**OUTPERFORM** 

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Reason for report: **EARNINGS** 

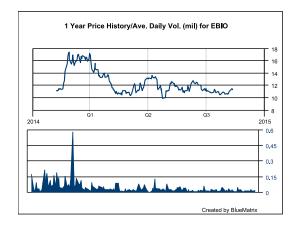


# **ELEVEN BIOTHERAPEUTICS, INC.**

In-line 3Q; We Remain Positive Heading Into Ph. 3 Dry Eye Results In 2Q'15

- Bottom Line: This morning, EBIO reported 3Q14 financial results that were relatively in line with our sales and net loss ests -- \$0.6m/(-\$11m) vs. our \$0.7m / (-\$8m), respectively. The increase in net loss was mainly due to the final enrollment costs of EBIO's Ph.3 dry eye trial. Key updates from the CC included: (1) confirmed timing for the read out of EBI-005's dry eye program – top-line data is expected in 2Q'15; (2) mgmt. will announce next steps for EBI-005's program in allergic conjunctivitis (AC) in 1H'15; & (3) a recently granted patent and further IP development highlight long-tail nature of EBI-005 opportunity. EBIO ended 3Q with ~ \$36m in cash, and the company believes the cash will last to 1Q'16. We remain OP and value EBIO at \$19/share.
- · With enrollment complete, Ph. 3 dry eye data remain on track to report out in 2Q'15. On 11/3, EBIO announced the Ph.3 trial for dry eye had been fully enrolled and on today's CC mgmt indicated half the pts have already completed the study. Mgmt expects to report top line data by 2Q'15. We remain positive on the outlook for the dry phase 3 study based on (1) mechanistically, IL-1 is an important mediator of dry eye inflammation; (2) EBIO's Phase 3 study addressed many of the pitfalls of prior dry eye disease (DED) studies which used an environmental chamber and the use of broad, nonselective symptom based endpoints. Also, the '005 study will restrict the use of rescue artificial tears in Ph. 3 (& document non-compliance). We currently forecast peak '005 sales of ~ \$500m.
- Next steps for allergic conjunctivitis likely to come in 1H'15. The Ph.2 data in AC using the modified CAPT model were stat sig showing EBI-005 had significant activity in the mod-severe AC population. Mgmt expects to use the CAPT model for further development in AC and noted trials in this indication can be run relatively quickly. Mgmt will provide an update in 1H'15 on the next steps for the program and whether '005 will go straight to Ph.3 or if another Ph.2 is required. With a current resource constraint - we believe mgmt. is waiting for the results from the higher priority dry eye indication before allocating additional resources to AC.
- · Strong IP for long-tail product. EBIO received a composition and method of use patent expiring in 2031. EBIO also noted they are pursuing additional patents on the '005 vehicle, that could extend IP protection further. Because EBI-005 is a biologic, we believe the IP and the added development difficulty/cost of biosimilar development provides additional hurdles for Gx co.'s.
- Changes to our model. We are updating our model to reflect (1) slightly increased opex vs. our previous forecasts for FY'14; (2) modest reduction in opex in '15 to correlate with EBIO's current cash position

Key Stats:	(NASDAQ:EBIO)
S&P 600 Health Care Ind	ex: 1,376.79
Price:	\$11.24
Price Target:	\$19.00
Methodology:	DCF analysis, 17.5% WACC
52 Week High:	\$19.33
52 Week Low:	\$9.50
Shares Outstanding (mil):	16.1
Market Capitalization (mil)	\$181.0
Cash Per Share:	\$2.20
Dividend (ann):	\$0.00
Dividend Yield:	0.0%



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arto (A) update	u singe c	Oui 12Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A	0.0	0.0	0.0	0.0	0.0	(\$0.08)	(\$0.09)	(\$0.09)	(\$0.08)	(\$0.39)	NM
2014E - New	0.6A	A8.0	0.5	8.0	2.7	(\$0.80)A	(\$0.51)A	(\$0.66)A	(\$0.33)	(\$2.09)	NM
2014E - Old	0.6A	A8.0	0.7	0.7	2.7	(\$0.80)A	(\$0.51)A	(\$0.45)	(\$0.36)	(\$1.93)	NM
2015E - New	0.2	0.2	0.2	0.2	1.0	(\$0.44)	(\$0.43)	(\$0.43)	(\$0.37)	(\$1.67)	NM
2015E - Old					1.0	j				(\$1.53)	NM

