

# Selecta Biosciences Announces Third Quarter 2017 Financial Results and Provides Corporate Update

- Patient Data From Ongoing Phase 2 Trial to be Presented Today at the American College of Rheumatology (ACR) 2017 Annual Meeting
- Preparations for Phase 3 Program Underway
- Received \$7.5 Million From Spark Therapeutics
- Strengthened Senior Management Team
- Company to Host Conference Call Today at 8:30 a.m. ET

**Watertown, Mass., November 7, 2017** – <u>Selecta Biosciences, Inc.</u> (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 third quarter ended September 30, 2017 and provided a corporate update.

"I am excited by the progress we have made to advance SEL-212 closer to its Phase 3 program and by the recent additions to senior management in support of this important milestone," said Werner Cautreels, Ph.D., CEO and Chairman of Selecta. "In our ongoing Phase 2 trial, the data show that SEL-212 exhibits strong clinical activity and continues to be generally well tolerated. We now are in the process of enrolling what we believe will be our final Phase 2 patients.

"In the field of gene therapy, we were pleased to have recently received \$7.5 million from Spark Therapeutics, bringing the aggregate payments resulting from our December 2016 license agreement to \$30 million. Meanwhile, progress continues to be made with our proprietary MMA and OTC deficiency gene therapy programs, as highlighted by promising preclinical data presented by our collaborators at the ESGCT meeting in October," Dr. Cautreels continued. "Based on our continued evolution, we recently enhanced our management team by adding a Chief Commercial Officer as well as a new Chief Financial Officer and Head of Corporate Strategy. With these accomplishments behind us and planning for our Phase 3 already underway, we believe we are positioning Selecta for a transformative 2018."

### SEL-212 Program Update

In the fourth quarter of 2016, Selecta began enrolling patients with symptomatic gout and elevated serum uric acid levels in an open-label, multiple ascending dose Phase 2 clinical trial of SEL-212. The primary and secondary endpoints for this trial include safety, tolerability, pharmacokinetics, reduction of serum uric acid levels and reduction of anti-drug antibody (ADA) levels. Data also are being collected regarding flares and other patient-related observations. Patients are being enrolled in multiple ascending dose cohorts with the primary goal to identify the dose regimens to take forward into Phase 3.

As of October 23, 2017, a total of 79 patients have been dosed in the Phase 2 trial at 15 active U.S. clinical sites. Dosing had been completed in an initial eight cohorts in the trial. A summary of clinical

activity from the trial as defined by the primary clinical endpoint (i.e., serum uric acid levels below 6 milligrams per deciliter) and safety information as of October 23, 2017 is as follows:

- Control and Low SVP-Rapamycin Dose Cohorts (Cohorts receiving five monthly doses of pegsiticase alone or three monthly doses of 0.2 mg/kg or 0.4 mg/kg of pegsiticase + 0.05 mg/kg of SVP-Rapamycin followed by two monthly doses of pegsiticase alone): As previously reported and as expected, dosing of patients in the control cohorts receiving pegsiticase alone was stopped early due to a loss of clinical activity caused by the immunogenicity of the enzyme. Clinical activity was lost by Week 12 in the majority of patients receiving pegsiticase in combination with the 0.05 mg/kg dose of SVP-Rapamycin.
- Mid SVP-Rapamycin Dose Cohorts (Cohorts receiving three monthly doses of 0.2 mg/kg or 0.4 mg/kg of pegsiticase + 0.08 or 0.10 mg/kg of SVP-Rapamycin followed by two monthly doses of pegsiticase alone): A majority of patients in these cohorts maintained clinical activity while receiving the combination therapy through Week 12. These results are consistent with the level of clinical activity observed through Day 30 at a similar SEL-212 dose level in Selecta's Phase 1b trial. At the 0.1 mg/kg dose level, half of the patients that maintained clinical activity through week 12 also maintained clinical activity through week 20.
- **Higher SVP-Rapamycin Dose Cohorts** (Cohorts receiving three monthly doses of 0.4 mg/kg of pegsiticase + 0.125 or 0.15 mg/kg of SVP-Rapamycin followed by two monthly doses of pegsiticase alone): Dosing of patients in these cohorts is now ongoing. At a similar dose level in Selecta's single ascending dose Phase 1b trial, 100 percent of patients achieved clinical activity through Day 30.

