May 14, 2015

HEALTHCARE/BIOTECHNOLOGY

Loxo Oncology

Competitor ASCO Abstracts Highlight LOXO-101 Differentiation

Stock Rating:

OUTPERFORM

12-18 mo. Price Target	$20.00
LOXO - NASDAQ	$11.11

3-5 Yr. EPS Gr. Rate	NA
52-Wk Range	$16.45-$9.90
Shares Outstanding	15.9M
Float	6.5M
Market Capitalization	$185.4M
Avg. Daily Trading Volume	45,820
Dividend/Div Yield	NA/NM
Book Value	NA
Fiscal Year Ends	Dec
2014E ROE	NA
LT Debt	$0.0M
Preferred	$0.0M
Common Equity	$108M
Convertible Available	No

Trading range since August 1, 2014 IPO.

EPS Diluted	Q1	Q2	Q3	Q4	Year	Mult.
2014E	--	--	(0.68)A	(0.25)	(0.90)	NM
2015E	--	--	--	--	(1.10)	NM

SUMMARY

ASCO abstracts for TRK inhibitors, entrectinib (Ignyta) and TSR-011 (Tesaro) were released last night. We note that TRK inhibitors discussed differ from LOXO-101, a highly-selective panTRKa/b/c inhibitor. Recall, entrectinib is a Trka/b/c, ROS1 and ALK-inhibitor and that TSR-011 is an ALK (IC50 = 0.7nM), TRKa/b/c (IC50 < 3nM) inhibitor. LOXO is investigating LOXO-101 in molecularly-defined patients with TRK fusions. In these patients aberrant TRK activation (via fusion) is potentially the singular molecular driver of disease. We note targeting multiple signaling pathways, TRK/ROS1/ALK for instance may be beneficial in tumors where multiple pathways are aberrantly activated, or to combat resistance emerging from incomplete knock-down of signaling drivers. However, such approaches have been traditionally limited by toxicities. LOXO abstracts TPS2624, 1533 contained previously presented info.

KEY POINTS

- Ignyta abstract (#2517) featured previously presented data from ESMO (Italian study of entrectinib). As previously reported, entrectinib induced significant antitumor response, observed in pts with relevant molecular alterations, notably ROS1 rearranged NSCLC at doses ≥ 400 mg/m2/day and the only NTRK1 rearranged (Trka) pt with CRC treated to date.
- Ignyta also presented data (abs2596) from entrectinib US dose escalation study that showed no responses at ≤200mg/m2 (400mg/m2-cohort recently-opened). We believe lack of response is due to inadequate doses, noting it is difficult to read-through to LOXO-101's potential efficacy from this data. TRK pts enrolled in the study included 5-point muts, 1 amp and 1 rearrange.
- Tesaro presented initial findings for TSR-011 (abs8063); however, it did not include data for TRK+ patients, though an update could come at ASCO. Tesaro's P1/2a enrollment of 11 TRK+ pts may not be comparable to LOXO's TRK-fusion pt group.
- We would caution interpreting TSR-011 results relative to LOXO-101's efficacy and opportunity noting that differences in TRK+ screening, which included co-expression of ligand and receptor by IHC; notably, TRK fusions activate signaling independent of ligand presence. We highlight that TSR-011 appears to have a limited therapeutic window, given DLT's of dysesthesia and QTc prolongation.

Stock Price Performance

Company Description

Loxo Oncology is developing targeted drugs for the treatment of cancer in genetically defined patient populations. The company's lead product candidate, LOXO-101, is an oral, selective and potent inhibitor of TRK, a family of signaling molecules that appear to play an important role in the development of a range of cancers.

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Stock prices of other companies mentioned in this report (as of 5/14/2015):

Ignyta (RXDX-NASDAQ, $8.88, Not Covered)

Tesaro (TSRO-NASDAQ, $53.87, Not Covered)

Investment Thesis

Loxo is an early-stage biotechnology company executing a business plan for targeted cancer drugs that benefit from **1)** clear precedent for clinical and commercial success, **2)** a rapid development path and **3)** well-defined chemistry, potency and selectivity around the target of interest (TRK). However, Loxo has yet to generate clinical data. Therefore, the investment thesis relies heavily on a belief that Loxo's targeted approach to the treatment of TRK-translocations will mirror a trajectory for successfully commercialized targeted agents, a prime example being Xalkori. We believe this thesis has merit and provides indirect proof-of-concept that lead asset LOXO-101 should generate enriched efficacy in TRK+ tumors.