Source: Company Information and Leerink Partners LLC Research

Revenues in MM



### INVESTMENT THESIS

We rate EBIO shares Outperform. We expect that EBIO shares will appreciate upon receipt of Ph. 3 top-line data for EBI-005 for treatment of dry eye disease, most likely in early 2015. The market for dry eye disease therapy is large and there remains a paucity of topical anti-inflammatory drugs that are both potent and tolerable. Based on improved understanding of the pathophysiology of dry eye, EBI-005 was developed to inhibit IL-1, which if left unchecked will promote expression of the other key inflammatory factors that exacerbate dry eye. Lastly, EBI-005 has the potential to be a very long-tailed asset, with pending patents projected to expire in 2031 and EBI-005 could enjoy additional exclusivity owing to the fact that it is a biologic.

### **CHANGES TO MODEL**

EPS & Total Sales Forecasts (2013-19E) (\$MM, except per share data)

Total Sales Forecasts 2013-19E										
	2013	2014E	2015E	2016E	2017E	2018E	2019E			
New	1	3	1	-	36	112	180			
Old	1	3	1		36	112	180			
Difference	-	-	-	-	-	-	-			
		Tota	al EPS Fore	casts 2013-	19E					
	2013	2014E	2015E	2016E	2017E	2018E	2019E			
New	(0.39)	(2.09)	(1.67)	(1.71)	(2.89)	0.54	3.19			
Old	(0.39)	(1.93)	(1.53)	(1.57)	(2.89)	0.54	3.19			
Difference	-	(0.16)	(0.14)	(0.13)	(0.01)	(0.01)	(0.01)			

Source: Leerink Partners, LLC estimate, Company information

### VALUATION

Our ~\$19 price target on EBIO shares is based on our risk-adjusted DCF through 2034 discounted at 17.5% WACC. Using our sales forecasts and applying a 5x multiple to 2023E sales (year of peak market share) discounted back 9 periods at 15% WACC & 55% POS translates to \$19. Our current valuation is solely predicated on EBI-005 for dry eye, and we view label expansion to allergic conjunctivitis as upside.

## **RISKS TO VALUATION**

Risks to our EBIO valuation include (1) EBI-005 drives our valuation and failure to demonstrate efficacy in Phase 3 trials would significantly reduce our valuation; (2) pipeline competitors develop more competitive product profiles, making it difficult for '005 to capture market share; and (3) generic threats to AGN's Restasis somehow materialize, making pricing/reimbursement for DED drugs more challenging.

#### EBIO Annual P&L Summary (Adj. Basis)

(figures in \$m, except per share data)

