

Equity Research

May 15, 2014

**Price: \$10.66** (05/14/2014)

**Price Target: \$35.00**

**OUTPERFORM (1)**

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**Key Data**

Symbol [NASDAQ: EBIO](#)

Market Cap (MM) [\\$173.1](#)

Company Quick Take

## *EBI-005 - As Well As Other Key Development Programs - Remain On Track*

### **The Cowen Insight**

Eleven reported Q1 earnings and disclosed that enrollment has completed for EBI-005's Phase II allergic conjunctivitis study, which should have topline data in Q4. Importantly, physicians remain enthused about EBI-005 in dry eye and topline data from the pivotal trial is expected in early 2015 as planned. Given Restasis' limitations and our consultants' views, we would be buying EBIO here.

### **EBI-005 Allergic Conjunctivitis And Dry Eye Data Expected In Q4 and Early 2015, Respectively**

Eleven Biotherapeutics reported Q1 earnings and provided updates on the Company's clinical development programs. We learned that patient enrollment in the Phase II EBI-005 (topical IL-1 inhibitor) allergic conjunctivitis study has completed and that topline data (ocular itching endpoint) will be reported in the fourth quarter of this year. Interestingly, we believe that very little-to-no valuation is being ascribed to the allergic conjunctivitis indications, which we believe is overly conservative. Additionally, 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. Eleven also recently presented EBI-005 and EBI-029 (IL-6 inhibitor) data at a variety of ophthalmology and industry conferences (ARVO; ASCRS; OIS; WOC; PEGS) this spring and feedback appeared to be largely positive. Importantly, physicians appear to be enthused and they assert that the scientific rationale behind EBI-005 and Eleven's other programs remain sound and that the new ocular pain symptoms endpoint for the dry eye trials is very relevant (commercially/clinically) to the disease. The bottom line is that 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 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 Eleven Annual P&L

ELEVEN - 2014-2025 ESTIMATED ANNUAL EPS BUILDUP (\$MM)															
	2012	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	CGR Comments
EBI-005 U.S. Sales															
Dry Eye Disease						\$50	\$120	\$225	\$305	\$400	\$525	\$650	\$775	\$880	- EBI-005 to initiate Phase III in 1H14; potential 2018 launch
Growth Rate								+88%	+36%	+31%	+31%	+24%	+19%	+14%	- Rapid growth expected with one real competitor; 2031-2034 patent expires
Allergic Conjunctivitis															- Phase II to start in 2014; assumes 2020 launch
Growth Rate															- More competitive and established market than DED
Collaboration Revenue		\$1.3													
Total Eleven Revenues						\$50.0	\$120.0	\$225.0	\$305.0	\$400.0	\$525.0	\$650.0	\$775.0	\$880.0	
% Change								+88%	+36%	+31%	+31%	+24%	+19%	+14%	
Cost of Goods						\$6.0	\$12.0	\$22.5	\$30.5	\$40.0	\$52.5	\$65.0	\$77.5	\$88.0	
Gross Profit		\$1.3				\$45.0	\$108.0	\$202.5	\$274.5	\$360.0	\$472.5	\$585.0	\$697.5	\$792.0	
Gross Margin						90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	- Solid margins
SG&A	\$4.2	\$4.0	\$6.0	\$8.0	\$12.0	\$40.0	\$75.0	\$115.0	\$130.0	\$160.0	\$210.0	\$240.0	\$280.0	\$315.0	+24% - Salesforce expansion in 2016/2017; in preparation for EBI-005 launch
% of Revs	NM	NM	NM	NM	NM	80.0%	62.5%	51.1%	42.6%	40.0%	40.0%	36.9%	36.1%	35.8%	- 100 reps @ \$300K adds \$30MM
R&D	\$15.3	\$13.8	\$20.0	\$20.0	\$20.0	\$25.0	\$30.0	\$40.0	\$45.0	\$55.0	\$65.0	\$85.0	\$100.0	\$100.0	+12%
% of Revs	NM	NM	NM	NM	NM	50.0%	25.0%	17.8%	14.8%	11.3%	12.4%	13.1%	12.9%	11.4%	- Additional clinical trials for EBI-005 indications and preclinical assets
Operating Expenses	\$19.5	\$17.8	\$26.0	\$28.0	\$32.0	\$65.0	\$105.0	\$155.0	\$175.0	\$205.0	\$275.0	\$325.0	\$380.0	\$415.0	+17%
% of Revenues	NM	NM	NM	NM	NM	130.0%	87.5%	68.9%	57.4%	51.3%	52.4%	50.0%	49.0%	47.2%	
Operating Income	(\$19.5)	(\$16.5)	(\$26.0)	(\$28.0)	(\$32.0)	(\$20.0)	\$3.0	\$47.5	\$89.5	\$155.0	\$197.5	\$260.0	\$317.5	\$377.0	NM - Operating profit expected in 2020
% Operating Margin	NM	NM	NM	NM	NM	NM	2.5%	21.1%	32.6%	38.8%	37.6%	40.0%	41.0%	42.8%	
Non-Operating Income															
Interest Income	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	
Interest Expense	(0.2)	(1.4)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other Income	(3.1)	(4.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Non-Operating Income	(\$3.3)	(\$5.4)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	
Pretax Income	(\$22.8)	(\$21.9)	(\$26.0)	(\$28.0)	(\$32.0)	(\$20.0)	\$3.0	\$47.5	\$89.5	\$155.0	\$197.5	\$260.0	\$317.5	\$377.0	NM
% of Revs	NM	NM	NM	NM	NM	NM	NM	32.6%	38.8%	37.6%	40.0%	41.0%	42.8%		
Income Taxes								\$16.6	\$34.8	\$54.3	\$69.1	\$81.0	\$111.1	\$132.0	NM
Income Tax Rate								35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	
Net Income - Operations	(\$22.8)	(\$21.9)	(\$26.0)	(\$28.0)	(\$32.0)	(\$20.0)	\$3.0	\$30.9	\$64.7	\$100.8	\$128.4	\$169.0	\$206.4	\$245.1	NM
% Net Margin	NM	NM	NM	NM	NM	NM	NM	21.2%	25.2%	24.5%	26.0%	26.6%	27.8%		
Extraordinary Items	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	
Reported Net Income	(\$22.8)	(\$21.9)	(\$26.0)	(\$28.0)	(\$32.0)	(\$20.0)	\$3.0	\$30.9	\$64.7	\$100.8	\$128.4	\$169.0	\$206.4	\$245.1	NM
Interest Add-Back	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	
EPS (GAAP) - Before Ex. Items	(\$22.93)	\$16.18	(\$1.60)	(\$1.65)	(\$1.85)	(\$1.15)	\$0.15	\$1.55	\$3.05	\$4.55	\$5.50	\$6.95	\$8.20	\$9.35	NM - Profitable in 2020 following the launch of EBI-005
Growth	NM	NM	NM	NM	NM	NM	NM	NM	NM	+49%	+21%	+26%	+18%	+14%	
EPS - Extraordinary Items	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	
EPS - Reported	(\$22.93)	\$16.18	(\$1.60)	(\$1.65)	(\$1.85)	(\$1.15)	\$0.15	\$1.55	\$3.05	\$4.55	\$5.50	\$6.95	\$8.20	\$9.35	NM
Shares - Fully Diluted (MM)	1.0	1.4	16.2	16.7	17.2	17.7	18.2	20.2	21.2	22.2	23.2	24.2	25.2	26.2	+78% - Diluted shares; assuming some onward dilution from options

