Loxo Oncology, Inc. (LOXO)

Initiating Coverage at Market Outperform; On Track for Success with a Capital-Efficient Business Model

MARKET DATA

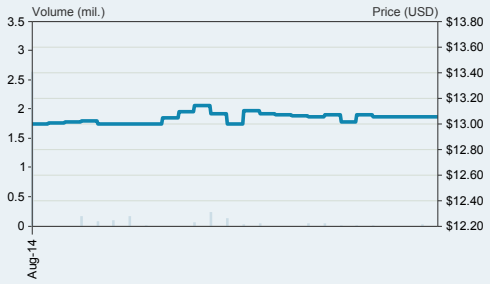
Price	$13.05
52-Week Range:	$12.72 - $13.42
Shares Out. (M):	15.2
Market Cap ($M):	$198.4
Average Daily Vol. (000):	24.0
Cash (M):	$79
Cash/Share:	$4.98
Enterprise Value (M):	$226
LT Debt (M):	$0

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014E	2015E	2016E
Revenue ($M)	1Q	$0.0A	--	--
	2Q	$0.0	--	--
	3Q	$0.0	--	--
	4Q	$0.0	--	--
	FY	**$0.0**	**$0.0**	**$0.0**
EPS	1Q	($0.68)A	--	--
	2Q	($0.81)	--	--
	3Q	($0.26)	--	--
	4Q	($0.30)	--	--
	FY	**($1.23)**	**($1.58)**	**($3.15)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



MARKET OUTPERFORM | Price: $13.05 | Target Price: $23.00

INVESTMENT HIGHLIGHTS

We are initiating coverage on Loxo Oncology (LOXO) with a Market Outperform rating and $23 price target based on our DCF and comparable valuation methodologies. Loxo Oncology is a clinical stage, small molecule oncology target discovery and drug development company applying a focused and capital efficient model to the furthering of novel, best-in-class cancer medicines. The company's lead asset, LOXO-101, is a selective Trk kinase inhibitor that is being directed toward the sub-fraction of solid tumor indications driven by specific genetic alterations of the Trk family of kinases. Loxo recently completed an initial public offering, raising gross proceeds of $71M, wherein JMP Securities participated as a co-manager.

Novel targets and genetically tractable oncology indications. Loxo's main, albeit not sole, thrust is a focus on the identification of oncology drug targets in tumors driven by translocations, or "driver" genes that are switched on by the abnormal relocation of a promoter from elsewhere in the genome rather than by a mutation in a signaling pathway. Classic examples include the Bcr-abl translocation in chronic myelogenous leukemia (CML) and the ELM-ALK4, ROS1, and RET translocations in non-small cell lung cancer (NSCLC). While not limited to this area, Loxo applies a great deal of emphasis to translocations as oncology drug targets, given their role as fundamental drivers of tumorigenesis and the relative dearth of competition compared to the kinase space.

Relationship with Array accelerates development timelines and drives capital efficiency. Loxo's unique relationship with Array BioPharma (ARRY, NC) wherein Array acts essentially as a bespoke chemistry provider endows Loxo with a number of benefits, including speed to market and efficient use of corporate resources. Upon the identification and validation of a new drug target, Array can quickly use its world-class chemistry to design a library of potential drug candidates, or, as in the case with LOXO-101, pull a family of target-directed compounds from its inventory for exploitation by Loxo. Array's chemistry platform has been validated by a vast number of the world's leading biopharmaceutical companies and is well-suited for the Loxo model, in our view.

Deep oncology drug development experience and formidable advisory board. Loxo's management, board, and scientific advisory board are comprised of individuals with substantial knowledge of oncology drug target identification and validation, along with a successful track record of clinical development and regulatory approval. CEO Josh Bilenker, MD, was a Medical Officer in the FDA's Office of Oncology, while Acting Chief Medical Officer, Lori Kunkel, MD, is a veteran oncology drug developer with bona fides from both Pharmacyclics (PCYC, MO, $200 PT) and Onyx Pharmaceuticals, now part of Amgen (AMGN, NC). The company's SAB is populated with some of the sector's

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most prominent translational scientists in the field of cancer biology, and plays an integral role in the company's discovery and development strategy.

LOXO-101 follows a development strategy that is tried, tested, and true in oncology. While the biologic validation behind Trk as a driver in NSCLC, colorectal, thyroid, and other tumor types is still in its early days, we believe the evidence is compelling regarding its role in tumorigenesis. Furthermore, the fact that Loxo has competition from other biopharmaceutical companies, large and small, provides additional comfort regarding Trk's validity. Finally, we believe LOXO-101 has the potential to be a best-in-class molecule given its minimal brain penetration – a theory being initially brought to bear with a Phase Ia advanced, mixed solid tumor read-out in 1Q15.

Establishing a twelve-month price target of $23 per share. Shares of LOXO look attractive to us on the basis of various metrics we use to value development-stage companies. If the company's hypothesis regarding the targeting of Trk proves correct, we believe the stock could realize significant upside by 1Q15. We derive our price target through a synthesis of our DCF ($18.90), SOTP ($23.36), CAGR ($25.50), and comparable company ($25.28) valuation methodologies.

INVESTMENT THESIS

We are initiating coverage on Loxo Oncology with a Market Outperform rating and 12-month price target of $23 per share. Loxo represents a modern take on a genetically driven oncology drug development model that began with Novartis' (NVS, NC) development of Gleevec to the more recent approvals of drugs such as Zelboraf (vemurafenib), Tafinlar (dabrafenib), Xalkori (crizotinib), and Zykadia (ceritinib). These drugs are directed against highly validated, genetically relevant targets, meaning that interdiction against the BRAF V600E mutation or the Bcr-abl or ELM-ALK4 translocations provides profound clinical benefit in patients that harbor these genetic alterations in their tumors.

As the industry's knowledge of detecting and validating novel targets has grown, the rapidity with which these agents have come to market has increased concomitantly. Loxo has assembled a formidable team of oncology-focused professionals with substantial relevant experience in the requisite skills for success in oncology drug development - from target identification and validation to translational science, to rapid clinical development, and efficient regulatory approval. A first-rate scientific advisory board further adds to the company's bona fides, the advisory board is chaired by Dr. Keith T. Flaherty of Mass General and Harvard Medical School. Dr. Flaherty played a key role in the successful development of Zelboraf.

Thrown into this mix is the world-class chemistry from Array BioPharma, which has formed a sort of symbiotic relationship with Loxo as its bespoke supplier of medicinal chemistry that we feel will aid in Loxo's quest to exploit the burgeoning knowledge of the genetic drivers of tumors. The relationship between Array and Loxo can also be viewed as benefiting Array from the standpoint of Loxo's ability to provide Array with additional development pathways for its chemistry. The company's lead asset, LOXO-101, came as the result of the acquisition of a group of chemistries owned by Array that were directed against the Trk kinase. Going forward, we expect to see a great deal of similarity between LOXO-101 and LOXO-200 when its identity is revealed during 1H15; that is, a family of compounds that is highly specific for a genetically defined tumor, where Loxo will either be an early, or the sole, party working on the target.

Finally, we applaud the capital-efficient model that is inherent in the Loxo story. We believe the company has correctly decided to focus on the aspects of true value creation: the identification and validation of novel oncology targets and the achievement of clinical proof of concept that intervention against these targets can have a profound effect on patient outcome. We would even go so far as to say that Loxo has defined, in our view, what the oncology drug development company of the future will look like.

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 Reports

VALUATION

We derive our twelve-month price target of $23 based on the synthesis of our discounted cash flow (DCF), NPV sum-of-the-parts, our proprietary CAGR valuation methodology, and a relative valuation analysis against a set of development-stage, oncology-focused, biotechnology companies (Figure 2).

FIGURE 2. Price Target Synthesis

Synthesis of Valuation Approaches	
Approach	Valuation
DCF Analysis	$18.90
SOTP NPV	$23.36
CAGR	$25.50
Comparables	$25.28
Price Target	**$23.00**

Source: JMP Securities LLC and Company Reports

Our DCF valuation projects LOXO-101 sales in the U.S. and royalty revenue from ex-U.S. sales (which we assumed to be led by a global commercial partner) until patent expiration in 2029, while subtracting cost of goods sold, projected operating expenses, and tax. Net cash flows to the company are discounted back to present values by 30%, representing a risk-adjusted discount rate that takes into account the LOXO-101's early stage of development of each drug candidate and its likelihood of success. A terminal value for the company, calculated by applying a -33% long-term growth rate was similarly discounted to present day. Present value of free cash flows, together with the terminal value, were added to arrive at a residual value for the company, to which estimated cash and long-term debt were added and subtracted, respectively. Thereby, we arrived at an equity valuation of $287MM. Dividing this by our estimated 2014 year-end outstanding share count, we derive a per share valuation of ~$18.90. Our DCF assumptions are detailed further in Figure 3.

