

Equity Research

July 27, 2015

Price: \$16.58 (07/27/2015)

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)	\$276.7

Quick Take: Company Update

LOXO-101 Achieves Proof Of Concept

The Cowen Insight

An article in *Cancer Discovery* reports on the first TRK+ patient treated in LOXO-101's ongoing Phase I trial. The patient, diagnosed with metastatic soft tissue sarcoma, achieved a PR after just 1 Cycle with the response ongoing through Cycle 4 (last reported follow up). We view this case as extremely encouraging for LOXO-101's future development in TRK driven tumors and remain at Outperform.

PR Reported In The First TRK+ Patient Treated With LOXO-101

The News: This afternoon, Loxo announced the publication of a peer-reviewed article in *Cancer Discovery* describing the efficacy and safety of LOXO-101 in the first TRK+ patient enrolled in the company's ongoing Phase I dose escalation trial. This soft tissue sarcoma patient achieved a partial response after 28 days of treatment.

Recall that in April 2014, Loxo initiated an open label, 3+3 dose-escalation, multicenter, Phase I trial of LOXO-101 in advanced solid tumors. The trial has two stages: (1) a Phase Ia dose escalation stage in all comers patients, and (2) a Phase Ib cohort expansion stage in patients with TRK alterations. In March 2015, the first patients with a TRK alteration (a TRK fusion patient) was enrolled in stage 1 of the trial. This female patient suffered from advanced soft tissue sarcoma widely metastatic to the lungs and refractory to a number of therapies (sorafenib, epirubicin, ifosfamide). Genomic profiling identified the cancer as harboring a TRK gene fusion later shown to be an LMNA-TRK gene fusion (exons 1-2 of lamin A/C gene fused to exons 11-17 of TRK gene). Genetic and functional biomarkers suggested the presence of a TRK driver oncogene, and the patient was recommended for the LOXO-101 trial. A baseline CT scan showed multiple large pulmonary metastases in both lungs. The patient received 100 mg of LOXO-101 twice a day. Treatment with LOXO-101 was associated with rapid and substantial decrease in pulmonary metastases and the patient achieved partial response after 28 days of treatment (Cycle 1). Moreover, the patient's shortness of breath rapidly resolved and she no longer required supplemental oxygen. Patient continue to show treatment benefit and demonstrated complete tumor disappearance of the largest tumor after 4 months of treatment. As of the latest update, there were no severe adverse events attributed to LOXO-101 and the patient continues on therapy.

Our Take: We are greatly encouraged by this first reported case of treatment with and response to LOXO-101 in a TRK-driven tumor. LOXO-101's ability to engender a rapid and near complete response in a patient with substantial and symptomatic lung involvement speaks to the drug's potency even at the lower doses currently being tested. Meanwhile the drug's seemingly benign safety profile should allow Loxo to continue push the dose higher. The Phase I trial continues to enroll patients at escalating oral doses of fixed QD and BID regimens which may go up to 400 mg.

Our Thesis On LOXO Shares: Loxo develops small molecule kinase inhibitors for patients with genetically defined cancers, an area of medicine we find compelling. Aside from its lead compound, LOXO-101, an inhibitor of the Tropomyosin Receptor Kinase (TRK) family that has shown proof of concept in an ongoing Ph. I study, the company has identified other interesting oncology targets (including RET, FGFR1-3, FLT3) and is deploying a collaboration with Array Biopharma to create a pipeline of up to five additional clinical candidates.

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.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon a 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 it there are any good methodologies for assigning a specific target price to such stocks.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
LOXO	Loxo Oncology

Analyst Certification

Each author of this research report hereby certifies that (i) the views expressed in the research report accurately reflect his or her personal views about any and all of the subject securities or issuers, and (ii) no part of his or her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed in this report.

Important Disclosures

Cowen and Company, LLC and/or its affiliates make a market in the stock of Loxo Oncology securities.

Loxo Oncology has been client(s) of Cowen and Company, LLC in the past 12 months.

Loxo Oncology is or was in the past 12 months a client of Cowen and Company, LLC; during the past 12 months, Cowen and Company, LLC provided IB services.

Cowen and Company, LLC and/or its affiliates received in the past 12 months compensation for investment banking services from Loxo Oncology.

Cowen and Company, LLC and/or its affiliates managed or co-managed a public offering of Loxo Oncology within the past twelve months.

Cowen and Company, LLC compensates research analysts for activities and services intended to benefit the firm's investor clients. Individual compensation determinations for research analysts, including the author(s) of this report, are based on a variety of factors, including the overall profitability of the firm and the total revenue derived from all sources, including revenues from investment banking. Cowen and Company, LLC does not compensate research analysts based on specific investment banking transactions.

Disclaimer

This research is for our clients only. Our research is disseminated primarily electronically and, in some cases, in printed form. Research distributed electronically is available simultaneously to all Cowen and Company, LLC clients. All published research can be obtained on the Firm's client website, <https://cowenlibrary.bluematrix.com/client/library.jsp>.

