

Eleven Biotherapeutics

Equity Research

May 23, 2014

Price: \$10.61 (05/22/2014)

Price Target: \$35.00

OUTPERFORM (1)

Ken Cacciatore

646.562.1305

ken.cacciatore@cowen.com

Tyler Van Buren, M.Sc.

646.562.1338

tyler.vanburen@cowen.com

Key Data

Symbol	NASDAQ: EBIO
Market Cap (MM)	\$172.5

Company Quick Take

Regulatory Environment Is Improving, Which Is A Clear Positive For Eleven

The Cowen Insight

We believe that Shire's recent disclosure that indicated that they will file the Lifitegrast NDA by Q1:2015 is further confirmation that the dry eye disease regulatory environment is improving - and we believe this is a clear positive for Eleven and its EBI-005 dry eye program. Given Restasis' limitations and our consultants' very positive views on EBI-005, this asset looks very attractive.

Shire Filing Disclosure Indicates That The Dry Eye Regulatory Environment Is Improving And The "Totality Of The Data" Thesis Is Intact

In our [EBIO initiation](#) in early March, we discussed at length the historically difficult dry eye disease regulatory environment, which is centered around the requirement of meeting two potentially non-correlated co-primary endpoints (signs and symptoms). However, we also noted how that environment has been easing/improving in recent years with what appears to be a more amenable FDA. Examples of this have been the emergence of the "totality of the data" thesis and the FDA's willingness to allow Shire to explore a novel, more simplistic and straightforward, patient-reported eye dryness symptoms endpoint (as opposed to the more complicated tradition OSDI measurement). Additionally, it appears the Agency may be amenable to allowing positive Phase III results for the signs and symptoms endpoints in separate Phase III studies (which is discussed in our note [here](#)). The bottom line is that it appears that the Agency is considering a more pragmatic pathway and the regulatory environment is improving. Ultimately, we believe this bodes well for Eleven Biotherapeutics' Phase III EBI-005 dry eye program.

The pivotal Phase III EBI-005 clinical trial in dry eye, which is ongoing, continues to enroll patients on schedule and topline data is expected in early 2015. A 12-month dry eye safety study should be initiated in the second half of this year as well, which is also on plan. Our consultants continue to indicate that Restasis is a fairly poor treatment given its efficacy and tolerability profile, nonetheless, is the market leader and the only approved dry eye drug with roughly \$1B in sales. Our consultants stress that a "better" therapeutic option could expand dry eye prescription utilization by 3-4x the current Restasis use, making the prescription target market likely actually closer to \$3-4B. Most importantly, given the profile, they indicate that EBI-005 would be an exceedingly welcome addition to the treatment paradigm. Our model has "peak" sales of roughly \$500MM, but we believe this is clearly a conservative number if the initial clinical profile holds up in Phase III. Stated another way, there is no reason why EBI-005 couldn't be a \$1B+ drug, in our view.

The Valuation Is Attractive Here

Assuming clinical and commercial success for EBI-005 (while excluding any potential other pipeline assets, including the AC indication for EBI-005) we arrive at a base valuation of \$35 per share. This assumes that Eleven takes the product to market via their own sales force in 2017, and that by year 5 of the launch EBI-005 has reached \$500MM+ in sales. Alternatively, a potential acquirer with its own commercial

Please see addendum of this report for important disclosures.

infrastructure — which would significantly lower our spending assumptions in the DCF — would argue for a valuation of the EBI-005 opportunity alone of \$50-55. Given our belief in the likelihood of clinical success and the potential commercial outcomes, we would be adding at these levels.

