



Eleven Biotherapeutics Reports Third Quarter 2017 Financial Results

November 20, 2017

-- Phase 3 Enrollment on Track to Complete in Q1 2018 --

-- Topline 3-Month Data from Phase 3 Trial of Vicinium™ on Track for Mid-2018 --

-- Strengthened Balance Sheet with \$8.0 million Capital Raise --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 20, 2017-- Eleven Biotherapeutics, Inc. (NASDAQ:EBIO), a late-stage clinical oncology company advancing novel product candidates based on its Targeted Protein Therapeutics (TPTs) platform, today reported financial results for the quarter ended September 30, 2017.

"I am very pleased with our progress this quarter. In addition to strengthening our balance sheet with a successful public offering in November, we also made strong progress during this quarter on our Phase 3 clinical trial examining Vicinium™ in patients with non-muscle invasive bladder cancer (NMIBC)," said Stephen Hurly, President and Chief Executive Officer of Eleven Biotherapeutics. "We are driving our Phase 3 enrollment forward and expect to achieve full enrollment in Q1 2018. The Company also remains on track to report top-line three-month data from our registration trial in mid-2018 with sufficient capital to carry us through this critical milestone. Also, we are excited that the combination trial of Vicinium™ and durvalumab, Astra Zeneca's checkpoint inhibitor, has opened at the National Cancer Institute and we will be gathering immune biomarker data that we believe will provide insight into the complementary mechanism of action between checkpoint inhibitors and our TPT platform."

Third Quarter Results, Recent Business Highlights and Anticipated Upcoming Milestones:

Vicinium™ is a single protein anti-epithelial cell adhesion molecule (anti-EpCAM) antibody fragment fused with Pseudomonas Exotoxin A (ETA) that is 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 NMIBC in subjects who have previously received two courses of Bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. The company also has a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) evaluating Vicinium™ in combination with AstraZeneca's checkpoint inhibitor, durvalumab.

- In September, the Company announced completion of the manufacturing of Vicinium™ necessary for the ongoing Phase 3 registration trial in patients with NMIBC, and the CRADA trial with the NCI.
- Completion of enrollment for the Phase 3 registration clinical trial of Vicinium™ is expected in the first quarter of 2018.
- Topline three-month data from the Phase 3 registration clinical trial of Vicinium™ is expected mid-2018 and topline twelve-month data is expected in the second quarter of 2019.
- Initiation of a Phase 1 trial of Vicinium™ and durvalumab through the NCI CRADA will collect immune response biomarker data in patients with NMIBC and is expected to commence in the fourth quarter of 2017, with initial biomarker data expected in the third quarter of 2018.

Corporate:

- In October, the Company announced the appointment of Richard F. Fitzgerald as Interim Chief Financial Officer, adding extensive capital raising and transaction execution experience to Eleven's management team.
- In November, the Company completed a public offering of 5,525,000 shares of its common stock, pre-funded warrants to purchase an aggregate of 4,475,000 shares of common stock, and common warrants to purchase up to an aggregate of 10,000,000 shares of common stock, raising approximately \$8.0 million in gross proceeds and \$7.0 million in net proceeds, after deducting underwriting discounts and commissions and estimated expenses payable by the Company.

TPT Pipeline:

Eleven's pipeline includes additional locally delivered product candidates, as well as a systemic TPT platform.

- Proxinium™ is a single protein anti-EpCAM antibody fragment fused with ETA for the treatment of late-stage, EpCAM-expressing, recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). In Phase 1 and 2 clinical trials, Proxinium™ demonstrated anti-tumor activity in both injected as well as un-injected tumors. The Company plans to evaluate Proxinium™ in a Phase 1/2a clinical trial in combination with a checkpoint inhibitor and is actively seeking partners for a combination program.
- VB6-845d is a systemically-administered TPT utilizing a proprietary, highly potent, de-immunized plant toxin, deBouganin, for the treatment of solid tumors. The Company plans to file an investigational new drug (IND) application for VB6-845d and initiate a Phase 1 trial, once funding or a partner is secured for this program.

The Company has deferred further development of Proxinium™ and VB6-84d in order to focus its efforts and resources on the advancement of its Phase 3 registration trial of Vicinium™. The Company is also exploring partnering and collaboration strategies to move these additional product candidates forward.

