

Selecta Biosciences Announces Fourth Quarter and Year End 2016 Financial Results and Provides Corporate Update

March 27, 2017 4:01 PM ET

- *New Data from Ongoing SEL-212 Phase 2 Trial Show Persistent Clinical Activity After Repeat Administration in Symptomatic Gout Patients*
- *Emerging Clinical and Preclinical Data Confirm the Broad Potential of Selecta's Immune Tolerance Platform to Enable Biologics that Avoid Unwanted Immunogenicity*
- *Company to Host Conference Call Today at 5:00 p.m. ET*

WATERTOWN, Mass., March 27, 2017 (GLOBE NEWSWIRE) -- [Selecta Biosciences, Inc.](#) (NASDAQ:SELB), a clinical-stage biopharmaceutical company focused on developing biologic therapies for rare and serious diseases that avoid unwanted immunogenicity, today reported financial results for the fourth quarter and full year ended December 31, 2016 and provided a corporate update.

“After a pivotal 2016, we believe that 2017 will be a year of great and lasting importance for Selecta Biosciences and for patients with rare and serious diseases,” said Werner Cautreels, Ph.D., CEO and Chairman of Selecta. “While we are still in the early stages of our Phase 2 trial of SEL-212 that was initiated in the fourth quarter of 2016, we are emboldened by its progress and the patient data that have been generated thus far. Patient enrollment has been faster than we expected, and SEL-212 has been generally well tolerated at clinically active doses. We are particularly pleased that we have already reached a dose level of SEL-212 that has thus far enabled all patients that had received a repeat administration to maintain persistent clinical activity. We are eager to collect additional patient data that we believe should be the basis for the development of a major new treatment for severe gout patients.”

“In recent months, we and various collaborators have also presented preclinical data demonstrating the transformative potential of our immune tolerance SVP technology to create novel and differentiated therapies in a number of additional strategic areas such as gene therapy, oncology and enzyme replacement therapy,” continued Cautreels. “We believe SVP has uniquely demonstrated the potential to avoid the immunogenicity that hampers today’s biologic treatments, which is garnering increasing interest throughout the industry.”

SEL-212 Phase 2 Trial Update

Published data show that uricases, exogenous biologic enzymes that metabolize uric acid, have the ability to significantly reduce serum uric acid levels and eliminate uric acid crystal deposits in severe gout patients. However, the efficacy and safety of currently marketed uricases have been compromised by the formation of anti-drug antibodies (ADAs) that are induced in most patients early in their treatment and prevent further administrations. Leveraging the immune tolerance application of Selecta’s SVP platform, SEL-212 (SVP-Rapamycin in combination with pegsiticase) is designed to be the first non-immunogenic version of uricase, which would allow for the effective and safe administration of multiple doses.

A prolonged elevation of serum uric acid levels can lead to the formation of uric acid crystal deposits in joints and tissue. These deposits have been shown to cause severe gout symptoms such as pain, inflammation of joints and debilitating flares, which can potentially exacerbate kidney and cardiovascular disease if untreated. Multi-dose treatment with SEL-212 has the potential to drastically and durably lower serum uric acid levels, enabling the removal of uric acid crystal burden over a short treatment cycle, which cannot be achieved for severe gout patients by oral therapy.

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. The primary and secondary endpoints for this trial include the safety, tolerability and pharmacokinetics of repeated monthly doses of SEL-212; the

clinical activity of SEL-212 as defined by the reduction of serum uric acid levels; and the reduction of ADA levels.

As of March 23, 2017, a total of 38 patients had been dosed in the Phase 2 trial at 10 active U.S. clinical sites. In the company's single-dose Phase 1a/b trial, it was determined that 0.4 mg/kg of pegsiticase combined with 0.1 mg/kg SVP-Rapamycin prevented the formation of ADAs, thereby enabling the control of uric acid for at least 30 days in the majority of patients. In the ongoing Phase 2 study, patients are being enrolled in multiple ascending dose cohorts to identify 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.