Figure 1 EBI-005 Dry Eye Market Build

ESTIMATED U.S. DRY EYE TREATMENT MARKET											
	2012	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	CGR	Comments
Restasis U.S. Penetration Of Est Dry Eye Market (AGN)											
Estimated Patients ('000)	80%	80%	80%	78%	74%	67%	62%	56%	51%		- Leading treatment - market creator
Average Price Per Year Due To Low Utilization	\$685	\$720	\$765	\$805	\$845	\$885	\$930	\$975	\$1,025		- Generics may not come upon market expiry; poor compliance
Annual Prescriptions ('000)	2,820	2,955	\$3,112	\$3,119	\$3,126	\$3,026	\$2,969	\$2,869	\$2,819		- ~5% annual price increases
Estimated Sales U.S. (\$MM)	\$750	\$895	\$1,000	\$1,055	\$1,110	\$1,125	\$1,160	\$1,175	\$1,215	+6%	- US sales dominate
Lifitegrast U.S. Penetration Of Est Dry Eye Market (SHPG)											
Patients ('000)				4%	8%	13%	16%	20%	22%		- First treatment to address symptoms of dry eye
Average Price Per Year				\$1,610	\$1,690	\$1,770	\$1,860	\$1,950	\$2,050		- Compliance should be better than Restasis due to efficacy
Annual Prescriptions ('000)				46	106	189	244	316	384		- Priced at a premium to Restasis; and higher utilization
Estimated Sales U.S. (\$MM)				\$50	\$120	\$225	\$305	\$415	\$530		- Expected to rapidly gain market share
EBI-005 U.S. Penetration Of Est Dry Eye Market											
Patients ('000)							4%	8%	10%		- Second player to reach market that treats symptoms effectively
Average Price Per Year							\$1,860	\$1,950	\$2,050		- Potential 2018 U.S. market launch
Annual Prescriptions ('000)							96	172	221		- Pricing in-line with Lifitegrast
Estimated Sales U.S. (\$MM)							\$50	\$120	\$225	\$305	- Strong launch anticipated in exceedingly large market
Steroids/Tears/Others U.S. Estimated Penetration Of Dry Eye Market											
Patients ('000)	21%	20%	20%	19%	18%	17%	15%	14%	13%		- Use declines with the entrance of new, more effective products
Average Price Per Year	\$215	\$225	\$235	\$245	\$255	\$270	\$285	\$300	\$315		- Compliance low and similar to Restasis; short duration of treatment
Estimated Sales U.S. (\$MM)	\$195	\$220	\$245	\$255	\$270	\$280	\$290	\$300	\$310	+6%	- Mainly generic or low priced products
Total U.S. Dry Eye Market Sales (MM)	\$945	\$1,115	\$1,245	\$1,360	\$1,500	\$1,680	\$1,875	\$2,115	\$2,380	+12%	- Larger % of market penetrated due to multiple treatment options
% Growth	+15%	+18%	+12%	+9%	+10%	+12%	+12%	+13%	+12%		- Growth should be rapid given new, more effective drugs

Source: Cowen and Company; PriceRx

Valuation Methodology And Risks

Valuation Methodology

Pharmaceuticals/Specialty

For our valuation methodology, we arrive at fair value utilizing a discounted cash flow (DCF) approach to derive our 12-month price target.

Investment Risks

Pharmaceuticals/Specialty

Risks include: (1) growing competitive dynamics in the specialty pharmaceuticals space; (2) the ability of management to execute on external growth by successfully acquiring new strategic, accretive products; (3) the ability to grow organically and keep the product pipeline robust; (4) potential regulatory delays, rejections, or failures of pipeline products; (5) economic sensitivity of any self-pay products or weakening consumer demand; (6) domestic or international pricing pressures for marketed products; and (7) failure to execute on new product launches.

Risks To The Price Target

Eleven is a development-stage specialty pharmaceutical company and with that carries risk. Failure to successfully develop EBI-005 could result in a significant decrease to our valuation.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
EBIO	Eleven Biotherapeutics

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 Eleven Biotherapeutics securities.

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

Eleven Biotherapeutics 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 Eleven Biotherapeutics.

Cowen and Company, LLC and/or its affiliates managed or co-managed a public offering of Eleven Biotherapeutics 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

© 2014 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 Dahlgren 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 03/31/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	407	57.08%	85	20.88%
Hold (b)	288	40.39%	8	2.78%
Sell (c)	18	2.52%	1	5.56%

(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.

Eleven Biotherapeutics Rating History as of 05/22/2014

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 1925
Chicago, IL 60602
312.577.2240

Houston

600 Travis Street
Suite 1970
Houston, TX 77002
281.657.6800

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