ADA levels in the trial continue to strongly correlate with serum uric acid levels. Data show that SVP-Rapamycin reduces the formation of ADAs in a dose-dependent manner, enabling pegsiticase to maintain its clinical activity.

Approximately 24 percent of patients receiving SEL-212 reported a gout flare during their first month of the trial. This is followed by a decline in flare rates during the remainder of the therapy. By comparison, 50% of patients reported a flare during the first month in the control cohorts receiving pegsiticase alone before treatment was stopped due to loss of efficacy and safety.

SEL-212 has been generally well tolerated at clinically active doses following repeated administrations in the trial. There have been 11 serious adverse events reported, four of which were reported to be not related or unlikely related to study drug and seven of which were infusion reactions that were previously reported by the company in its June 2017 data readout. All SAEs were successfully treated and resolved without further issues.

Additional patient data from these cohorts will be included in a presentation entitled "Selecta Q3 2017 Conference Call Presentation" that will be posted to Selecta's website by 8:30 a.m. ET this morning. To access this presentation, please visit www.selectabio.com, select Investors & Media and then Events & Presentations.

Selecta plans to present additional data from this trial at a medical meeting in the first quarter of 2018, participate in an End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA) during the first half of 2018 and initiate its Phase 3 program in 2018.

### **Other Recent Business Highlights and Activities**

- <u>Received Payment From Spark Therapeutics</u>: In December 2016, Selecta and Spark Therapeutics entered into license and stock purchase agreements providing Spark Therapeutics with exclusive worldwide rights to SVP-Rapamycin for co-administration with gene therapy vectors for Hemophilia A and up to four additional pre-specified and undisclosed indications. On October 31, 2017, Selecta received a payment of \$2.5 million under the license agreement and proceeds from share purchases under the stock purchase agreement in the amount of \$5.0 million, or \$7.5 million in the aggregate, bringing the total amount of proceeds received by Selecta from Spark Therapeutics to \$30 million. Selecta also is eligible to receive up to \$430 million in milestone payments for each indication. In addition, Spark Therapeutics will pay Selecta tiered mid-single to low-double-digit royalties on worldwide annual net sales of any resulting commercialized gene therapy.
- <u>Strengthened Senior Management Team</u>: In October 2017, Selecta announced two important additions to its management team to further the company's development with the appointment of John Leaman, M.D., as the company's new Chief Financial Officer, Treasurer and Head of Corporate Strategy, and the addition of Stephen Smolinski to the newly created role of Chief Commercial Officer. Dr. Leaman most recently served as Head of Corporate Development at InfaCare Pharmaceutical Corp., a specialty pharmaceutical company that was recently acquired by Mallinckrodt plc. Mr. Smolinski most recently served as Vice President and Head of Sanofi/Genzyme's North American Rheumatology Business Unit.

