - YE13	1Q14A	2Q14A	3Q14A	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
<b>Product Sales and Royalties:</b>																					
<b>LOXO-101</b>																					
US Sales							-	-	-	99.9	203.1	316.6	457.0	576.8	637.1	685.5	714.7	742.3	770.9	800.7	831.5
ROW Royalties							-	-	-	-	14.1	36.8	59.8	82.9	106.0	124.1	134.3	138.0	139.7	141.4	143.2
<b>Total Product Sales and Royalties</b>	-	-	-	-	-	-	-	-	-	99.9	217.3	353.4	516.8	659.7	743.2	809.7	849.0	880.3	910.6	942.1	974.7
Cost of Goods Sold										12.0	24.4	38.0	54.8	69.2	76.5	82.3	85.8	89.1	92.5	96.1	99.8
<b>Gross Profit</b>	-	-	-	-	-	-	-	-	-	87.9	192.9	315.4	462.0	590.5	666.7	727.4	763.2	791.2	818.1	846.0	874.9
<b>Operating Expenses:</b>																					
Research and development with related party	9.4	1.3	1.7	2.4	1.9	7.3	8.2	9.1	9.6	10.1	10.6	10.6	10.6	10.6	10.6	10.6	10.6	10.6	10.6	10.6	10.6
Research and development	0.3	0.7	0.9	2.6	1.5	5.7	11.4	22.8	45.5	72.8	87.4	96.1	100.9	106.0	111.3	114.6	118.0	121.6	125.2	129.0	132.9
General and administrative	0.6	0.9	1.3	1.7	1.2	5.2	10.3	18.0	29.8	47.6	66.7	80.0	92.0	99.4	105.4	110.6	112.9	115.1	117.4	119.8	122.2
Milestone Expense to ArrayBiopharm								10.0	10.0	25.0	10.0	10.0	10.0	10.0							
<b>Total operating expenses</b>	10.3	2.9	3.9	6.7	4.6	18.1	29.9	59.9	94.9	155.5	174.7	196.7	213.6	226.0	227.2	235.8	241.5	247.3	253.2	259.3	265.6
<b>Operating income (loss)</b>	(10.3)	(2.9)	(3.9)	(6.7)	(4.6)	(18.1)	(29.9)	(59.9)	(94.9)	(67.6)	18.2	118.7	248.4	364.5	439.5	491.6	521.7	543.9	564.9	586.7	609.3
Operating margin (%)										-67.6%	8.4%	33.6%	48.1%	55.3%	59.1%	60.7%	61.5%	61.8%	62.0%	62.3%	62.5%
<b>Other income (expense):</b>																					
Interest income																					
Interest expense																					
<b>Total other income, net</b>	-	-	-	-	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Pretax income (loss)</b>	(10.3)	(2.9)	(3.9)	(6.7)	(4.6)	(18.1)	(29.9)	(59.9)	(94.9)	(67.6)	18.2	118.7	248.4	364.5	439.5	491.6	521.7	543.9	564.9	586.7	609.3
Income tax benefit (provision)						0.0	0.0	0.0	0.0	0.0	(0.9)	(11.9)	(49.7)	(109.4)	(153.8)	(172.0)	(182.6)	(190.4)	(197.7)	(205.3)	(213.3)
Tax Rate											5%	10%	20%	30%	35%	35%	35%	35%	35%	35%	35%
<b>Comprehensive income (loss)</b>	(10.3)	(2.9)	(3.9)	(6.7)	(4.6)	(18.1)	(29.9)	(59.9)	(94.9)	(67.6)	17.3	106.8	198.7	255.2	285.7	319.5	339.1	353.6	367.2	381.3	396.1
Accretion of redeemable convertible preferred stock	(0.0)	(0.0)	0.0																		
<b>Net income (loss) attributable to common stockholders</b>	(10.3)	(2.9)	(3.9)	(6.7)	(4.6)	(18.2)	(29.9)	(59.9)	(94.9)	(67.6)	17.3	106.8	198.7	255.2	285.7	319.5	339.1	353.6	367.2	381.3	396.1
<b>Basic EPS to common shareholders</b>	\$ (4.25)	\$ (0.68)	\$ (14.39)	\$ (0.68)	\$ (0.30)	\$ (1.48)	\$ (1.93)	\$ (3.74)	\$ (5.14)	\$ (3.23)	\$ 0.80	\$ 4.76	\$ 8.58	\$ 10.67	\$ 11.58	\$ 12.57	\$ 12.95	\$ 13.12	\$ 13.25	\$ 13.38	\$ 13.53
<b>Diluted EPS to common shareholders</b>	\$ (4.25)	\$ (0.68)	\$ (14.39)	\$ (0.68)	\$ (0.30)	\$ (1.48)	\$ (1.93)	\$ (3.74)	\$ (5.14)	\$ (3.23)	\$ 0.61	\$ 3.68	\$ 6.67	\$ 8.34	\$ 9.10	\$ 9.93	\$ 10.29	\$ 10.47	\$ 10.62	\$ 10.78	\$ 10.94
Basic shares outstanding	2.4	4.3	0.3	9.9	15.2	12.2	15.5	16.0	18.4	20.9	21.7	22.4	23.2	23.9	24.7	25.4	26.2	27.0	27.7	28.5	29.3
Diluted shares outstanding	0.1	4.3	0.3	9.9	15.2	12.2	15.5	16.0	18.4	20.9	28.3	29.0	29.8	30.6	31.4	32.2	33.0	33.8	34.6	35.4	36.2