FIGURE 3. Discounted Cash Flow Analysis

Discounted Cash Flow Model	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026-2029E
LOXO-014 Revenue													
NSCLC, US	-	-	-	-	78.9	145.9	222.5	307.8	372.5	386.4	400.9	415.9	
CRC, US	-	-	-	-	21.0	52.4	81.8	126.0	170.4	204.6	230.5	239.8	
Thyroid, US	-	-	-	-	-	4.8	12.3	23.3	33.9	46.2	54.1	59.0	
Ex-US Royalties	-	-	-	-	-	14.1	36.8	59.8	82.9	106.0	124.1	134.3	
Total Revenues	$ -	$ -	$ -	$ -	$ 99.9	$ 217.3	$ 353.4	$ 516.8	$ 659.7	$ 743.2	$ 809.7	$ 849.0	
Cost of product sales				-	12.0	24.4	38.0	54.8	69.2	76.5	82.3	85.8	
COGS as % of revenue					*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	
Gross Profit	-	-	-	-	87.9	192.9	315.4	462.0	590.5	666.7	727.4	763.2	
R&D expense	10.8	16.0	25.6	43.7	65.3	77.0	83.8	87.5	91.4	95.5	98.1	100.8	
R&D as a % of revenue					*65%*	*35%*	*24%*	*17%*	*14%*	*13%*	*12%*	*12%*	
SG&A expense	4.2	8.4	14.8	24.3	39.0	54.5	65.4	75.3	81.3	86.2	90.5	92.3	
SG&A as a % of revenue					*39%*	*25%*	*19%*	*15%*	*12%*	*12%*	*11%*	*11%*	
Milestone expense		-	10.0	10.0	25.0	10.0	10.0	10.0	10.0	-	-	-	
Total operating expenses	15.0	24.4	50.4	78.0	129.2	141.5	159.2	172.8	182.7	181.7	188.6	193.1	
Operating income (EBIT)	**(15.0)**	**(24.4)**	**(50.4)**	**(78.0)**	**(41.3)**	**51.3**	**156.2**	**289.2**	**407.8**	**485.0**	**538.8**	**570.2**	
Operating margin (%)					*-41.3%*	*23.6%*	*44.2%*	*56.0%*	*61.8%*	*65.3%*	*66.5%*	*67.2%*	
Taxes	-	-	-	-	-	2.6	15.6	57.8	122.3	169.8	188.6	199.6	
Tax rate						*5%*	*10%*	*20%*	*30%*	*35%*	*35%*	*35%*	
After tax operating income	(15.0)	(24.4)	(50.4)	(78.0)	(41.3)	48.8	140.6	231.4	285.5	315.3	350.2	370.6	
Discount year	-	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	
Discount factor	1.0	1.3	1.7	2.2	2.9	3.7	4.8	6.3	8.2	10.6	13.8	17.9	
PV	(15.0)	(18.8)	(29.8)	(35.5)	(14.5)	13.1	29.1	36.9	35.0	29.7	25.4	20.7	48.7
Residual value of cash flow	$212											**Terminal Value**	16.6
+ Cash and Cash equivalents	75												
Company value	287												
- Long-term debt on 12/31/14	0												
Value of equity	$287												
Fully diluted shares outstanding on 12/31/14	15.2												
Price/share	$18.90												
Discount Rate	30.0%												
Terminal growth rate	-33%												

Source: JMP Securities LLC and Company Reports

To further test our assessment of LOXO's valuation, we completed a sum-of-the-parts analysis, incorporating U.S. sales and ex-U.S. royalty income from each of the three primary indications wherein we anticipate LOXO-101 approval. NPV contributions from LOXO-101 used in the treatment of NSCLC, colorectal and thyroid cancer are detailed in Figure 4.

FIGURE 4. Sum-of-the-Parts NPV Analysis

Sum-of-the-Parts Analysis		
LOXO-101 Indication	**Value ($MM)**	**Per Share**
NSCLC	**$165.4**	**$10.90**
US	138.1	9.10
Ex-US Royalty	27.3	1.80
Colorectal Cancer	**$85.5**	**$5.63**
US	65.0	4.28
Ex-US Royalty	20.5	1.35
Thyroid Cancer	**$13.9**	**$0.91**
US	12.8	0.84
Ex-US Royalty	1.1	0.07
Pipeline Valuation	**$15.0**	**$0.99**
YE Cash and Equivalents	**$74.8**	**$4.93**
Total NPV	**$354.6**	**$23.36**

LOXO-101 - NSCLC													
Year	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026-2029**
US Sales ($MM)					$ 78.9	$ 145.9	$ 222.5	$ 307.8	$ 372.5	$ 386.4	$ 400.9	$ 415.9	
Contribution Margin					*15%*	*25%*	*37%*	*45%*	*45%*	*45%*	*45%*	*45%*	
CF to Loxo					**11.8**	**36.5**	**82.3**	**138.5**	**167.6**	**173.9**	**180.4**	**187.1**	
Growth						*208%*	*126%*	*68%*	*21%*	*4%*	*4%*	*4%*	
Discount Period					4	5	6	7	8	9	10	11	
PV of CF					**4.1**	**9.8**	**17.1**	**22.1**	**20.5**	**16.4**	**13.1**	**10.4**	**24.5**
Discount Rate	30%												
NPV	**$138.1**												
# Shares outstanding	15.2												
Incremental Price	**$9.1**												
EU and JPN Sales ($MM)						$ 66.8	$ 158.9	$ 247.1	$ 321.5	$ 386.4	$ 432.6	$ 447.6	
Royalty rate						*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	
Contribution Margin						*70%*	*68%*	*65%*	*65%*	*65%*	*65%*	*65%*	
Royalty to LOXO						**7.0**	**16.2**	**24.1**	**31.3**	**37.7**	**42.2**	**43.6**	
Growth							*131%*	*49%*	*30%*	*20%*	*12%*	*3%*	
Discount Period						5	6	7	8	9	10	11	
PV to CF						**1.9**	**3.4**	**3.8**	**3.8**	**3.6**	**3.1**	**2.4**	**5.3**
Discount Rate	30%												
NPV	**$27.3**												
# Shares outstanding	15.2												
Incremental Price	**$1.8**												

LOXO-101 - Colorectal Cancer													
Year	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026-2029**
US Sales ($MM)					$ 21.0	$ 52.4	$ 81.8	$ 126.0	$ 170.4	$ 204.6	$ 230.5	$ 239.8	
Contribution Margin					*15%*	*22%*	*35%*	*45%*	*45%*	*45%*	*45%*	*45%*	
CF to Loxo					**3.1**	**11.5**	**28.6**	**56.7**	**76.7**	**92.0**	**103.7**	**107.9**	
Growth						*266%*	*148%*	*98%*	*35%*	*20%*	*13%*	*4%*	
Discount Period					4	5	6	7	8	9	10	11	
PV of CF					**1.1**	**3.1**	**5.9**	**9.0**	**9.4**	**8.7**	**7.5**	**6.0**	**14.2**
Discount Rate	30%												
NPV	**$65.0**												
# Shares outstanding	15.2												
Incremental Price	**$4.3**												
EU and JPN Sales ($MM)						$ 27.6	$ 84.7	$ 145.4	$ 219.7	$ 303.0	$ 371.2	$ 419.4	
Royalty rate						*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	
Contribution Margin						*70%*	*68%*	*65%*	*65%*	*65%*	*65%*	*65%*	
Royalty to LOXO						**2.9**	**8.6**	**14.2**	**21.4**	**29.5**	**36.2**	**40.9**	
Growth							*198%*	*64%*	*51%*	*38%*	*23%*	*13%*	
Discount Period						5	6	7	8	9	10	11	
PV of CF						**0.8**	**1.8**	**2.3**	**2.6**	**2.8**	**2.6**	**2.3**	**5.3**
Discount Rate	30%												
NPV	**$20.5**												
# Shares outstanding	15.2												
Incremental Price	**$1.3**												

LOXO-101 - Thyroid Cancer													
Year	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026-2029**
US Sales ($MM)						$ 4.8	$ 12.3	$ 23.3	$ 33.9	$ 46.2	$ 54.1	$ 59.0	
Contribution Margin						*18%*	*26%*	*35%*	*45%*	*45%*	*45%*	*45%*	
CF to Loxo						**0.9**	**3.2**	**8.1**	**15.2**	**20.8**	**24.4**	**26.6**	
Growth							*272%*	*155%*	*87%*	*36%*	*17%*	*9%*	
Discount Period						5	6	7	8	9	10	11	
PV of CF						**0.2**	**0.7**	**1.3**	**1.9**	**2.0**	**1.8**	**1.5**	**3.5**
Discount Rate	30%												
NPV	**$12.8**												
# Shares outstanding	15.2												
Incremental Price	**$0.8**												
EU and JPN Sales ($MM)							$ 2.1	$ 6.0	$ 11.7	$ 17.6	$ 23.7	$ 28.1	
Royalty rate							*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	
Contribution Margin							*68%*	*65%*	*65%*	*65%*	*65%*	*65%*	
Royalty to Loxo							**0.2**	**0.6**	**1.1**	**1.7**	**2.3**	**2.7**	
Growth								*180%*	*94%*	*50%*	*35%*	*19%*	
Discount Period							6	7	8	9	10	11	
PV of CF							**0.0**	**0.1**	**0.1**	**0.2**	**0.2**	**0.2**	**0.3**
Discount Rate	30%												
NPV	**$1.1**												
# Shares outstanding	15.2												
Incremental Price	**$0.1**												

Source: JMP Securities LLC and Company Reports

We also arrived at a valuation based on our standardized CAGR methodology. We began by calculating the profitable biotech PEG ratio (1.12), based on the mean 2014 P/E of 19.9, and a mean forward CAGR of 17.6%. Based on projected EPS in the year 2020 and a discount rate of 30%, we arrived at a valuation of $25.50 per share. Our assumptions, together with a sensitivity analysis, are detailed in Figure 5.

FIGURE 5. CAGR Valuation Model and Sensitivity Analysis

CAGR Valuation	
Comparables	
Biotech Group P/E (2014)	19.9
Biotech Group Forward CAGR ('14- '16)	17.6%
Valued Company	
Year used for discounting	2020
Price Target Year	2014
5-year EPS CAGR	22.5%
EPS in the discounting year	$ 4.84
Discount Rate	30.0%
# Years for Discounting	6
Target Price	**$25.50**

Sensitivity Analysis					
	Discount Rate				
CAGR	27.0%	28.5%	30.0%	31.5%	33.0%
7.5%	**$9.74**	**$9.07**	**$8.46**	**$7.90**	**$7.38**
12.5%	**$16.27**	**$15.16**	**$14.14**	**$13.20**	**$12.33**
17.5%	**$22.80**	**$21.25**	**$19.82**	**$18.50**	**$17.28**
22.5%	**$29.33**	**$27.34**	**$25.50**	**$23.80**	**$22.24**
27.5%	**$35.86**	**$33.42**	**$31.18**	**$29.10**	**$27.19**
32.5%	**$42.40**	**$39.51**	**$36.85**	**$34.40**	**$32.14**
37.5%	**$48.93**	**$45.60**	**$42.53**	**$39.70**	**$37.09**

Source: JMP Securities LLC and Company Reports

Finally, by taking the mean market cap valuation from a peer group of platform and/or early-stage, oncology-focused biotechnology companies, we derive a comparable valuation for LOXO of $25.28 (Figure 6).

