

Selecta Biosciences Announces First Quarter 2017 Financial Results and Provides Corporate Update

May 11, 2017 4:05 PM ET

- *On Track to Complete Phase 2 Trial of Lead Product Candidate, SEL-212, in 2017*
- *Licensed LMB-100, a Clinical-Stage Candidate for Mesothelioma and Pancreatic Cancer, from the National Cancer Institute (NCI)*
- *Obtained Synthetic Transgene License for MMA Gene Therapy Program*
- *Initiated Nicotine Vaccine Phase 1 Trial for Smoking Cessation and Relapse Prevention with Funding Primarily from the National Institutes of Health (NIH)*
- *Company to Host Conference Call Today at 5:00 p.m. ET*

WATERTOWN, Mass., May 11, 2017 (GLOBE NEWSWIRE) -- [Selecta Biosciences, Inc.](#) (NASDAQ:SELB), a clinical-stage biopharmaceutical company focused on unlocking the full potential of biologic therapies by avoiding unwanted immune responses, today reported financial results for the first quarter ended March 31, 2017 and provided a corporate update.

“Selecta continues to make great strides in 2017,” said Werner Cautreels, Ph.D., CEO and Chairman of Selecta. “Enrollment in the Phase 2 trial of our lead product candidate, SEL-212, continues to be faster than anticipated, and we remain on track to complete the trial in 2017. In addition, we recently added a clinical-stage oncology product candidate, LMB-100, to our proprietary pipeline and plan to combine it with SVP-Rapamycin in a clinical program for mesothelioma and pancreatic cancer with our collaborators at NCI. We also obtained a key license for our MMA gene therapy program, and we began dosing patients in a Phase 1 trial of our nicotine vaccine candidate for smoking cessation and relapse prevention. These programs highlight the far-reaching potential of our Synthetic Vaccine Particles (SVP™) technology platform and the strong execution of the Selecta team.”

SEL-212 Phase 2 Trial Update

In the fourth quarter of 2016, Selecta began enrolling patients with symptomatic gout and elevated serum uric acid levels (above 6.0 mg/dL) in an open-label, multiple ascending dose Phase 2 clinical trial of SEL-212 (SVP-Rapamycin in combination with pegsiticase). The primary and secondary endpoints for this trial include safety, tolerability, pharmacokinetics, reduction of serum uric acid levels and reduction of ADA levels. Data also are being collected regarding flares and additional laboratory and clinical assessments. Patients are being enrolled in multiple ascending dose cohorts to enable the identification of the optimal dose ratio of SVP-Rapamycin and pegsiticase, the minimal effective dose level of SEL-212 for repeat monthly administration, and the dose regimen to take forward into Phase 3.

As of May 10, 2017, a total of 58 patients had been dosed in the Phase 2 trial in eight cohorts. During the week of June 12, 2017, Selecta is presenting at the Annual European Congress of Rheumatology (EULAR 2017) in Madrid, Spain and at the Federation of Clinical Immunology Societies Annual Meeting (FOCIS 2017) in Chicago and plans to report additional data from the ongoing Phase 2 trial at that time. The company expects that it will complete the trial in 2017 and initiate its Phase 3 program in 2018.

Additional Recent Business Highlights and Activities

- **Entered the Field of Oncology:** Earlier this month, Selecta announced that it had licensed LMB-100, a clinical-stage, next-generation recombinant immunotoxin, from the Center for Cancer Research at NCI, part of NIH. LMB-100 contains a potent toxin that is derived from *Pseudomonas* exotoxin A and is attached to an antibody that targets mesothelin. Mesothelin is overexpressed in all mesotheliomas, pancreatic adenocarcinomas and a high percentage of other malignancies, including ovarian, lung and breast cancers. Clinical data with LMB-100 indicate that undesired antibody responses to this immunotoxin have prevented most patients from receiving the intended four or more treatment cycles. However, tumor regression was observed in the two patients who were able to receive more than

two cycles of a precursor to LMB-100 in combination with potent immunosuppressive drugs. On the basis of these clinical data and preclinical data produced together with NCI, Selecta believes that a combination of LMB-100 and SVP-Rapamycin may allow patients to avoid these antibody responses and benefit from multiple treatment cycles. Selecta and NCI are currently in discussions regarding a planned Phase 1b clinical trial to evaluate multiple cycles of this combination treatment.

