



November 13, 2014

Eleven Biotherapeutics Reports Third Quarter 2014 Financial Results

Management to host conference call today at 8:30 am EST

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Eleven Biotherapeutics (NASDAQ: EBIO), a clinical-stage biopharmaceutical company discovering and developing protein therapeutics to treat diseases of the eye, today reported financial results for the third quarter ended September 30, 2014 and recent business highlights.

"We have made good progress advancing our lead product candidate, EBI-005, since the second quarter of this year. We are encouraged by the Phase 2 top-line safety and efficacy results for EBI-005 in patients with moderate to severe allergic conjunctivitis, as we believe these data further validate EBI-005 as a clinically active anti-inflammatory ocular agent," said Abbie Celniker, PhD, President and Chief Executive Officer. "Additionally, we recently completed patient enrollment in our first pivotal Phase 3 study of EBI-005 in patients with dry eye disease and expect to report top-line results of that trial in the second quarter of 2015."

Recent Business Highlights:

- Reported top-line results from our proof of concept Phase 2 clinical trial of EBI-005 in patients with moderate to severe allergic conjunctivitis where we compared two models of the disease. In a modified CAPT (conjunctival allergen provocation test) model, patients treated with EBI-005 showed statistically significant improvements in a number of clinically meaningful symptoms that were secondary and exploratory endpoints in this trial, including reduction of ocular itching, nasal symptoms and tearing. Importantly, EBI-005 was generally well-tolerated, with no treatment-related serious adverse events and no drug-specific antibodies detected. This Phase 2 study did not meet the primary endpoint of reduction in mean ocular itching in patients treated with EBI-005 compared to vehicle-control in a modified environmental exposure chamber model. These data will help us to determine our path forward with EBI-005 as a potential new treatment option for patients with moderate to severe allergic conjunctivitis.
- Completed patient enrollment in the OASIS study (A Multi-Center, Double-Masked, Randomized, Controlled, Efficacy and Safety Study of EBI-005 5 mg/mL Topical Ophthalmic Solution Versus Vehicle Control in Subjects with Moderate to Severe Dry Eye Disease), our first pivotal Phase 3 clinical study for EBI-005 in patients with dry eye disease. Over half of the subjects have completed the study, and we expect to report top-line results in the second quarter of 2015.
- Granted a U.S. patent for EBI-005 which contains both composition-of-matter and methods of use claims, which expires in 2031.
- Appointed industry veteran Wendy L. Dixon, PhD, former Chief Marketing Officer and President of Global Marketing for Bristol Myers Squibb, to our Board of Directors.

Third Quarter 2014 Financial Results

- **Revenue:** Revenue was \$0.5 million for the three months ended September 30, 2014, compared to \$0.6 million for the same period in 2013.
- **R&D Expenses:** Research and development expenses were \$8.9 million for the three months ended September 30, 2014 compared to \$3.4 million for the same period in 2013. This increase was primarily due to EBI-005 related development expenses.
- **G&A Expenses:** General and administrative expenses were \$2.3 million for the three months ended September 30, 2014, compared to \$0.8 million for the same period in 2013. This increase was primarily due to increased operating costs related to operating as a public company since February 2014 and increased stock-based compensation expense.
- **Net Loss:** Net loss applicable to common stockholders was \$10.7 million, or \$0.66 per share, for the three months ended September 30, 2014, compared to net loss applicable to common stockholders of \$4.7 million, or \$3.39 per share, for the same period in 2013.
- **Cash and Cash Equivalents:** Cash and cash equivalents were \$35.9 million as of September 30, 2014. We believe that our cash and cash equivalents as of September 30, 2014 will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the first quarter of 2016.

Upcoming Events and Presentations:

- Medical Contact Lens and Ocular Surface Association's 21st Annual Scientific Meeting in London on Friday, November 28, 2014
- Oppenheimer 25th Annual Healthcare Conference in New York on December 11, 2014 at 10:55 a.m. ET

Conference Call Information:

Eleven Biotherapeutics' management team will host a conference call and audio webcast today at 8:30 a.m. EST to discuss the third quarter 2014 results and provide a corporate update. To access the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) at least five minutes prior to the start time and refer to conference ID 28098475.

