

Loxo Oncology, Inc. (LOXO)

Reports 1Q15 Earnings Results on the Heels of ASCO Abstracts Release

MARKET DATA

Price	\$11.04
52-Week Range:	\$9.90 - \$16.45
Shares Out. (M):	16.6
Market Cap (\$M):	\$183.3
Average Daily Vol. (000):	41.0
Cash (M):	\$108
Cash/Share:	\$6.47
Enterprise Value (M):	\$212
Float (M):	16.2
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

MARKET OUTPERFORM | Price: \$11.04 | Target Price: \$23.00

INVESTMENT HIGHLIGHTS

Loxo Oncology reports 1Q15 earnings results and highlights upcoming ASCO presentations; 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. LOXO reported a net loss of \$6.2MM, or (\$0.38) EPS for the quarter, somewhat lower than the JMP estimate of \$7.6MM, or (\$0.50) EPS. R&D costs were \$3.8MM versus our estimate of \$5.3MM, reflective of expanded clinical activities for LOXO-101 and support of preclinical and manufacturing activities at its partnering site, Array BioPharma (ARRY, NC). G&A costs were \$2.4MM, in line with our estimate of \$2.3MM. LOXO finished the quarter with a strong balance sheet of \$112.9MM in cash and cash equivalents, continuing to guide to a cash runway into 2017, with a cash burn of \$30MM to \$33MM in 2015. A comparison of 1Q15 results versus JMP estimates and changes to our model are provided in Figures 5 and 6, respectively. 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.

FY DEC		2014A	2015E	2016E
Revenue (\$M)	1Q	\$0.0	\$0.0A	--
	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)	(\$0.38)A	--
	2Q	(\$14.39)	(\$0.41)	--
	3Q	(\$0.68)	(\$0.48)	--
	4Q	(\$0.57)	(\$0.51)	--
	FY	(\$3.06)	(\$1.78)	(\$3.42)
Previous FY		NC	(\$2.10)	(\$3.95)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



LOXO-101 on TRK and on show at ASCO. Abstracts for the annual American Society of Clinical Oncology to be held in Chicago on May 29-June 2 were released yesterday, which describe LOXO's efforts to identify TRK (tropomyosin receptor kinase) mutations that may contribute to tumorigenesis as well as data of the ongoing, open-label, multi-center, dose-escalation Phase Ia trial evaluating LOXO-101, an oral, pan-TRK inhibitor in solid tumors (Figure 4). LOXO-101 has been shown in preclinical work to inhibit TRK family members in the nanomolar range with 100x selectivity over other kinases. Preliminary pharmacokinetic data from the trial at AACR in Philadelphia suggest that the drug is achieving biologically relevant systemic exposures (greater than what was predicted from the clinical studies) without producing any drug-related safety signals (Figure 2). As a reminder, 15 patients have been enrolled in the trial, across three dosing cohorts: 50 mg QD (n=4), 100mg QD (n=5), and 100 mg BID (n=6). Reported adverse events were predominantly Grades 1 or 2 in nature: fatigue, dizziness, and anemia. We are encouraged by the data in the 15 patients (with one confirmed NTRK1 fusion) revealed thus far.

Defining the patient population. Abstract #1553 describes the use of next-generation sequencing of ~10,000 patient tumor samples that were analyzed for potentially activating mutations in the NTRK gene family (NTRK1, NTRK2 or NTRK3) and may contribute to tumorigenesis. LOXO identified 732 distinct mutation clusters across >20 tumors. Interestingly, a disproportionate number of the mutation clusters were in NTRK3. The top three clusters corresponded to mutations in the NTRK3 kinase domain

and were found in head and neck, lung, upper gastrointestinal, melanoma and colon cancers. Alterations by definition could represent mutations, gene amplifications or fusions. Therefore, by determining the majority of alterations that confer gene addiction, a drug could have greater anti-tumor activity.

