Lion Biotechnologies Reports Third Quarter 2016 Financial Results and Provides Corporate Update

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SAN CARLOS, CA -- (Marketwired) -- 11/04/16 --

- Company appoints new CFO, Greg Schiffman
 - CRADA with NCI extended for five more years
 - Company entered into license agreement with Karolinska Institute/PolyBioCept AB
 - Company to present four posters at upcoming SITC meeting

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

"Lion continues building momentum in broadening the utility of our TIL technology in new indications through internal R&D as well as with our collaborators. We recently announced our collaboration with the Karolinska Institute which expands the utility of TIL into two new indications, glioblastoma and pancreatic cancer. We also extended our Cooperative Research and Development Agreement (CRADA) with Professor Rosenberg at the National Cancer Institute (NCI) for an additional 5 years. We continue our process development work in optimizing the process of manufacturing TIL. Some of our preliminary work on developing a more robust and lower cost processes for growth of TIL will be presented at the upcoming 2016 SITC meeting. We are building our team to become a fully integrated immuno-oncology company with new members with extensive expertise in cell-based therapy as evident by our recent hire of our CFO, Greg Schiffman. We have now doubled the number of our employees since June 2016 and moved to our San Carlos headquarters," said Dr. Maria Fardis, Chief Executive Officer of Lion Biotechnologies.

Recent Business Highlights and Anticipated Milestones

- Appointed New Chief Financial Officer: In October 2016, Greg Schiffman, was appointed Chief Financial Officer (CFO) of Lion. Mr. Schiffman has extensive experience in drug development and therapeutics using cellular technologies. Prior to joining Lion Biotechnologies, Mr. Schiffman was Executive Vice President and CFO of StemCells, Inc, a publicly traded company engaged in the research, development, and commercialization of stem cell therapeutics. Prior to that he served as Executive Vice President and CFO of Dendreon Corporation, a publicly traded biotechnology company engaged in the discovery, development and commercialization of novel therapeutics using a proprietary cellular immunotherapy technology.
- Entered into License with PolyBioCept AB and Related Clinical Trials Agreement with Karolinska University Hospital: In September 2016, the Company entered into an Exclusive License Agreement with PolyBioCept AB, a Swedish corporation. PolyBioCept has filed two patent applications with claims related to a cytokine cocktail for use in expansion of lymphocytes. Under the License Agreement, 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. The licenses are for the use in all cancers and are worldwide in scope, with the exception that the uses in melanoma are not included for certain countries of the former Soviet Union. The agreement has an initial term of 30 years. Under the terms of the 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.
- Cooperative Research and Development Agreement with NCI Extended: In August 2016, the Company entered into the second amendment of the 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.

- Two Additional Programs to Enter Phase 2 in 2017: The Company plans to initiate Phase 2 trials for LN-145 for the potential treatment of head and neck and cervical cancers in 2017.
- Enrollment in LN-144 Phase 2 Melanoma Study Continues: Lion continues enrollment of patients in the LN-144 Phase 2 melanoma study and intends to present initial data at an upcoming medical conference in 2017.
- Headcount: During the three months ended September 30, 2016, the Company increased its headcount from 23 employees to 45 employees to support the expansion of the Company's clinical product pipeline and development activities including next generation TIL technologies.
- Opened New Corporate Headquarters: Lion's corporate headquarters has now moved to the San Carlos, California location. Lion will, however, retain its existing New York City and Tampa offices.

Third Quarter and Year-to-Date 2016 Financial Results

As of September 30, 2016 the Company held \$179.3 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, which included a one-time deemed dividend charge of \$49.5 million incurred as a result of the conversion feature of the Series B convertible preferred stock, for the quarter ended September 30, 2016 was \$68.2 million, or (\$1.15) per share, compared to GAAP net loss attributable to common stockholders of \$7.6 million or (\$0.16) per share for the quarter ended September 30, 2015. The deemed dividend did not have any monetary impact for the Company.

