

Eleven Biotherapeutics Reports Second 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 second quarter ended June 30, 2015, and recent business highlights.

"We are continuing to focus on advancing our ocular therapeutics pipeline. We recently initiated a pivotal Phase 3 study of EBI-005 in moderate to severe allergic conjunctivitis patients suffering from the late-phase inflammatory response and are now planning to advance development of EBI-031 for the treatment of diabetic macular edema and uveitis with an IND filing expected in the first half of 2016. Our development plans are supported by data presented recently on both EBI-005 and EBI-031 at the ARVO 2015 Annual Meeting," said Abbie Celniker, Ph.D., President and Chief Executive Officer of Eleven Biotherapeutics. "We are excited about the potential of our novel protein therapeutic drug candidates for the treatment of ocular disease and have sufficient financial resources to continue to invest in this promising pipeline."

Second Quarter and Recent Business Highlights:

- **Initiated a Phase 3 study of EBI-005 for the treatment of moderate to severe allergic conjunctivitis patients suffering from the late-phase inflammatory response.** EBI-005 offers the potential to mediate this late-phase allergic response by blocking the interleukin-1 (IL-1) receptor, believed to play a key role in ocular surface disease, while also exhibiting an acceptable safety and tolerability profile to date. Top-line data from this study is expected in the first quarter of 2016. The initiation of this Phase 3 study follows completion of a Phase 2 clinical trial in which EBI-005 achieved statistically significant improvements in ocular itching, ocular tearing and nasal symptoms in the late phase allergen response in moderate to severe allergic conjunctivitis patients following allergen exposure in a modified direct conjunctival allergen challenge (CAPT) model.
- **Presented clinical data for EBI-005 for the treatment of allergic conjunctivitis at the Association for Research in Vision and Ophthalmology (ARVO) 2015 Annual Meeting.** EBI-005 showed clinically relevant, statistically significant improvements in multiple endpoints including ocular itching, ocular tearing and nasal symptoms associated with the late phase allergen response. These data further support the important role of IL-1 as a key target for ocular surface inflammation associated with allergic conjunctivitis, a mechanistically different disease from dry eye disease due to its single, central mechanism of allergen stimulation as opposed to the many diverse causes of ocular surface inflammation in dry eye disease.
- **Presented preclinical data for EBI-031 for the treatment of diabetic macular edema (DME) at the ARVO 2015 Annual Meeting.** Preclinical data exhibit the potential ability of EBI-031 to potently inhibit interleukin-6 (IL-6) signaling with extended vitreal retention compared to existing therapies. Based on these data, which we believe support our design criteria necessary for an intravitreal IL-6 antagonist, Eleven plans to file an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) in the first half of 2016 for the clinical development of EBI-031 in DME and uveitis.
- **Presented at the 12th Annual International Symposium on Ocular Pharmacology and Therapeutics (ISOPT) on ocular surface inflammation and the use of EBI-005 in patients with allergic conjunctivitis and dry eye disease.**
- **Reported top-line results from the OASIS study, a pivotal Phase 3 study of EBI-005, in moderate to severe dry eye disease.** The co-primary endpoints of the Phase 3 study were the total corneal fluorescein staining score and the patient-reported measurement related to ocular pain and discomfort based on the ocular surface disease index (OSDI), comparing the mean change from baseline at week 12 for treatment with EBI-005 to treatment with vehicle control. In this study, EBI-005 did not meet either of these two co-primary endpoints. Eleven does not plan to pursue further development of EBI-005 for dry eye disease. Eleven is focusing on developing EBI-005 to meet unmet medical needs in allergic conjunctivitis, based on our previously-reported Phase 2 data and scientific rationale supporting EBI-005 as a treatment for allergic conjunctivitis.

Second Quarter 2015 Financial Results:

- **Revenue:** Revenue was \$0.1 million for the three months ended June 30, 2015, compared to \$0.8 million for the same period in 2014.

- **R&D Expenses:** Research and development expenses were \$6.3 million for the three months ended June 30, 2015, compared to \$6.8 million for the same period in 2014. This decrease was primarily due to lower EBI-005 related development expenses partially offset by increases in EBI-031 related development expenses.
- **G&A Expenses:** General and administrative expenses were \$2.2 million for the three months ended June 30, 2015, compared to \$2.1 million for the same period in 2014.
- **Net Loss:** Net loss applicable to common stockholders was \$6.9 million, or \$0.36 per share, for the three months ended June 30, 2015, compared to net loss applicable to common stockholders of \$8.1 million, or \$0.51 per share, for the same period in 2014.
- **Cash and Cash Equivalents:** Cash and cash equivalents were \$53.5 million as of June 30, 2015. We believe that our cash and cash equivalents as of June 30, 2015 will enable us to fund our operating expenses and debt service obligations into the second half of 2016.

Upcoming Events and Presentations:

- NewsMakers in the Biotech Industry, September 10, 2015 at 3:30 p.m. ET in New York.

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 second 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 98342235.

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 inflammatory diseases at the surface of the eye. 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, pain, redness, itching and other symptoms associated with ocular surface diseases. EBI-005 is currently in Phase 3 clinical development for the treatment of moderate to severe allergic conjunctivitis. In a completed Phase 2 clinical trial, EBI-005 exhibited biological activity in improving the symptoms of late-phase allergic responses in patients with moderate to severe allergic conjunctivitis in a CAPT model.

About EBI-031

Eleven Biotherapeutics' most advanced preclinical product candidate is EBI-031 for treatment of diabetic macular edema, or DME and uveitis. 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 in the first half of 2016 for the purpose of conducting clinical trials of EBI-031 in DME and uveitis.

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. The Company'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 quarterly report on Form 10-Q most recently filed with the Securities and Exchange Commission 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Collaboration revenue	\$ 114	\$ 761	\$ 358	\$ 1,329
Operating expenses:				
Research and development	6,269	6,754	11,507	12,573
General and administrative	2,247	2,052	4,850	3,990
Total operating expenses	8,516	8,806	16,357	16,563
Loss from operations	(8,402)	(8,045)	(15,999)	(15,234)
Other income (expense), net	1,496	(76)	2,569	(109)
Net loss	\$ (6,906)	\$ (8,121)	\$ (13,430)	\$ (15,343)
Cumulative preferred stock dividends	-	-	-	(519)
Net loss applicable to common stockholders	\$ (6,906)	\$ (8,121)	\$ (13,430)	\$ (15,862)
Net loss per share applicable to common stockholders— basic and				
diluted	\$ (0.36)	\$ (0.51)	\$ (0.72)	\$ (1.23)
Weighted-average number of common shares used in net loss per				
share applicable to common stockholders—basic and diluted	19,087	16,055	18,532	12,863

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

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 53,494	\$ 54,059
Prepaid expenses and other current assets	938	342
Total current assets	54,432	54,401
Property and equipment, net	580	486
Restricted cash	94	94

Other assets	16	19
Total assets	<u>\$ 55,122</u>	<u>\$ 55,000</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,880	\$ 2,458
Accrued expenses	618	1,987
Notes payable, current portion	2,523	251
Deferred revenue	451	506
Total current liabilities	<u>5,472</u>	<u>5,202</u>
Other liabilities	164	4
Notes payable, net of current portion	12,171	9,749
Warrant liability	96	3,219
Stockholders' equity:		
Common stock	19	18
Additional paid-in capital	142,380	128,558
Accumulated deficit	(105,180)	(91,750)
Total stockholders' equity	<u>37,219</u>	<u>36,826</u>
Total liabilities and stockholders' equity	<u>\$ 55,122</u>	<u>\$ 55,000</u>

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

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