Accordingly, LOXO appears to be focusing specifically on TRK fusions as the target for the drug candidate. Recall that in the expansion phase of the current study evaluating LOXO-101, patients with solid tumor with NTRK alterations will be assessed. LOXO-101 is expected to advance into clinical development with TRK-altered patients in 2H15, initially believed to be in lung cancer patients, wherein a TRK fusion protein is the key “driver” of the cancer. However, the overarching goal is to also identify one or more areas of TRK biology to rapidly advance into the Phase I study. We are encouraged by the additional tumor analyses conducted, which provide greater insight into additional tumor types LOXO may potentially explore with its lead drug candidate.

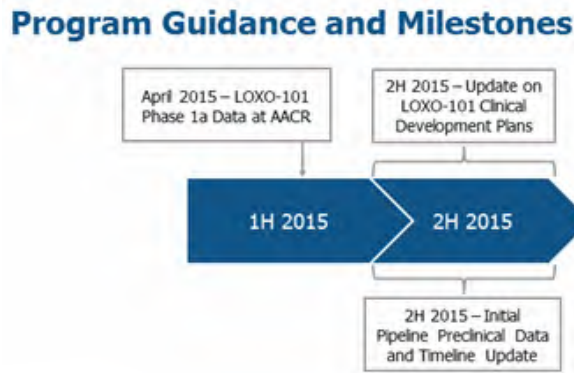
Previous Nature article suggests there are more TRK mutations than originally recognized.

Recall, 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 in a Nature article (Stransky et al. 2014;5:4846) that we reported in a previous note, TRK fusions were found in many more tumor types than previously elucidated, suggesting a broader market potential for LOXO-101. One fundamental assumption underlies the findings in this breakthrough paper, entitled, “The landscape of kinase fusions in cancer.” There is a tremendous amount of genomic “white space” in nearly all tumor types (except for those instances in which a tumor is driven by a single mutation); thus, just as we believed it is reasonable to hypothesize that there are additional, undiscovered gene fusions underpinning tumor subtypes, LOXO appears to have uncovered such potential tumor subtypes. Overall, the investigators in the Nature publication found kinase fusions in 3% of samples of 20 tumor types, in a range of 0-12.9%. Pertinent to LOXO and the TRK space, the investigators located five novel TRK fusions in NTRK1, 2 and 3 in tumor types that had not been previously known to carry such. As a reminder, LOXO-101 binds all three subtypes of the TRK receptors, i.e., TRKA, B, and C, and the drug is being developed under license from Array BioPharma (ARRY, NC).

Other TRK inhibitors to be featured at ASCO. We note that there will be additional presentations highlighting TRK inhibitors in patients with advanced solid tumors at ASCO this year. Specifically, Tesaro (TSRO, NC), Ignyta (RXDX, NC), and Mirati Therapeutics (MRTX) are expected to present data from the respective TRK inhibitor programs. We note that the different clinical trials are not necessarily assessing patients with the same type of TRK alteration as LOXO (specifically TRK fusions), and therefore it may be difficult to directly compare the anti-tumor activity of the drugs at this juncture. Additionally, although the space appears to be populated with drugs (Figure 3), we believe LOXO-101 may be 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).

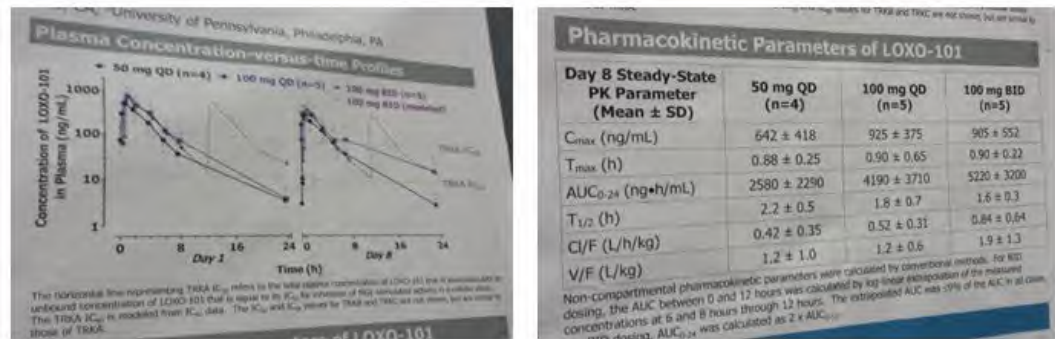
We believe an investment in LOXO represents an investment in a modern model of the oncology drug development company of the future. More concretely, we believe LOXO-101 represents a compound with a high likelihood of clinical benefit and, ultimately, regulatory and commercial success. In our view, LOXO-101 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