Source: Cowen and Company

Figure 2 EBI-005 Dry Eye Market Build

ESTIMATED U.S. DRY EYE TREATMENT MARKET											
	2012	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	CGR	Comments
<b>Restasis U.S. Penetration Of Est Dry Eye Market (AGN)</b>	80%	80%	80%	78%	74%	67%	62%	56%	51%		- Leading treatment - market creator
Estimated Patients ('000)	1,825	2,070	2,180	2,185	2,190	2,120	2,080	2,010	1,975		- Generics may not come upon market expiry; poor compliance
Average Price Per Year Due To Low Utilization	\$685	\$720	\$765	\$805	\$845	\$885	\$930	\$975	\$1,025		- ~5% annual price increases
Annual Prescriptions ('000)	2,820	2,955	\$3,112	\$3,119	\$3,126	\$3,026	\$2,969	\$2,869	\$2,819		
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
<b>Lifitegrast U.S. Penetration Of Est Dry Eye Market (SHPG)</b>				4%	8%	13%	16%	20%	22%		- First treatment to address symptoms of dry eye
Patients ('000)				39	89	159	205	266	323		- Compliance should be better than Restasis due to efficacy
Average Price Per Year				\$1,610	\$1,690	\$1,770	\$1,860	\$1,950	\$2,050		- Priced at a premium to Restasis; and higher utilization
Annual Prescriptions ('000)				46	106	189	244	316	384		
Estimated Sales U.S. (\$MM)				\$50	\$120	\$225	\$305	\$415	\$530		- Expected to rapidly gain market share
<b>EBI-005 U.S. Penetration Of Est Dry Eye Market</b>							4%	8%	10%		- Second player to reach market that treats symptoms effectively
Patients ('000)							81	144	186		- Potential 2018 U.S. market launch
Average Price Per Year							\$1,860	\$1,950	\$2,050		- Pricing in-line with Lifitegrast
Annual Prescriptions ('000)							96	172	221		
Estimated Sales U.S. (\$MM)							\$50	\$120	\$225	\$305	- Strong launch anticipated in exceedingly large market
<b>Steroids/Tears/Others U.S. Estimated Penetration Of Dry Eye Market</b>	21%	20%	20%	19%	18%	17%	15%	14%	13%		- Use declines with the entrance of new, more effective products
Patients ('000)	1,510	1,630	1,740	1,735	1,765	1,730	1,695	1,665	1,640		- Compliance low and similar to Restasis; short duration of treatment
Average Price Per Year	\$215	\$225	\$235	\$245	\$255	\$270	\$285	\$300	\$315		- Mainly generic or low priced products
Estimated Sales U.S. (\$MM)	\$195	\$220	\$245	\$255	\$270	\$280	\$290	\$300	\$310	+6%	- Use remains steady
<b>Total U.S. Dry Eye Market Sales (MM)</b>	<b>\$945</b>	<b>\$1,115</b>	<b>\$1,245</b>	<b>\$1,380</b>	<b>\$1,500</b>	<b>\$1,680</b>	<b>\$1,875</b>	<b>\$2,115</b>	<b>\$2,380</b>	<b>+12%</b>	- Larger % of market penetrated due to multiple treatment options
<b>% Growth</b>	<b>+15%</b>	<b>+18%</b>	<b>+12%</b>	<b>+9%</b>	<b>+10%</b>	<b>+12%</b>	<b>+12%</b>	<b>+13%</b>	<b>+12%</b>		- Growth should be rapid given new, more effective drugs

Source: Cowen and Company; PriceRx

## *Valuation Methodology And Risks*

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### **Valuation Methodology**

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#### **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**

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#### **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**

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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

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**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

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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%

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### Eleven Biotherapeutics Rating History as of 05/14/2014

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

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