Non-GAAP net loss attributable to common stockholders, which excludes amounts related to stock-based compensation and the non-cash deemed dividend, for the quarter ended September 30, 2016 was \$10.1 million, or (\$0.17) per share, compared to non-GAAP net loss attributable to common stockholders of \$5.2 million, or (\$0.11) per share for the quarter ended September 30, 2015. The non-GAAP net loss attributable to common stockholders for the three months ended September 30, 2016 excludes \$8.6 million of non-cash stock-based compensation and a non-cash deemed dividend of \$49.5 million. The stock compensation increase year-over-year of \$6.3 million is primarily driven by the departure of the Company's former CFO. The deemed dividend will only impact the current quarter's financial statements.

GAAP net loss attributable to common stockholders for the nine months ended September 30, 2016, which includes a one-time deemed dividend related to a charge of \$49.5 million incurred as a result of the conversion feature of the Series B convertible preferred stock was \$86.7 million, or (\$1.64) per share, compared to GAAP net loss attributable to common stockholders of \$19.3 million or (\$0.44) per share for the nine months ended September 30, 2015. Non-GAAP net loss, which excludes amounts related to stock-based compensation and the non-cash deemed dividend for the nine months ended September 30, 2016 was \$21.4 million, or (\$0.40) per share, compared to non-GAAP net loss of \$13.5 million or (\$0.31) per share for the nine months ended September 30, 2015.

The Company believes that it is important for investors to understand these non-cash charges as they are materially impacting the quarterly 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 of \$8.5 million for the quarter ended September 30, 2016 increased by \$3.5 million compared to the quarter ended September 30, 2015. The increase in R&D expense is due to increased spending on clinical activities for LN-144. In addition, R&D-associated stock option expenses were \$0.6 million for the

three months ended September 30, 2016 and \$1.8 million for the nine months ended September 30, 2016. Non-GAAP R&D expenses of \$7.8 million for the quarter ended September 30, 2016 increased by \$3.7 million, compared to \$4.1 million for the quarter ended September 30, 2015.

GAAP general and administrative (G&A) expenses of \$10.5 million increased by \$7.8 million compared to the quarter ended September 30, 2015. Non-GAAP G&A expenses of \$2.5 million for the quarter ended September 30, 2016 increased by \$1.3 million, compared to \$1.2 million for the quarter ended September 30, 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 our 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 our 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.

2016 Cash Expectations

Lion anticipates the ending cash, cash equivalents and short-term investments as of December 31, 2016, to be in excess of \$164.0 million.

Upcoming Events & Presentations

- Society for Immunotherapy of Cancer's (SITC) 31st Annual Meeting & Associated Programs in National Harbor, Maryland, November 9-13, 2016
- Piper Jaffray 28th Annual Health Care Conference, at the Lotte New York Palace hotel in New York City, November 30 at 2:30 p.m. ET

Webcast and Conference Call

Lion will host a conference call today at 8:30 a.m. ET to discuss these third quarter 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 <u>http://www.lbio.com/</u> or you may use the link: <u>http://edge.media-server.com/m/p/usbgqbbo</u>.

A replay of the call will be available one hour after the end of the call on November 4, 2016 until 8:30 a.m. ET on November 11, 2016. To access the replay, please dial 1-855-859-2056 (domestic) or 1-404-537-3406 (international) and reference the access code 3946579. The archived webcast will be available for thirty days in the Investors section of Lion

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 lymphocytes (TIL) for the treatment of patients with refractory metastatic melanoma. TIL therapy is also being evaluated in clinical trials at the National Cancer Institute and Moffitt Cancer Center. For more information, please visit <u>http://www.lionbio.com</u>.