Source: JMP Securities LLC and Company Reports

FIGURE 2. LOXO-101 Profile



Source: AACR 2015, Abstract #4529

FIGURE 3. Ongoing Clinical 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	Ignitya	Phase I/II in different tumor types with molecular alterations in TRKA, TRKb, TRKC, ROS1, and ALK	NCT02097810
PLX7496	Plexoikon	Phases I/II in advanced solid tumors; in part IIC 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
M6CD516	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 with NSCLC with ROS1 or NTRK fusions or increased MET or AXL activity	NCT01639508

Source: JMP Securities LLC and Company Reports

FIGURE 4. ASCO Presentations

Poster Session: Developmental Therapeutics—Clinical Pharmacology and Experimental Therapeutics

Date: Saturday, May 30

Poster Viewing Session: 8:00 – 11:30a.m. CDT

Location: S Hall A

Poster Number: 328b

Title: A first-in-human study of LOXO-101, a highly selective inhibitor of the tropomyosin receptor kinase (TRK) family. (Abstract # TPS2624, Trials in Progress)

Lead Author: Howard A. Burris, M.D.

Poster Session: Cancer Prevention, Genetics, and Epidemiology

Date: Monday, June 1

Poster Viewing Session: 1:15-4:45p.m. CDT

Location: S Hall A

Poster Number: 377

Title: Identification of tropomyosin kinase receptor (TRK) mutations in cancer. (Abstract # 1553)

Lead Author: Nisha Nanda, Ph.D.

Source: Company Reports

FIGURE 5. 1Q15 Results vs. JMP Estimates

LOXO Oncology (LOXO) (\$ MM)	1Q15 Results			
	JMP Estimate	Street Consensus	Actual	Variance (JMP vs. Actual)
Total Revenues		-		0.0
Operating Expenses	7.60	7.90	6.23	1.38
Research and development	5.30		3.83	1.5
General and administrative	2.30		2.39	(0.09)
Operating income (loss)	(7.60)	(7.90)	(6.23)	(1.38)
Other income (expense)	0.00		0.04	(0.04)
Pretax income (loss)	(7.60)		(6.18)	(1.42)
Net income (loss)	(7.60)	(7.90)	(6.18)	(1.42)
EPS Calculations				
Basic EPS	\$ (0.50)	\$ (0.50)	\$ (0.38)	\$ (0.12)
Diluted EPS	\$ (0.50)	\$ (0.50)	\$ (0.38)	\$ (0.12)
Basic shares outstanding	15.219		16.474	(1.255)
Diluted shares outstanding	15.219		16.474	(1.255)

