

Eleven Biotherapeutics Reports Fiscal First Quarter 2014 Financial Results

- Enrollment Complete in EBI-005 Phase 2 Allergic Conjunctivitis Study -

Management to host conference call today at 8:30 am 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 and operational highlights for the quarter ended March 31, 2014.

"Eleven Biotherapeutics is off to a strong start in 2014," stated Abbie Celniker, President and Chief Executive Officer. "We are pleased to announce that we completed patient enrollment in the EBI-005 Phase 2 clinical trial for allergic conjunctivitis and are on-track to report top-line clinical data in the fourth quarter of 2014 as planned. In addition, our pivotal Phase 3 clinical study of EBI-005 in dry eye disease continues to enroll patients on schedule, and our plan to initiate a twelve-month safety study with EBI-005 is also on track for the second half of this year."

"Earlier this year, we completed our initial public offering, improving our balance sheet and attracting a number of new shareholders, and strengthened our leadership team with the appointments of ophthalmology industry veterans to our board and management team. We were also pleased by the interest of the medical and scientific community in the data we presented at a number of ophthalmology industry conferences this spring, including clinical data on EBI-005, the first IL-1 (Interleukin-1) signaling inhibitor designed for topical ocular administration, and preclinical data on EBI-029, an IL-6 (Interleukin-6) inhibitor optimized for localized ocular administration in diabetic macular edema."

First Quarter 2014 and Recent Business Highlights:

Pipeline:

- Initiated a pivotal Phase 3 clinical study with EBI-005 in dry eye disease with top-line results expected in early 2015.
- Initiated and completed patient enrollment in a Phase 2 clinical trial of EBI-005 for the treatment of allergic conjunctivitis with top-line results expected in the fourth quarter of 2014.
- Presented at a number of ophthalmology industry conferences including:
 - **Association for Research in Vision and Ophthalmology (ARVO) 2014 Annual Meeting**, at which Eleven Biotherapeutics researchers gave three poster presentations elaborating on Eleven's understanding of cytokine biology to target the treatment of front and back of eye diseases. These posters included clinical data on EBI-005 demonstrating improvements in signs and symptoms in patients with dry eye disease through IL-1 Inhibition, and preclinical data on EBI-029 demonstrating inhibition of IL-6 as a validated target for treating diabetic macular edema.
 - **2014 American Society of Cataract and Refractive Surgery (ASCRS) Annual Symposium**, at which Michael H. Goldstein, M.D., M.B.A., Eleven Biotherapeutics' Vice President of Clinical Research and co-director of the Cornea, External Disease and Cataract Service group at Tufts University/ New England Eye Center, presented Phase 1b/2a clinical data on Eleven's lead product candidate EBI-005 for the treatment of dry eye disease. Dr. Goldstein received the honor of a 'Best Paper in Session' award and was listed in Eye World Today and the ASCRS meeting newspaper.
 - **2014 Ophthalmology Innovation Summit (OIS) @ American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting**, at which Abbie Celniker participated in a session, along with other industry leaders, on the topic of dry eye disease. The participants in the session, who represented a cross section of industry and scientific thought leaders, discussed the role dry eye technologies and therapies play in ophthalmic practice.
 - **World Ophthalmology Congress (WOC) 2014**, at which Michael Goldstein, M.D., presented on the topic of IL-1 inhibition for dry eye disease and highlighted EBI-005 clinical data as a case study.
 - **10th Annual Protein and Engineering Summit (PEGS)**, at which Eleven Biotherapeutics researchers presented data demonstrating the power of Eleven's AMP-Rx platform to design and engineer novel protein therapeutics. Eleven's presentation topics included modulating cytokines to treat front and back of eye disease such as IL-1 inhibition with EBI-005, IL-6 inhibition with EBI-029 and IL-17 inhibition with EBI-028 and designing topical treatments of ocular surface inflammatory disorders, such as EBI-005, to have low immunogenicity potential.

Corporate:

- Completed our initial public offering, with aggregate net proceeds of approximately \$50.2 million, net of underwriting discounts and commissions and other offering expenses payable by us.
- Strengthened our leadership team with the appointment of ophthalmic industry veterans, including Paul Chaney as a member of our Board of Directors and Gary Sternberg, M.D., M.B.A., as Executive Vice President Corporate and Business Development.
- Added to the Russell Indexes on March 31, 2014, including the Russell 2000 and Russell 3000 index.