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 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, and the amount of Cash and cash equivalents it will have at the end of 2016. 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 <u>www.sec.gov</u> or <u>www.lionbio.com</u>. 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)

	Sep(U	December 31, 2015		
Cash, cash equivalents and short-term investments	\$	179,282	\$	103,700
Total assets	\$	182,325	\$	105,653
Stockholders' equity	\$	179,131	\$	104,023

Condensed Statements of Operations

(unaudited; in thousands, except per share data)

		ree Months Endo otember 30,	ed 1	For the Nine Months Ended September 30,				
	2016	2016 2015		2016	2015			
Revenues	\$	- \$	\$	- \$	-			

Costs and expenses*								
Research and development		8,481		4,960		17,200		11,413
General and administrative		10,498		2,683		20,517		7,968
Total costs and expenses		18,979		7,643		37,717		19,381
Loss from operations		(18,979)		(7,643)		(37,717)		(19,381)
Other income								
Interest income		221		8		511		81
Net Loss	\$	(18,758)	\$	(7,635)	\$ <u> </u>	(37,206) \$	5	(19,300)
Deemed dividend related to beneficial conversion feature of convertible preferred								
stock		(49,454)		-		(49,454)		-
Net loss Attributable to Common Stockholders	\$	(68,212)	\$	(7,635)	\$	(86,660) \$	5	(19,300)
Net Loss Per Common Share, Basic and								
Diluted	\$	(1.15)	\$	(0.16)	\$	(1.64) \$	5	(0.44)
Weighted-Average Common Shares								
Outstanding, Basic and Diluted		59,113		47,272		52,963		43,399
* Includes stack based commonsation as follows								
* Includes stock-based compensation as follows Research and development	\$	640	\$	855	\$	1,818 \$	2	2,051
General and administrative	φ	8,005	φ	1,533	φ	13,963)	2,031 3,727
		8,005		1,333		13,903		3,121
	\$	8,645	\$	2,388	\$	15,781 \$	s	5,778

Lion Biotechnologies, Inc. ⁽¹⁾ Reconciliation of Selected GAAP Measurers to Non-GAAP (unaudited; in thousands, except per share data)

		For the Three Me Septembe	For the Nine Months Ended September 30,				
	_	2016	2015	_	2016		2015
Reconciliation of GAAP to non-GAAP Research and development							
GAAP Research and development	\$	8,481 \$	4,960	\$	17,200	\$	11,413
Less:							
Non-cash stock-based compensation (2)		(640)	(855)	_	(1,818)		(2,051)
Non-GAAP Research and development	\$	7,841 \$	4,105	\$	15,382	\$	9,362
Reconciliation of GAAP to non-GAAP General and administrative							

GAAP General and administrative	\$	10,498	\$	2,683	\$	20,517	\$	7,968
Less:								
Non-cash stock-based compensation ⁽²⁾	_	(8,005)	-	(1,533)		(13,963)	_	(3,727)
Non-GAAP General and administrative	\$	2,493	\$	1,150	\$	6,554	\$_	4,241
Non-GAAP Net loss attributable to common stockholders reconciliation								
GAAP Net loss attributable to common stockholders	\$	(68,212)	\$	(7,635)	\$	(86,660)	\$	(19,300)
Add back:								
Non-cash stock-based compensation ⁽²⁾		8,645		2,388		15,781		5,778
Non-cash Deemed dividend related to beneficial conversion feature of convertible preferred stock ⁽³⁾	_	49,454				49,454	_	
Non-GAAP Net loss attributable to common stockholders	\$	(10,113)	\$	(5,247)	\$	(21,425)	\$	(13,522)
		For the Three Months Ended September 30,			For the Nine Months Ended September 30,			
	_	2016	-	2015	_	2016	_	2015
Non-GAAP net loss per share reconciliation								
GAAP net loss per basic and diluted share:	\$	(1.15)	\$	(0.16)	\$	(1.64)	\$	(0.44)
Add back:								
Non-cash stock-based compensation ⁽²⁾		0.15		0.05		0.30		0.13
Non-cash Deemed dividend related to beneficial conversion feature of convertible preferred stock ⁽³⁾	_	0.83	_			0.94	_	<u>-</u>
Non-GAAP net loss per basic and diluted share	\$	(0.17)	\$	(0.11)	\$	(0.40)	\$	(0.31)
Weighted-Average Common Shares Outstanding, Basic and Diluted	-	59,113	-	47,272		52,963	-	43,399

- (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.

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