

Loxo Oncology, Inc. (LOXO)

Announces 3Q14 Financial Results

MARKET DATA

Price	\$11.45
52-Week Range:	\$10.00 - \$16.45
Shares Out. (M):	16.6
Market Cap (\$M):	\$190.1
Average Daily Vol. (000):	11.0
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

MARKET OUTPERFORM | Price: \$11.45 | Target Price: \$23.00

INVESTMENT HIGHLIGHTS

Loxo Oncology reported 3Q14 earnings and outlined current and future milestones; reiterate our Market Outperform rating and \$23 price target based on a synthesis of our 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 \$6.73MM, or (\$0.68) EPS, greater than our estimate of \$4MM, or (\$0.26) EPS, primarily due to greater than expected operating expenses. R&D costs were \$2.62MM versus our estimate of \$1.2MM, while G&A costs were \$2.62MM versus our estimate of \$1.1MM, a difference primarily reflective of increased employment costs and fees associated with its IND filing. The company also reported recent preclinical progress with its lead asset LOXO-101.

Highlights from the quarter include presentation of preclinical data and management changes. LOXO announced that it will present preclinical data in a poster session at the EORTC "Triple Meeting" taking place in Barcelona November 18-21, on the company's pan-TRK inhibitor that is in development; LOXO's presentation will be on November 20. The poster will describe the activity of LOXO-101 in TRK-driven tumor types. The company also highlighted the promotion of Jennifer Low, MD, PhD to Chief Medical Officer, who also continues her tenure as EVP of Research and Development. Dr. Lori Kunkel will transition from Acting CMO to her role as a non-employee director on the board.

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 in 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.

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)
Previous FY		(\$1.23)	(\$1.58)	(\$3.15)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



FIGURE 1. Upcoming Catalysts

Timing	Catalyst
1Q15	LOXO-101 Phase I safety and tolerability data
2Q15	Nomination of second pipeline candidate – LOXO-200
2Q15	Initiation of LOXO-101 Phase Ib trial in TRK+ solid tumors
2H15	IND filing for LOXO-200

Source: Company presentations

FIGURE 2. Actual versus Estimates

LOXO Oncology (LOXO) (\$ MM)	3Q14 Results		
	JMP Estimate	Actual	Variance (JMP vs. Actual)
Total Revenues	-	-	0.0
Operating Expenses	2.30	4.33	(2.0)
Research and development	1.20	2.62	(1.4)
General and administrative	1.10	1.71	(0.6)
Operating income (loss)	(4.00)	(6.73)	2.7
Other income (expense)	0.00	0.00	0.0
Pretax income (loss)	(4.00)	(6.73)	2.7
Net income (loss)	(4.00)	(6.73)	2.7
EPS Calculations			
Basic EPS	\$ (0.26)	\$ (0.68)	0.4
Diluted EPS	\$ (0.26)	\$ (0.68)	0.4
Basic shares outstanding	15.103	9.947	5.2
Diluted shares outstanding	15.103	9.947	5.2

Source: JMP Securities LLC, Company filings

FIGURE 3. Changes to Our Model

LOXO Oncology (LOXO) (\$ MM)	4Q14E		FY 2014E		FY 2015E		FY 2016E	
	Old	New	Old	New	Old	New	Old	New
Collaboration Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other	-	-	-	-	-	-	-	-
Total Revenues	-	-	-	-	-	-	-	-
COGS	-	-	-	-	-	-	-	-
Gross Profit	-	-	-	-	-	-	-	-
Operating Expenses	4.6	4.6	19.2	18.1	24.4	29.9	40.4	59.9
Research and development	3.4	3.4	10.8	13.0	16.0	19.5	25.6	31.9
General and administrative	1.2	1.2	8.4	5.2	8.4	10.3	14.8	28.0
Operating income (loss)	(4.6)	(4.6)	(19.2)	(18.1)	(24.4)	(29.9)	(40.4)	(59.9)
Other income (expense)	-	-	-	-	-	-	-	-
Interest income	-	-	-	-	-	-	-	-
Pretax income	(4.6)	(4.6)	(15.0)	(18.1)	(24.4)	(29.9)	(50.4)	(59.9)
Provision for Income Tax	-	-	-	-	-	-	-	-
Net income	(4.6)	(4.6)	(15.0)	(18.1)	(24.4)	(29.9)	(50.4)	(59.9)
Basic EPS	\$ (0.30)	\$ (0.30)	\$ (1.23)	\$ (1.48)	\$ (1.58)	\$ (1.93)	\$ (3.15)	\$ (3.74)
Diluted EPS	\$ (0.30)	\$ (0.30)	\$ (1.23)	\$ (1.48)	\$ (1.58)	\$ (1.93)	\$ (3.15)	\$ (3.74)
Basic shares outstanding	15.18	15.18	12.22	12.22	15.45	15.45	16.01	16.01
Diluted shares outstanding	15.18	15.18	12.22	12.22	15.45	15.45	16.01	16.01

Source: JMP Securities LLC and Company Reports

FIGURE 4. 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
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	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							
Total operating expenses	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
Operating income (loss)	(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%
Other income (expense):																					
Interest income																					
Interest expense																					
Total other income, net	-	-	-	-	-	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
Pretax income (loss)	(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%
Comprehensive income (loss)	(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																		
Net income (loss) attributable to common stockholders	(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
Basic EPS to common shareholders	\$ (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
Diluted EPS to common shareholders	\$ (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, Company filings

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

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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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.

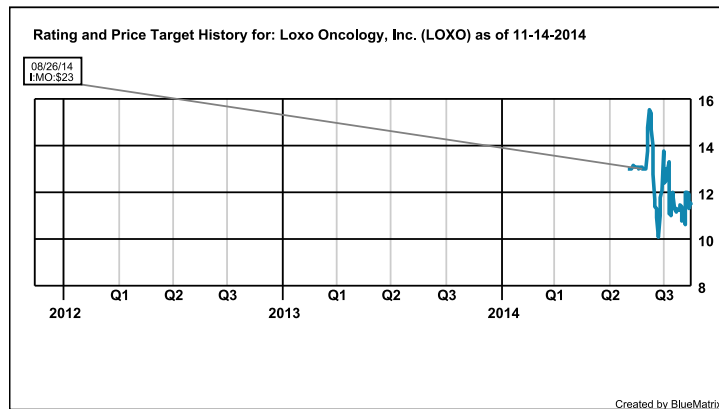
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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months				
				Regulatory Equivalent	# Co's Under Coverage	% of Total	% of Co's With This Rating	
MARKET OUTPERFORM	Buy	285	60.90%	Buy	285	60.90%	103	36.14%
MARKET PERFORM	Hold	142	30.34%	Hold	142	30.34%	15	10.56%
MARKET UNDERPERFORM	Sell	2	0.43%	Sell	2	0.43%	0	0%
COVERAGE IN TRANSITION		36	7.69%		36	7.69%	0	0%
TOTAL:		468	100%		468	100%	120	25.64%

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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