March 24, 2017

Eleven Biotherapeutics Reports Fourth Quarter and Full Year 2016 Financial Results

-- Advancing Late-Stage Targeted Protein Therapeutics Pipeline for Treatment of Cancers with High Unmet Medical Need --

-- Completed Integration of Viventia Bio --

-- Topline Phase 3 Data for Lead Drug Candidate Vicinium™, in Development for Non-Muscle Invasive Bladder Cancer, Expected in 2018 --

- Management to Host Conference Call Today at 8:00 a.m. ET -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Eleven Biotherapeutics, Inc. (NASDAQ:EBIO), a late-stage clinical oncology company advancing a broad pipeline of novel product candidates based on its Targeted Protein Therapeutics (TPTs) platform, today reported financial results for the fourth quarter and the full year ended December 31, 2016, and provided a corporate update.

"2016 was a transformative year for Eleven. Following our acquisition of Viventia Bio Inc. in September, we evolved into a late-stage clinical oncology company with a broad pipeline of TPTs, each designed to overcome the limitations of existing antibody drug conjugates (ADCs) and to provide patients with safer, more effective treatment options," said Stephen A. Hurly, President and Chief Executive Officer of Eleven Biotherapeutics. "In the year ahead, we plan to progress our ongoing Phase 3 registration clinical trial of Vicinium, initiate a Phase 1/2a clinical trial of Proxinium in combination with a checkpoint inhibitor and continue preclinical development of VB6-845d, the lead product candidate in our systemic pipeline. With $25.3 million in cash as of December 31, 2016, we expect to have sufficient funds to support our clinical and preclinical development efforts into early 2018."

Fourth Quarter and Recent Business Highlights and Anticipated Upcoming Milestones:

Vicinium™: Vicinium is a single protein anti-epithelial cell adhesion molecule (anti-EpCAM) protein fused with *Pseudomonas* Exotoxin A (ETA) designed to specifically target and deliver a potent anti-cancer payload directly into tumor cells. Vicinium is currently in a Phase 3 registration clinical trial for the treatment of high-grade non-muscle invasive bladder cancer (NMIBC) in subjects who have previously received two courses of Bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Eleven intends to enroll 134 subjects in the trial, including 77 subjects with carcinoma *in situ* (CIS), at over 65 centers in the United States and Canada. Primary and secondary endpoints include complete response (CR) rate in CIS subjects, time to disease recurrence and event free survival.

- Complete enrollment for Phase 3 registration clinical trial expected in second half of 2017
- Topline data from Phase 3 registration clinical trial expected in 2018

Proxinium™: Proxinium is a single protein anti-EpCAM antibody fragment fused with ETA for the treatment of late-stage squamous cell carcinoma of the head and neck (SCCHN). Phase 2 data showed observable reductions in target tumor size in 71% of evaluable subjects, as well as tumor growth control in 80% of evaluable subjects presenting with multiple tumors. By generating a host anti-tumor immune response, Proxinium has also demonstrated the potential to improve the efficacy of checkpoint inhibitors.

Proxinium has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), and Fast Track designation from the FDA.

- Initiation of Phase 1/2a clinical trial evaluating Proxinium in combination with a checkpoint inhibitor expected in the second half of 2017

Systemically-administered TPT Pipeline: Eleven's initial systemically-administered TPTs leverage a highly potent, de-immunized, plant toxin, deBouganin. DeBouganin has picomolar killing, has demonstrated multi-drug resistance avoidance, and may potentially induce an effect against cancer stem cells. Its safety profile based upon a prior clinical trial also provides a broad therapeutic window, which suggests deBouganin-based therapies may be effective against a wide spectrum of different cancers.

- Investigational New Drug Application (IND) submission planned for the first quarter of 2018.

Partnered Programs: In August 2016, Eleven completed an exclusive License Agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche) for its IL-6 antagonist antibody technology, including EBI-031. Eleven has received $30.0 million in payments from Roche, including a $7.5 million upfront payment and a $22.5 million milestone payment once the IND application for EBI-031 became effective. Roche has also agreed to pay up to an additional $240.0 million upon the achievement of specified regulatory, development and commercial milestones, the first of which is $20.0 million upon the initiation of the first Phase II clinical trial. In addition, Eleven is entitled to receive royalties based on net sales of potential future products containing EBI-031 or any other potential future products containing other IL-6 compounds.

Corporate: In September 2016, Eleven entered into a share purchase agreement and simultaneously acquired Viventia Bio Inc. (Viventia). Under the terms of the agreement, Eleven purchased all outstanding capital stock of Viventia in exchange for the issuance of 4,013,431 newly issued shares of Eleven common stock, which represented approximately 19.9% of the voting power of Eleven, as of immediately prior to the issuance of such shares, and the agreement by Eleven to pay selling shareholders certain post-closing contingent cash payments upon the achievement of specified milestones and based upon net sales of Vicinium.

