

## **Lion Biotechnologies Reports Fourth Quarter and Full-Year 2016 Financial Results and Provides Corporate Update**

March 7, 2017 6:39 AM ET

### **Company to Host Conference Call at 4:30pm ET Today**

SAN CARLOS, CA -- (Marketwired) -- 03/07/17 --

Lion Biotechnologies, Inc. (NASDAQ: LBIO), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported its fourth quarter and full-year 2016 financial results and provided a corporate update.

"During the second half of 2016, we significantly expanded our employee base, optimized the process of manufacturing TIL while increasing our capacity, continued enrollment in our LN-144 melanoma study and initiated start up activities for cervical and head and neck indications. In addition, we expanded our available data through further collaborations with the NCI and Moffitt Cancer Center and we shared some of our preliminary process development data at SITC in the later part of 2016," said Dr. Maria Fardis, Chief Executive Officer of Lion Biotechnologies. "Our 2017 priorities include implementing our newly developed shorter manufacturing process at our contract manufacturing facilities, expanding our clinical program in melanoma to examine the new process, and initiating two company-sponsored trials. We will also start at least two other clinical trials through collaborators in order to investigate the efficacy of TIL in new indications. Simultaneously, we will define our melanoma regulatory path with multiple health authorities and present clinical data at upcoming medical forums."

#### ***Recent Highlights***

##### ***Corporate Leadership:***

##### ***Strengthened the Management Team and More Than Doubled the Employee Base Since June 1, 2016:***

- ***Iain Dukes, D.Phil. joined the Company's Board of Directors as chairman of the board in August 2016. Iain Dukes was formerly senior vice president, business development and licensing at Merck & Co. and currently is a Venture Partner at OrbiMed Advisors LLC***
- ***Wayne Rothbaum was appointed to the Company's Board of Directors on June 7, 2016. Wayne Rothbaum is currently president and managing member of Quogue Capital, LLC.***
- ***Maria Fardis, Ph.D., appointed as the Company's President and Chief Executive Officer and added as a new member of the Board of Directors in June 2016***
- ***Greg Schiffman, appointed as the Company's Chief Financial Officer in October 2016***
- ***The Company increased its headcount from approximately 20 employees at June 1, 2016 to 51 employees at December 31, 2016***

##### ***2016 Achievements:***

- ***Manufacturing Services Agreement (MSA) with WuXi AppTec for increased production capacity: In November 2016, the Company entered into a new three-year MSA with WuXi AppTec, Inc., a leading global contract researcher for many of the world's largest pharmaceutical, biotech and medical device companies. This agreement significantly increases the Company's production capacity to support both late-stage clinical development and commercial demands.***
- ***Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) extended five years: In August 2016, the Company entered into the second amendment of its CRADA with the NCI, for research and development related to an adoptive cell therapy utilizing TIL in the treatment of metastatic***

*melanoma. The amendment extended the term of the CRADA by five years to August 2021 and modified the focus on the development of TIL as a stand-alone therapy or in combination with FDA-licensed products and commercially available reagents routinely used for adoptive cell therapy.*