FIGURE 6. Comparable Company Valuation

Comparable Stage Biotech Companies						
Comparable	**Ticker**	**Price**	**Market Cap**	**Cash**	**Debt**	**EV**
Array Biopharma Inc	ARRY	$3.87	$510	$110	$0	$400
Exelixis	EXEL	$4.20	$819	$286	$0	$534
Five Prime Therapeutics Inc	FPRX	$12.05	$259	$141	$0	$119
Infinity Pharmaceuticals Inc	INFI	$11.33	$550	$141	$0	$409
Ignyta Inc	RXDX	$7.50	$147	$78	$0	$69
TG Therapeutics Inc	TGTX	$7.92	$302	$45	$0	$257
Verastem Inc	VSTM	$8.99	$232	$106	$0	$127
Average			**$403**			**$273**
Loxo Oncology Inc	LOXO	$13.08	$209	$27	$0	$182

Comparable Valuation	**$25.28**

Source: JMP Securities LLC and Thomson One

COMPANY OVERVIEW

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.

LOXO-101 - BREAKING THE HOLD OF ONCOGENE ADDICTION

The approach to drug development being undertaken by Loxo adapts a paradigm that in recent years has delivered more than a handful of novel therapies from a point of early discovery to the market with record-setting speed compared to traditional drug development at large. By focusing on specific subsets of cancer indications where data demonstrate a clear, direct relationship between the aberrant signaling of a genetically altered kinase and the pathogenesis of that cancer, this industry has delivered agents with groundbreaking activity. Perhaps the archetypal example in this context is Gleevec, a Bcr-Abl inhibitor for use in the treatment of CML that was approved within three years of discovery. More recently, agents such as Zelboraf and Tafinlar for mutant $BRAF^{V600}$ melanoma and Xalkori and Zykadia for ALK+ lung cancer have been able to reach market within four to five years from IND. In our opinion, it stands to reason that next generation EGFR inhibitors CO-1686 (CLVS, NC) and AZD9291 (AZN, NC) could be the next to attain this distinction in solid tumors (both expect to reach market in 2016 according to Bloomberg estimates), benefiting from rapid approval strategies in $EGFR^{T790M}$ mutationally resistant NSCLC.

LOXO sees a similar opportunity with its lead molecule LOXO-101 – a specific, pan-Trk small molecule kinase inhibitor. As elaborated in detail below, genetic modifications of Trk kinase have begun to surface as an oncogenic driver in a number of solid tumor disease subsets, particularly in lung and colon cancer, and in a manner that evades the activity of current small inhibitors of ALK or EGFR. Although Trk-driven cancers represent a small proportion of the overall solid tumor market, we believe LOXO-101 faces a meaningful commercial opportunity, exceeding $1 billion in sales within five years of product launch.

FIGURE 7. Development Timelines for Targeted Oncology Products

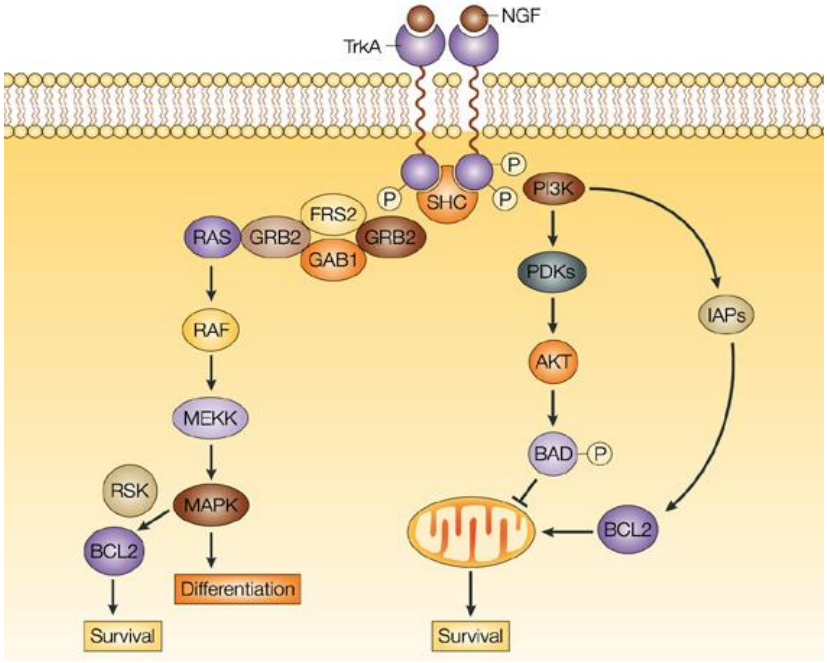
Development Timelines for Targeted Oncology Products			
Drug	**Company**	**Indication**	**IND to Approval**
Zelboraf (vemurafenib)	Plexikkon/Roche	BRAF+ Melanoma	IND - Q3 2006 Approval - Q3 2011
Tafinlar (dabrafenib)	GSK (now NVS)	BRAF+ Melanoma	IND - Q3 2009 Approval - Q2 2013
Xalkori (crizotinib)	Pfizer	ALK+ NSCLC	ALK+ activity reported in Q3 2007 Approved Q3 2011
Zykadia (ceritinib)	Novartis	ALK+ NSCLC	IND - Q4 2010 Approval - Q2 2014
CO-1686	Clovis (CLVS)	EGFR T790M NSCLC	IND - Q1 2012 Reg. Phase II - initiated mid-2014 Phase III - expt initiation 2H 2014 Expected approval: 2016
AZD9291	AZN	EGFR T790M NSCLC	IND - unknown Phase I - Q3 2013 Phase III - Opened Q2 2014, not yet recruiting Expected approval: 2016

Source: Company reports and Bloomberg

Background on Trk kinase and cancer pathogenesis

Tropomyosin-related kinase, or Trk, comprises a family of neurotrophin receptor kinases that normally play a critical role in the development of the central and peripheral nervous system during embryogenesis. Neurotrophic Tyrosine Kinase Receptor genes *NTRK1*, *NTRK2*, *NTRK3*, coding for receptors TrkA, TrkB, and TrkC, respectively, have each been shown to possess important, distinct functionality in the transmission of neuronal growth factor signaling in order to regulate processes that include neuronal survival and differentiation, memory formation, sensory, and motor function. As depicted in Figure 8, ligand-activated Trk shares much of the downstream effector signaling machinery common to other growth factor receptors such as the RAS/MAPK and PI3K/AKT/mTOR signaling axes.

FIGURE 8. Overview of Trk Family Kinase Signaling



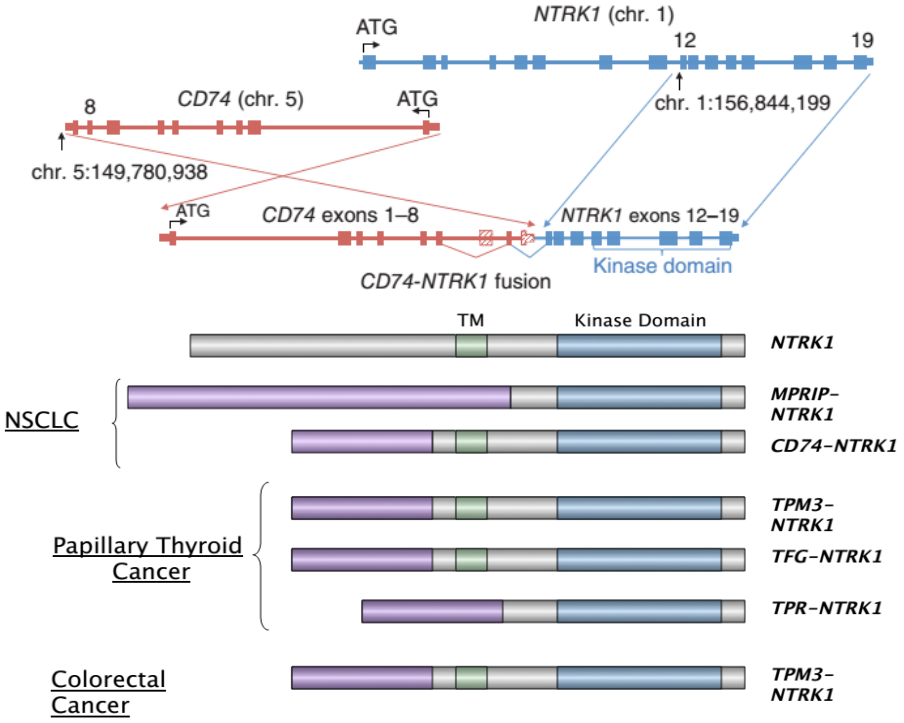
Source: Nature Reviews Cancer, 2003

While Trk kinase dysfunction has been most extensively characterized for its role in neuropathic pain, recently, genetic alterations of Trk have been linked to cancer pathogenesis, stemming from activating translocations between receptor kinase domains and gene promoter elements. These translocations, and their downstream impact, manifest in a manner similar to those observed with the anaplastic lymphoma kinase gene, or ALK (the EML4-ALK translocation), a well-known oncogenic driver of ~4-8% of NSCLC cases (up to 20% among non-smokers).

NTRK1 (the gene encoding for TrkA) was originally identified as part of a chimeric oncogene cloned from a colorectal cancer-derived cDNA library, wherein the region coding for the TrkA kinase domain was fused to the gene TPM3, coding for tropomyosin 3 - an abundantly expressed actin-binding protein. Subsequently characterized oncogenic TrkA fusions include TPR-NTRK1 and TGF-NTRK1, which were identified in papillary thyroid cancer models and, more recently, MPRIP-NTRK1 and CD74-NTRK1, that were identified in patient-derived lung adenocarcinomas (Figures 9 and 10). Oncogenic fusions with NTRK3 (coding for TrkC) have also been observed, most commonly with the ETS-variant gene ETV6 in a diversity of tumor types including breast, renal, and salivary gland cancers (Figure 10).

FIGURE 9. NTRK1 (TrkA) Gene Translocations in Lung Cancer

Example *CD74-NTRK1* TrkA translocation between c hromsomes 1 and 5



Source: DeBraud et al., ASCO 2014, Abstract #2052

The overall frequency of Trk translocation remains somewhat difficult to determine from publicly available sources and appears to vary significantly across tumor types. Estimates cited by the literature suggest that 5-15% of papillary thyroid cancer, 2-5% of NSCLC, and ~5% of colorectal cancer (CRC) are positive for activating Trk rearrangements (Figure 10).

