Eleven Biotherapeutics Reports First Quarter Financial Results and Pipeline Updates

May 15, 2018

Company to Host Conference Call in Conjunction with AUA Presentation on May 21, 2018

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 15, 2018-- Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a late-stage clinical company developing next-generation antibody-drug conjugate (ADC) therapies for the treatment of cancer, today reported pipeline updates and operating results for the quarter ended March 31, 2018.

“2018 is set to be a transformational year for the company and, already in the first quarter, we have made important progress in advancing our lead program, Vicinium™, for high-grade non-muscle invasive bladder cancer, or NMIBC,” said Stephen Hurly, president and chief executive officer of Eleven Biotherapeutics. “Our Phase 3 registration trial, the VISTA Trial, investigating Vicinium for patients with high-grade NMIBC, is progressing well and recently completed enrollment. We look forward to presenting three-month data from the trial in an oral presentation at the American Urological Association Annual Meeting on May 21st, a significant catalyst for the company and our Vicinium program. High-grade NMIBC is a disease for which there is a desperate need for new treatment options, and we look forward to further exploring Vicinium as a potential treatment for these patients.”

Pipeline Progress and Updates

- Eleven Biotherapeutics will present three-month data from its ongoing Phase 3 VISTA Trial, which is evaluating Vicinium for the treatment of patients with high-grade NMIBC who have been previously treated with bacillus Calmette-Guérin (BCG). The data will be presented during a plenary session on Monday, May 21, 2018 at 11:00 a.m. PDT at the American Urological Association Annual Meeting being held in San Francisco. In March 2018, the company announced enrollment completion in the VISTA Trial.
- In April 2018, Eleven Biotherapeutics presented preclinical data from its deBouganin program at the 2018 American Association for Cancer Research Annual Meeting. DeBouganin is a potent deimmunized plant-based toxin designed for systemic use in the treatment of cancer and other indications. The data presented suggest that VB6-845d, a next generation ADC that is composed of an anti-EpCAM antibody fragment fused to deBouganin, mediates tumor cell killing by an immunogenic cell death (ICD) pathway. The potential cross-priming effect initiated by VB6-845d-induced ICD suggests that VB6-845d in combination with immune checkpoint inhibitors may enhance their effectiveness in EpCAM-positive epithelial cancers. Additionally, in collaboration with Crescendo Biologics, the company presented data demonstrating that a potent fusion protein comprised of the company’s deBouganin payload and Crescendo’s Humabody® is expressible as a soluble protein in E. coli supernatant and capable of potent killing of cancer cell lines.

First Quarter 2018 Financial Results

- **Cash Position:** Cash and cash equivalents were $19.7 million as of March 31, 2018, compared to $20.3 for the same period in 2017.
- **Revenue:** There was no revenue for the quarter ended March 31, 2018, compared to $0.4 million for the same period in 2017. The decrease was due to a reduction in revenue recognized from the company’s license agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche).
- **R&D Expenses:** Research and development expenses were $3.3 million for the quarter ended March 31, 2018, compared to $2.9 million for the same period in 2017. The increase was due primarily to increases in clinical costs.
- **G&A Expenses:** General and administrative expenses were $2.0 million for the quarter ended March 31, 2018, compared to $2.2 million for the same period in 2017. The decrease was due primarily to reductions in legal and professional costs.
- **Net Loss:** Net loss was $4.0 million, or $0.11 per share, for the quarter ended March 31, 2018, compared to net loss of $6.1 million, or $0.25 per share, for the same period in 2017. The decrease was due primarily to the change in the fair value of contingent consideration.
- **Financial Guidance:** Following Eleven Biotherapeutics’ $10.0 million financing in March 2018 and receipt of approximately $4.2 million from the exercise of common stock warrants through mid-May, the company maintains it will have capital to fund its current operating plans into early 2019.

Conference Call Information

The company will host a conference call on May 21, 2018 at 5 p.m. ET to review the data being presented at AUA. To participate in the conference call, please dial (844) 831-3025 (domestic) or (315) 625-6887 (international) and refer to conference ID 4453267. The webcast can be accessed in the Investor Relations section of the company's website at www.elevenbio.com. The replay of the webcast will be available in the investor section of the company’s website at www.elevenbio.com for 60 days following the call.

