

# Loxo Oncology, Inc. (LOXO)

LOXO Reports FY14 Results

MARKET DATA	
Price	\$13.17
52-Week Range:	\$9.90 - \$16.45
Shares Out. (M):	16.6
Market Cap (\$M):	\$218.6
Average Daily Vol. (000):	60.0
Cash (M):	\$44
Cash/Share:	\$2.64
Enterprise Value (M):	\$212
Float (M):	16.2
LT Debt (M):	\$0
Source: Thomson Reuters and JMP Securities LLC	

FY DEC	2014A	2015E	2016E							
Revenue (\$M) 1C	\$0.0	\$0.0								
20	\$0.0	\$0.0								
30	\$0.0	\$0.0								
40	\$0.0	\$0.0								
FY	\$0.0	\$0.0	\$0.0							
EPS 10	(\$0.68)	(\$0.50)								
20	(\$14.39)	(\$0.50)								
30	(\$0.68)	(\$0.56)								
40	(\$0.57)	(\$0.58)								
FY	(\$3.06)	(\$2.10)	(\$3.95)							
Previous FY	(\$1.48)	(\$1.93)	(\$3.74)							
Source: Company reports and JMP Securities LLC										



MARKET OUTPERFORM | Price: \$13.17 | Target Price: \$23.00

#### **INVESTMENT HIGHLIGHTS**

Loxo Oncology reported 4Q14 earnings and FY14 results; reiterate our Market Outperform rating and \$23 price target derived through a synthesis of discounted cash flow, sum-of-the-parts, and compound annual growth valuation methodologies. We remind investors that as an early discovery and clinical stage company, LOXO's performance is primarily derived through the progression of its pipeline assets, both partnered and wholly owned, against developmental milestones, and not necessarily through financial results. The company reported a net loss of \$7.14MM, or (\$0.57) EPS for the quarter, greater than our estimate of \$4.6MM, or (\$0.30) EPS, primarily due to greater than expected operating expenses. R&D costs were \$4.9MM versus our estimate of \$3.4MM, while G&A costs were \$2.22MM versus our estimate of \$1.2MM, a difference primarily reflective of increased employment costs and fees associated with its IND filing and initiation of the Phase Ia clinical trial of LOXO-101. LOXO finished the quarter with an aggregate \$112.9MM in cash and cash equivalents, guiding to a cash runway into 2017, with a cash burn of \$30MM to \$35MM in 2015 (see Figure 2 for a review of 4Q14 and FY14 results versus our estimates).

Reminder of LOXO's 2015 quidance. Upcoming LOXO catalysts that should attract investor interest include an initial pharmacokinetic and safety Phase Ia readout of LOXO's lead asset (LOXO-101) 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 the 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. In addition, LOXO expects to pursue preclinical development of the three new receptor tyrosine kinase targets that the company unveiled recently: 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 a collaboration the company has secured with Array BioPharma. Even though the exclusivity targets that LOXO holds with ARRY have 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

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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 April 2015 – LOXO-101 Phase 1a Data at AACR 2H 2015 – Update on LOXO-101 Clinical Development Plans 1H 2015 2H 2015 – Initial Pipeline Precinical Data and Timeline Update

Source: JMP Securities LLC and Company Reports

FIGURE 2. LOXO 4Q14 and FY14 Results vs. JMP Estimates

LOXO Oncology (LOXO)		4Q14 F	Results		FY14 Results							
(\$ MM)	JMP Estimate	Street Actual (		Variance (JMP vs. Actual)	JMP Estimate	Street Consensus	Actual	Variance (JMP vs. Actual)				
Total Revenues	-	-	-	0.0	-	-	-	0.0				
Operating Expenses Research and development General and administrative	<b>4.60</b> 3.40 1.20	6.75	<b>7.15</b> 4.9 2.22	<b>(2.6)</b> (1.5) (1.0)	13.00	20.34	<b>20.69</b> 14.5 6.18	<b>(9.8)</b> (1.5) (1.0)				
Operating income (loss)	(4.60)	(6.75)	(7.15)	2.6	(18.14)	(20.34)	(20.69)	(2.6)				
Other income (expense) Pretax income (loss)	0.00 (4.60)	0.02 (6.73)	0.02 (7.14)	(0.0) 2.5	0.00 (18.14)	0.02 (20.32)	0.02 (20.67)	<b>(0.0)</b> (2.5)				
Net income (loss)	(4.60)	(6.73)	(7.14)	2.5	(18.14)	(20.35)	(20.67)	(2.5)				
EPS Calculations												
Basic EPS Diluted EPS	\$ (0.30) \$ (0.30)				, , ,			(1.6 <sub>)</sub> (1.6 <sub>)</sub>				
Basic shares outstanding Diluted shares outstanding	15.180 15.180		12.588 12.588	2.6 2.6	12.224 12.224		6.774 6.774	5.5 5.5				