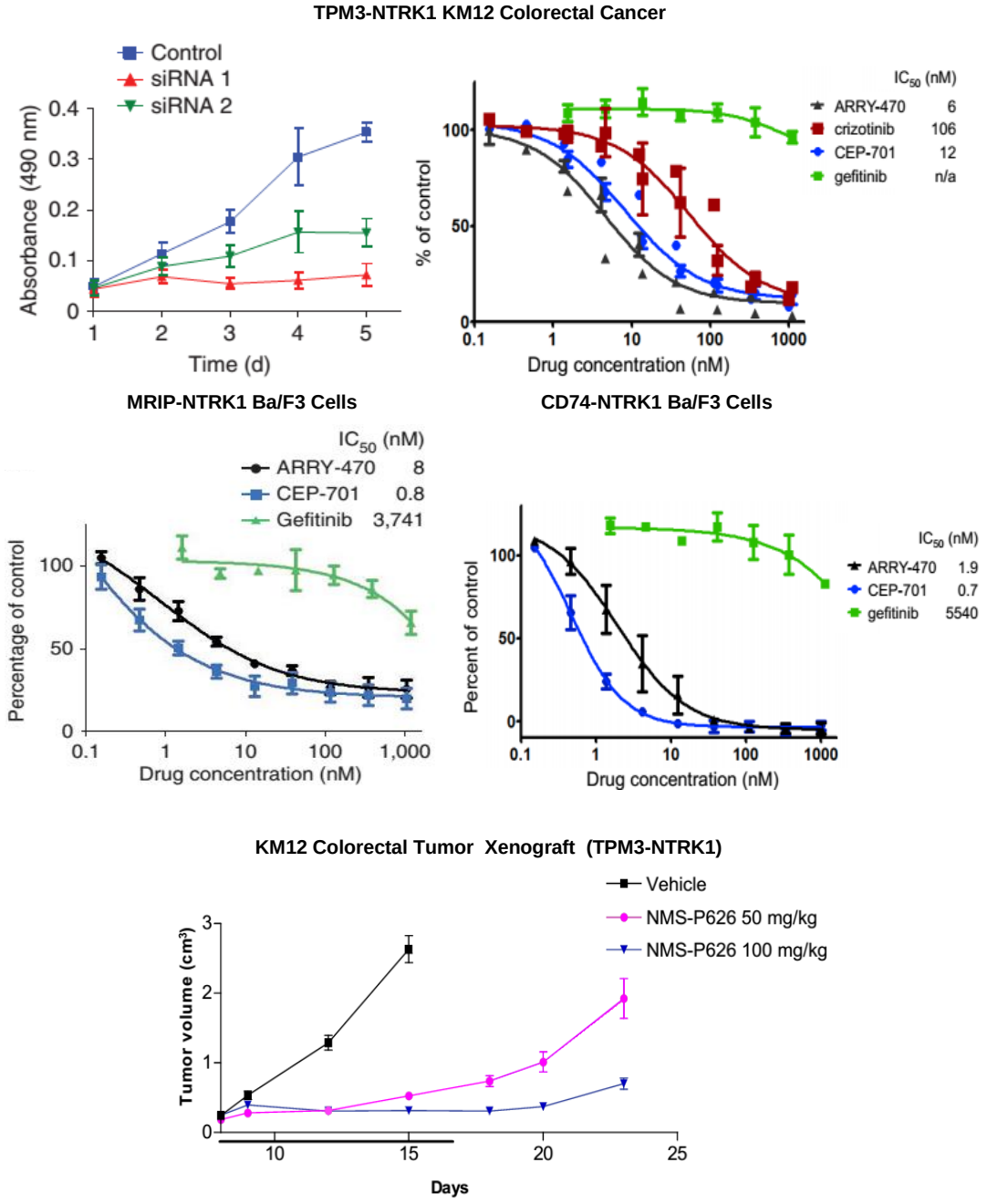
FIGURE 10. Frequency of NTRK/Trk Kinase Mutations in Cancer

Frequency of Trk Kinase Alterations in Cancer						
	***NTRK1* (TrkA)**					***NTRK3* (TrkC)**
	TFG-NTRK1	*TPM3-NTRK1*	*TPR-NTRK1*	*MPRIP-NTRK1*	*CD74-NTRK1*	*ETV6-NTRK3*
Overall Frequency	0.4% (2 of 495 samples)	5% (32 of 629)	1.4% (7 of 498)	~ 3%	~ 3%	14% (145 of 1023 samples)
Lung				3-5% 1-2 of 36	3-5% 1-2 of 36	
Colorectal Cancer		unknown				
Thyroid	0.4% (2 of 495)	5% (30 of 559)	1.4% (7 of 498)			5%
Large intestine		3% (2 of 70)				1%
Breast						10%
Heme malignancy						3%
Kidney						47%
Soft tissue						23%
Salivary Gland						67%
Pediatric high grade glioma	40 - 47% across *NTRK1/2/3*					

Source: COSMIC, Wellcome Trust Sanger Institute; Vaishanavi et al., Nature Medicine, 2013; Wu et al., Nature Genetics, 2014

Much in the same way that has been demonstrated in *EML4-ALK* positive NSCLC, tumors harboring oncogenic Trk mutations demonstrate an exquisite sensitivity to selective Trk inhibition in preclinical tumor models. As shown in Figure 11, recent work from the labs of Pasi Janne and Robert Doebele at the Dana Farber Cancer Institute and the University of Colorado, respectively, (Vaishnavi et al., Nature Medicine, 2013) shows the proliferation of the *TPM3-NTRK1*+ KM12 colorectal cancer cells to be sensitive to *NTRK1* depletion by siRNA. Similarly, the growth of *MRIP-NTRK1*-expressing BaF3 cells was shown to be sensitive to Trk kinase inhibition using low concentrations of a selective small molecule inhibitor, ARRY-470 (Array BioPharma), yet insensitive to EGFR inhibition using gefitinib. Separate studies performed by scientists at Nerviano Medical Sciences (Ardini et al., Molecular Oncology, 2014) showed effective KM12 xenograft tumor growth inhibition in vivo using the small molecule pan-Trk inhibitor NMS-P626.

FIGURE 11. Genetic and Small Molecule Inhibition of Trk Slows TrkA-Driven Tumor Growth



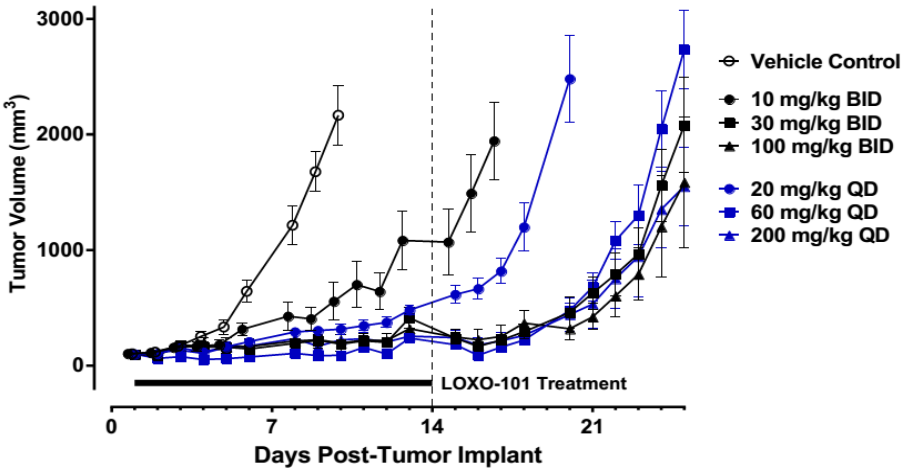
Source: Vaishnavi et al., Nature Medicine, 2013; Ardini et al., Molecular Oncology, 2014.

LOXO-101 Pre-clinical Development

Loxo's leading drug candidate, LOXO-101, is a pan-Trk kinase inhibitor currently undergoing evaluation in a Phase I dose-escalation study. LOXO-101 was either selected or chemically modified from a portfolio of Trk inhibitor compounds licensed from Array BioPharma in May 2013 at the company's inception. Specific details regarding LOXO-101's potency and selectivity to the Trk family kinases remain somewhat limited. However, LOXO-101 has been described as having low nanomolar potency for Trk kinases A, B, and C, with at least 100-fold selectivity over the next most inhibited and kinase (not specified) targets, and greater than 1,000-fold selectivity against non-kinase targets. In addition, LOXO-101 is described as having high oral bioavailability, with moderate protein binding and limited distribution to the brain and CNS. Pre-clinical PK studies indicate limited risk of drug-drug interaction, as LOXO-101 is neither a significant inhibitor nor inducer of cytochrome P450 or CYP3A4. In pre-clinical xenograft studies in mice using a TrkA-driven tumor model (undisclosed), LOXO-101 demonstrated significant tumor growth inhibition under both once-daily (QD) and twice-daily (BID) dosing schedules (Figure 12), without causing weight loss in the animals.

We note that early pre-clinical presentations describing the Array portfolio of Trk kinase inhibitors, candidate molecules ARRY-470, AR-772, and AR-523, were detailed as having pan-Trk IC_{50} concentrations ranging from 9.7 – 42nM, with roughly equivalent favorable kinase selectivity (devoid of additional kinase inhibition at 1μM), and relatively greater distribution in the periphery versus CNS. We presume similar biochemical properties with LOXO-101 given its origination from this portfolio.

