



April 30, 2015

Eleven Biotherapeutics Reports First Quarter 2015 Financial Results

Management to host conference call today at 8:30 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a clinical-stage biopharmaceutical company discovering and developing protein therapeutics to treat diseases of the eye, today reported financial results for the first quarter ended March 31, 2015, and recent business highlights.

"Recently, we've presented and published a comprehensive body of clinical data related to Eleven's ocular therapeutics pipeline in peer-reviewed journals and at ocular disease meetings," said Abbie Celniker, Ph.D., President and Chief Executive Officer of Eleven Biotherapeutics. "These data further define the patient population and proposed Phase 3 trial design for EBI-005 in the treatment of allergic conjunctivitis and describe how data from the completed phase 1b/2a study of EBI-005 in patients with dry eye disease influenced the design of the pivotal Phase 3 study. We remain on-track with our pivotal Phase 3 clinical study of EBI-005 in dry eye disease. Patient enrollment in this study completed in the fourth quarter of 2014 and communication of top line data is expected this quarter sometime after ARVO 2015."

First Quarter and Recent Business Highlights:

- Presented Phase 2 clinical data on EBI-005 for the treatment of allergic conjunctivitis at the American Society of Cataract and Refractive Surgery (ASCRS) 2015 Annual Meeting. EBI-005, the first IL-1 (Interleukin-1) receptor inhibitor designed for topical ocular administration, demonstrated statistically significant improvements in ocular itching, ocular tearing and nasal symptoms associated with the late phase allergen response in patients with allergic conjunctivitis utilizing a modified direct conjunctival allergen model. Based on these results, we plan to initiate a Phase 3 environmental clinical study of EBI-005 in patients with moderate to severe allergic conjunctivitis in the second half of 2015. The key data highlights were:
 - Statistically significant improvements in ocular itching (mean change from baseline) compared with vehicle were demonstrated at the final two efficacy time points ($p = 0.033$ at visit 6, study day 18, and $p = 0.046$ at visit 7, study day 19).
 - Statistically significant improvements in ocular tearing (mean change from baseline) compared with vehicle were demonstrated at the final two efficacy time points ($p = 0.027$ at visit 6 and $p = 0.044$ at visit 7).
 - Statistically significant improvements in total nasal symptoms (mean change from baseline) compared with vehicle were demonstrated at the final two efficacy time points ($p = 0.004$ at visit 6 and $p = 0.011$ at visit 7).
 - EBI-005 was well tolerated with no treatment related serious adverse events and no evidence of drug specific antibodies.
- Published clinical data in the May 2015 issue of *Eye and Contact Lens*. In the paper, "A Phase 2 Exploratory Study of a Novel Interleukin-1 Receptor Inhibitor (EBI-005) in the Treatment of Moderate-to-Severe Allergic Conjunctivitis," Michael H. Goldstein, M.D., Eleven's Chief Medical Officer, describes Phase 2 clinical data supporting the clinical benefit of EBI-005 in treating more severe forms of allergic conjunctivitis. By inhibiting the underlying inflammation driving the late phase response, EBI-005 is well positioned to address up to 5.8 million moderate to severe allergic conjunctivitis patients whose needs are not adequately met with current therapies.
- Presented a pipeline and corporate overview at the Ophthalmology Innovation Summit (OIS) this month, an industry meeting established to highlight the companies driving ophthalmic innovation.

First Quarter 2015 Financial Results

- **Revenue:** Revenue was \$0.2 million for the three months ended March 31, 2015, compared to \$0.6 million for the same period in 2014.
- **R&D Expenses:** Research and development expenses were \$5.2 million for the three months ended March 31, 2015 compared to \$5.8 million for the same period in 2014. This decrease was primarily due to lower EBI-005 related development expenses.
- **G&A Expenses:** General and administrative expenses were \$2.6 million for the three months ended March 31, 2015, compared to \$1.9 million for the same period in 2014. 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 \$6.5 million, or \$0.36 per share, for the three months ended

March 31, 2015, compared to net loss applicable to common stockholders of \$7.7 million, or \$0.80 per share, for the same period in 2014.