Source: JMP Securities LLC and Company Reports

## Company Description

Loxo Oncology, based in Stamford, CT, is a biotechnology company focused on the development of targeted, small molecule therapeutics for the treatment of cancer in genetically defined patient populations. By focusing on the engagement molecular targets exhibiting the hallmarks of oncogene addiction, Loxo aims to maximize the probability of clinical success while reducing the time, cost, and risks associated with drug development.

The company's lead product candidate, LOXO-101, is a potent selective inhibitor of tropomyosin receptor kinase (Trk), currently in a Phase I dose escalation trial, expected to give a preliminary safety and PK/PD read-out in early 2015. Trk comprises a family of membrane-bound signaling molecules that, when aberrantly expressed through genetic alterations, play an important role in the pathogenesis of various cancers. The company also intends to expand its pipeline with additional small molecule inhibitors targeting cancers driven by specific genetic alterations, nominating a new candidate in 1H15.

## Investment Risks

Potential risks to our price target include, but are not limited to, clinical, regulatory, commercial and competitive factors.

**Clinical.** Drug development is an inherently risky business. Like all clinical trials, LOXO-101 clinical development carries some risk of failure. LOXO-101 may fail to maintain the requisite safety or demonstrate meaningful efficacy to warrant further development through to regulatory approval.

**Regulatory and commercial.** The ability of Loxo or its future potential partners to market its drugs depends on those drugs obtaining approval from the FDA and foreign regulatory agencies. Failure to achieve approval or delays in the timelines to approval could negatively impact the company's share price.

**Competitive.** Oncology drug development is an increasingly competitive field. Loxo faces competition from companies developing existing small molecule agents that target the Trk family of kinases, and agents inhibiting cancer-related mechanisms of action applicable to intended indications with LOXO-101. Some of the companies may have access to greater resources and expertise compared to Loxo Oncology.

**Partnering.** The development of LOXO-101 and additional candidate programs is governed, in part, by a multi-year strategic collaboration agreement with Array BioPharma (ARRY), wherein Loxo has been granted access to Array's compound library and chemistry platform. Changes to this collaboration agreement could have a substantially negative impact on Loxo's ability to expand its pipeline and, in turn, valuation.

**Financial.** Taking into account ~\$60MM in net proceeds raised through its IPO, we estimate that Loxo will finish 3Q and FY2014 with cash and cash equivalents of \$79MM and \$75MM, respectively, which we believe should be adequate resources to fund operations into 1H17. We anticipate that Loxo will seek additional equity financing in the form of a secondary offering in order to complete the development of LOXO-101 and advance its future pipeline candidates, exposing existing shareholders to some degree of dilution risk.

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JMP Securities expects to receive OR intends to seek compensation for investment banking services from Loxo Oncology, Inc. in the next 3 months.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

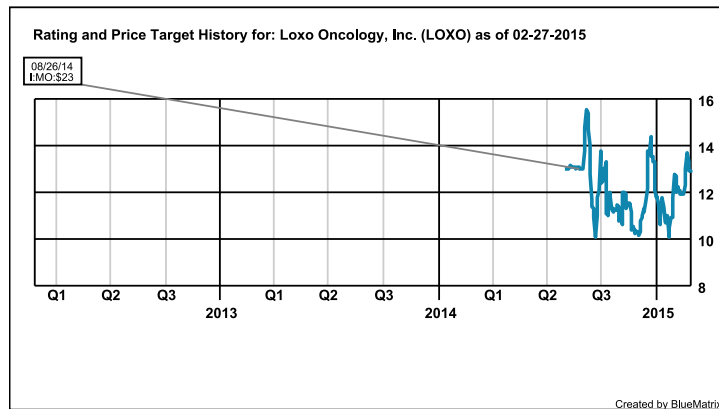
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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months				
				Regulatory Equivalent	# Co's Under Coverage	% of Total	% of Co's With This Rating	
MARKET OUTPERFORM	Buy	283	63.17%	Buy	283	63.17%	88	31.10%
MARKET PERFORM	Hold	154	34.38%	Hold	154	34.38%	22	14.29%
MARKET UNDERPERFORM	Sell	8	1.79%	Sell	8	1.79%	0	0%
COVERAGE IN TRANSITION		1	0.22%		1	0.22%	0	0%
TOTAL:		448	100%		448	100%	111	24.78%

### Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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