FIGURE 12. LOXO-101 Inhibits TrkA-driven Xenograft Tumor Growth



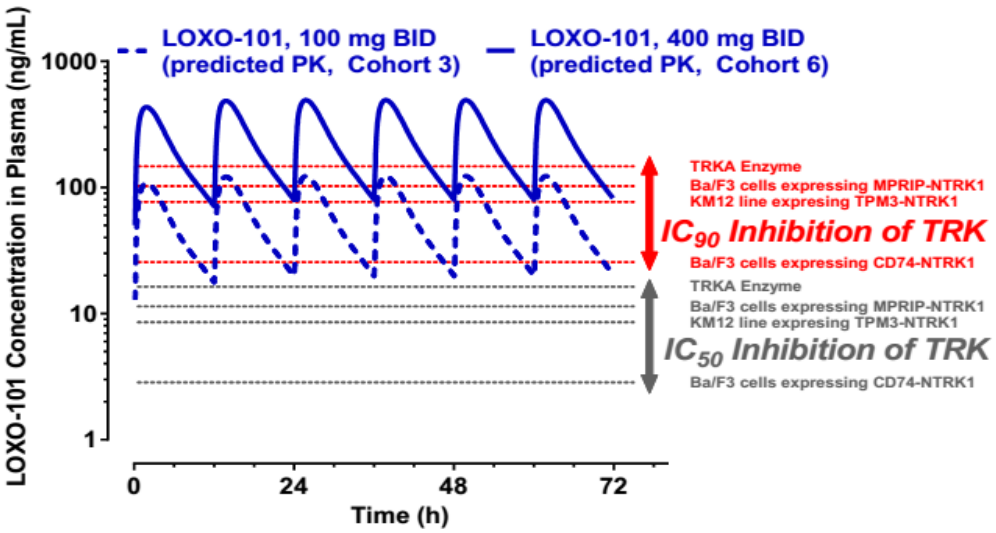
Source: Loxo company presentation

Clinical Development

Clinical evaluation of LOXO-101 is currently underway in a two-stage Phase I trial in patients with advanced solid tumors. The initial part of the trial is designed to establish the drug's safety, tolerability, pharmacokinetics, and pharmacodynamics, predominately in a patient population not specifically selected for its mutation status, before proceeding to a Phase Ib expansion trial, enrolling up to 33 patients in at least three cohorts: TrkA fusion positive NSCLC, NSCLC with other Trk alterations, and other solid tumors containing Trk fusion genes.

While the first real opportunity for observing Trk targeted antitumor efficacy will take place toward the end of the Phase Ib trial, preliminary pharmacokinetic modeling in humans suggests very favorable coverage of Trk kinase activity. As shown in Figure 13, physiologically based pharmacokinetic (PBPK) modeling of LOXO-101 suggest that BID dosing at 100mg and 400mg, respectively, can achieve blood plasma concentrations that meet or exceed the IC_{50} and IC_{90} concentrations of several TrkA-driven preclinical tumor models. Confirmation of these plasma concentrations in the initial Phase I PK/PD analysis, expected to read-out in 1Q15, is one of two key parameters to further establishing the likelihood of success of LOXO-101 in the Phase Ib portion of the study. As we note in greater detail below, the demonstration of limited exposure of the CNS to LOXO-101 will also play an important role in establishing the drug's long-term safety profile given that disruption of neuronal TrkA function has been linked to cerebellar ataxia (involuntary muscle movement) and has been a dose-limiting phenomenon among other Trk kinase inhibitors in development.

FIGURE 13. Pharmacokinetic Modeling of LOXO-101 in Humans



Source: Loxo company presentation

Companion Diagnostic Development

As part of its clinical development and regulatory strategy, Loxo plans to develop one or more companion diagnostics capable of identifying Trk gene translocations and other relevant genetic alterations in a patient's tumor. Specifics related to the diagnostic program have yet to be disclosed; however, we believe Loxo is likely to pursue development in collaboration with a technology partner, focusing on a molecular-based assay with the potentially greater yield sensitivity over an immunohistochemical approach. Independent of Loxo's diagnostic efforts, we note the recent incorporation of Trk family genes into the FoundationOne pan-cancer diagnostics (FMI, MO, $45 PT, Haresco) that are able to detect mutations of NTRK1, 2, and 3, and gene translocations of NTRK1 and 2.

As detailed on the company's second quarter earnings update, approximately two-thirds of FoundationOne's demand originates from clinical sites, showing 33% sequential growth to 3,300 tests in 2Q14. We believe this trend bodes well for Loxo, both in its ability to recruit Trk+ patients into Phase Ib and future clinical trials with LOXO-101 and to better assess the real-world frequency of relevant genetic alternation of Trk and targets of forthcoming pipeline candidates.

Competitive landscape

Our research shows there are several early stage development programs addressing Trk kinase-driven cancer indications that either directly or tangentially compete with LOXO-101 (Figure 14). Chief among these, in our view, is RXDX-101 in development by Ignyta, Inc (RXDX, NC). Currently in Phase I/II development, RXDX-101 is a potent, orally available multi-pan Trk, ROS1, ALK tyrosine kinase inhibitor (IC_{50} values ranging from 0.1 to 1.7nM). Pre-clinical data with RXDX-101 in xenograft experiments in mice show it to have anti-tumor activity comparable to LOXO-101 in a TrkA-driven tumor model, in addition to potent tumor growth inhibition of ALK-driven NSCLC models. Phase I data recently presented at ASCO showed good overall tolerability, with most adverse events being Grade 1/2.

Notably, Grade 1/2 paresthesia (skin tingling) was observed in over half of patients treated, perhaps reflecting an appreciable level of CNS exposure, in line with preclinical data showing brain penetration and anti-tumor activity in a brain metastasis mouse model. However, no dose-limiting toxicities (DLTs) were reported. With respect to clinical activity, RXDX-101 achieved partial responses in two of eight patients with ALK rearranged NSCLC, and in one of two patients with ROS1 rearranged NSCLC. Notably, a rapid partial response was observed in the single patient whose tumor (colorectal cancer) harbored a TrkA translocation. While it is difficult to predict the likelihood of success on the basis of data from one patient, the rapidity of the response (symptom relief in a multiple refractory patient within one cycle of therapy, and a confirmed partial response within the second cycle) lends itself to strong in-man support for the oncogene addiction hypothesis of Trk -positive cancer. Phase I expansion cohort analysis with RXDX-101 is ongoing, with updated clinical read-outs expected at ESMO 2014 in September (Madrid, Spain). In addition to RXDX-101, Ignyta's pipeline also contains RXDX-102, a pan-Trk selective inhibitor in the pre-clinical stage of development.

The next most advanced Trk-targeted oncology program, in our view, is TSR-011 – also a dual ALK/pan-Trk kinase inhibitor in development at Tesaro (TSRO, NC). Preclinical and early Phase I clinical data presented at ESMO 2013 detail similarly low nanomolar inhibitory activity against purified ALK and Trk enzymes (IC_{50}s ranging 0.7 – 2.5nM) and against the proliferation of ALK and TrkA-driven cancer cell lines (EML4-ALK H3122 NSCLC cells and TPM3-TRKA KM12 colorectal cancer cells). Despite good oral bioavailability in humans and a drug half-life supportive of QD dosing, initial Phase I testing uncovered a number of DLTs at higher doses, including dysaesthesia (sensory discomfort), again likely indicative of a level of CNS exposure, and QT prolongation. Two of three treated patients whose tumors were positive for ALK translocations responded to TSR-011. However, in contrast to RXDX-101, none of the treated patients were identified as positive for Trk alterations, thus leaving its clinical activity as a Trk inhibitor an outstanding question. Phase IIa data with TSR-011, including a cohort of Trk rearranged solid tumors, are anticipated for ESMO in September.

Trk inhibitors of different stages of development also reside with the ranks of large pharma. Nerviano Medical Sciences' melciclib (PHA-848215) is described in the literature as a dual-cyclin dependent kinase 2 (CDK2)/TrkA inhibitor (IC_{50}s of 45nM and 53nM, respectively), and is in Phase II development for the treatment of thymic cancers, including thymic carcinoma and previously treated malignant thyoma based on Phase I efficacy data showing two PRs in thymic carcinoma patients of a total of fourteen evaluable patients. Here again, Phase I safety also uncovered neurological DLTs of Grade 3/4 ataxia and tremors, suggesting significant CNS penetration, thereby limiting the Phase II dose and schedule.

AstraZeneca's AZD7451 is also described preclinically as a potent pan-Trk kinase inhibitor (IC_{50} range of 0.2 – 3nM against TrkA, TrkB, and TrkC). A Phase I trial, conducted in collaboration with the NCI, in patients with recurrent glioma was recently noted as being completed according to clinicaltrials.gov, having enrolled fourteen of an originally anticipated 60 patients. Data from the Phase I trial have yet to be disclosed, although, based on the slow rate of recruitment, we would infer negatively with respect to the drug's safety and efficacy.

Daiichi Sankyo's PLX7486 (obtained through the acquisition of Plexikkon, Inc. in 2011), despite a dearth of publicly disclosed data, is described as a dual FMS/pan-Trk kinase inhibitor, and is currently undergoing Phase I evaluation as a single-agent in Trk mutation/fusion positive advanced solid tumors and in combination with gemcitabine/Abraxane in first-line pancreatic cancer.

Older generation tyrosine kinase inhibitors, such as Novartis' dovitinib and TEVA's lestaurtinib (CEP-701) have also been noted for the ability to target Trk family kinases, among other receptors. Preclinical work with lestaurtinib shows low nanomolar potency for the Trk family kinases and FLT3, with >10 fold selectivity over other purified kinases. Phase I testing in children with refractory neuroblastoma (an indication chosen for its purported relationship to TrkB activation) showed moderate activity (4-11% response rate) that was most pronounced in the bone marrow, and limited tolerability at higher doses due to liver enzyme elevations. Whether lestaurtinib could affect better outcomes in a Trk+ tumor setting remains unknown. However, given the compound's expired patent life, we anticipate little to no further clinical development outside of a government entity or cooperative group.