- **Cash and Cash Equivalents:** Cash and cash equivalents were \$45.5 million as of March 31, 2015. We believe that our cash and cash equivalents as of March 31, 2015 will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into 2016.

Upcoming Events and Presentations:

- Association for Research in Vision and Ophthalmology (ARVO) 2015 annual meeting taking place May 3-7, 2015, in Denver, CO.
 - Oral presentation titled, "Comparison of Two Clinical Repeat Allergen Challenge Models to Evaluate EBI-005 in the Late Phase Inflammatory Response in Allergic Conjunctivitis," describing the Phase 2 study in subjects with late phase allergic conjunctivitis. EBI-005 was evaluated in two different clinical models adapted for the late phase inflammatory response, an area of high unmet need and the patient population for which EBI-005 is being developed for allergic conjunctivitis.
 - Poster presentation titled, "Optimized Intravitreal IL-6 antagonist for the Treatment of Diabetic Macular Edema," describing the role of IL-6 blockade in diabetic macular edema and the ability of EBI-031 to potentially inhibit IL-6 signaling in preclinical pharmacokinetic studies. This data further supports the potential utility of IL-6 inhibition in diabetic macular edema and our plans to file an IND by the end of the year.
 - Poster presentation titled, "Clinical Development of EBI-005, a Novel Interleukin-1 Receptor Inhibitor, for Patients with Ocular Surface Inflammation," describing how data related to dosing, disease severity, patient selection, and endpoint selection from a completed phase 2 study of EBI-005 in patients with moderate to severe dry eye disease shaped the design of the pivotal, Phase 3 study in dry eye disease.

Conference Call Information:

Eleven Biotherapeutics' management team will host a conference call and audio webcast today at 8:30 a.m. ET to discuss the first quarter 2015 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 14070086.

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 EBI-031

Eleven Biotherapeutics' most advanced preclinical product candidate is EBI-031 for treatment of diabetic macular edema, or DME. EBI-031 has been designed and engineered for intravitreal delivery using our AMP-Rx platform. EBI-031 is a potent blocker of both free IL-6 and IL-6 complexed to the soluble IL-6 receptor (IL-6R) and has demonstrated a longer vitreal retention time in preclinical models than antibodies and antibody like molecules approved for intravitreal injection. We are undertaking the necessary manufacturing development work and nonclinical safety studies to support the submission of an investigational new drug application, or IND, to the FDA by the end of 2015 for the purpose of conducting clinical trials of EBI-031 in DME.

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. For more information please refer to the company's website www.elevenbio.com.

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 annual report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2015 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 March 31,	
	2015	2014
Collaboration revenue	\$ 244	\$ 568
Operating expenses:		
Research and development	5,238	5,819
General and administrative	2,603	1,938
Total operating expenses	7,841	7,757
Loss from operations	(7,597)	(7,189)
Other income (expense), net	1,073	(33)
Net loss	\$ (6,524)	\$ (7,222)
Cumulative preferred stock dividends	-	(519)
Net loss applicable to common stockholders	\$ (6,524)	\$ (7,741)
Net loss per share applicable to common stockholders— basic and diluted	\$ (0.36)	\$ (0.80)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	17,971	9,635

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

	March 31, December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 45,549	\$ 54,059
Prepaid expenses and other current assets	495	342

Restricted cash	94	-
Total current assets	46,138	54,401
Property and equipment, net	422	486
Restricted cash	-	94
Other assets	18	19
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Total assets	\$ 46,578	\$ 55,000
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 2,043	\$ 2,458
Accrued expenses	1,327	1,987
Notes payable, current portion	1,010	251
Deferred revenue	262	506
Total current liabilities	4,642	5,202
Other liabilities	65	4
Notes payable, net of current portion	8,990	9,749
Warrant liability	1,915	3,219
Stockholders' equity:		
Common stock	18	18
Additional paid-in capital	129,222	128,558
Accumulated deficit	(98,274)	(91,750)
Total stockholders' equity	30,966	36,826
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Total liabilities and stockholders' equity	\$ 46,578	\$ 55,000

Eleven Biotherapeutics
Leah Monteiro, 617-714-0619
Leah.Monteiro@elevenbio.com

Source: Eleven Biotherapeutics, Inc.

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