## Third Quarter Financial Results:

- <u>Revenue</u>: For the third quarter of 2017, the company's total revenue was less than \$0.1 million, which compares with \$1.0 million for the third quarter of 2016. The decline is primarily the result of reduced revenue recognized from the company's nicotine vaccine candidate grant award from the National Institute on Drug Abuse.
- <u>Research and Development Expenses</u>: Research and development expenses for the third quarter of 2017 were \$9.5 million, which compares with \$6.0 million for the third quarter of 2016. The increase is primarily the result of greater clinical costs related to the company's Phase 2 trial of SEL-212, planning for the SEL-212 Phase 3 program and incremental headcount-related expenses.
- <u>General and Administrative Expenses</u>: General and administrative expenses for the third quarter of 2017 were \$4.4 million, which compares with \$2.5 million for the third quarter of 2016. The increase is primarily the result of greater headcount and related salaries needed to support a clinical-stage public company.
- <u>Net Loss</u>: For the third quarter of 2017, Selecta reported a net loss attributable to common stockholders of \$(14.7) million, or \$(0.66) per share, compared to a net loss of \$(7.7) million, or \$(0.43) per share, for the same period in 2016.
- <u>Cash Position</u>: Selecta had \$104.8 million in cash, cash equivalents, short-term deposits, investments and restricted cash as of September 30, 2017, which compares with a balance of \$113.0 million at June 30, 2017. 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-2019.

## About Chronic Severe Gout, SEL-212 and Selecta's Ongoing Phase 2 Trial

According to market research, more than 500,000 gout patients in the U.S. are treated by rheumatologists and approximately 160,000 of these patients have chronic severe gout. These patients typically have an inflammatory build-up of uric acid deposits called tophi in their joints and tissue that causes pain, inflammation of joints and debilitating flares. If untreated, these deposits also can potentially exacerbate kidney and cardiovascular disease and increase morbidity. In fact, a study published in 2016 involving more than 600 patients diagnosed with tophaceous gout showed a 60% increased risk of mortality when compared to more than 2,800 patients without tophi.<sup>1</sup>

Published data show that uricase enzymes have the unique ability to rapidly eliminate uric acid crystal deposits and tophi in patients with chronic severe gout.<sup>2</sup> However, since these are biologic enzymes that are recognized as "foreign" by the immune system, anti-drug antibodies (ADAs) are induced in most patients early in their treatment, compromising efficacy and safety as well as preventing further administrations.

SEL-212 (SVP-Rapamycin in combination with the uricase enzyme pegsiticase) is designed to be the first monthly uricase treatment and the first uricase treatment that avoids immunogenicity. It is intended to remove the patient's uric acid burden through a short induction treatment cycle, thereby improving acute symptoms such as pain, inflammation of joints and debilitating flares. Selecta also envisions that additional SEL-212 treatment cycles could be re-administered if severe gout symptoms were to recur.

In the fourth quarter of 2016, Selecta began enrolling patients with symptomatic gout and elevated serum uric acid levels in an open-label, multiple ascending dose Phase 2 clinical trial of SEL-212. More information about the trial (NCT02959918) is available at <u>www.clinicaltrials.gov</u>.

## **Conference Call Reminder**

Selecta management will host a conference call at 8:30 a.m. ET today to provide a corporate update and review the company's third 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, <a href="http://selectabio.com">http://selectabio.com</a>. Individuals may also participate in the live call via telephone by dialing (844) 845-4170 (domestic) or (412) 717-9621 (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 10113768.

### 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<sup>™</sup>) with a range of biologics for rare and serious diseases that require new treatment options. The company's current proprietary pipeline includes SVP-enabled

<sup>&</sup>lt;sup>1</sup> Vincent Z et al, Predictors of Mortality in People with Recent Onset of Gout: A Prospective Observational Study, ACR, Sept. 2016

<sup>&</sup>lt;sup>2</sup> Araujo E, Bayat S, Petsch C, Matthias E, Faustini F, Kleyer A, Hueber A, Cavallaro A, Lell M, Dalbeth N, et al. June 2015. Tophus resolution with pegloticase: a prospective dual-energy CT study. Rheumatic & Musculoskeletal Diseases.