- Further Advanced its Lead Gene Therapy Program in MMA: In April 2017, Selecta licensed a proprietary synthetic transgene known as synthetic polynucleotides encoding human methylmalonyl-CoA mutase (synMUT) from the U.S. Department of Health and Human Services, part of NIH. Discovered in the laboratory of Dr. Charles Venditti, synMUT was optimized for expression of human methylmalonyl-CoA mutase, the enzyme missing or defective in patients suffering from Methylmalonic Acidemia (MMA), and demonstrated curative efficacy in animal disease models. Selecta is utilizing synMUT with its proprietary Anc80 viral capsid for MMA. In the first quarter of 2017, Selecta signed a manufacturing agreement with Lonza Houston, Inc. for Anc80. Preclinical data regarding the use of Anc80-synMUT in MMA is being presented today (Abstract 404) at the Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT) in Washington, D.C. In addition, a team led by Federico Mingozzi, Ph.D., Head of Immunology and Liver Gene Therapy at Genethon, is presenting preclinical data tomorrow at ASGCT (Abstract 521) regarding repeated gene therapy administration using SVP-Rapamycin.
- Commenced Dosing in a Phase 1 Trial of a Nicotine Vaccine for Smoking Cessation and Relapse Prevention Trial: In a separate announcement today, Selecta reported that it has commenced dosing in a Phase 1 clinical trial to assess the safety, tolerability and pharmacodynamic profile of SELA-070, a nicotine vaccine candidate in development for smoking cessation and relapse prevention. Unlike Selecta's immune tolerance product candidates, which seek to avoid the production of antibodies, this treatment is intended to produce a high level of anti-nicotine antibodies that bind to the nicotine inhaled by smokers, thus preventing it from crossing the blood-brain barrier and triggering an addictive response. Funding for the product candidate and the Phase 1 trial is being provided primarily by the National Institute on Drug Abuse (NIDA), part of NIH (grant # U01DA037592).

First Quarter Financial Results:

- Revenue: For the first quarter of 2017, the company's total revenue was \$0.1 million, which compares with \$2.1 million for the first quarter of 2016. The decline is primarily the result of reduced revenue from the company's award with NIDA as well as the recent termination of the company's collaboration with Sanofi.
- Research and Development Expenses: Research and development expenses for the first quarter of 2017 were \$11.0 million, which compares with \$6.6 million for the first quarter of 2016. The increase is primarily the result of increased clinical trial-related activities as well as increased headcount, salary and stock compensation expense.
- General and Administrative Expenses: General and administrative expenses for the first quarter of 2017 were \$3.9 million, which compares with \$2.4 million for the first quarter of 2016. The increase is primarily the result of increased salary, legal, accounting, consulting and insurance fees associated with being a public company.
- Net Loss: For the first quarter of 2017, Selecta reported a net loss attributable to common stockholders of \$(15.1) million, or \$(0.82) per share, compared to a net loss of \$(9.8) million, or \$(4.52) per share, for the same period in 2016. The decrease in net loss per share in the most recent quarter is primarily the result of shares of common stock that were issued in the company's June 2016 initial public offering (IPO) and conversion of Selecta's redeemable preferred stock into common stock in connection with the IPO, partially offset by an increase in net loss for the period.
- Cash Position: Selecta had \$68.9 million in cash, cash equivalents, short-term deposits, investments and restricted cash as of March 31, 2017, which compares with a balance of \$84.5 million at December 31, 2016. Selecta continues

to expect that its cash, cash equivalents, short-term deposits, investments and restricted cash will be sufficient to fund the company's operating expenses and capital expenditure requirements into mid-2018.

Conference Call Reminder

Selecta management will host a conference call at 5:00 p.m. ET today to provide a corporate update and review the company's first quarter financial results. Investors and the public can access a live and archived webcast of this call via the Investors & Media section of the company's website, <http://selectabio.com>. Individuals may also participate in the call via telephone by dialing (877) 270-2148 (domestic) or (412) 902-6510 (international) and may access a teleconference replay for one week by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and using confirmation code 10106207.

About Selecta Biosciences, Inc.

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company that is focused on unlocking the full potential of biologic therapies by avoiding unwanted immune responses. Selecta plans to combine its tolerogenic Synthetic Vaccine Particles (SVP™) to a range of biologics for rare and serious diseases that require new treatment options. The company's current proprietary pipeline includes SVP-enabled enzyme, oncology and gene therapies. SEL-212, the company's lead candidate in Phase 2, is being developed to treat severe gout patients and resolve their debilitating symptoms, including flares and gouty arthritis. Selecta's clinical oncology candidate, LMB-100, is in a Phase 1 program targeting pancreatic cancer and mesothelioma. Its two proprietary gene therapy product candidates are being developed for rare inborn errors of metabolism and have the potential to enable repeat administration. The use of SVP is also being explored in the development of vaccines and treatments for allergies and autoimmune diseases. Selecta is based in Watertown, Massachusetts. For more information, please visit <http://selectabio.com> and follow @SelectaBio on Twitter.