- *Sponsored Research and Clinical Grant Agreements with H. Lee Moffitt Cancer Center and Research Institute for TIL combination therapy trial: In December 2016, the Company entered into a new three-year Sponsored Research Agreement with the H. Lee Moffitt Cancer Center and Research Institute. The Company also entered into a Clinical Grant Agreement with the H. Lee Moffitt Cancer Center and Research Institute Hospital to support an ongoing clinical trial at Moffitt that combines TIL therapy with nivolumab for the treatment of patients with metastatic melanoma.*
- *Insight into process development and research activities were provided via scientific presentations at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2016: Several presentations related to the Company's TIL technology were made at SITC detailing the feasibility of growing TIL from non-melanoma solid tumors and development of TIL therapies for other solid tumors, evaluation of artificial antigen presenting cells (aAPC) as a potential substitute for allogeneic peripheral blood mononuclear cells (PBMC), addressing the need to assess lytic potential of TILs and the effect of cryopreservation on the measured phenotypic characteristics of TIL. In addition, Lion has been selected for a presentation at the upcoming American Association for Cancer Research (AACR) meeting as a poster titled 'Emigrant pre-REP tumor infiltrating lymphocytes profoundly differ from remnant T-cells.'*
- *License with PolyBioCept AB and related Clinical Trials Agreement with Karolinska University Hospital for cytokine cocktail, TIL manufacturing and two clinical trials to start in 2017: In September 2016, the Company entered into an Exclusive License Agreement with PolyBioCept AB, a Swedish corporation, for a cytokine cocktail for use in the expansion of lymphocytes. The Company received the exclusive right and license to PolyBioCept's intellectual property to develop, manufacture, market and genetically engineer TIL produced by expansion, selection and enrichment using a cytokine cocktail. The Company also received a co-exclusive license (with PolyBioCept) to develop, manufacture and market genetically engineered TIL under the same intellectual property. Under a related clinical trials agreement, Lion will fund two clinical studies in glioblastoma and pancreatic cancer to be conducted at the Karolinska University Hospital in which TIL is manufactured using the licensed combination of cytokines. Both Phase 1 trials are expected to begin in 2017.*

#### *2017 Anticipated Milestones:*

##### *Clinical: Trials:*

- *Enrollment in LN-144 Phase 2 melanoma study continues: Lion is expanding the LN-144 Phase 2 trial in melanoma to include two new cohorts of patients. One cohort of patients will receive TIL from the Company's new shorter manufacturing process, while the other added cohort will allow for re-treatment of melanoma patients. Lion plans to present interim data from this study at an upcoming medical meeting.*
- *Two additional programs to enter Phase 2 in 2017: The Company is initiating two Phase 2 trials for LN-145 for the treatment of head and neck and cervical cancers in 2017.*
- *Karolinska University Hospital to initiate two Phase 1 clinical trials: Karolinska University Hospital has agreed to initiate Phase 1 clinical trials in both glioblastoma and pancreatic cancer using TIL manufactured with a new combination of cytokines developed by researchers at the Karolinska Institute.*

##### *Regulatory:*

- *Define the regulatory approval pathway for TIL in melanoma: The Company plans to hold discussions with health authorities to gain clarity around the regulatory requirements for approval of LN-144, Lion lead*

*melanoma drug candidate currently in Phase 2 development.*

**Partnerships:**

- *Pipeline expansion through additional partnerships: Lion intends to continue expansion of its pipeline through internally conducted studies as well as through current and potentially additional partnerships.*

**Fourth Quarter and Full-Year 2016 Financial Results**

*As of December 31, 2016 the Company held \$166.5 million in cash and cash equivalents and short-term investments, compared to \$103.7 million as of December 31, 2015.*

**GAAP and Non-GAAP net loss attributable to common stockholders**

*GAAP net loss attributable to common stockholders for the quarter ended December 31, 2016 was \$15.7 million, or (\$0.25) per share, compared to GAAP net loss attributable to common stockholders of \$8.4 million or (\$0.17) per share for the quarter ended December 31, 2015.*

*Non-GAAP net loss attributable to common stockholders, which excludes amounts related to stock-based compensation, for the quarter ended December 31, 2016 was \$12.6 million, or (\$0.20) per share, compared to non-GAAP net loss attributable to common stockholders of \$5.6 million, or (\$0.11) per share for the quarter ended December 31, 2015. The non-GAAP net loss attributable to common stockholders for the quarter ended December 31, 2016 excludes \$3.1 million of non-cash stock-based compensation.*

*GAAP net loss attributable to common stockholders for the year ended December 31, 2016, which included a one-time deemed dividend related to a charge of \$49.5 million incurred as a result of the conversion feature of the recently issued Series B convertible preferred stock was \$102.3 million, or (\$1.85) per share, compared to GAAP net loss attributable to common stockholders of \$27.7 million or (\$0.62) per share for the year ended December 31, 2015. Non-GAAP net loss, which excludes amounts related to stock-based compensation and the \$49.5 million non-cash deemed dividend for the year ended December 31, 2016 was \$34.0 million, or (\$0.62) per share, compared to non-GAAP net loss of \$19.1 million or (\$0.43) per share for the year ended December 31, 2015.*