Upcoming Events and Presentations:

- Contact Lens Association of Ophthalmologists (CLAO), June 14, 2014
- International Society of Ophthalmologists (ISOPT), June 19-22, 2014

Financial Results

Revenues were \$0.6 million during the quarter ended March 31, 2014 compared to \$0 for the quarter ended March 31, 2013 and include amounts from the Thrombogenics collaboration which began in May 2013.

Total operating expenses for the quarter ended March 31, 2014 were \$7.8 million compared to \$5.4 million for the quarter ended March 31, 2013.

Net cash used in operating activities during the quarter ended March 31, 2014 was \$5.0 million compared to \$5.4 million for the quarter ended March 31, 2013. Eleven Biotherapeutics held \$54.0 million in cash and cash equivalents as of March 31, 2014. We have identified and are planning additional expenditures that we believe will enhance the likelihood of EBI-005's clinical and commercial success. A majority of these additional expenses will be contingent upon positive results from our first Phase 3 clinical study. If we make such expenditures, the Company expects to have sufficient cash and cash equivalents to fund current operations into the first quarter of 2016. This is an update from previous guidance in which cash was forecast to be sufficient into the second half of 2016.

Net loss applicable to common stockholders was \$7.7 million, or \$0.80 per share, for the quarter ended March 31, 2014, compared to net loss applicable to common stockholders of \$6.4 million, or \$5.14 per share, for the quarter ended March 31, 2013.

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 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 44137135.

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, which was designed, engineered and generated using the Company's AMP-Rx platform and is being developed as a topical treatment for dry eye disease and allergic conjunctivitis. In 2013, Eleven Biotherapeutics completed a Phase 1b/2a clinical trial of EBI-005 in patients with moderate to severe dry eye disease. The EBI-005 program is based on the role that elevated levels of the inflammatory cytokine interleukin-1, or IL-1, play in the initiation and maintenance of the inflammation and pain associated with dry eye disease and the redness and itching associated with allergic conjunctivitis. EBI-005 is currently being evaluated in a pivotal Phase 3 clinical study in subjects with dry eye disease and a Phase 2 clinical study in subjects with allergic conjunctivitis.

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.

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, 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 31, 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.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2014	2013
Collaboration revenue	\$ 568	\$ —
Operating expenses:		
Research and development	5,819	4,496
General and administrative	1,938	939
Total operating expenses	7,757	5,435
Loss from operations	(7,189)	(5,435)
Other income (expense):		
Other (expense) income, net	51	2
Interest expense	(84)	(79)
Total other expense, net	(33)	(77)
Net loss and comprehensive loss	\$ (7,222)	\$ (5,512)
Cumulative preferred stock dividends	(519)	(893)
Net loss applicable to common stockholders	\$ (7,741)	\$ (6,405)
Net loss per share applicable to common stockholders—basic and diluted	\$ (0.80)	\$ (5.14)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	9,635	1,247

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

March 31, December 31,
2014 2013

Assets		
Current assets:		
Cash and cash equivalents	\$ 53,964	\$ 7,942
Prepaid expenses and other current assets	443	88
Total current assets	54,407	8,030
Property and equipment, net	708	759
Restricted cash	94	94
Other assets	18	2,354
Total assets	\$ 55,227	\$ 11,237
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 3,070	\$ 1,746
Accrued expenses	457	850
Notes payable, current portion	1,642	1,642
Deferred revenue, current portion	1,134	1,115
Total current liabilities	6,303	5,353
Deferred revenue, net of current portion	223	355
Restricted stock liability	8	10
Notes payable, net of current portion	2,466	2,876
Warrant liability	-	297
Series A convertible preferred stock	-	45,035
Series B convertible preferred stock	-	11,643
Stockholders' equity (deficit):		
Common stock	16	2
Additional paid-in capital	111,027	3,260
Accumulated deficit	(64,816)	(57,594)
Total stockholders' equity (deficit)	46,227	(54,332)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 55,227	\$ 11,237

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