(figures in \$m, except per share data)																								CAGR
	2012	2013	1Q14	2Q14	3Q14	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026	19-24E
EBI-005 (IL-1 blockade; dry eye disease) EBI-005 (IL-1 blockade; allergic conjunctivitis) Collaboration revenue		- 0.8	- 0.6	- - 0.8	- - 0.5	- - 0.8	2.7	- - 0.2	- - 0.2	- - 0.2	- - 0.2	0.6	-	36	112	180	265	367	465	562	583	605	628	27% na
Total Rev (MM)	_	0.8	0.6	0.8	0.5	0.8	2.7	0.2	0.2	0.2	0.2	1	_	36	112	180	265	367	465	562	583	605	628	27%
% y/y growth	na	na	na	na	na	na	na	na	na	na	na	na	na	nm	208%	61%	47%	39%	27%	21%	4%	4%	4%	/-
cogs	-	-		-		-	-		-	-	-	-	-	5	13	18	26	37	47	56.2	58.3	60.5	62.8	27%
% of sales	nm	0%	na	na	na	na	0%	na	na	na	na	0%	nm	15%	12%	10%	10%	10%	10%	10%	10%	10%	10%	
Gross Income	-	0.8	0.6	0.8	0.5	0.8	2.7	0.2	0.2	0.2	0.2	0.6	-	31	98	162	238	331	419	505.4	524.7	544.8	565.6	27%
% of net sales	nm	1					100.0%					100.0%	nm	85.0%	88.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	
EBI-005 clinical development costs	8.7	7.6	4.1	5.1	6.5	3.8	19.5	3.7	3.6	3.8	3.9	15.0	15.0	8.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	0%
Employee costs & other study costs	6.6	6.5	1.7	1.7	2.4	1.7	7.5	1.6	1.7	1.7	1.7	6.6	6.9	7.3	7.6	8.0	8.4	8.8	9.3	9.8	10.2	10.8	11.3 5.0	5%
Other programs Total R&D	15.3	14.1	5.8	6.8	8.9	5.6	27.0	5.3	5.3	5.5	5.6	21.6	21.9	3.0 18.3	4.0 13.6	5.0 15.0	5.0 15.4	5.0 15.8	5.0 16.3	5.0 16.8	5.0 17.2	5.0 17.8	18.3	3%
% of sales	nm	nm	na	na	na	na	1000%	na	na	na	na	3600%	nm	50%	12%	8%	6%	4%	4%	3%	3%	3%	3%	378
G&A	4.2	3.5	1.9	2.1	2.3	2.2	8.5	2.1	2.2	2.2	2.1	8.6	9.0	17.5	20.0	21.4	22.9	24.5	26.2	28.1	30.0	32.1	34.4	7%
% of sales	nm	422%	na	na	na	na	315%	na	na	na	na	1433%	nm	48%	18%	12%	9%	7%	6%	5%	5%	5%	5%	
Total S&M	-	-	-	-	-	-	-	-	-	-	-	-	-	55	54	57	60	63	66	69	73	76	80	5%
Total operating expenses	19.5	17.6	7.8	8.8	11.1	7.8	35.5	7.4	7.5	7.7	7.7	30.2	31.0	90.8	87.9	93.4	98.1	103.1	108.4	114.0	120.0	126.2	132.8	
Operating (loss)/gain	(19.5)	(16.8)	(7.2)	(8.0)	(10.6)	(7.0)	(32.8)	(7.3)	(7.3)	(7.5)	(7.6)	(29.6)	(31.0)	(59.9)	10.5	68.4	140.0	227.6	310.2	391.4	404.8	418.6	432.8	43%
% of sales	nm	nm	na	na	na	na	-1215%	na	na	na	na	-4933%	nm	-165%	9%	38%	53%	62%	67%	70%	69%	69%	69%	
Net financial expense	(0.2)	(0.8)	(0.0)	(0)	(0)	(0)	(0.3)	(0.0)	(0)	(0)	(1)	(0.7)	(0.7)	(0.7)	1.0	1.0	2.0	3.0	4.0	5.0	10.0	11.0	12.0	58%
Pre-tax Income	(19.7)	(17.5)	(7.2)	(8.1)	(10.7)	(7.0)	(33.1)	(7.3)	(7.4)	(7.6)	(8.1)	(30.3)	(31.7)	(60.6)	11.5	69.4	142.0	230.6	314.2	396.4	414.8	429.6	444.8	43%
% Pre-tax Margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	-166.6%	10.3%	38.6%	53.7%	62.7%	67.5%	70.6%	71.1%	71.0%	70.8%	
Taxes (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	81	110	139	145	150	156	na
% Tax rate	0.0%	0.0%	-	-	-	-	0.0%	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	
Preferred stock dividends	(3.1)	(3.6)	(1)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Net Income/(loss) (MM)	(23)	(21)	(8)	(8)	(11)	(7)	(33)	(7)	(7)	(8)	(8)	(30)	(32)	(61)	12	69	142	150	204	258	270	279	289	31%
% of net sales	NM	NM	N/M	N/M	N/M	N/M	NM	N/M	N/M	N/M	N/M	nm	nm	-166.6%	10.3%	38.6%	53.7%	40.8%	43.9%	45.9%	46.2%	46.1%	46.0%	
Basic & Diluted EPS Y/Y	(\$0.50) NM	(\$0.39) NM	(\$0.80)	(\$0.51)	(\$0.66)	(\$0.33)	(\$2.09) NM	(\$0.44)	(\$0.43)	(\$0.43)	(\$0.37)	(\$1.67) NM	(\$1.71) NM	(\$2.89) 69%	<b>\$0.54</b> -119%	<b>\$3.19</b> <i>4</i> 91%	<b>\$6.39</b> 101%	\$6.61 3%	\$8.83 34%	\$10.92 24%	\$11.21 3%	\$11.38 2%	\$11.55 2%	29%
1/1	INIVI	INIVI					IVIVI					IVIVI	IVIVI	09%	-119%	491%	101%	3%	34%	24%	3%	2%	2%	
Weighted Avg Basic & Diluted Shares (MM)	45.2	54.2	9.6	16.1	16.1	21.4	15.8	16.5	17.0	17.5	21.7	18.2	18.5	20.9	21.4	21.8	22.2	22.7	23.1	23.6	24.1	24.5	25.0	2%
% growth	NM	20%					-71%					15%	2%	13%	2%	2%	2%	2%	2%	2%	2%	2%	2%	