Source: JMP Securities LLC and Company Reports

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# FIGURE 3. Changes to Our Model

LOXO Oncology (LOXO)		1Q1	I5E		2Q <sup>2</sup>	15E		3Q <sup>,</sup>	15E	4Q15E		FY 2015E		
(\$ MM)	C	Old	New	0	ld	New	c	Old	New	Old		New	Old	New
Collorboration Revenue Other		-	0.0		-	0.0		,	0.0		-	0.0	0.0	0.0
Total Revenues		-	-		-	-		-	-		-	-	-	-
COGS		-	-		-	-		-	-		_	-	-	-
Gross Profit		-	-		-	-			-		-	-	-	-
Operating expenses Research and development General and administrative		<b>4.8</b> 3.6 1.2	<b>7.6</b> 5.3 2.3		<b>5.2</b> 3.9 1.3	<b>7.7</b> 5.4 2.3		<b>5.7</b> 4.3 1.4	<b>8.4</b> 6.0 2.4		<b>5.7</b> 4.5 1.2	8.8 6.3 2.5	<b>24.</b> 4 16.0 8.4	23.0
Operating income (loss)		(4.8)	(7.6)		(5.2)	(7.7)	_	(5.7)	(8.4)		5.7)	(8.8)		0.0
Other income (expense) Interest income		-	-		-	-		-	-		-	-	-	- 1
Pretax income Provision for Income Tax		(4.8)	(7.6)		(5.2)	(7.7)		(5.7)	(8.4)	(	5.7) -	(8.8)	(24.4	(32.5)
Net income		(4.8)	(7.6)		(5.2)	(7.7)		(5.7)	(8.4)	(	5.7)	(8.8)	(24.4	(32.5)
Basic EPS Diluted EPS	\$	(0.32) (0.32)			(0.18) (0.18)			(0.38) (0.38)			.38) .38)		\$ (1.58 \$ (1.58	
Basic shares outstanding Diluted shares outstanding		15.22 15.22	15.22 15.22		15.26 15.22	15.26 15.22		15.10 15.10	15.10 15.10	_	.18 .18	15.18 15.18	15.45 15.45	