Fourth Quarter and Full Year 2016 Financial Results:

- **Cash Position**: Cash and cash equivalents were $25.3 million as of December 31, 2016, compared to $36.1 million as of December 31, 2015, a decrease of $10.8 million, which was primarily driven by the repayment of the note payable partially offset by cash provided by operations.
- **Revenue**: Revenue was $0.8 million for the three months ended December 31, 2016, compared to $0.6 million for the same period in 2015. Revenue was $30.0 million for the twelve months ended December 31, 2016, compared to $1.0 million for the same period in 2015. This increase was related to revenue recognized from the License Agreement with Roche, which was partially offset by reduced fees under the former collaboration agreement with ThromboGenics N.V.
- **R&D Expenses**: Research and development expenses were $2.8 million for the three months ended December 31, 2016, compared to $8.1 million for the same period in 2015. The decrease was due primarily to a decrease of isunakinra-related development expenses, for which development activities are no longer ongoing, as well as decreases in EBI-031 related development expenses due to the License Agreement with Roche. These decreases were partially offset by increases in Vicinium-related development expenses. Research and development expenses were $13.5 million for the twelve months ended December 31, 2016, compared to $26.3 million for the same period in 2015.
- **G&A Expenses**: General and administrative expenses were $2.8 million for the three months ended December 31, 2016, compared to $2.3 million for the same period in 2015. This increase was due primarily to accounting and legal fees related to the integration of Viventia. General and administrative expenses were $14.7 million for the twelve months ended December 31, 2016, compared to $9.9 million for the same period in 2015.
- **Net Income (Loss)**: Net loss was $3.5 million, or $0.15 per share, for the three months ended December 31, 2016, compared to net loss of $10.3 million, or $0.53 per share, for the same period in 2015. Net income was $1.9 million, or $0.09 per share, for the twelve months ended December 31, 2016, compared to net loss of $33.5 million, or $1.76 per share, for the same period in 2015.
- **Financial Guidance:** Based on current operating plans, Eleven expects to have cash to fund research and development programs and operations into early 2018.

Upcoming Events and Presentations:

- American Association for Cancer Research (AACR) Annual Meeting, April 1-5, 2017 in Washington D.C.
- Protein Engineering Summit, May 1-5, 2017 in Boston, Massachusetts.

Conference Call Information:

Eleven Biotherapeutics' management team will host a conference call and audio webcast today at 8:00 a.m. ET to discuss the fourth quarter and full 2016 financial results and provide a corporate update. To access the conference call, please dial (844) 831-3025 (domestic) or (973) 638-3081 (international) at least five minutes prior to the start time and refer to conference ID 83715570.

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 Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a late-stage clinical oncology company advancing a broad pipeline of novel product candidates based upon the Company's TPT platform. The Company's TPTs incorporate a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule in order to achieve focused tumor cell killing. The Company believes its TPT approach offers significant advantages in treating cancer over existing ADC technologies. The Company believes its TPTs provide effective tumor targeting with broader cancer cell-killing properties than are achievable with small molecule payloads that require tumor cell proliferation and face multi-drug resistance mechanisms. Additionally, the Company believes that its TPT's cancer cell-killing properties promote an anti-tumor immune response that will potentially combine well with immune oncology drugs such as checkpoint inhibitors. For more information please refer to the Company's website at www.elevenbio.com.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, 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 occurrence of any event change or other circumstances that could give rise to the termination of the License Agreement, the uncertainties inherent in receiving future payments pursuant to the License Agreement, the uncertainties inherent in the initiation and conduct of clinical trials, our ability to successfully develop our product candidates and complete our planned clinical programs, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical trials, availability and timing of data from clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical studies will be indicative of the results of future studies, the adequacy of any clinical models, expectations regarding regulatory approvals, our ability to obtain, maintain and protect our intellectual property for our technology and products, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, other matters that could affect the financial performance of the Company, other matters that could affect the availability or commercial potential of the Company's product candidates and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed 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 CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Total revenue	$ 825	$ 565	$ 29,981	$ 990
Operating expenses:				
Research and development	2,795	8,084	13,479	26,336
General and administrative	2,752	2,319	14,736	9,850
(Gain) loss from change in fair value of contingent consideration	(1,100)	-	(1,100)	-
Total operating expenses	4,447	10,403	27,115	36,186
Income (loss) from operations	(3,622)	(9,838)	2,866	(35,196)
Other income (expense), net	96	(491)	(970)	1,744
Net income (loss) before income taxes	(3,526)	(10,329)	1,896	(33,452)
Provision for income taxes	5	-	5	-
Net income (loss)	$ (3,531)	$ (10,329)	$ 1,891	$ (33,452)

Net income (loss) per share —basic	$ (0.15)	$ (0.53)	$ 0.09	$ (1.76)
Weighted-average number of common shares used in net income (loss) per share —basic	24,296	19,547	21,083	18,993
Net income (loss) per share —diluted	$ (0.15)	$ (0.53)	$ 0.09	$ (1.76)
Weighted-average number of common shares used in net income (loss) per share —diluted	24,296	19,547	21,733	18,993

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

	December 31,	
	2016	**2015**
Assets		
Current assets:		
Cash and cash equivalents	$ 25,342	$ 36,079
Prepaid expenses and other current assets	585	232
Total current assets	25,927	36,311
Property and equipment, net	796	407
Restricted cash	10	94
Intangible assets	60,500	-
Goodwill	16,864	-
Other assets	-	13
Total assets	$ 104,097	$ 36,825
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,667	$ 1,246
Accrued expenses	1,774	1,794
Deferred revenue	425	406
Due to related party	114	-
Notes payable, current portion	-	4,134
Total current liabilities	3,980	7,580
Other liabilities	-	423
Notes payable, net of current portion	-	9,763
Warrant liability	5	115
Deferred tax liability	16,335	-
Contingent consideration	45,100	-
Stockholders' equity:		
Common stock	25	20
Additional paid-in capital	161,963	144,126
Accumulated deficit	(123,311)	(125,202)
Total stockholders' equity	38,677	18,944
Total liabilities and stockholders' equity	$ 104,097	$ 36,825

View source version on businesswire.com: http://www.businesswire.com/news/home/20170324005095/en/

Stern Investor Relations
Hannah Deresiewicz, 212-362-1200
hannahd@sternir.com

Source: Eleven Biotherapeutics, Inc.