Enrollment has been completed for the first six patient cohorts, and recruitment of two additional patient cohorts is ongoing. Serum uric acid data was available as of March 23, 2017. Multiple serum samples have been collected from all patients for the measurement of ADA levels, and this analysis was ongoing. Patient and enrollment data as of March 23, 2017 was as follows:

- Mid-Dose Cohorts (three monthly doses of 0.08 mg/kg of SVP-Rapamycin + 0.2 mg/kg or 0.4 mg/kg of pegsiticase followed by two monthly doses of pegsiticase alone): Of the 13 patients in these cohorts, 11 patients continue to be dosed and all had maintained serum uric acid control through March 23, 2017. Nine of these patients had received three monthly doses and the other two patients had received two monthly doses. Of the two patients no longer being dosed, one was removed from the trial for a protocol deviation and one reached the trial's stopping rules.
- Low-Dose Cohorts (three monthly doses of 0.05 mg/kg of SVP-Rapamycin + 0.2 mg/kg or 0.4 mg/kg of pegsiticase followed by two monthly doses of pegsiticase alone): Of the 19 patients in these cohorts, one patient had completed the full five-month regimen and maintained serum uric acid control for the duration of the trial, and three have received three monthly doses while maintaining serum uric acid control and continue to be dosed. Of the 15 patients no longer being dosed, seven dropped out of the trial and eight reached the trial's stopping rules.
- Control Cohorts (five monthly doses of 0.2 mg/kg or 0.4 mg/kg of pegsiticase alone) – As expected, based upon the known immunogenicity of uricase enzymes, five of six patients who received pegsiticase alone were unable to maintain serum uric acid control. Consequently, enrollment in these control cohorts was stopped early.

Additional patient data from these cohorts are included in a presentation entitled "Selecta Q4 and Year End 2016 Conference Call Presentation" that Selecta posted to its website today. To access this presentation, please visit www.selectabio.com, select Investors & Media and then Events & Presentations.

Selecta developed stopping rules for its Phase 2 trial to ensure patient safety given the well-recognized immunogenicity of uricase enzymes. The loss of serum uric acid control during treatment is an accepted surrogate for the formation of ADAs and potential risk of subsequent infusion reactions. In order to ensure patient safety, these rules call for serum uric acid levels to be rapidly analyzed and dosing to cease upon a loss of serum uric acid control at Day 21 following a dose. As expected, these stopping rules have been applied more frequently in cohorts dosed with pegsiticase alone and the lower SVP-Rapamycin dose.

Consistent with the expected reduction in immunogenicity of pegsiticase as SVP-Rapamycin doses increase, SEL-212 has been generally well tolerated thus far in patients in the mid-dose cohorts, with no SAEs being reported for these patients. One infusion reaction was reported in the control cohorts, which was classified as a serious adverse event (SAE) and successfully treated. Two infusion reactions occurred in the low-dose cohorts; they were classified as SAEs and were successfully treated.

In March 2017, recruiting began for two higher dose cohorts of patients, which will receive three monthly doses of 0.1 mg/kg of SVP-Rapamycin plus 0.2 mg/kg or 0.4 mg/kg of pegsiticase followed by two monthly doses of 0.2 mg/kg or 0.4 mg/kg of pegsiticase alone.

Selecta plans to present initial data from this trial at a medical meeting by the end of June 2017. The Phase 2 trial is

expected to be completed in 2017. Following an End of Phase 2 Meeting with the U.S. Food and Drug Administration (FDA), the company expects to initiate its Phase 3 program in 2018.

Additional Recent Business Highlights and Activities

- [Licensed SVP to Spark Therapeutics for up to Five Gene Therapy Indications:](#) In December 2016, Selecta entered into a license agreement providing Spark Therapeutics with exclusive worldwide rights to SVP-Rapamycin for co-administration with AAV-based gene therapy vectors for Hemophilia A and up to four additional pre-specified and undisclosed indications.
- [Advanced its Proprietary Gene Therapy Programs:](#) Selecta has continued to advance its two proprietary gene therapy programs focused on inborn errors of metabolism: Methylmalonic Acidemia (MMA) and Ornithine Transcarbamylase Deficiency (OTC). In February 2017, Selecta announced a strategic manufacturing agreement with Lonza for the production of an Anc80-AAV-based gene therapy product for MMA, which is the more advanced of these programs. Selecta intends to submit an Investigational New Drug (IND) Application for MMA to the FDA in the first half of 2018.
- [Teamed with the National Cancer Institute \(NCI\):](#) LMB-100 is a next-generation recombinant immunotoxin being developed in the clinic for the treatment of solid tumors. Preclinical data was presented in October 2016 by an NCI research team led by Ira Pastan, MD, demonstrating SVP-Rapamycin's mitigation of ADAs against LMB-100. Selecta is collaborating with NCI to advance a combination of SVP-Rapamycin with LMB-100 as a treatment for mesothelioma and pancreatic cancer.
- [Announced Pompe Disease Data:](#) Preclinical data was presented in February 2017 by a research team led by Priya Kishnani, MD, Chief of Medical Genetics at Duke University Medical Center, regarding the use of SVP-Rapamycin in combination with alglucosidase alfa (marketed as Myozyme® and Lumizyme®) to treat Pompe disease. The data demonstrate that this combination treatment could mitigate the formation of ADAs against alglucosidase alfa and improve functional outcomes in an animal model of Pompe disease. More broadly, the data demonstrate the potential of Selecta's immune tolerance SVP technology to mitigate ADAs against enzyme replacement therapies.
- [Presented Peanut Allergy and Celiac Disease Data:](#) Preclinical data was presented in February 2017 demonstrating the potential benefit of an SVP-enabled peanut allergy therapeutic vaccine and an SVP-enabled celiac disease treatment. Selecta continues to evaluate strategic opportunities to advance these programs.