Source: JMP Securities LLC and Company Reports

# **FIGURE 4.Income Statement**

LOXO Oncology (LOXO)	2014E	1Q15E	2Q15E	3Q15A	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Income Statement (\$MM)	2014E	1Q15E	2Q15E	3Q15A	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Product Sales and Royalties:																				
LOXO-101																				
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
Total Product Sales and Royalties	-	-	-	-	-	-	-	-	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
Gross Profit	-	-	-	-	-	-	-	-	87.9	192.9	315.4	462.0	590.5	666.7	727.4	763.2	791.2	818.1	846.0	874.9
Operating Expenses:																				
Research and development with related party	7.568	2.4	2.5	2.8	3.0	10.7	12.0	12.6	13.2	13.9	13.9	13.9	13.9	13.9	13.9	13.9	13.9	13.9	13.9	13.9
Research and development	6.947	2.9	2.9	3.2	3.3	12.3	24.6	49.2	78.7	94.5	103.9	109.1	114.6	120.3	123.9	127.6	131.4	135.4	139.4	143.6
General and administrative	6.175	2.3	2.3	2.4	2.5	9.5	16.6	27.4	43.9	61.4	73.7	84.8	91.6	97.1	101.9	104.0	106.0	108.2	110.3	112.5
Milestone Expense to ArrayBiopharm							10.0	10.0	25.0	10.0	10.0	10.0	10.0							
Total operating expenses	20.690	7.6	7.7	8.4	8.8	32.5	63.2	99.2	160.8	179.8	201.5	217.8	230.0	231.2	239.7	245.5	251.4	257.4	263.7	270.0
Operating income (loss)	(20.690)	(7.6)	(7.7)	(8.4)	(8.8)	(32.5)	(63.2)	(99.2)	(72.9)	13.1	113.9	244.2	360.5	435.5	487.7	517.8	539.9	560.7	582.3	604.9
Operating margin (%)	, ,	, ,	, ,	. ,	, ,	, ,	, ,	, ,	-72.9%	6.0%	32.2%	47.2%	54.6%	58.6%	60.2%	61.0%	61.3%	61.6%	61.8%	62.1%
Other income (expense):																				1
Interest income	0.018																			1
Interest expense																				
Total other income, net	0.018	-	-	-	-	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
Pretax incomee (loss)	(20.672)	(7.6)	(7.7)	(8.4)	(8.8)	(32.5)	(63.2)	(99.2)	(72.9)	13.1	113.9	244.2	360.5	435.5	487.7	517.8	539.9	560.7	582.3	604.9
Comprehensive income (loss) Tax Rate						0.0	0.0	0.0	0.0	(0.7) 5%	(11.4) 10%	(48.8) 20%	(108.2) 30%	(152.4) 35%	(170.7) 35%	(181.2) 35%	(188.9) 35%	(196.2) 35%	(203.8) 35%	(211.7) 35%
Comprehensive income (loss)	(20.672)	(7.6)	(7.7)	(8.4)	(8.8)	(32.5)	(63.2)	(99.2)	(72.9)	12.5	102.5	195.4	252.4	283.1	317.0	336.5	350.9	364.4	378.5	393.2
								<u> </u>												
Accretion of redeemable convertible preferred stock	-0.034																			
Net income (loss) attributable to common stockholders	(20.706)	(7.6)	(7.7)	(8.4)	(8.8)	(32.5)	(63.2)	(99.2)	(72.9)	12.5	102.5	195.4	252.4	283.1	317.0	336.5	350.9	364.4	378.5	393.2
Basic EPS to common shareholders	\$ (3.06)	\$ (0.50)	\$ (0.50)		\$ (0.58)					\$ 0.57	\$ 4.57	\$ 8.43	\$ 10.55	\$ 11.48	\$ 12.47	\$ 12.85	\$ 13.02	\$ 13.15	\$ 13.28	\$ 13.43
Diluted EPS to common shareholders	\$ (3.06)	\$ (0.50)	\$ (0.50)	\$ (0.56)	\$ (0.58)	\$ (2.10)	\$ (3.95)	\$ (5.38)	\$ (3.48)	\$ 0.44	\$ 3.53	\$ 6.55	\$ 8.25	\$ 9.02	\$ 9.85	\$ 10.21	\$ 10.39	\$ 10.54	\$ 10.70	\$ 10.86
Basic shares outstanding	6.8	15.2	15.3	15.1	15.2	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	6.8	15.2	15.2	15.1	15.2	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
	3.0	10.2				.0.0	.0.0		20.0	20.0	20.0	20.0	55.0	07	02.2	55.0	55.0	00	55.4	00.2

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 was manager or co-manager of a public offering of securities for Loxo Oncology, Inc. (LOXO) in the past 12 months, and received compensation for doing so.

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

#### **JMP Securities Investment Opinion Definitions:**

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.

Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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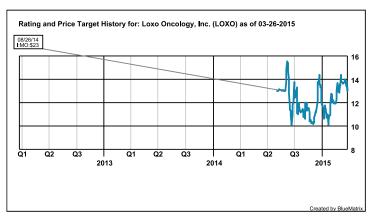
							# Co's	
							Receiving	
							IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	285	63.62%	Buy	285	63.62%	89	31.23%
MARKET PERFORM	Hold	153	34.15%	Hold	153	34.15%	21	13.73%
MARKET UNDERPERFORM	Sell	8	1.79%	Sell	8	1.79%	0	0%
COVERAGE IN TRANSITION		1	0.22%		1	0.22%	0	0%
TOTAL		440	4000/		440	4000/	440	0.4.550/
TOTAL:		448	100%		448	100%	110	24.55%

#### **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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