*The Company believes that it is important for investors to understand these non-cash charges as they materially impact the loss and EPS calculations. See "Use of Non-GAAP Financial Measures" below for a description of the Company's Non-GAAP Financial Measures. Reconciliation between certain GAAP and Non-GAAP measures is provided at the end of this press release.*

**GAAP and Non-GAAP expenses**

*GAAP research and development (R&D) expenses were \$10.9 million for the quarter ended December 31, 2016, an increase of \$6.8 million compared to the quarter ended December 31, 2015. The increase in R&D expense is due to increased spending on clinical activities for LN-144 and manufacturing. In addition, R&D-associated stock option expenses were \$1.4 million for the three months ended December 31, 2016 and \$3.3 million for the year ended December 31, 2016. Non-GAAP R&D expenses were \$9.5 million for the quarter ended December 31, 2016, an increase of \$5.6 million, compared to \$3.9 million for the quarter ended December 31, 2015.*

*GAAP general and administrative (G&A) expenses were \$5.0 million, an increase of \$0.6 million compared to the quarter ended December 31, 2015. Non-GAAP G&A expenses, which excludes amounts related to stock-based compensation, of \$3.3 million for the quarter ended December 31, 2016 increased by \$1.4 million, compared to \$1.9 million for the quarter ended December 31, 2015.*

*Reconciliation between certain GAAP and Non-GAAP measures is provided at the end of this press release.*

## *Use of Non-GAAP Financial Measures*

*This press release contains non-GAAP financial measures, including expenses adjusted to exclude certain non-cash expenses. These measures are not in accordance with, or an alternative to, generally accepted accounting principles, or GAAP, and may be different from non-GAAP financial measures used by other companies. The items included in GAAP presentations but excluded for purposes of determining non-GAAP financial measures for the periods presented in this press release are: (i) the non-cash stock-based compensation expense which may fluctuate from period to period based on factors including the timing and accounting of grants for stock options and changes in the Company's stock price which impacts the fair value of options granted, and (ii) the one-time non-cash deemed dividend related to the conversion feature of the Series B Preferred Stock. The Company believes the presentation of non-GAAP financial measures provides useful information to management and investors regarding various financial and business trends relating to the Company's financial condition and results of operations. When GAAP financial measures are viewed in conjunction with non-GAAP financial measures, investors are provided with a more meaningful understanding of Lion's ongoing operating performance. In addition, these non-GAAP financial measures are among those indicators the Company uses as a basis for evaluating operational performance, allocating resources and planning and forecasting future periods. Non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP financial measures. To the extent this release contains historical or future non-GAAP financial measures, the Company has also provided corresponding GAAP financial measures for comparative purposes. Reconciliation between certain GAAP and non-GAAP measures is provided at the end of this press release.*

## *Upcoming Events & Presentations*

- *Cowen and Company 37<sup>th</sup> Annual Health Care Conference, Boston, Massachusetts, March 6-8, 2017*
- *29th Annual ROTH Conference Health Care Conference, Orange County, California, March 12-15, 2017*

## *Webcast and Conference Call*

*Lion will host a conference call today at 4:30 p.m. ET to discuss these fourth quarter and full-year 2016 results. In order to participate in the conference call, please dial 1-844-646-4465 (domestic) or 1-615-247-0257 (international). The live webcast can be accessed under "Events and Presentation" in the "Investors" section of the Company's website at <http://www.lbio.com/> or you may use the link: <http://edge.media-server.com/m/p/usbgqbbo>.*

*A replay of the call will be available one hour after the end of the call on March 7, 2017 until 4:30 p.m. ET on March 17, 2017. To access the replay, please dial 1-855-859-2056 (domestic) or 1-404-537-3406 (international) and reference the access code 75631507. The archived webcast will be available for thirty days in the Investors section of Lion Biotechnologies' website at <http://www.lbio.com>.*