Fourth Quarter Financial Results:

- [Revenue:](#) For the fourth quarter of 2016, the company's total revenue was \$2.9 million, which compares with \$2.1 million for the same period in the prior year. The increase is primarily the result of accelerated revenue recognition associated with the notification of termination of the company's collaboration with Sanofi as well as initial revenue recognized from the company's license agreement with Spark Therapeutics.
- [Research and Development Expenses:](#) Research and development expenses for the fourth quarter of 2016 were \$11.0 million, which compares with \$7.2 million for the same period in the prior year. The increase is primarily the result of a milestone payment that was made subject to the company's pegsiticase license agreement, increased clinical trial-related activities as well as increased salary and stock compensation expense.
- [General and Administrative Expenses:](#) General and administrative expenses for the fourth quarter of 2016 were \$5.8 million, which compares with \$2.0 million for the same period in the prior year. The increase is primarily the result of an SVP-related sublicensing payment made to the Massachusetts Institute of Technology resulting from Selecta's license agreement with Spark Therapeutics as well as increased salary, legal, accounting, consulting and insurance fees associated with being a public company.

- **Net Loss:** For the fourth quarter of 2016, Selecta reported a net loss attributable to common stockholders of \$(14.1) million, or \$(0.77) per share, compared to a net loss of \$(9.2) million, or \$(4.26) per share, for the same period in 2015. 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.
- **Cash Position:** Selecta had \$84.5 million in cash, cash equivalents, short-term deposits, investments and restricted cash as of December 31, 2016, which compares with a balance of \$79.9 million at September 30, 2016. The increase is primarily a result of \$15.0 million worth of cash payments from, and stock purchases by, Spark Therapeutics pursuant to the recent license agreement and stock purchase agreement, partially offset by the Selecta's fourth quarter net operating expenditures.
- **Financial Guidance:** Based on the cash received in the fourth quarter of 2016 from the company's recent license agreement and stock purchase agreement with Spark Therapeutics and the company's current operating plans, Selecta now expects 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 fourth quarter and year end 2016 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 live 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 10100540.

About Selecta Biosciences, Inc.

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on developing biologic therapies for rare and serious diseases that avoid the immune responses that compromise efficacy and lead to life-threatening complications. Selecta is applying its proprietary Synthetic Vaccine Particles (SVP™) to a range of therapeutic areas in which immunogenicity is a key challenge. SEL-212, the company's lead candidate in Phase 2, is being developed to treat severe gout patients and reduce their debilitating symptoms, including flares and inflammatory arthritis. Further, Selecta's two proprietary gene therapy product candidates have the unique potential to enable repeat administration, allowing for dose adjustment in patients and maintenance of therapeutic activity over time. The company is seeking to expand the use of its SVP platform in other areas, such as immuno-oncology, allergies, autoimmune diseases and vaccines. Selecta is based in Watertown, Massachusetts. For more information, please visit <http://selectabio.com>.

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 development of its pipeline, the ability of the company's SVP platform, including SVP-Rapamycin, to mitigate immune response and create better therapeutic outcomes, the potential treatment applications for products utilizing the SVP platform in areas such as gene therapy, immuno-oncology, allergies, autoimmune diseases and vaccines, whether the company's proprietary gene therapy product candidates will enable repeat administration, allow for dose adjustment in patients or maintain therapeutic activity over time, the receipt of additional payments under the company's license agreement and/or stock purchase agreement with Spark Therapeutics, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on November 10, 2016, 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)