Forward-Looking Statements

Any statements in this press release about the future expectations, plans and prospects of Selecta Biosciences, Inc. ("the company"), including without limitation, statements regarding the progress of the Phase 1/2 clinical program of SEL-212 including the pace of enrollment, the potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, whether the Phase 2 of SEL-212 will be completed in 2017 and whether the Phase 3 trial will be initiated in 2018, the company's ability to unlock the full potential of biologic therapies, the potential applications for products utilizing the SVP platform in areas such as enzyme therapy, gene therapy, oncology therapy, vaccines and treatments for allergies and autoimmune diseases, whether the combination of LMB-100 and SVP-Rapamycin may allow patients to avoid antibody responses and benefit from a full treatment of LMB-100, whether Selecta and NCI initiate a Phase 1b clinical trial of the LMB-100 and SVP-Rapamycin combination, the potential of the company's two gene therapy product candidates to enable repeat administration, the progress of the company's Phase I clinical trial in SELA-070, statements regarding the ability of SELA-070 to achieve smoking cessation and relapse prevention, statements regarding SELA-070's ability to produce a high level of anti-nicotine antibodies and ultimately prevent nicotine from crossing the blood-brain barrier, the sufficiency of the company's cash, cash equivalents, investments, and restricted cash and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," 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, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including their uncertain outcomes, the unproven approach of the company's SVP technology, undesirable side effects of the company's product candidates, its reliance on third parties to manufacture its product candidates and to conduct its clinical trials, the company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, substantial fluctuation in the price of its common stock, a significant portion of the company's total outstanding shares have

recently become eligible to be sold into the market, and other important factors discussed in the “Risk Factors” section of the company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 28, 2017, and in other filings that the company makes with the SEC. In addition, any forward-looking statements included in this press release represent the company’s views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The company specifically disclaims any obligation to update any forward-looking statements included in this press release.

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

(In thousands, except for shares and par value)

	March 31, 2017	December 31, 2016
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,637	\$ 58,656
Short-term deposits and investments	41,885	25,485
Restricted cash	81	78
Accounts receivable	63	215
Prepaid expenses and other current assets	2,820	2,382
Total current assets	71,486	86,816
Property and equipment, net	2,054	2,047
Restricted cash and other deposits	316	316
Other assets	—	122
Total assets	\$ 73,856	\$ 89,301
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	\$ 1,317	\$ 3,882
Accrued expenses	5,521	3,921
Loans payable, current portion	4,519	4,067
Deferred revenue, current portion	1,947	1,836
Total current liabilities	13,304	13,706
Non-current liabilities:		
Deferred rent and lease incentive	210	222
Loans payable, net of current portion	6,867	7,977
Deferred revenue, net of current portion	12,385	12,439
Total liabilities	32,766	34,344
Stockholders’ equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively.	—	—

Common stock, \$0.0001 par value; 200,000,000 shares authorized; 18,552,385 and 18,438,742 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively.

Additional paid-in capital	212,249	211,125
Receivable from stock option exercises	(70)	(75)
Accumulated deficit	(166,710)	(151,576)
Accumulated other comprehensive loss	(4,380)	(4,518)
Total stockholders' equity	41,090	54,957
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 73,856	\$ 89,301

Selecta Biosciences, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2017	2016
Grant and collaboration revenue	\$ 137	\$ 2,088
Operating expenses:		
Research and development	11,044	6,648
General and administrative	3,875	2,381
Total operating expenses	14,919	9,029
Loss from operations	(14,782)	(6,941)
Investment income	113	13
Foreign currency transaction gain (loss), net	(165)	(220)
Interest expense	(300)	(310)
Other expense, net	—	(18)
Net loss	(15,134)	(7,476)
Other comprehensive loss:		
Foreign currency translation adjustment	123	231
Unrealized gain (loss) on securities	15	—
Comprehensive loss	\$ (14,996)	\$ (7,245)
Net loss	(15,134)	(7,476)
Accretion of redeemable convertible preferred stock	—	(2,356)
Net loss attributable to common stockholders	\$ (15,134)	\$ (9,832)
Net loss per share attributable to common stockholders		
Basic and diluted	\$ (0.82)	\$ (4.52)
Weighted average common shares outstanding		
Basic and diluted	18,474,227	2,175,037

Contact Information:
Jason Fredette
Selecta Biosciences, Inc.
617-231-8078
jfredette@selectabio.com

 Primary Logo

Selecta Biosciences