COWEN
AND COMPANY

Biotechnology

Loxo Oncology

Equity Research

Quick Take: Company Update

April 21, 2015

Price: $13.02 (04/20/2015)

Price Target: NA

OUTPERFORM (1)

Eric Schmidt, Ph.D.
646.562.1345
eric.schmidt@cowen.com

Cristina Ghenoiu, Ph.D.
646.562.1401
cristina.ghenoiu@cowen.com

Yatin Suneja
646.562.1388
yatin.suneja@cowen.com

Key Data

Symbol	NASDAQ: LOXO
Market Cap (MM)	$216.6

LOXO-101 Moving Forward With An Encouraging Safety And PK Profile

The Cowen Insight

Loxo Oncology reported initial data from lead candidate LOXO-101's Phase I trial in solid tumors. LOXO-101 was well tolerated and exhibited a favorable bioavailability profile that should support BID or QD dosing. Later this year the drug will proceed into a Phase Ib expansion study that will enroll patients with TRK+ tumors and potentially provide a clear efficacy signal. We remain at Outperform.

The News: This afternoon at the AACR meeting Loxo presented a poster revealing interim Phase Ia data from LOXO-101's first-in-human study in patients with advanced solid tumors. As of the data cut off of March 26, 2015, 15 patients have been treated. LOXO-101 was well tolerated and achieved systemic exposures that are predicted to correlate with anti-cancer activity. The Phase Ia dose escalation portion of the trial will continue until an MTD is reached.

Study Design: In April 2014, Loxo initiated an open label, 3+3 dose-escalation, multicenter, Phase I trial of LOXO-101 in advanced solid tumors. This trial has two stages: (1) a Phase Ia dose escalation stage and (2) a Phase Ib expansion stage. LOXO-101 is being administered orally for a single day, between 3 and 7 days prior to the start of Cycle 1, followed by QD and BID doses for continuous 28-day cycles. LOXO-101 plasma concentrations were quantified by LC-MS/MS after the single-day dose, and Days 1 and 9 of Cycle 1. Today's poster included data from 15 individuals with advanced solid tumors. The poster notes that the trial has enrolled one patient with an TRK-fusion (a soft tissue sarcoma patient) who might reasonably be expected to respond to LOXO-101. However, this patient was enrolled fairly recently (on March 10) and remained on the study as of the March 26 data cut off date.

Safety Data: At the doses tested (50mg QD, 100mg QD, 100mg BID), LOXO-101 appeared well tolerated with most common adverse events being Grade 1 and 2 fatigue (47%), dizziness (27%) and anemia (33%). No study-related SAEs were reported, and an MTD had not yet been reached. One DLT of Grade 3 delirium occurred at the 100 mg BID dose, but it was not deemed related to the study drug and resolved within 72 hours. This patient's dose was reduced to 100 mg QD.

PK Profile: A number of pharmacokinetic parameters were reported. LOXO-101 achieved maximum plasma concentration within the first hour after dosing, regardless of the dose administered. Cmax in ng/ml (Mean) was 642 at 50 mg QD (n=4), 925 at 100 mg QD (n=5), and 905 at 100 mg BID (n=5). The drug exhibited a short half life (1.6 - 2.2 hours) but was able to maintain 24-hour plasma concentrations in excess of the predicted IC50 level at the two highest doses.

Our Take: We view LOXO-101 Phase I profile as encouraging and supportive of continued development. We are interested in the performance of the TRK-positive sarcoma patient, but caution that the dose escalation phase is still progressing and that there is little known about the potential of TRK-fusions to act as drivers mutations

in soft tissue sarcoma. Nonetheless, any anti-tumor activity seen in this patient would be encouraging. We are also encouraged by the fact that ataxia was not been observed. Ataxia is a potential side effect of TRKB inhibition in the CNS.

Valuation Methodology And Risks

Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

Risks To The Price Target

Loxo Oncology is unprofitable, has no approved products, and will likely need to raise additional capital from the public markets prior to turning profitable. Loxo's lead candidate LOXO-101 faces a number of clinical, regulatory, and commercial hurdles prior to becoming successful.