FIGURE 14. Trk Inhibitor Competitive Landscape

Trk Kinase Inhibitors in Development						
Drug Candidate	**Company**	**Ticker**	**Inhibitor Profile**	**Potency (IC_{50})**	**Stage**	**Indication**
LOXO-101	Loxo Oncology	LOXO	pan-Trk	pan-Trk: low nanomolar > 100-fold selectivity	Phase I	Part 1:Advanced solid tumors Part 2: Trk altered tumor indications
RXDX-101	Ignyta	RXDX	pan-Trk, ROS1, ALK	TrkA: 1.7nM TrkB,C: 0.1nM ROS1: 0.2nM ALK: 1.6nM	Phase I/IIa	Advanced/metastatic solid tumors
RXDX-102	Ignyta	RXDX	pan-Trk		preclinical	
TSR-011	Tesaro	TSRO	ALK,TRK	ALK: 0.7nM TRK A,B,C: 0.5 - 2.4nM	Phase I/II	ALK+ NSCLC, ALK+ or TRK+ solid tumors and lymphomas
PLX7486	Daiichi Sankyo	JP:4568	Flt3, cFMS, TRK	Not disclosed	Phase I	Advanced solid tumors in combination with gen/Abraxane
Melciclib (PHA-848125)	Nerviano		CDK2/TrkA	CDK2: 45nM TRKA: 53nM 3-8 fold selectivity for other CDKs	Phase II	Thymic carcinoma Malignant Thyoma
AZD7451	AstraZeneca	AZN			Phase I	Glioblastoma multiforme
Lestaurtinib (CEP-701)	Teva	TEVA	FLT3, RET, pan-Trk	Trk: 4nM Flt-3: 3.2nM VEGFR2: 65nM PDFGR-B: 226nM RET: 50-150nM	Phase III	Childhood ALL Myelofibrosis, AML, Prostate cancer, Myeloma, AML, Severe Psoriasis, High Risk Neuroblastoma
ARRY-470				TRK A,B,C: <11nM > 100-fold selective		
AZD6918	AstraZeneca	AZN			Discontinued	

Source: JMP Securities LLC and Company Reports

Commercial opportunity and revenue model

We model LOXO-101 sales in the U.S., Europe and Japan for the treatment of Trk+ advanced NSCLC, metastatic colorectal cancer and advanced papillary thyroid cancer. Together, we believe these markets represent ~$1.5 billion peak sales opportunity within seven years of the product launch as detailed below (Figures 15-18).

NSCLC

Beginning in the U.S., our lung cancer market model assumes an annual incidence rate of ~188,000 new diagnoses per year (based on SEER database estimates), approximately 60% of which are of advanced stage requiring systemic treatment, and 85% having access to therapy. Based on current literature, we estimate that 5% of such patients will harbor tumors positive for Trk kinase alterations, resulting in an initial eligible target market of ~5,000 patients. Our model assumes product launch in 2018, penetration ramping from 25% to 70% in year 5, and an eight-months mean duration of therapy (similar duration to the median PFS with Xalkori (crizotinib) ALK+ NSCLC).

Finally, we assume an initial launch price of $11,500 per month of therapy, taking the average of several recently launched oral, solid tumor, targeted therapies. Thus, we arrive at U.S. sales of ~$400MM in 2025. Similar assumptions are modeled in the EU and Japan, however, we begin with lung cancer incidence rates of ~200K and ~95K (based on Globocan 2012 database estimates), and product launches in 2019 and 2020, respectively. In Europe, we anticipate a lower price point of roughly 80% of that in the U.S. All told, we estimate combined sales from Trk+ NSCLC of ~$860MM in 2025. A summary of our projected NSCLC revenue build and our detailed U.S. market model is provided in Figure 16.

Colorectal cancer

In addition to NSCLC, we anticipate clinical success with LOXO-101 in a subpopulation of advanced colorectal carcinoma (CRC) patients with activating TrkA translocations. Again, beginning with SEER estimates, we assume an annual CRC incidence in the U.S. of ~150K, of which we assume 50% are unresectable metastatic disease at diagnosis. We conservatively assume 4% of new diagnoses to be driven by genetic alterations of Trk kinase, and thus, candidates for LOXO-101 therapy. Our model assumes a CRC market launch in late 2018, ramping to peak penetration of 65% in year 7, arriving at U.S. sales of $240MM in 2025. Using similar assumptions regarding the proportion of eligible patients and respective annual incidence rates of ~230K and ~115K in Europe and Japan (again based on Globocan 2012 database estimates), respectively, we arrive at a combined worldwide 2025 sales estimate of $650MM within the indication.

Thyroid cancer

Finally, we model a smaller, but still meaningful $90MM worldwide commercial opportunity from the use of LOXO-101 in the treatment of metastatic thyroid cancer. Our model assumes an annual target population of 500 patients in the U.S., assuming a 12% rate of Trk translocations among the 10% of ~40,000 newly diagnosed papillary thyroid cancer that is metastatic and refractory to initial radiation therapy. We anticipate 2025 sales in thyroid cancer of $60MM in the U.S., $20 in the EU, and $8MM in Japan.

FIGURE 15. LOXO-101 Revenue Breakdown by Geography and Indication

LOXO-101 Revenue Summary	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
WW Sales			**$ 100**	**$ 297**	**$ 562**	**$ 856**	**$ 1,130**	**$ 1,344**	**$ 1,513**	**$ 1,610**
US			100	203	317	457	577	637	686	715
Ex-US Sales			-	94	246	399	553	707	827	895
Effective royalty rate			*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
Royalty Revenue to LOXO			**$ -**	**$ 14**	**$ 37**	**$ 60**	**$ 83**	**$ 106**	**$ 124**	**$ 134**
Breakdown by Geography and Indication										
US			**$ 100**	**$ 203**	**$ 317**	**$ 457**	**$ 577**	**$ 637**	**$ 686**	**$ 715**
NSCLC			79	146	222	308	372	386	401	416
mCRC			21	52	82	126	170	205	231	240
Thyroid			-	5	12	23	34	46	54	59
EU				**$ 94**	**$ 188**	**$ 281**	**$ 375**	**$ 465**	**$ 522**	**$ 547**
NSCLC				67	119	175	214	253	273	273
mCRC				28	67	101	151	199	232	254
Thyroid				-	2	5	9	13	18	20
JPN					**$ 58**	**$ 117**	**$ 178**	**$ 241**	**$ 305**	**$ 348**
NSCLC					40	72	107	133	160	174
mCRC					18	44	68	104	139	166
Thyroid					-	1	2	4	6	8

Source: JMP Securities LLC and Company Reports

FIGURE 16. LOXO-101 NSCLC, U.S.

US

LOXO-101 TRK+ NSCLC ($MM)	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Incidence NSCLC, US	192,172	194,382	196,618	198,879	201,166	203,479	205,819	208,186	210,580	213,002
% Growth	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*	*1.2%*
% of patients with Stage III-IV disease	*60.3%*	*60.0%*	*59.8%*	*59.5%*	*59.3%*	*59.0%*	*58.8%*	*58.5%*	*58.3%*	*58.0%*
# of Stage III or IV NSCLC Patients	115,784	116,629	117,479	118,333	119,191	120,053	120,919	121,789	122,663	123,541
TRK+										
% patients accessing therapy	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*
% TRK+ translocations	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*
Addressable TRK+ patients	4,921	4,957	4,993	5,029	5,066	5,102	5,139	5,176	5,213	5,250
Market Penetration			***25%***	***35%***	***45%***	***60%***	***70%***	***70%***	***70%***	***70%***
LOXO-101 pts on therapy			1,248	1,760	2,280	3,061	3,597	3,623	3,649	3,675
Duration on therapy (mos)			5.5	7.0	8.0	8.0	8.0	8.0	8.0	8.0
Total patient mos on therapy			6,865	12,321	18,236	24,491	28,779	28,986	29,194	29,403
% growth				*79%*	*48%*	*34%*	*18%*	*1%*	*1%*	*1%*
Cost per month of therapy			$ 11,500	$ 11,845	$ 12,200	$ 12,566	$ 12,943	$ 13,332	$ 13,732	$ 14,144
% price increase				*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*
LOXO-101 NSCLC Sales, US ($MM)			**$ 79**	**$ 146**	**$ 222**	**$ 308**	**$ 372**	**$ 386**	**$ 401**	**$ 416**
% Growth				*26%*	*74%*	*56%*	*52%*	*54%*	*29%*	*18%*

Source: JMP Securities LLC and Company Reports

FIGURE 17. LOXO-101 mCRC, U.S.

US

LOXO-101 in mCRC ($MM)	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Colorectal Carcinoma Incidence, US	149,075	150,566	152,072	153,593	155,128	156,680	158,247	159,829	161,427	163,042
% Growth	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*
% pts with unresectable metastatic disease	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
# pts with metastatic CRC	74,538	75,283	76,036	76,796	77,564	78,340	79,123	79,914	80,714	81,521
% with TrkA translocations	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*	*4%*
Addressable Trk+ mCRC pts	2,982	3,011	3,041	3,072	3,103	3,134	3,165	3,197	3,229	3,261
Market Penetration			***10%***	***18%***	***27%***	***40%***	***52%***	***60%***	***65%***	***65%***
LOXO-101 pts on therapy			304	553	838	1,253	1,646	1,918	2,099	2,120
Duration on therapy (mos)			6.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0
Total patients months on therapy			1,825	4,423	6,702	10,028	13,166	15,344	16,788	16,956
% growth				*242%*	*152%*	*150%*	*131%*	*117%*	*109%*	*101%*
Cost per cycle of therapy			$ 11,500	$ 11,845	$ 12,200	$ 12,566	$ 12,943	$ 13,332	$ 13,732	$ 14,144
% price increase				*3%*	*3%*	*3%*	*3%*	*3%*	*3%*	*3%*
LOXO-101 mCRC Sales, US ($MM)			**$ 21**	**$ 52**	**$ 82**	**$ 126**	**$ 170**	**$ 205**	**$ 231**	**$ 240**
% growth				*150%*	*56%*	*54%*	*35%*	*20%*	*13%*	*4%*

Source: JMP Securities LLC and Company Reports

FIGURE 18. LOXO-101 Thyroid, U.S.

US

LOXO-101 Thyroid ($MM)	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Thyroid Cancer Incidence, US	50,974	51,484	51,999	52,519	53,044	53,575	54,110	54,651	55,198	55,750
% Growth	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*	*1%*
% papillary thyroid cancer	*80%*	*80%*	*80%*	*80%*	*80%*	*80%*	*80%*	*80%*	*80%*	*80%*
% Metastatic and RAI-refractory	*10%*	*10%*	*10%*	*10%*	*10%*	*10%*	*10%*	*10%*	*10%*	*10%*
# Advanced patients	4,078	4,119	4,160	4,202	4,244	4,286	4,329	4,372	4,416	4,460
% with TrkA translocations	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*
Addressable Trk+ Advanced PTC patients	489	494	499	504	509	514	519	525	530	535
Market Penetration				***10%***	***18%***	***30%***	***42%***	***55%***	***62%***	***65%***
LOXO-101 pts on therapy				50	92	154	218	289	329	348
Duration on therapy (mos)				8.0	11.0	12.0	12.0	12.0	12.0	12.0
Total patients months on therapy				403	1,008	1,852	2,618	3,463	3,942	4,175
% growth					*250%*	*184%*	*141%*	*132%*	*114%*	*106%*
Cost per cycle of therapy				$ 11,845	$ 12,200	$ 12,566	$ 12,943	$ 13,332	$ 13,732	$ 14,144
% price increase					*3%*	*3%*	*3%*	*3%*	*3%*	*3%*
LOXO-101 PTC Sales, US ($MM)				**$ 5**	**$ 12**	**$ 23**	**$ 34**	**$ 46**	**$ 54**	**$ 59**
% growth					*157%*	*89%*	*46%*	*36%*	*17%*	*9%*

Source: JMP Securities LLC and Company Reports

SUMMARY AND CONCLUSION

As previously stated, 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. Therefore, we initiate coverage of LOXO with a Market Outperform rating and 12-month price target of $23 per share.