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 58,656	\$ 32,337
Short-term deposits and investments	25,485	4,125
Restricted cash	78	133
Accounts receivable	215	824
Prepaid expenses and other current assets	2,382	1,494
Total current assets	86,816	38,913
Property and equipment, net	2,047	2,029
Restricted cash and other deposits	316	316
Other assets	122	1,566
Total assets	\$ 89,301	\$ 42,824
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 3,882	\$ 2,179
Accrued expenses	3,921	3,378
Loans payable, current portion	4,067	—
Deferred revenue, current portion	1,836	1,313
Contingently repayable grant funding	—	420
Total current liabilities	13,706	7,290
Non-current liabilities:		

Deferred rent and lease incentive	222	105
Loans payable, net of current portion	7,977	11,855
Deferred revenue, net of current portion	12,439	2,295
Other long-term liabilities	—	290
Total liabilities	34,344	21,835
Redeemable Convertible Preferred Stock:		
Series A redeemable convertible preferred stock, \$0.0001 par value; 0 and 2,589,868 shares authorized; 0 and 2,589,868 shares issued and outstanding; as of December 31, 2016 and December 31, 2015 respectively.	—	3,644
Series B redeemable convertible preferred stock, \$0.0001 par value; 0 and 7,437,325 shares authorized; 0 and 7,437,325 shares issued and outstanding; as of December 31, 2016 and December 31, 2015 respectively.	—	21,448
Series C redeemable convertible preferred stock, \$0.0001 par value; 0 and 5,000,002 shares authorized; 0 and 5,000,002 shares issued and outstanding; as of December 31, 2016 and December 31, 2015 respectively.	—	20,178
Series D redeemable convertible preferred stock, \$0.0001 par value; 0 and 8,166,662 shares authorized; 0 and 8,099,994 shares issued and outstanding; as of December 31, 2016 and December 31, 2015 respectively.	—	42,902
Series SRN redeemable convertible preferred stock, \$0.0001 par value; 0 and 5,611,112 shares authorized; 0 and 2,111,109 shares issued and outstanding; as of December 31, 2016 and December 31, 2015 respectively.	—	12,082
Series E redeemable convertible preferred stock, \$0.0001 par value; 0 and 9,030,654 shares authorized; 0 and 8,888,888 shares issued and outstanding; as of December 31, 2016 and December 31, 2015 respectively.	—	37,228
Total redeemable convertible preferred stock	—	137,482
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 10,000,000 and 0 shares authorized; 0 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively.	—	—
Common stock, \$0.0001 par value; 200,000,000 and 62,164,377 shares authorized at December 31, 2016 and December 31, 2015 respectively; 18,438,742 and 2,180,976 shares issued, 18,438,742 and 2,173,399 shares outstanding as of December 31, 2016 and December 31, 2015, respectively.	1	—
Additional paid-in capital	211,125	1
Receivable from stock option exercises	(75) —
Accumulated deficit	(151,576) (111,508)
Accumulated other comprehensive loss	(4,518) (4,986)
Total stockholders' equity (deficit)	54,957	(116,493)
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 89,301	\$ 42,824

Selecta Biosciences, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss

(Unaudited, amounts in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Grant and collaboration revenue	\$ 2,930	\$ 2,134	\$ 8,083	\$ 6,011
Operating expenses:				
Research and development	11,033	7,211	29,702	22,980
General and administrative	5,757	2,030	13,051	8,335
Total operating expenses	16,790	9,241	42,753	31,315
Loss from operations	(13,860)	(7,107)	(34,670)	(25,304)
Investment income	113	22	234	171
Foreign currency transaction gain (loss), net	(96)	317	(525)	933
Interest expense	(322)	(105)	(1,253)	(948)
Other expense, net	82	24	4	(26)
Net loss	(14,083)	(6,849)	(36,210)	(25,174)
Other comprehensive loss:				
Foreign currency translation adjustment	88	(347)	504	(1,110)
Unrealized gain (loss) on securities	(52)	—	(36)	—
Comprehensive loss	\$ (14,047)	\$ (7,196)	\$ (35,742)	\$ (26,284)
Net loss	(14,083)	(6,849)	(36,210)	(25,174)
Accretion of redeemable convertible preferred stock	—	(2,376)	(4,566)	(7,335)
Net loss attributable to common stockholders	\$ (14,083)	\$ (9,225)	\$ (40,776)	\$ (32,509)
Net loss per share attributable to common stockholders				
Basic and diluted	\$ (0.77)	\$ (4.26)	\$ (3.89)	\$ (15.13)
Weighted average common shares outstanding				
Basic and diluted	18,265,771	2,167,769	10,493,939	2,150,422

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



Selecta Biosciences