An audio webcast of the call will also be available on the Investors & Media section of the Company's website www.elevenbio.com. An archived webcast will be available on the Company's website approximately two hours after the event and will be available for 30 days.

About EBI-005

Eleven Biotherapeutics' most advanced product candidate is EBI-005, a novel, topically-administered interleukin-1 (IL-1) receptor blocker in development as a protein therapeutic for dry eye disease and allergic conjunctivitis. The EBI-005 program is based on the role that elevated levels of the inflammatory cytokine IL-1 play in the initiation and maintenance of the inflammation and pain associated with dry eye disease and the itching and other symptoms associated with allergic conjunctivitis. EBI-005 has been evaluated in a Phase 2 study in patients with moderate to severe allergic conjunctivitis and is currently being evaluated in a pivotal Phase 3 study in dry eye disease.

About Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a clinical-stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. Eleven's therapeutic approach is based on the role of cytokines in diseases of the eye, the company's understanding of the structural biology of cytokines and the company's ability to rationally design and engineer proteins to modulate the effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, advancement or maturation of its product candidates and product pipeline, clinical development of the Company's therapeutic candidates, including expectations regarding timing of initiation of clinical trials, patient enrollment and availability of results, regulatory requirements for initiation of clinical trials and registration of product candidates, sufficiency of cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from ongoing clinical trials, whether results of early clinical trials will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals and other factors discussed in the "Risk Factors" section of the Company's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2014 and other reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

ELEVEN BIOTHERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

Three Months Ended
September 30,

Nine Months Ended
September 30,

	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Collaboration revenue	\$ 539	\$ 622	\$ 1,868	\$ 824
Operating expenses:				
Research and development	8,872	3,376	21,445	10,576
General and administrative	2,269	786	6,259	2,606
Total operating expenses	<u>11,141</u>	<u>4,162</u>	<u>27,704</u>	<u>13,182</u>
Loss from operations	(10,602)	(3,540)	(25,836)	(12,358)
Other income (expense):				
Other income, net	2	16	56	(96)
Interest expense, net	(74)	(289)	(237)	(505)
Total other expense	<u>(72)</u>	<u>(273)</u>	<u>(181)</u>	<u>(601)</u>
Net loss	<u>\$ (10,674)</u>	<u>\$ (3,813)</u>	<u>\$ (26,017)</u>	<u>\$ (12,959)</u>
Cumulative preferred stock dividends	-	(905)	(519)	(2,715)
Net loss applicable to common stockholders	<u>\$ (10,674)</u>	<u>\$ (4,718)</u>	<u>\$ (26,536)</u>	<u>\$ (15,674)</u>
Net loss per share applicable to common stockholders—basic and diluted	<u>\$ (0.66)</u>	<u>\$ (3.39)</u>	<u>\$ (1.90)</u>	<u>\$ (11.87)</u>
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	<u>16,098</u>	<u>1,390</u>	<u>13,954</u>	<u>1,320</u>

ELEVEN BIOTRAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(unaudited)
(in thousands)

	<u>September 30, 2014</u>	<u>December 31, 2013</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 35,943	\$ 7,942
Prepaid expenses and other current assets	348	88
Total current assets	<u>36,291</u>	<u>8,030</u>
Property and equipment, net	585	759
Restricted cash	94	94
Other assets	<u>11</u>	<u>2,354</u>
Total assets	<u>\$ 36,981</u>	<u>\$ 11,237</u>
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 2,588	\$ 1,746
Accrued expenses	1,656	850
Notes payable, current portion	1,642	1,642
Deferred revenue, current portion	621	1,115
Total current liabilities	<u>6,507</u>	<u>5,353</u>
Deferred revenue, net of current portion	45	355
Restricted stock liability	6	10
Notes payable, net of current portion	1,645	2,876
Warrant liability	-	297
Series A convertible preferred stock	-	45,035
Series B convertible preferred stock	-	11,643

Stockholders' equity (deficit):		
Preferred stock	-	-
Common stock	16	2
Additional paid-in capital	112,373	3,260
Accumulated deficit	(83,611)	(57,594)
Total stockholders' equity (deficit)	<u>28,778</u>	<u>(54,332)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 36,981</u>	<u>\$ 11,237</u>

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Source: Eleven Biotherapeutics

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