Source: JMP Securities LLC and Company Reports

FIGURE 6. Changes to Our Model

LOXO Oncology (LOXO) (\$ MM)	2Q15E		3Q15E		4Q15E		FY 2015E		FY 2016E		FY 2017E	
	Old	New	Old	New	Old	New	Old	New	Old	New	Old	New
Collaboration Revenue	-	0.0	-	0.0	-	0.0	0.0	0.0	0.0	0.0	99.9	99.9
Other	-	-	-	-	-	-	-	-	-	-	99.9	99.9
Total Revenues	-	-	-	-	-	-	-	-	-	-	99.9	99.9
COGS	-	-	-	-	-	-	-	-	-	-	12.0	12.0
Gross Profit	-	-	-	-	-	-	-	-	-	-	87.94	87.94
Operating expenses	7.7	6.7	8.4	7.3	8.8	7.8	32.5	28.0	63.2	55.6	160.8	140.2
Research and development	5.4	4.4	6.0	4.9	6.3	5.3	23.0	18.4	36.6	28.8	91.9	70.9
General and administrative	2.3	2.3	2.4	2.4	2.5	2.5	9.5	9.6	26.6	26.8	68.9	69.3
Operating income (loss)	(7.7)	(6.7)	(8.4)	(7.3)	(8.8)	(7.8)	(32.5)	(28.0)	(63.2)	(55.6)	(72.9)	(52.2)
Other income (expense)	-	-	-	-	-	-	-	0.0	-	-	-	-
Interest income	-	-	-	-	-	-	-	0.0	-	-	-	-
Pretax income	(7.7)	(6.7)	(8.4)	(7.3)	(8.8)	(7.8)	(32.5)	(28.0)	(63.2)	(55.6)	(72.9)	(52.2)
Provision for Income Tax	-	-	-	-	-	-	-	-	-	-	-	-
Net income	(7.7)	(6.7)	(8.4)	(7.3)	(8.8)	(7.8)	(32.5)	(28.0)	(63.2)	(55.6)	(72.9)	(52.2)
Basic EPS	\$ (0.50)	\$ (0.41)	\$ (0.56)	\$ (0.48)	\$ (0.58)	\$ (0.51)	\$ (2.10)	\$ (1.78)	\$ (3.95)	\$ (3.42)	\$ (3.48)	\$ (2.47)
Diluted EPS	\$ (0.50)	\$ (0.41)	\$ (0.56)	\$ (0.48)	\$ (0.58)	\$ (0.51)	\$ (2.10)	\$ (1.78)	\$ (3.95)	\$ (3.42)	\$ (3.48)	\$ (2.47)
Basic shares outstanding	15.26	16.51	15.10	15.10	15.18	15.18	15.45	15.70	16.01	16.26	20.93	21.18
Diluted shares outstanding	15.22	16.47	15.10	15.10	15.18	15.18	15.45	15.70	16.01	16.26	20.93	21.18

Source: JMP Securities LLC and Company Reports

FIGURE 7. Updated Income Statement

LOXO Oncology (LOXO)	2014A	1Q15A	2Q15E	3Q15A	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Income Statement (\$MM)	2014A	1Q15A	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
Collaboration Revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	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	1.9	2.2	2.4	2.6	9.1	10.2	10.7	11.3	11.8	11.8	11.8	11.8	11.8	11.8	11.8	11.8	11.8	11.8	11.8
Research and development	6.947	1.9	2.2	2.5	2.7	9.3	18.6	37.3	59.6	71.5	78.7	82.6	86.8	91.1	93.8	96.6	99.5	102.5	105.6	108.8
General and administrative	6.175	2.4	2.3	2.4	2.5	9.6	16.8	27.7	44.3	62.0	74.4	85.6	92.5	98.0	102.9	105.0	107.1	109.2	111.4	113.6
Milestone Expense to ArrayBioPharm							10.0	10.0	25.0	10.0	10.0	10.0	10.0							
Total operating expenses	20.690	6.225	6.7	7.3	7.8	28.0	55.6	85.7	140.2	155.4	175.0	190.1	201.0	200.9	208.6	213.4	218.4	223.6	228.8	234.2
Operating income (loss)	(20.690)	(6.225)	(6.7)	(7.3)	(7.8)	(28.0)	(55.6)	(85.7)	(52.2)	37.5	140.4	271.9	389.5	465.8	518.8	549.8	572.8	594.5	617.2	640.7
Operating margin (%)									-52.3%	17.3%	39.7%	52.6%	59.0%	62.7%	64.1%	64.8%	65.1%	65.3%	65.5%	65.7%
Other income (expense):																				
Interest income	0.018	0.043				0.0														
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	0.0
Pretax income (loss)	(20.672)	(6.182)	(6.7)	(7.3)	(7.8)	(28.0)	(55.6)	(85.7)	(52.2)	37.5	140.4	271.9	389.5	465.8	518.8	549.8	572.8	594.5	617.2	640.7
Comprehensive income (loss)																				
Tax Rate										5%	10%	20%	30%	35%	35%	35%	35%	35%	35%	35%
Comprehensive income (loss)	(20.672)	(6.2)	(6.7)	(7.3)	(7.8)	(28.0)	(55.6)	(85.7)	(52.2)	35.6	126.4	217.5	272.6	302.8	337.2	357.4	372.3	386.5	401.2	416.5
Accretion of redeemable convertible preferred stock	-0.034																			
Net income (loss) attributable to common stockholders	(20.706)	(6.2)	(6.7)	(7.3)	(7.8)	(28.0)	(55.6)	(85.7)	(52.2)	35.6	126.4	217.5	272.6	302.8	337.2	357.4	372.3	386.5	401.2	416.5
Basic EPS to common shareholders	\$ (3.06)	\$ (0.38)	\$ (0.41)	\$ (0.48)	\$ (0.51)	\$ (1.78)	\$ (3.42)	\$ (4.58)	\$ (2.47)	\$ 1.62	\$ 5.58	\$ 9.29	\$ 11.28	\$ 12.15	\$ 13.14	\$ 13.52	\$ 13.69	\$ 13.82	\$ 13.96	\$ 14.11
Diluted EPS to common shareholders	\$ (3.06)	\$ (0.38)	\$ (0.41)	\$ (0.48)	\$ (0.51)	\$ (1.78)	\$ (3.42)	\$ (4.58)	\$ (2.47)	\$ 1.25	\$ 4.32	\$ 7.24	\$ 8.84	\$ 9.57	\$ 10.40	\$ 10.76	\$ 10.94	\$ 11.10	\$ 11.26	\$ 11.43
Basic shares outstanding	6.8	16.5	16.5	15.1	15.2	15.7	16.3	18.7	21.2	21.9	22.7	23.4	24.2	24.9	25.7	26.4	27.2	28.0	28.7	29.5
Diluted shares outstanding	6.8	16.5	16.5	15.1	15.2	15.7	16.3	18.7	21.2	21.9	22.7	23.4	24.2	24.9	25.7	26.4	27.2	28.0	28.7	29.5