Third Quarter 2017 Financial Results:

- **Cash Position:** Cash and cash equivalents were \$11.3 million as of September 30, 2017, compared to \$25.3 million as of December 31, 2016. These amounts do not include the approximately \$7.0 million of net proceeds from the Company's November 2017

- public offering.
- **Revenue:** Eleven did not record any revenue for the three months ended September 30, 2017, compared to revenue of \$28.7 million for the same period in 2016. This decrease was due to revenue recognized in 2016 from the Company's License Agreement with Roche. The next licensing milestone payment expected from Roche, if any, will be triggered upon commencement of a Phase 2 clinical trial by Roche.
 - **R&D Expenses:** Research and development expenses were \$3.6 million for the three months ended September 30, 2017, compared to \$2.8 million for the same period in 2016. This increase was primarily due to higher costs incurred for the Company's ongoing Phase 3 clinical trial for NMIBC that were partially offset by the absence of costs associated with the product candidate licensed to Roche in 2016 and lower compensation related costs.
 - **G&A Expenses:** General and administrative expenses were \$1.6 million for the three months ended September 30, 2017, compared to \$6.4 million for the same period in 2016. This decrease was driven primarily by a reduction in severance, retention and stock-based compensation and professional fees related to the Company's 2016 review of strategic alternatives and the acquisition of Viventia Bio, Inc.
 - **Net Loss:** Net loss was \$9.1 million, or \$0.37 per basic and diluted share, for the three months ended September 30, 2017, compared to net income of \$19.5 million, or \$0.95 per basic share and \$0.91 per diluted share, for the same period in 2016. The change was primarily the result of revenue recognized in 2016 from the Company's License Agreement with Roche.
 - **Financial Guidance:** Based on current operating plans, the Company anticipates that cash at September 30, 2017, plus the net \$7.0 million raised in November 2017, will fund research and development programs and operations into mid-2018.

About Eleven Biotherapeutics:

Eleven Biotherapeutics, Inc. is a late-stage, clinical oncology company advancing novel product candidates based upon the Company's targeted protein therapeutics (TPTs) platform. The Company's TPTs incorporate a tumor-targeting antibody fragment and a cytotoxic protein payload within 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 antibody drug conjugate technologies. The Company believes its TPTs provide effective tumor targeting with broader cancer cell-killing properties than generally achievable with small molecule cytotoxic payloads that require tumor cell proliferation to be effective and can face challenges overcoming multi-drug resistance mechanisms within tumor cells. 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 (License Agreement) with F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc., 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, the Company's projected use of proceeds from its November 2017 public offering, 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 AND COMPREHENSIVE INCOME (LOSS)
(unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Total revenue	\$ -	\$ 28,650	\$ 425	\$ 29,156
Operating expenses:				
Research and development	3,619	2,754	9,402	10,684
General and administrative	1,631	6,366	6,085	11,984
Loss from change in fair value of contingent consideration	3,900	-	7,600	-
Total operating expenses	9,150	9,120	23,087	22,668

(Loss) income from operations	(9,150)	19,530	(22,662)	6,488
Other income (expense), net	45	(43)	180	(1,066)
Net (loss) income and comprehensive (loss) income	\$ (9,105)	\$ 19,487	\$ (22,482)	\$ 5,422
Net (loss) income per share —basic	\$ (0.37)	\$ 0.95	\$ (0.91)	\$ 0.27
Weighted-average number of common shares used in net (loss)				
income per share —basic	24,691	20,495	24,663	20,004
Net (loss) income per share —diluted	\$ (0.37)	\$ 0.91	\$ (0.91)	\$ 0.26
Weighted-average number of common shares used in net (loss)				
income per share —diluted	24,691	21,423	24,663	20,796

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

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,338	\$ 25,342
Prepaid expenses and other current assets	770	585
Total current assets	12,108	25,927
Property and equipment, net	585	796
Restricted cash	10	10
Intangible assets	46,400	60,500
Goodwill	13,064	16,864
Other assets	101	-
Total assets	\$ 72,268	\$ 104,097
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,366	\$ 1,667
Accrued expenses	2,915	1,774
Deferred revenue	-	425
Due to related party	123	114
Total current liabilities	4,404	3,980
Other liabilities	170	-
Warrant liability	-	5
Deferred tax liability	12,528	16,335
Contingent consideration	38,100	45,100
Stockholders' equity:		
Common stock	25	25
Additional paid-in capital	162,825	161,963
Accumulated deficit	(145,784)	(123,311)
Total stockholders' equity	17,066	38,677
Total liabilities and stockholders' equity	\$ 72,268	\$ 104,097

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Stern Investor Relations, Inc.
Michael Schaffzin, 212-362-1200
michael@sternir.com