Source: Company reports and Leerink Research estimates



# Disclosures Appendix Analyst Certification

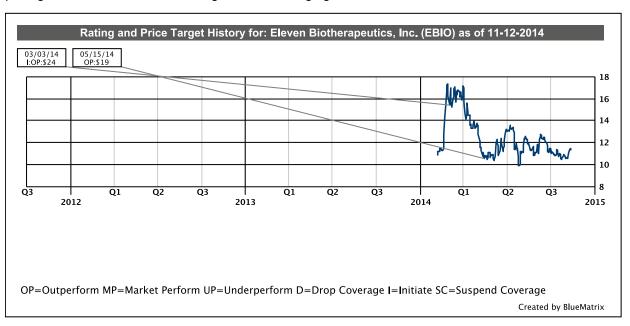
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

## **Valuation**

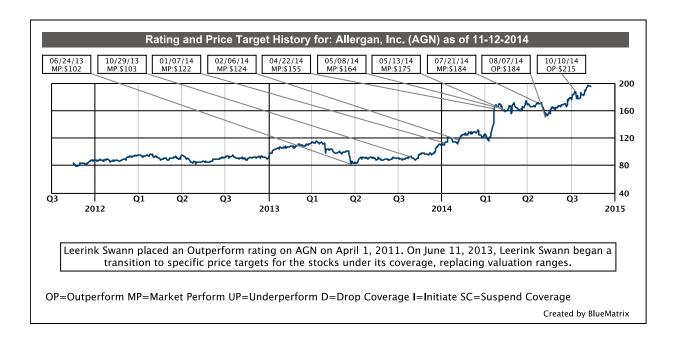
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Risks to our EBIO valuation include (1) EBI-005 drives our valuation and failure to demonstrate efficacy in Phase 3 trials would significantly reduce our valuation; (2) pipeline competitors develop more competitive product profiles, making it difficult for '005 to capture market share; and (3) generic threats to AGN's Restasis somehow materialize, making pricing/reimbursement for DED drugs more challenging.









Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14 IB Serv./Pa								
Rating	Count	Percent	Count	Percent				
BUY [OP]	138	69.30	51	37.00				
HOLD [MP]	61	30.70	2	3.30				
SELL [ŪP]	0	0.00	0	0.00				

# **Explanation of Ratings**

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

<u>Market Perform (Hold/Neutral):</u> We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

# **Important Disclosures**

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In the past 12 months, the Firm has received compensation for providing investment banking services to Eleven Biotherapeutics, Inc. .

Leerink Partners LLC makes a market in Eleven Biotherapeutics, Inc.



Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of Allergan, Inc. on a principal basis.

Leerink Partners LLC has acted as the manager for a public offering of Eleven Biotherapeutics, Inc. in the past 12 months.

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