



March 4, 2015

Eleven Biotherapeutics Reports Fourth Quarter and Year-End 2014 Financial Results

Management to host conference call today at 8:30 a.m. 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 fourth quarter and full year ended December 31, 2014.

"We made significant progress advancing our pipeline of novel protein therapeutics for eye disease including our lead product candidate, EBI-005, which is in late-stage clinical development for dry eye disease and allergic conjunctivitis," said Abbie Celniker, Ph.D., President and Chief Executive Officer. "We completed patient enrollment in our pivotal Phase 3 clinical study for EBI-005 in patients with moderate to severe dry eye disease and expect to report top-line results from that study in the second quarter of 2015. One of the requirements for regulatory approval and an important milestone for the pivotal clinical program was the initiation of a twelve-month safety study with EBI-005 in dry eye disease. We also reported encouraging Phase 2 top-line safety and efficacy results for EBI-005 in patients with moderate to severe allergic conjunctivitis, further validating EBI-005 as a clinically active anti-inflammatory ocular agent. In addition to the progress made with EBI-005 we are also pleased with the progress that we have made with our second product candidate in development for diabetic macular edema with a planned IND filing by the end of 2015."

Fourth Quarter and Recent Business Highlights:

- 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. Top-line results are expected in the second quarter of 2015.
- Initiated a twelve-month clinical study in patients with moderate to severe dry eye disease to assess the long-term safety and tolerability of EBI-005 as part of its ongoing pivotal Phase 3 program.
- Reported in October top-line results from our proof of concept Phase 2 clinical trial of EBI-005 in patients with moderate to severe allergic conjunctivitis. In a modified CAPT (conjunctival allergen provocation test) model, patients treated with EBI-005 showed statistically significant improvements in mean change from baseline in patient reported ocular itching, ocular tearing and total nasal symptoms compared to vehicle-control at the second to last and final assessment time points. These data helped us to determine our path forward with EBI-005 as a potential new treatment option for patients with moderate to severe allergic conjunctivitis. We will be making comments on our allergic conjunctivitis development plan on today's call.
- Granted a U.S. patent for EBI-005 encompassing both composition-of-matter and methods of use claims, which expires in 2031.
- Advanced our EBI-031 (anti-IL-6) program toward an expected IND filing for the indication of diabetic macular edema (DME) by the end of 2015. EBI-031 is an antibody with the potential for a longer half-life compared with approved intravitreal protein therapeutics.
- Raised \$20 million in a private placement financing of Eleven Biotherapeutics common stock and warrants. Funding from the financing will be used to further advance Eleven's pipeline of protein therapeutics to treat diseases of the eye including EBI-005 for the treatment of moderate to severe dry eye disease and moderate to severe allergic conjunctivitis.
- Appointed industry and academic leaders Wendy L. Dixon, PhD, Jay S. Duker, MD and Barry Gertz, MD, PhD to our Board of Directors. Dr. Dixon is the former Chief Marketing Officer and President of Global Marketing for Bristol Myers Squibb. Dr. Duker is professor and chair of Ophthalmology at Tufts University School of Medicine and director of the New England Eye Center. Dr. Gertz is a venture partner at Clarus Ventures, Chief Medical Advisor for Relay Pharmaceuticals and former Senior Vice President of Global Clinical Development at Merck.

Fourth Quarter and Year-End 2014 Financial Results

- **Revenue:** Revenue was \$0.4 million for the three months ended December 31, 2014, compared to \$0.5 million for the same period in 2013. Revenue was \$2.2 million for the twelve months ended December 31, 2014 compared to \$1.3 million for the same period in 2013.

- **R&D Expenses:** Research and development expenses were \$5.3 million for the three months ended December 31, 2014 compared to \$3.2 million for the same period in 2013. This increase was primarily due to EBI-005 related development expenses. Research and development expenses were \$26.7 million for the twelve months ended December 31, 2014 compared to \$13.8 million for the same period in 2013.
- **G&A Expenses:** General and administrative expenses were \$2.2 million for the three months ended December 31, 2014, compared to \$1.4 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. General and administrative expenses were \$8.5 million for the twelve months ended December 31, 2014 compared to \$4.0 million for the same period in 2013.
- **Net Loss:** Net loss applicable to common stockholders was \$8.1 million, or \$0.49 per share, for the three months ended December 31, 2014, compared to net loss applicable to common stockholders of \$6.2 million, or \$4.29 per share, for the same period in 2013. Net loss applicable to common stockholders was \$34.7 million, or \$2.37 per share, for the twelve months ended December 31, 2014 compared to \$21.9 million, or \$16.18 per share, for the same period in 2013.
- **Cash and Cash Equivalents:** Cash and cash equivalents were \$54.1 million as of December 31, 2014. We believe that our cash and cash equivalents as of December 31, 2014 will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into 2016.

Upcoming Events and Presentations:

- 2015 American Society of Cataract and Refractive Surgery (ASCRS) annual symposium, in San Diego, April 17-21, 2015.
- Association for Research in Vision and Ophthalmology (ARVO) annual meeting, in Denver, May 3-7, 2015.

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 fourth quarter and year-end 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 87544666.

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. We designed and engineered EBI-031 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 a longer vitreal retention time than antibodies and antibody like molecules approved for intravitreal injection. We are undertaking the necessary CMC 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.

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 November 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 December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Collaboration revenue	\$ 375	\$ 510	\$ 2,243	\$ 1,334
Operating expenses:				
Research and development	5,258	3,212	26,703	13,788
General and administrative	2,212	1,418	8,471	4,024
Total operating expenses	7,470	4,630	35,174	17,812
Loss from operations	(7,095)	(4,120)	(32,931)	(16,478)
Other income (expense):				
Other expense, net	(905)	(51)	(849)	(147)
Interest expense, net	(139)	(895)	(376)	(1,400)
Total other expense	(1,044)	(946)	(1,225)	(1,547)
Net loss	\$ (8,139)	\$ (5,066)	\$ (34,156)	\$ (18,025)
Cumulative preferred stock dividends	-	(1,142)	(519)	(3,857)
Net loss applicable to common stockholders	\$ (8,139)	\$ (6,208)	\$ (34,675)	\$ (21,882)
Net loss per share applicable to common stockholders—basic and diluted	\$ (0.49)	\$ (4.29)	\$ (2.37)	\$ (16.18)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	16,692	1,447	14,644	1,352

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

December 31,
2014 2013

Assets

Current assets:

Cash and cash equivalents	\$ 54,059	\$ 7,942
Prepaid expenses and other current assets	342	88
Total current assets	54,401	8,030
Property and equipment, net	486	759
Restricted cash	94	94
Other assets	19	2,354
Total assets	\$ 55,000	\$ 11,237

Liabilities, convertible preferred stock, and stockholders' equity (deficit)

Current liabilities:

Accounts payable	\$ 2,458	\$ 1,746
Accrued expenses	1,987	850
Notes payable, current portion	251	1,642
Deferred revenue, current portion	506	1,115
Total current liabilities	5,202	5,353
Deferred revenue, net of current portion	-	355
Restricted stock liability	4	10
Notes payable, net of current portion	9,749	2,876
Warrant liability	3,219	297
Series A convertible preferred stock	-	45,035
Series B convertible preferred stock	-	11,643
Stockholders' equity (deficit):		
Preferred stock	-	-
Common stock	18	2
Additional paid-in capital	128,558	3,260
Accumulated deficit	(91,750)	(57,594)
Total stockholders' equity (deficit)	36,826	(54,332)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 55,000	\$ 11,237

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