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 oncology candidate, SEL-403, leverages a potent recombinant immunotoxin (LMB-100) that is in a Phase 1 program targeting pancreatic cancer and mesothelioma. Its two proprietary gene therapy product candidates, SEL-302 and SEL-313, 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 <a href="http://selectabio.com">http://selectabio.com</a> 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, the potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, the company's plans to participate in a medical meeting in the first quarter of 2018 and to present data concerning the Phase 2 of SEL-212, whether the company will determine an appropriate dose of SEL-212 for a Phase 3, whether the company will hold an End-of-Phase 2 meeting in the first half of 2018, whether the Phase 3 trial will be initiated in 2018 or at all, 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, the potential of the company's two gene therapy product candidates to enable repeat administration, 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 August 11, 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 (Unaudited) (In thousands, except for shares and par value)

	September 30, 2017			December 31, 2016	
Assets					
Current assets:					
Cash and cash equivalents	\$	72,151	\$	58,656	
Short-term deposits and investments		32,237		25,485	
Restricted cash		76		78	
Accounts receivable		_		215	
Prepaid expenses and other current assets		2,888		2,382	
Total current assets		107,352		86,816	
Property and equipment, net		2,055		2,047	
Restricted cash and other deposits		316		316	
Other assets		—		122	
Total assets	\$	109,723	\$	89,301	
Liabilities and stockholders' equity Current liabilities:					
Accounts payable	\$	1,519	\$	3,882	
Accrued expenses		6,547		3,921	
Loans payable, current portion		_		4,067	
Deferred revenue, current portion		3,256		1,836	
Total current liabilities		11,322		13,706	
Non-current liabilities:					
Deferred rent and lease incentive		168		222	
Loans payable, net of current portion		20,954		7,977	
Deferred revenue, net of current portion		10,953		12,439	
Other long-term liabilities		1,250		_	
Total liabilities		44,647		34,344	
Stockholders' equity:					
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30,					
2017 and December 31, 2016, respectively.		_		_	
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 22,120,507 and 18,438,742 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively.		2		1	
Additional paid-in capital		266,836		211,125	
Receivable from stock option exercises		_		(75)	
Accumulated deficit		(197,353)		(151,576)	
Accumulated other comprehensive loss		(4,409)		(4,518)	
Total stockholders' equity		65,076	·	54,957	
Total liabilities and stockholders' equity	\$	109,723	\$	89,301	
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# Selecta Biosciences, Inc. and Subsidiaries Consolidated Statements of Operations and Comprehensive Loss (Unaudited) (In thousands, except share and per share data)

	Three Months Ended September 30,				Nine Months Ended September 30,			
		2017		2016		2017		2016
Grant and collaboration revenue	\$	27	\$	1,048	\$	190	\$	5,153
Operating expenses:								
Research and development		9,504		6,021		31,542		18,669
General and administrative		4,377		2,495		13,155		7,294
Total operating expenses		13,881		8,516		44,697		25,963
Loss from operations		(13,854)		(7,468)		(44,507)		(20,810)
Investment income		165		98		379		121
Loss on extinguishment of debt		(673)		_		(673)		—
Foreign currency transaction gain (loss), net		(30)		(51)		(113)		(429)
Interest expense		(268)		(311)		(847)		(931)
Other expense, net		(16)		4		(16)		(78)
Net loss		(14,676)		(7,728)		(45,777)		(22,127)
Other comprehensive loss:								
Foreign currency translation adjustment		(1)		15		79		416
Unrealized gain (loss) on securities		5		16		30		16
Comprehensive loss	\$	(14,672)	\$	(7,697)	\$	(45,668)	\$	(21,695)
Net loss		(14,676)		(7,728)		(45,777)		(22,127)
Accretion of redeemable convertible preferred stock		—		—		—		(4,566)
Net loss attributable to common stockholders	\$	(14,676)	\$	(7,728)	\$	(45,777)	\$	(26,693)
Net loss per share attributable to common stockholders								
Basic and diluted	\$	(0.66)	\$	(0.43)	\$	(2.31)	\$	(3.39)
Weighted average common shares outstanding								
Basic and diluted		22,082,207		18,108,014		19,803,551		7,881,625

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