Price Target Calculation

We value Loxo using a discounted cash flow (DCF) analysis with a weighted average cost of capital (WACC) of 15% and a 0% terminal growth rate post 2032, generating a price target of $20 and yielding a terminal value of ~$68 million. Our valuation framework utilizes a 15% discount rate for pre-commercial stage companies that have not achieved clear Phase 2 proof-of-concept.

Key Risks to Price Target

Key risks to our price target include: **1)** Loxo has not generated any clinical data for LOXO-101, and the investment thesis relies entirely on preclinical results, conviction in a novel mechanism, and precedent from approved drugs targeting fusion oncogenes. **2)** Limited clinical efficacy for LOXO-101 and/or unacceptable toxicity in Phase 1a/1b may indicate further development is unwarranted. **3)** More rapid development and approval of competitive TRK inhibitors (for example, RXDX-101) could pressure LOXO-101's share of the TRK market.

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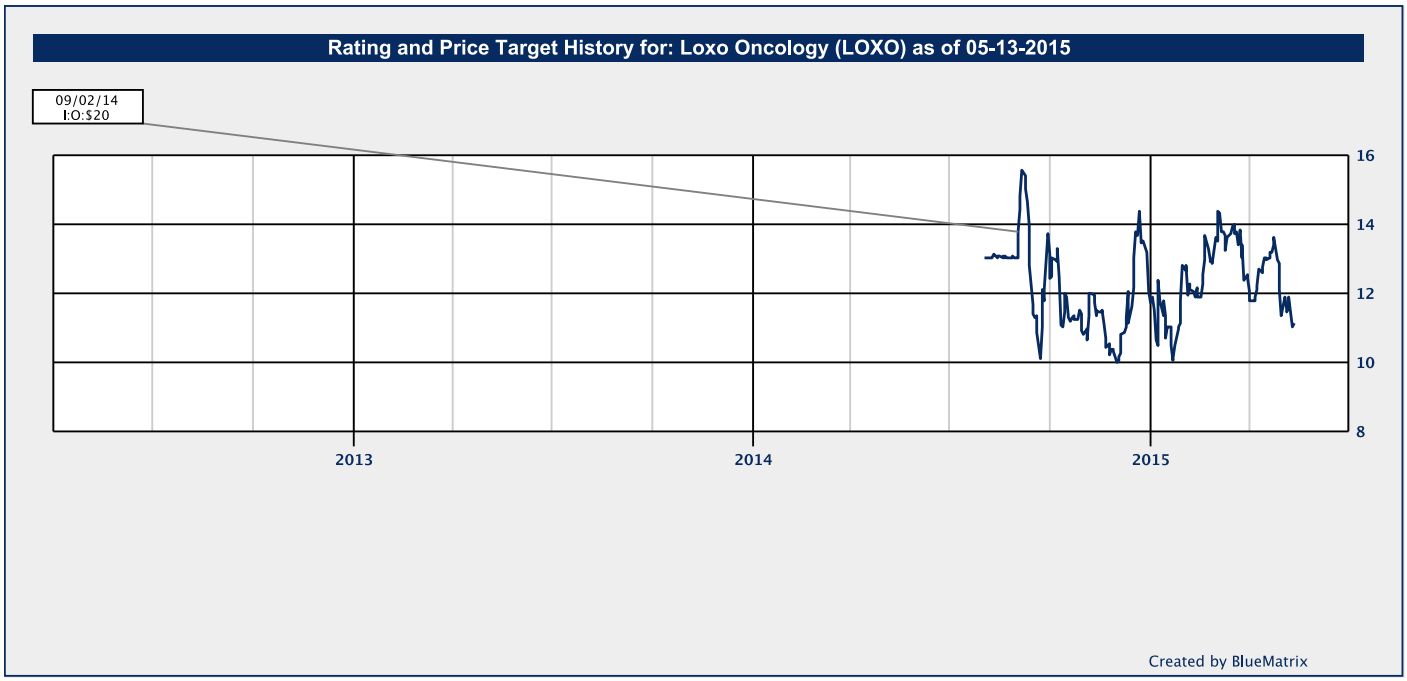

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			IB Serv/Past 12 Mos.	
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