About Vicinium™

Vicinium™, also known as VB4-845, is Eleven Biotherapeutics’ lead product candidate and is a next-generation antibody-drug conjugate (ADC), developed using the company’s proprietary Targeted Protein Therapeutics platform, for the treatment of high-grade non-muscle invasive bladder cancer (NMIBC). Vicinium is comprised of a recombinant fusion protein that targets epithelial cell adhesion molecule (EpCAM) antigens on the surface of tumor cells to deliver a potent protein payload, *Pseudomonas* Exotoxin A (ETA). Vicinium is constructed with a stable, genetically engineered peptide linker to ensure the payload remains attached until it is internalized by the cancer cell, which is believed to decrease the risk of toxicity to healthy tissues, thereby improving its safety. In prior clinical studies conducted by Eleven Biotherapeutics, EpCAM has been shown to be overexpressed in NMIBC cells with minimal to no EpCAM expression observed on normal bladder cells. Eleven Biotherapeutics is currently conducting the Phase 3 VISTA Trial, designed to support the registration of Vicinium for the treatment of high-

grade NMIBC in patients who have previously received two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Three-month data from the ongoing trial are planned for presentation at the 2018 American Urological Association Annual Meeting on May 21, 2018, with 12-month data anticipated in mid-2019. Additionally, Eleven Biotherapeutics believes that Vicinium's cancer cell-killing properties promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicinium in BCG-unresponsive NMIBC is also being explored at the US National Cancer Institute in combination with AstraZeneca's immune checkpoint inhibitor durvalumab.

About Eleven Biotherapeutics
Eleven Biotherapeutics, Inc. is a late-stage clinical company advancing next-generation antibody-drug conjugate therapies for the treatment of cancer based on the company's Targeted Protein Therapeutics platform. The company's lead program, Vicinium™, also known as VB4-845, is currently in a Phase 3 registration trial, the VISTA Trial, for the treatment of high-grade non-muscle invasive bladder cancer. Three-month results from the VISTA Trial are planned for presentation at the 2018 American Urological Association Annual Meeting on May 21, 2018, with 12-month data anticipated in mid-2019. Vicinium incorporates a tumor-targeting antibody fragment and a protein cytotoxic payload into a single protein molecule designed to selectively and effectively kill cancer cells while sparing healthy cells. For more information, please visit 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 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; expectations regarding the adequacy of our existing capital resources to fund our operations through early 2019; our ability to obtain additional capital to continue to fund operations 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 BALANCE SHEETS
(unaudited)
(in thousands)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 19,688	$ 14,680
Prepaid expenses and other current assets	638	301
Total current assets	20,326	14,981
Property and equipment, net	473	522
Restricted cash	10	10
Intangible assets	46,400	46,400
Goodwill	13,064	13,064
Other assets	19	120
Total assets	$ 80,292	$ 75,097
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,393	$ 907
Accrued expenses	3,853	3,813
Total current liabilities	5,246	4,720
Other liabilities	260	215
Deferred tax liability	12,528	12,528
Contingent consideration	38,400	39,600
Stockholders' equity:		
Common stock	43	35
Additional paid-in capital	180,109	170,330
Accumulated deficit	(156,294)	(152,331)
Total stockholders' equity	23,858	18,034
Total liabilities and stockholders' equity	$ 80,292	$ 75,097

ELEVEN BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2018	2017
Total revenue	$ -	$ 425
Operating expenses:		
Research and development	3,255	2,874
General and administrative	1,952	2,213
(Gain) loss from change in fair value of contingent consideration	(1,200)	1,500
Total operating expenses	4,007	6,587
Loss from operations	(4,007)	(6,162)
Other income, net	44	101
Net loss and comprehensive loss	$ (3,963)	$ (6,061)
Net loss per share —basic and diluted	$ (0.11)	$ (0.25)
Weighted-average number of common shares used in net loss per share —basic and diluted	35,674	24,610

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Source: Eleven Biotherapeutics, Inc.

THRUST
Monique Allaire, 617-895-9511
monique@thrustir.com
or
Alicia Davis, 910-620-3302
alicia@thrustir.com