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Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
LOXO	Loxo Oncology

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Cowen and Company, LLC. New York (646) 562-1000 **Boston** (617) 946-3700 **San Francisco** (415) 646-7200 **Chicago** (312) 577-2240 **Cleveland** (440) 331-3531 **Atlanta** (866) 544-7009 **London** (affiliate) 44-207-071-7500

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

Underperform (3): Stock expected to underperform the S&P 500

Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

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Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

Cowen And Company Rating Definitions

Distribution of Ratings/Investment Banking Services (IB) as of 03/31/15

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	450	58.67%	103	22.89%
Hold (b)	302	39.37%	8	2.65%
Sell (c)	15	1.96%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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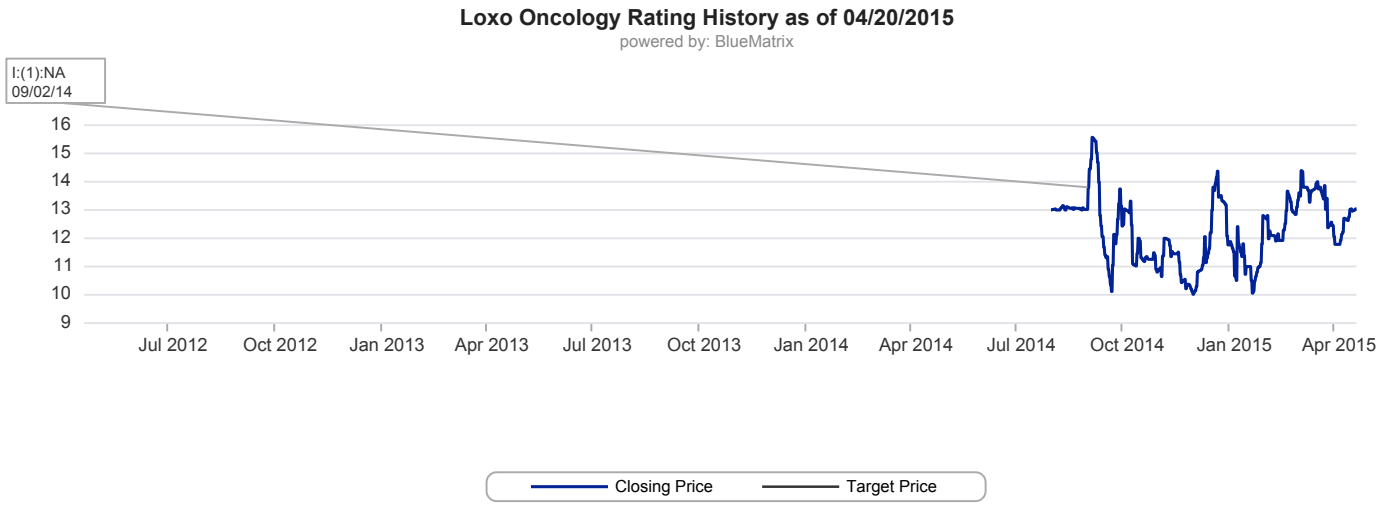

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

Points Of Contact

Reaching Cowen

Main U.S. Locations

New York
599 Lexington Avenue
New York, NY 10022
646.562.1000
800.221.5616

Boston
Two International Place
Boston, MA 02110
617.946.3700
800.343.7068

Cleveland
20006 Detroit Road
Suite 100
Rocky River, OH 44116
440.331.3531

San Francisco
555 California Street, 5th Floor
San Francisco, CA 94104
415.646.7200
800.858.9316

Atlanta
3399 Peachtree Road NE
Suite 417
Atlanta, GA 30326
866.544.7009

Chicago
181 West Madison Street
Suite 3135
Chicago, IL 60602
312.577.2240

International Locations

Cowen International Limited

London
1 Snowden Street - 11th Floor
London EC2A 2DQ
United Kingdom
44.20.7071.7500

Cowen and Company (Asia) Limited

Hong Kong
Suite 1401 Henley Building
No. 5 Queens Road Central
Central, Hong Kong
852 3752 2333

@CowenResearch

Cowen and Company