



November 4, 2015

## Eleven Biotherapeutics Reports Third 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 third quarter ended September 30, 2015, and recent business highlights.

"We made great strides in the advancement of our ophthalmic therapeutics pipeline this quarter. We completed patient enrollment in the first of two planned pivotal Phase 3 clinical trials of isunakinra (EBI-005), for moderate to severe allergic conjunctivitis patients suffering from the late-phase inflammatory response. This Phase 3 study follows completion in 2014 of a Phase 2 clinical trial in which isunakinra showed clinically relevant, statistically significant improvements in multiple endpoints including ocular itching, ocular tearing and nasal symptoms associated with the late phase allergen response," said Abbie Celniker, Ph.D., President and Chief Executive Officer of Eleven Biotherapeutics. "In addition, we are continuing the preclinical work necessary to advance development of EBI-031 for the treatment of diabetic macular edema and uveitis. We remain on track to report top-line data for the ongoing isunakinra Phase 3 clinical trial in the first quarter of 2016 and to file an IND for EBI-031 in the first half of 2016."

### Third Quarter and Recent Business Highlights:

- Completed enrollment in a Phase 3 study of isunakinra for the treatment of moderate to severe allergic conjunctivitis in 258 patients suffering from the late-phase inflammatory response. Isunakinra 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. If the results of this first Phase 3 trial are favorable, Eleven intends to initiate a second Phase 3 trial in the second half of 2016.

### Third Quarter 2015 Financial Results:

- Revenue: Revenue was \$0.1 million for the three months ended September 30, 2015, compared to \$0.5 million for the same period in 2014.
- R&D Expenses: Research and development expenses were \$6.7 million for the three months ended September 30, 2015, compared to \$8.9 million for the same period in 2014. This decrease was primarily due to lower isunakinra related development expenses partially offset by increases in EBI-031 related development expenses.
- G&A Expenses: General and administrative expenses were \$2.7 million for the three months ended September 30, 2015, compared to \$2.3 million for the same period in 2014.
- Net Loss: Net loss applicable to common stockholders was \$9.7 million, or \$0.50 per share, for the three months ended September 30, 2015, compared to net loss applicable to common stockholders of \$10.7 million, or \$0.66 per share, for the same period in 2014.
- Cash and Cash Equivalents: Cash and cash equivalents were \$46.4 million as of September 30, 2015. We believe that our cash and cash equivalents as of September 30, 2015 will enable us to fund our operating expenses and debt service obligations into the second half of 2016.

### Upcoming Events and Presentations:

- 2015 Citi Global Healthcare 1x1 Conference, November 5, 2015 in New York.
- 2015 Ophthalmology Innovation Summit (OIS@AAO), November 12, 2015 in Las Vegas.

### 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 third 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 65898954.

An audio webcast of the call will also be available on the Investors & Media section of the Company's website, [www.elevenbio.com](http://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 Isunakinra (EBI-005)**

Eleven Biotherapeutics' most advanced product candidate is isunakinra, 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 isunakinra 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. Isunakinra is currently in Phase 3 clinical development for the treatment of moderate to severe allergic conjunctivitis. In a completed Phase 2 clinical trial, isunakinra 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. 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](http://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 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 for the quarter ended June 30, 2015 as 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 September 30, Nine Months Ended September 30,**

	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Collaboration revenue	\$ 67	\$ 539	\$ 425	\$ 1,868
Operating expenses:				
Research and development	6,745	8,872	18,252	21,445
General and administrative	2,681	2,269	7,531	6,259
Total operating expenses	9,426	11,141	25,783	27,704
Loss from operations	(9,359)	(10,602)	(25,358)	(25,836)
Other income (expense), net	(334)	(72)	2,235	(181)
Net loss	<u>\$ (9,693)</u>	<u>\$ (10,674)</u>	<u>\$ (23,123)</u>	<u>\$ (26,017)</u>
Cumulative preferred stock dividends	-	-	-	(519)
Net loss applicable to common stockholders	<u>\$ (9,693)</u>	<u>\$ (10,674)</u>	<u>\$ (23,123)</u>	<u>\$ (26,536)</u>
Net loss per share applicable to common stockholders—basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.66)</u>	<u>\$ (1.23)</u>	<u>\$ (1.90)</u>
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	19,345	16,098	18,806	13,954

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

	<u>September 30, 2015</u>	<u>December 31, 2014</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 46,362	\$ 54,059
Prepaid expenses and other current assets	653	342
Total current assets	47,015	54,401
Property and equipment, net	480	486
Restricted cash	94	94
Other assets	14	19
Total assets	<u>\$ 47,603</u>	<u>\$ 55,000</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,279	\$ 2,458
Accrued expenses	1,146	1,987
Notes payable, current portion	3,711	251
Deferred revenue	471	506
Total current liabilities	7,607	5,202
Other liabilities	275	4
Notes payable, net of current portion	11,023	9,749
Warrant liability	33	3,219
Stockholders' equity:		
Common stock	20	18
Additional paid-in capital	143,518	128,558
Accumulated deficit	(114,873)	(91,750)
Total stockholders' equity	<u>28,665</u>	<u>36,826</u>
Total liabilities and stockholders' equity	<u>\$ 47,603</u>	<u>\$ 55,000</u>

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