Further information on any of the above securities may be obtained from our offices. This report is published solely for information purposes, and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Other than disclosures relating to Cowen and Company, LLC, the information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete statement or summary of the available data. Any opinions expressed herein are statements of our judgment on this date and are subject to change without notice.

For important disclosures regarding the companies that are the subject of this research report, please contact Compliance Department, Cowen and Company, LLC, 599 Lexington Avenue, 20th Floor, New York, NY 10022. In addition, the same important disclosures, with the exception of the valuation methods and risks, are available on the Firm's disclosure website at <https://cowen.bluematrix.com/sellside/Disclosures.action>.

Price Targets: Cowen and Company, LLC assigns price targets on all covered companies unless noted otherwise. The price target for an issuer's stock represents the value that the analyst reasonably expects the stock to reach over a performance period of twelve months. The price targets in this report should be considered in the context of all prior published Cowen and Company, LLC research reports (including the disclosures in any such report or on the Firm's disclosure website), which may or may not include price targets, as well as developments relating to the issuer, its industry and the financial markets. For price target valuation methodology and risks associated with the achievement of any given price target, please see the analyst's research report publishing such targets.

Notice to UK Investors: This publication is produced by Cowen and Company, LLC which is regulated in the United States by FINRA. It is to be communicated only to persons of a kind described in Articles 19 and 49 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. It must not be further transmitted to any other person without our consent.

Copyright, User Agreement and other general information related to this report

© 2015 Cowen and Company, LLC. Member NYSE, FINRA and SIPC. All rights reserved. This research report is prepared for the exclusive use of Cowen clients and may not be reproduced, displayed, modified, distributed, transmitted or disclosed, in whole or in part, or in any form or manner, to others outside your organization without the express prior written consent of Cowen. Cowen research reports are distributed simultaneously to all clients eligible to receive such research reports. Any unauthorized use or disclosure is prohibited. Receipt and/or review of this research constitutes your agreement not to reproduce, display, modify, distribute, transmit, or disclose to others outside your organization the contents, opinions, conclusion, or information contained in this report (including any investment recommendations, estimates or price targets). All Cowen trademarks displayed in this report are owned by Cowen and may not be used without its prior written consent.

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

COWEN AND COMPANY RATING DEFINITIONS

Cowen and Company Rating System effective May 25, 2013

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

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

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 06/30/15

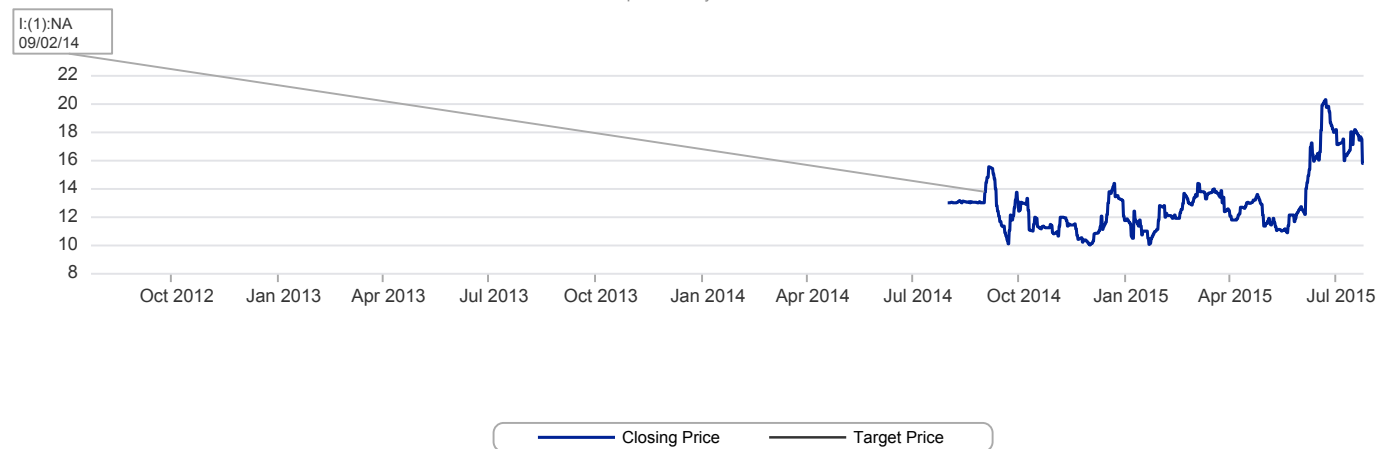
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	476	59.20%	110	23.11%
Hold (b)	314	39.05%	7	2.23%
Sell (c)	14	1.74%	0	0.00%

(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.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.

Loxo Oncology Rating History as of 07/24/2015

powered by: BlueMatrix



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

