Loxo Oncology, Inc. (LOXO)

LOXO Presents Encouraging Preliminary Update from the Phase Ia Study

MARKET OUTPERFORM | Price: $13.22 | Target Price: $23.00

MARKET DATA

Price	$13.22
52-Week Range:	$9.90 - $16.45
Shares Out. (M):	16.6
Market Cap ($M):	$219.5
Average Daily Vol. (000):	40.0
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)	1Q	$0.0	$0.0	--
	2Q	$0.0	$0.0	--
	3Q	$0.0	$0.0	--
	4Q	$0.0	$0.0	--
	FY	**$0.0**	**$0.0**	**$0.0**
EPS	1Q	($0.68)	($0.50)	--
	2Q	($14.39)	($0.50)	--
	3Q	($0.68)	($0.56)	--
	4Q	($0.57)	($0.58)	--
	FY	**($3.06)**	**($2.10)**	**($3.95)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Loxo Oncology presents encouraging preliminary update from the company's Phase Ia study of LOXO-101; reiterate our Market Outperform rating and $23 price target based on a synthesis of discounted cash flow, sum-of-the-parts, and compound annual growth valuation methodologies. Yesterday, LOXO provided a preliminary clinical update of the ongoing Phase Ia dose-escalation study of the company's leading clinical asset, LOXO-101. We find the data from the interim analysis from the first fifteen evaluable patients as encouraging and look forward to the clinical update in 2H15 at a future medical meeting.

The update. The data shown were from the dose-escalation portion of the Phase Ia trial in all comers, being run at four sites (Sarah Cannon Research Institute, U Penn, MGH and University of Colorado) to determine the maximum tolerated dose (MTD), which has not yet been reached, according to the trial investigator. Interestingly, one soft tissue sarcoma patient with a NTRK1 fusion in this portion of the study has been identified (Figure 1). However, any greater detail of the patient's response to treatment (enrolled on March 10, 2015) has not yet been disclosed. Briefly, the drug has been well tolerated by the patients treated in the three dose cohorts (n=4, 15mg QD; n=5, 100mg QD; n=6, 100mg BID to date), with most adverse events observed either Grades 1 or 2, consisting of fatigue, dizziness and anemia (Figure 2). Pharmacokinetic data also showed good systemic exposure of the drug after oral dosing with greater exposures observed than what was predicted from the preclinical studies (Figure 3). As the data are immature to glean further insight into the TRK patient's response to LOXO-101 at this juncture, we continue to remain optimistic of the drug.

Our expectations. In the expansion phase of the study, patients with solid tumor with a neurotrophic tyrosine kinase receptor (NTRK) alteration will be assessed. 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 the Phase I study. Specifically, 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 4), 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.

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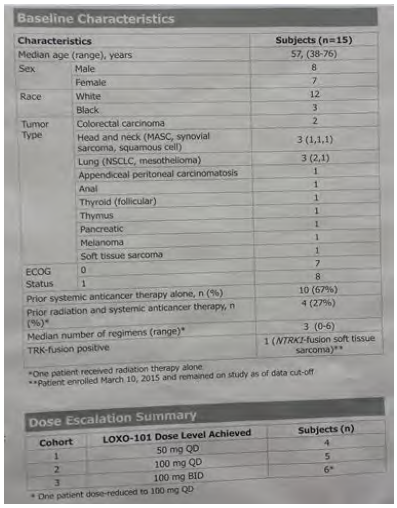
Quick refresher on TRK and LOXO-101. Recall that the TRK family of neurotrophin receptors, exemplified by TRKA, TRKB and TRKC, function primarily in the growth, differentiation and survival of neurons. NTRK1 fusions have been described in a subset of lung adenocarcinoma patients; and more recently, TRK fusions were found in many more tumor types than previously elucidated 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.