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

Analyst Certification:

The research analyst(s) who prepared this report does/do hereby certify that the views presented in this report are in accordance with my/our personal views on the securities and issuers discussed in this report. As mandated by SEC Regulation AC no part of my/our compensation was, is or will be directly or indirectly related to the specific views or recommendations expressed herein. This certification is made under the obligations set forth in SEC Regulation AC. Any other person or entity may not use it for any other purpose. This certification is made based on my/our analysis on the date of this report's publication. I/We assume no obligation to update this certification to reflect any facts, circumstances or events that may subsequently come to my/our attention. Signed Michael G. King

JMP Securities Disclosures:

JMP Securities currently makes a market in the security of Loxo Oncology, Inc.

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.

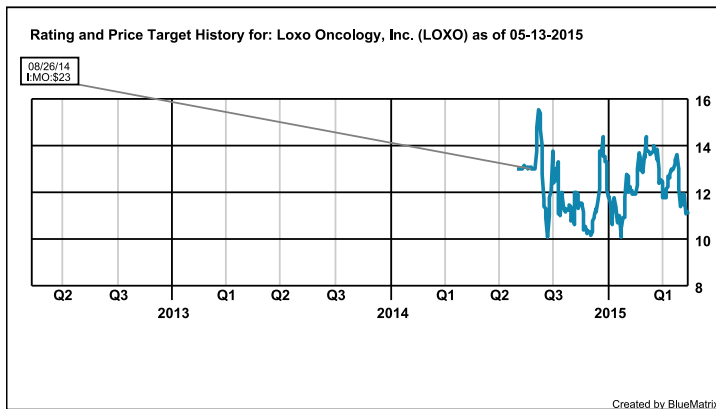
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of May 14, 2015)

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	279	62.00%	Buy	279	62.00%	95	34.05%
MARKET PERFORM	Hold	140	31.11%	Hold	140	31.11%	17	12.14%
MARKET UNDERPERFORM	Sell	9	2.00%	Sell	9	2.00%	0	0%
COVERAGE IN TRANSITION		21	4.67%		21	4.67%	4	19.05%
TOTAL:		450	100%		450	100%	116	25.78%

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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