## *About Lion Biotechnologies, Inc.*

*Lion Biotechnologies, Inc. is a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. The Company's lead product candidate is an adoptive cell therapy using tumor-infiltrating lymphocyte (TIL) technology for the treatment of patients with refractory metastatic melanoma. The Company is also pursuing TIL technology in both head and neck and cervical cancer indications. For more information, please visit <http://www.lionbio.com>.*

## *Forward-Looking Statements*

*This press release contains "forward-looking statements" regarding, among other things, the Company's future goals, its operating and financial performance, additional studies and product development, expansion of the company's research platform, and market position and business strategy. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate, or if known or unknown risks or uncertainties materialize, actual results could vary materially from the*

*expectations and projections. Risks and uncertainties include, but are not limited to, the Company's ability to implement the newly developed shorter manufacturing process, initiate a Phase 2 trial for LN-145 in 2017, its ability to continue to enroll patients in the Phase 2 trial for LN-144, the initiation in 2017 by the Karolinska University Hospital of two Phase 1 trials and the conduct thereafter of those trials, the further development of TIL under the CRADA. A further list and description of these and other risks, uncertainties and other factors can be found in Lion Biotechnologies, Inc. most recent Annual Report on Form 10-K and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov) or [www.lionbio.com](http://www.lionbio.com). Any forward-looking statement made in this release speaks only as of the date of this release. Lion Biotechnologies, Inc. does not undertake to update any forward-looking statements as a result of new information or future events or developments.*

**Lion Biotechnologies, Inc.**  
**Selected Balance Sheet Data**  
(unaudited; in thousands)

		<i>December 31,</i> <i>2016</i>		<i>December 31,</i> <i>2015</i>
Cash, cash equivalents and short-term investments	\$	166,470	\$	103,700
Total assets	\$	171,886	\$	105,653
Stockholders' equity	\$	166,918	\$	104,023

**Condensed Statements of Operations**  
(unaudited; in thousands, except per share data)

	<i>For the Three Months Ended</i>		<i>Year Ended December 31,</i>	
	<i>December 31,</i>	<i>December 31,</i>	<i>2016</i>	<i>2015</i>
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
<b>Revenues</b>	\$ -	\$ -	\$ -	\$ -
<b>Costs and expenses*</b>				
Research and development	10,901	4,057	28,037	15,470
General and administrative	5,022	4,422	25,602	12,390
Total costs and expenses	<u>15,923</u>	<u>8,479</u>	<u>53,639</u>	<u>27,860</u>
<b>Loss from operations</b>	(15,923)	(8,479)	(53,639)	(27,860)
<b>Other income</b>				
Interest income	234	119	745	200
<b>Net Loss</b>	<u>\$ (15,689)</u>	<u>\$ (8,360)</u>	<u>\$ (52,894)</u>	<u>\$ (27,660)</u>
Deemed dividend related to beneficial conversion feature of convertible preferred stock	-	-	(49,454)	-
<b>Net loss Attributable to Common Stockholders</b>	<u>\$ (15,689)</u>	<u>\$ (8,360)</u>	<u>\$ (102,348)</u>	<u>\$ (27,660)</u>

<b>Net Loss Per Common Share, Basic and Diluted</b>	\$ <u>(0.25)</u>	\$ <u>(0.17)</u>	\$ <u>(1.85)</u>	\$ <u>(0.62)</u>
<b>Weighted-Average Common Shares Outstanding, Basic and Diluted</b>	<u>62,130</u>	<u>47,912</u>	<u>55,268</u>	<u>44,410</u>
<b>* Includes stock-based compensation as follows</b>				
Research and development	\$ 1,449	\$ 197	\$ 3,267	\$ 2,248
General and administrative	1,674	2,548	15,637	6,275
	<u>\$ 3,123</u>	<u>\$ 2,745</u>	<u>\$ 18,904</u>	<u>\$ 8,523</u>

**Lion Biotechnologies, Inc. <sup>(1)</sup>**  
**Reconciliation of Selected GAAP Measures to Non-GAAP**  
(unaudited; in thousands, except per share data)