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. Patient Baseline Characteristics and Dose Escalation Summary



Baseline Characteristics

Characteristics		Subjects (n=15)
Median age (range), years		57, (38-76)
Sex	Male	8
	Female	7
Race	White	12
	Black	3
Tumor Type	Colorectal carcinoma	2
	Head and neck (MASC, synovial sarcoma, squamous cell)	3 (1,1,1)
	Lung (NSCLC, mesothelioma)	3 (2,1)
	Appendiceal peritoneal carcinomatosis	1
	Anal	1
	Thyroid (follicular)	1
	Thymus	1
	Pancreatic	1
	Melanoma	1
	Soft tissue sarcoma	1
ECOG Status	0	7
	1	8
Prior systemic anticancer therapy alone, n (%)		10 (67%)
Prior radiation and systemic anticancer therapy, n (%)*		4 (27%)
Median number of regimens (range)*		3 (0-6)
TRK-fusion positive		1 (*N7RK1*-fusion soft tissue sarcoma)**

*One patient received radiation therapy alone
**Patient enrolled March 10, 2015 and remained on study as of data cut-off

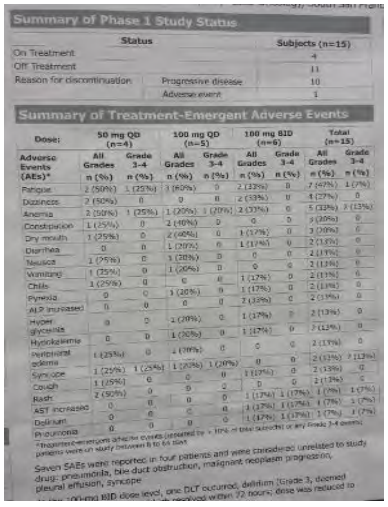
Dose Escalation Summary

Cohort	LOXO-101 Dose Level Achieved	Subjects (n)
1	50 mg QD	4
2	100 mg QD	5
3	100 mg BID	6*

* One patient dose-reduced to 100 mg QD

Source: AACR 2015, Abstract #4529

FIGURE 2. Adverse Effects



Summary of Phase 1 Study Status

Status		Subjects (n=15)
On Treatment		4
Off Treatment		11
Reason for discontinuation	Progressive disease	10
	Adverse event	1

Summary of Treatment-Emergent Adverse Events

Dose:	50 mg QD (n=4)		100 mg QD (n=5)		100 mg BID (n=6)		Total (n=15)	
Adverse Events (AEs)*	All Grades n (%)	Grade 3-4 n (%)	All Grades n (%)	Grade 3-4 n (%)	All Grades n (%)	Grade 3-4 n (%)	All Grades n (%)	Grade 3-4 n (%)
Fatigue	2 (50%)	1 (25%)	3 (60%)	0	2 (33%)	0	7 (47%)	1 (7%)
Dizziness	2 (50%)	0	0	0	2 (33%)	0	4 (27%)	0
Anemia	2 (50%)	1 (25%)	1 (20%)	1 (20%)	2 (33%)	0	5 (33%)	2 (13%)
Constipation	1 (25%)	0	2 (40%)	0	0	0	3 (20%)	0
Dry mouth	1 (25%)	0	2 (40%)	0	1 (17%)	0	3 (20%)	0
Diarrhea	0	0	1 (20%)	0	1 (17%)	0	2 (13%)	0
Nausea	1 (75%)	0	1 (20%)	0	0	0	2 (13%)	0
Vomiting	1 (25%)	0	1 (20%)	0	0	0	2 (13%)	0
Chills	1 (25%)	0	0	0	1 (17%)	0	2 (13%)	0
Pyrexia	0	0	1 (20%)	0	1 (17%)	0	2 (13%)	0
ALP increased	0	0	0	0	2 (33%)	0	2 (13%)	0
Hyperglycemia	0	0	1 (20%)	0	1 (17%)	0	2 (13%)	0
Hypokalemia	0	0	1 (20%)	0	1 (17%)	0	2 (13%)	0
Peripheral edema	1 (25%)	0	1 (20%)	0	0	0	2 (13%)	0
Syncope	1 (25%)	1 (25%)	1 (20%)	1 (20%)	0	0	2 (13%)	0
Cough	1 (25%)	0	0	0	1 (17%)	0	2 (13%)	0
Rash	2 (50%)	0	0	0	0	0	2 (13%)	0
AST increased	0	0	0	0	1 (17%)	1 (17%)	1 (7%)	1 (7%)
Delirium	0	0	0	0	1 (17%)	1 (17%)	1 (7%)	1 (7%)
Hypercalcemia	0	0	0	0	1 (17%)	1 (17%)	1 (7%)	1 (7%)