APPENDIX – BIOGRAPHIES

Management Team

Joshua H. Bilenker, M.D. – CEO

Dr. Joshua H. Bilenker, M.D., founder of Loxo Oncology, serves as President and Chief Executive Officer, and sits on the board of directors. Previously, Dr. Bilenker was a Partner at Aisling Capital, a multi-strategy healthcare investment firm based in NY, where he remains an Operating Partner. From 2004-2006, Dr. Bilenker was a Medical Officer at the U.S. FDA in the Office of Oncology. Dr. Bilenker trained at the University of Pennsylvania in internal medicine and medical oncology, earning board certification in these specialties. He received his M.D. from The Johns Hopkins School of Medicine and his A.B. degree from Princeton University.

Mikel P. Moyer, Ph.D. - Chief Scientific Officer

Mikel P. Moyer, Ph.D. serves as Chief Scientific Officer. Prior to joining Loxo Oncology, Mike was Vice President, Molecular Discovery and Preclinical Development at Epizyme (NASDAQ:EPZM). Previously, Dr. Moyer served in a variety of management roles at the Broad Institute of MIT and Harvard, Pfizer, and Abbott Laboratories. While at Pfizer, Mike led medicinal chemistry teams that discovered marketed drugs erlotinib (Tarceva) and tofacitinib (Xeljanz). Mike received his Ph.D. in synthetic organic chemistry from The University of California, Berkeley and his B.S. in Chemistry from The University of Michigan.

Lori A. Kunkel, M.D. – Chief Medical Officer

Dr. Lori A. Kunkel serves as Chief Medical Officer. In this role at previous companies, Pharmacyclics and Proteolix, Dr. Kunkel provided critical leadership in the development of two recently approved drugs, Ibrutinib (Imbruvica) and Carfilzomib (Kyprolis). Dr. Kunkel's career in drug development has also included roles at ACT Therapeutics, Syndax, Xencor, Genitope, Genentech, Chiron and Baxter Healthcare. Dr. Kunkel trained in internal medicine at Baylor College of Medicine, and in hematology-oncology at UCLA, earning board certification in these specialties. Dr. Kunkel received her M.D. from UCLA and her B.A. degree from UCSD.

Dov Goldstein, M.D. – Chief Financial Officer

In addition to his new role as Chief Financial Officer, Dr. Goldstein also serves on the Loxo Oncology Board of Directors. Dr. Goldstein is an Operating Partner at Aisling Capital and was most recently a Partner at Aisling, responsible for leading and managing investments in numerous therapeutic companies. Dr. Goldstein previously served as Executive Vice President and Chief Financial Officer of Vicuron Pharmaceuticals. He helped lead Vicuron through its initial public offering and its acquisition by Pfizer.

Jennifer Low, M.D., Ph.D. - Executive VP R&D

Dr. Low most recently served as Senior Group Medical Director in Product Development at Genentech, a member of the Roche Group. In that role, Dr. Low led the development of Erivedge (vismodegib, the first approved hedgehog pathway inhibitor) from the first-in-man study to global approvals, and supervised the development teams for numerous drugs and drug candidates including Zelboraf (vemurafenib, the first approved inhibitor of BRAF V600), Tarceva (erlotinib, EGFR inhibitor) and cobimetinib (GDC-0973, MEK1/2 inhibitor). Prior to Genentech, Dr. Low was a Senior Investigator in the Investigational Drug Branch of the Cancer Therapy Evaluation Program (CTEP) at the National Cancer Institute (NCI) and an attending physician at the National Institutes of Health Clinical Center in Bethesda, Maryland.

Nisha Nanda - VP Development

Nisha Nanda serves as VP of Development. Nisha has had increasing roles of responsibility in both clinical and pre-clinical development. Most recently Nisha worked on the clinical development of carfilzomib (Kyprolis) and the approval of omacetaxine (Synribo). Nisha's career in drug development has included roles at Onyx, ChemGenex, Portola, Millennium and Cor. Nisha has a BSc Hons in Biochemistry and Molecular Genetics from UNSW, Sydney, Australia and a Ph.D. in Biochemistry and Molecular Genetics from UNSW and the Victor Chang Cardiac Research Institute, Sydney, Australia.

Jacob S. Van Naarden - VP Corporate Development and Strategy

Jacob S. Van Naarden serves as VP of Corporate Development and Strategy. In his previous roles, Mr. Van Naarden served in various biotechnology investing, operating, and advisory capacities. Previously, Mr. Van Naarden served as a public equity biotechnology analyst at HealthCor Management, a multi-billion dollar, healthcare-dedicated investment firm based in NYC. Prior to HealthCor, Mr. Van Naarden was an Associate at Aisling Capital, a multi-strategy healthcare investment firm based in NY. Mr. Van Naarden started his career in the Healthcare Group of the Investment Banking Division at Goldman Sachs. He received his A.B. degree in molecular biology from Princeton University, graduating magna cum laude and Phi Beta Kappa.

Sara Slifka - Senior Director of Operations

Sara Slifka serves as Senior Director of Operations. Previously, Ms. Slifka was a Vice President in Equity Research at Morgan Stanley covering the biotech sector. In her prior role, Ms. Slifka analyzed small- and large-cap biotechnology companies from a financial, clinical, regulatory, and commercial perspective. Ms. Slifka received her A.B. degree from Princeton University.

Scientific Advisory Board

Keith T. Flaherty, M.D. - Director and SAB Chair

Dr. Keith T. Flaherty has served as SAB Chair since company inception, and sits on the board of directors. He is Director of the Henri and Belinda Termeer Center for Targeted Therapy, Massachusetts General Hospital Cancer Center, and is an Associate Professor of Medicine at Harvard Medical School. Dr. Flaherty trained in internal medicine at Brigham and Women's Hospital, and in medical oncology at the University of Pennsylvania, earning board certification in these specialties. He received his M.D. from The Johns Hopkins School of Medicine and his B.S. degree from Yale University.

Jeffrey A. Engelman, M.D., Ph.D.

Dr. Jeffrey A. Engelman is the Director of Thoracic Oncology and the Director of Molecular Therapeutics at the Massachusetts General Hospital Cancer Center and is an Associate Professor of Medicine at Harvard Medical School. Dr. Engelman is also the PI of his own laboratory at the MGH Cancer Center. The overarching aim of his research is to develop new and more potent therapeutic strategies for the treatment of cancer, with a particular emphasis on lung cancer. Dr. Engelman completed his medical residency in Internal Medicine at Brigham and Women's Hospital and his fellowship in Hematology and Oncology at the Dana-Farber Cancer Institute/Massachusetts General Hospital combined program. He received his MD and PhD degrees from the Albert Einstein College of Medicine and his B.A. from Northwestern University.

Ross Levine, M.D.

Dr. Ross L. Levine is an Associate Attending Physician at Memorial-Sloan Kettering Cancer Center, an Associate Professor of Medicine at Weill Cornell Medical College, and is the Laurence Joseph Dineen Chair in Leukemia Research at MSKCC. Dr. Levine manages a research lab that is focused on targeted therapies in myeloid malignancies, and is interested in the application of next generation sequencing technology to the practice of medicine in hematologic cancers. Dr. Levine trained in internal medicine at Massachusetts General Hospital, and in hematology-oncology at the Dana Farber Cancer Institute, earning board certification in these specialties. He received his M.D. from The Johns Hopkins University School of Medicine and his A.B. degree from Harvard College.

Ben Ho Park, M.D., Ph.D.

Dr. Ben Ho Park is an Attending Physician at The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Hospital, and is an Associate Professor of Oncology in the Breast Cancer Research Program at Johns Hopkins University. Dr. Park manages a research lab that is focused on novel targets and mechanisms of drug resistance in breast cancer. Dr. Park trained in internal medicine and medical oncology at The University of Pennsylvania, earning board certification in these specialties. He received his M.D. and Ph.D. from The University of Pennsylvania, and his A.B. degree from The University of Chicago.

David B. Solit, M.D.

Dr. David Solit is the Geoffrey Beene Chairman, and Director of both the Center for Molecular Oncology and Developmental Therapeutics at Memorial-Sloan Kettering Cancer Center. Dr. Solit manages a research lab that is focused on developing cancer therapies that primarily target tyrosine kinase and steroid receptor signaling. Dr. Solit trained in internal medicine at Barnes Jewish Hospital and in medical oncology at Memorial-Sloan Kettering Cancer Center, earning board certification in these specialties. He received his M.D. and B.A. degree from The University of Pennsylvania.

Board of Directors

Joshua H. Bilenker, M.D. - CEO

Dov Goldstein , M.D. - CFO

Keith T. Flaherty, M.D. - Director and Chair of the SAB

David Bonita, M.D.

Dr. Bonita is a Private Equity Partner at OrbiMed, where he serves on the boards of Ambit, Clementia, ViewRay, CardiAQ, and Keystone Heart. He previously served on the board of Enobia. Prior to joining OrbiMed, Dr. Bonita worked in the healthcare investment banking groups of Morgan Stanley and UBS. He has published several scientific articles in peer-reviewed journals based on research performed at the Harvard Medical School. Dr. Bonita received his A.B. degree magna cum laude in Biological Sciences from Harvard University and his joint M.D./M.B.A. from Columbia University where he was elected to the Alpha Omega Alpha Medical Honor Society and Beta Gamma Sigma Business Honor Society.