	<b>For the Three Months Ended</b>		<b>Year Ended December 31,</b>	
	<b>December 31,</b>			
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
<b>Reconciliation of GAAP to non-GAAP</b>				
<b>Research and development</b>				
GAAP Research and development	\$ 10,901	\$ 4,057	\$ 28,037	\$ 15,470
Less:				
Non-cash stock-based compensation <sup>(2)</sup>	<u>(1,449)</u>	<u>(197)</u>	<u>(3,267)</u>	<u>(2,248)</u>
Non-GAAP Research and development	<u>\$ 9,452</u>	<u>\$ 3,860</u>	<u>\$ 24,770</u>	<u>\$ 13,222</u>
<b>Reconciliation of GAAP to non-GAAP</b>				
<b>General and administrative</b>				
GAAP General and administrative	\$ 5,022	\$ 4,422	\$ 25,602	\$ 12,390
Less:				
Non-cash stock-based compensation <sup>(2)</sup>	<u>(1,674)</u>	<u>(2,548)</u>	<u>(15,637)</u>	<u>(6,275)</u>
Non-GAAP General and administrative	<u>\$ 3,348</u>	<u>\$ 1,874</u>	<u>\$ 9,965</u>	<u>\$ 6,115</u>
<b>Non-GAAP Net loss attributable to common stockholders reconciliation</b>				
GAAP Net loss attributable to common stockholders	\$ (15,689)	\$ (8,360)	\$ (102,348)	\$ (27,660)
Add back:				
Non-cash stock-based compensation <sup>(2)</sup>	3,123	2,745	18,904	8,523
Non-cash Deemed dividend related to beneficial conversion feature of convertible preferred stock <sup>(3)</sup>	<u>-</u>	<u>-</u>	<u>49,454</u>	<u>-</u>

Non-GAAP Net loss attributable to common stockholders	\$ <u>(12,566)</u>	\$ <u>(5,615)</u>	\$ <u>(33,990)</u>	\$ <u>(19,137)</u>
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	<i>For the Three Months Ended</i>		<i>Year Ended December 31,</i>	
	<i>December 31,</i>		<i>2016</i>	<i>2015</i>
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
<b><i>Non-GAAP net loss per share reconciliation</i></b>				
GAAP net loss per basic and diluted share:	\$ (0.25)	\$ (0.17)	\$ (1.85)	\$ (0.62)
Add back:				
Non-cash stock-based compensation <sup>(2)</sup>	0.05	0.06	0.34	0.19
Non-cash Deemed dividend related to beneficial conversion feature of convertible preferred stock <sup>(3)</sup>	<u>-</u>	<u>-</u>	<u>0.89</u>	<u>-</u>
Non-GAAP net loss per basic and diluted share	\$ <u>(0.20)</u>	\$ <u>(0.11)</u>	\$ <u>(0.62)</u>	\$ <u>(0.43)</u>
<b><i>Weighted-Average Common Shares Outstanding, Basic and Diluted</i></b>				
	<u>62,130</u>	<u>47,912</u>	<u>55,268</u>	<u>44,410</u>

- (1) This presentation includes non-GAAP measures. The Company's non-GAAP measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read only in conjunction with its financial statements prepared in accordance with GAAP.
- (2) All stock-based compensation was excluded for the non-GAAP analysis.
- (3) The deemed dividend related to the conversion feature of the Series B Preferred Stock was excluded for non-GAAP analysis.

***Investor Contact:***  
***Sarah McCabe***  
***Stern Investor Relations, Inc.***  
***212-362-1200***  
[\*\*\*sarah@sternir.com\*\*\*](mailto:sarah@sternir.com)

***Media Contact:***  
***Alex Ferrara***  
***inVentivHealth Public Relations***  
***212-849-9487***  
[\*\*\*Alexandra.Ferrara@inventivhealth.com\*\*\*](mailto:Alexandra.Ferrara@inventivhealth.com)

***Source: Lion Biotechnologies, Inc.***

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