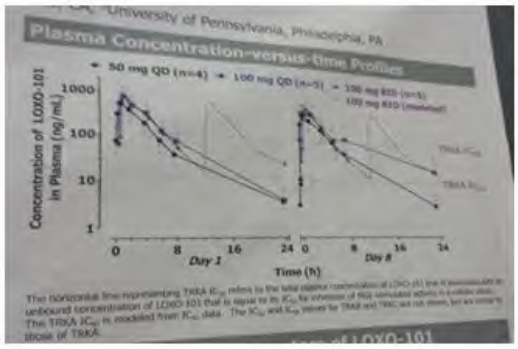
*Treatment-emergent adverse events (assessed by ≥ 10% of total subjects) or any Grade 3-4 events; patients were on study between 8 to 64 days

Seven SAEs were reported in four patients and were considered unrelated to study drug: pneumonitis, bile duct obstruction, malignant neoplasm progression, pleural effusion, syncope

One DLT occurred, delirium (Grade 3, deemed

Source: AACR 2015, Abstract #4529

FIGURE 3. LOXO-101 Profile



Pharmacokinetic Parameters of LOXO-101

Day 8 Steady-State PK Parameter (Mean ± SD)	50 mg QD (n=4)	100 mg QD (n=5)	100 mg BID (n=5)
C_{max} (ng/mL)	642 ± 418	925 ± 375	905 ± 552
T_{max} (h)	0.88 ± 0.25	0.90 ± 0.65	0.90 ± 0.22
AUC_{0-24} (ng•h/mL)	2580 ± 2290	4190 ± 3710	5220 ± 3200
$T_{1/2}$ (h)	2.2 ± 0.5	1.8 ± 0.7	1.6 ± 0.3
Cl/F (L/h/kg)	0.42 ± 0.35	0.52 ± 0.31	0.84 ± 0.64
V/F (L/kg)	1.2 ± 1.0	1.2 ± 0.6	1.9 ± 1.3

Non-compartmental pharmacokinetic parameters were calculated by conventional methods. For BID dosing, the AUC between 0 and 12 hours was calculated by log-linear extrapolation of the measured concentrations at 6 and 8 hours through 12 hours. The extrapolated AUC was ≤9% of the AUC in all cases. For QD dosing, AUC_{0-24} was calculated as 2 x AUC_{0-12}

Source: AACR 2015, Abstract #4529

FIGURE 4. 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
Entrectinhib/RXDX-101	Ignyta	Phase I/II in different tumor types with molecular alterations in TRKA,TRKb, TRKC, ROS1, and ALK	NCT02097810
PLX7486	Plexxikon	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/PDGFRA/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 5. 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):																				
Interest income	0.018																			
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)						0.0	0.0	0.0	0.0	(0.7)	(11.4)	(48.8)	(108.2)	(152.4)	(170.7)	(181.2)	(188.9)	(196.2)	(203.8)	(211.7)
Tax Rate										*5%*	*10%*	*20%*	*30%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*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
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)	$ (0.56)	$ (0.58)	$ (2.10)	$ (3.95)	$ (5.38)	$ (3.48)	$ 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

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.

JMP FACTS AND DISCLOSURES

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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.

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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.
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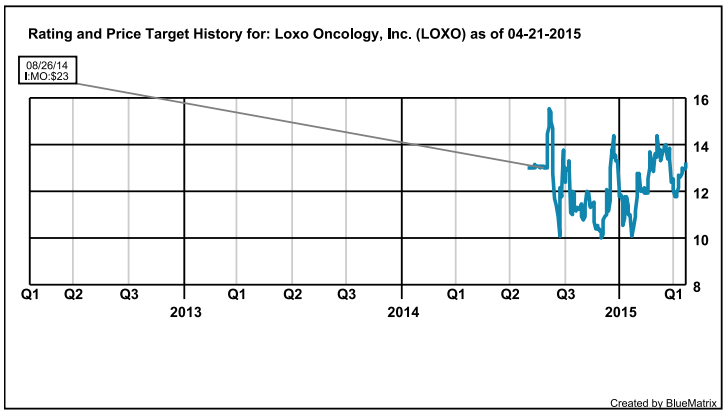
JMP Securities Research Ratings and Investment Banking Services: (as of April 22, 2015)

JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	287	*63.36%*	Buy	287	*63.36%*	97	*33.80%*
MARKET PERFORM	Hold	145	*32.01%*	Hold	145	*32.01%*	20	*13.79%*
MARKET UNDERPERFORM	Sell	8	*1.77%*	Sell	8	*1.77%*	0	*0%*
COVERAGE IN TRANSITION		12	*2.65%*		12	*2.65%*	1	*8.33%*
TOTAL:		453	*100%*		453	*100%*	118	*26.05%*

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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