Steve Elms

Mr. Elms is currently a Managing Partner at Aisling Capital, a leading private equity fund investing in life science companies, and serves on the board of a number of public and private life sciences companies. Previously, Mr. Elms was a senior member of the Life Sciences Investment Banking Group of Hambrecht & Quist and was involved in over 60 financing and M&A transactions, which helped clients raise in excess of $3.3 billion in capital. His previous healthcare sector experience includes over two years as a pharmaceutical sales representative for Marion Laboratories. Mr. Elms received an M.B.A. from the Kellogg Graduate School of Management at Northwestern University, and a B.A. in Human Biology from Stanford University.

Avi Z. Naider

Mr. Naider is Chairman and CEO of ACES Risk Management Corp. He represents a private group of investors on the Loxo board of directors. Mr. Naider is a successful entrepreneur who has founded and managed companies in various sectors, including internet advertising and mortgage industry software. He previously worked in private equity and for the Boston Consulting Group. Mr. Naider received his A.B. from the Woodrow Wilson School of Public and International Affairs at Princeton University, where he graduated Phi Beta Kappa.

Source: Company website

FIGURE 19. Loxo Oncology Income Statement

Income Statement ($MM)	Incep.-YE13	1Q14A	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Product Sales and Royalties:														
LOXO-101														
US Sales							-	-	-	99.9	203.1	316.6	457.0	576.8
ROW Royalties							-	-	-	-	14.1	36.8	59.8	82.9
Total Product Sales and Royalties	-	-	-	-	-	-	-	-	-	99.9	217.3	353.4	516.8	659.7
Cost of Goods Sold								-	-	12.0	24.4	38.0	54.8	69.2
Gross Profit	-	-	-	-	-	-	-	-	-	87.9	192.9	315.4	462.0	590.5
Operating Expenses:														
Research and development with related party	9.4	1.3	1.5	1.7	1.9	6.4	7.1	8.0	8.4	8.8	9.3	9.3	9.3	9.3
Research and development	0.3	0.7	1.0	1.2	1.5	4.4	8.8	17.6	35.3	56.5	67.8	74.5	78.3	82.2
General and administrative	0.6	0.9	1.0	1.1	1.2	4.2	8.4	14.8	24.3	39.0	54.5	65.4	75.3	81.3
Milestone Expense to ArrayBiopharm								10.0	10.0	25.0	10.0	10.0	10.0	10.0
Total operating expenses	10.3	2.9	3.5	4.0	4.6	15.0	24.4	50.4	78.0	129.2	141.5	159.2	172.8	182.7
Operating income (loss)	(10.3)	(2.9)	(3.5)	(4.0)	(4.6)	(15.0)	(24.4)	(50.4)	(78.0)	(41.3)	51.3	156.2	289.2	407.8
Operating margin (%)										*-41.3%*	*23.6%*	*44.2%*	*56.0%*	*61.8%*
Other income (expense):														
Interest income														
Interest expense														
Total other income, net	-	-	-	-	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax income (loss)	(10.3)	(2.9)	(3.5)	(4.0)	(4.6)	(15.0)	(24.4)	(50.4)	(78.0)	(41.3)	51.3	156.2	289.2	407.8
Income tax benefit (provision)						0.0	0.0	0.0	0.0	0.0	(2.6)	(15.6)	(57.8)	(122.3)
Tax Rate											*5%*	*10%*	*20%*	*30%*
Comprehensive income (loss)	(10.3)	(2.9)	(3.5)	(4.0)	(4.6)	(15.0)	(24.4)	(50.4)	(78.0)	(41.3)	48.8	140.6	231.4	285.5
Accretion of redeemable convertible preferred stock	(0.0)	(0.0)												
Net income (loss) attributable to common stockholders	(10.3)	(2.9)	(3.5)	(4.0)	(4.6)	(15.0)	(24.4)	(50.4)	(78.0)	(41.3)	48.8	140.6	231.4	285.5
Basic EPS to common shareholders	**$ (4.25)**	$ (0.68)	$ (0.81)	$ (0.26)	$ (0.30)	**$ (1.23)**	**$ (1.58)**	**$ (3.15)**	**$ (4.23)**	**$ (1.97)**	**$ 2.25**	**$ 6.27**	**$ 9.99**	**$ 11.94**
Diluted EPS to common shareholders	**$ (4.25)**	$ (0.68)	$ (0.81)	$ (0.26)	$ (0.30)	**$ (1.23)**	**$ (1.58)**	**$ (3.15)**	**$ (4.23)**	**$ (1.97)**	**$ 1.73**	**$ 4.84**	**$ 7.76**	**$ 9.33**
Basic shares outstanding	2.4	4.3	4.3	15.1	15.2	12.2	15.5	16.0	18.4	20.9	21.7	22.4	23.2	23.9
Diluted shares outstanding	0.1	4.3	4.3	15.1	15.2	12.2	15.5	16.0	18.4	20.9	28.3	29.0	29.8	30.6

Source: Company reports and JMP Securities LLC

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JMP Securities currently makes a market in the securities of Epizyme, Inc., Foundation Medicine, Inc., Infinity Pharmaceuticals, Inc. and Pharmacyclics, Inc.

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

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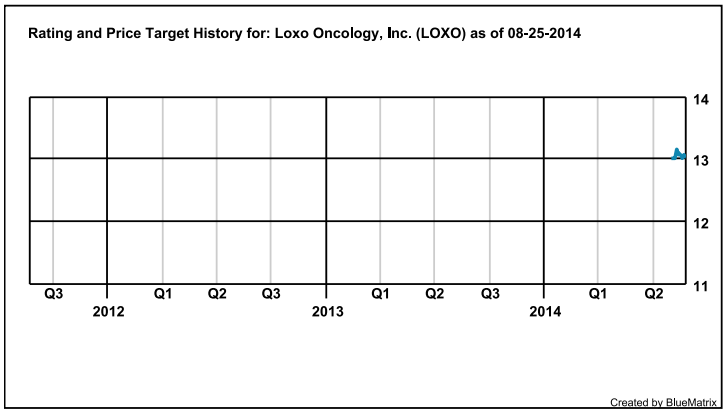
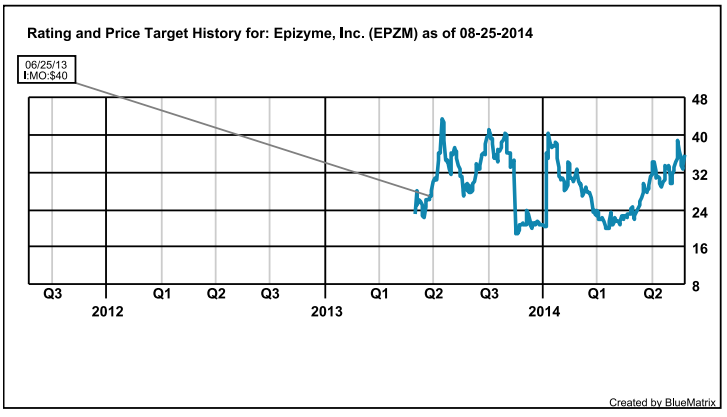
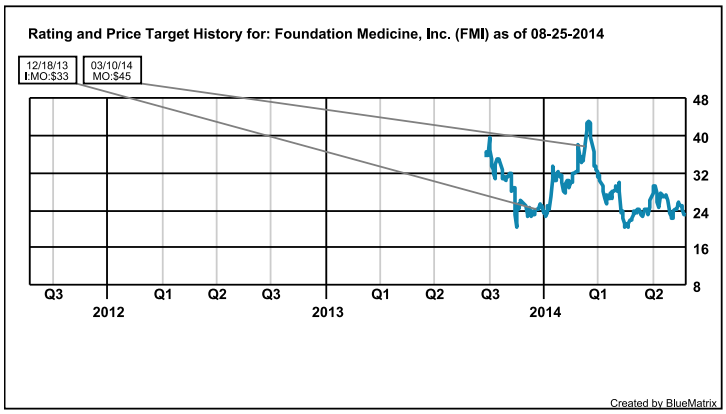
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	271	*60.22%*	Buy	271	*60.22%*	101	*37.27%*
MARKET PERFORM	Hold	139	*30.89%*	Hold	139	*30.89%*	19	*13.67%*
MARKET UNDERPERFORM	Sell	4	*0.89%*	Sell	4	*0.89%*	0	*0%*
COVERAGE IN TRANSITION		36	*8.00%*		36	*8.00%*	0	*0%*
TOTAL:		450	*100%*		450	*100%*	120	*26.67%*

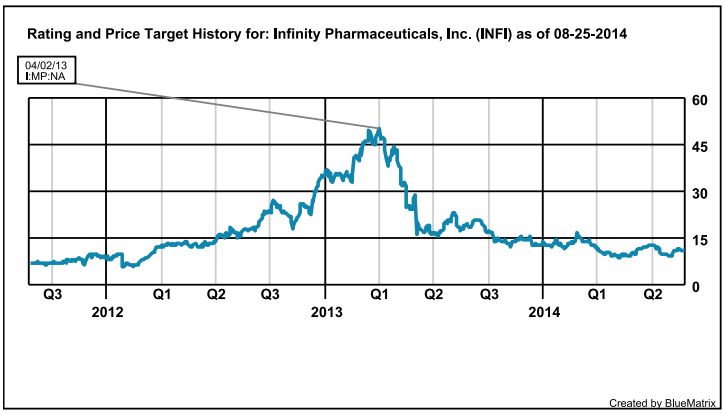
Stock Price Chart of Rating and Target Price Changes:

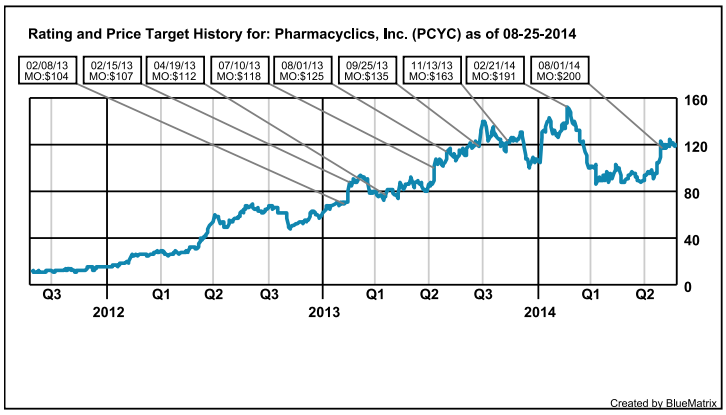
Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent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











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