Selecta Biosciences Announces Second Quarter 2016 Financial Results and Provides Corporate Update

August 9, 2016 7:00 AM ET

- Demonstrated clinical activity in Phase 1 program of SEL-212
- Advanced two proprietary gene therapy programs based on the same SVP-Rapamycin immunotherapy as SEL-212
- Successfully completed Initial Public Offering with net proceeds of $64.5 million, including proceeds from the exercise of the underwriters' option to purchase additional stock
- At the end of the second quarter of 2016, Selecta had cash, cash equivalents, investments and restricted cash of $85.3 million

WATERTOWN, Mass., Aug. 09, 2016 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (Nasdaq:SELB), a clinical-stage biopharmaceutical company developing targeted antigen-specific immune therapies for rare and serious diseases, today reported financial results and provided a corporate update for the second quarter ended June 30, 2016.

"We have made significant progress this year to advance our SVP™ platform in antigen-specific tolerance, demonstrating clinical activity in the Phase 1 program of our lead program SEL-212 for refractory and tophaceous gout, and securing collaborators and resources to advance our differentiated gene therapy programs toward the clinic. In addition, we completed a successful initial public offering of our common stock, which gives us the financial runway to advance and expand our pipeline, and, we believe, indicates confidence in our science, our team and our data to date," said Werner Cautreels, Ph.D, President, CEO and Chairman of Selecta Biosciences. "Looking ahead, we are on track to initiate the Phase 2 trial of SEL-212 later this year and expect to announce initial data from this Phase 2 trial in the first half of next year. We also continue to advance our gene therapy programs, designed to overcome immunogenicity and enable repeat dosing."

Second Quarter and Recent Business Highlights:

- **Progressing with Lead Program SEL-212 in Gout:** The objectives of the Phase 1a/b program in patients with hyperuricemia were achieved by identifying clinically active doses of SEL-212 (SVP-Rapamycin plus pegsiticase), and by identifying a maximum tolerated dose of the product candidate. The role of SVP-Rapamycin in the SEL-212 product candidate is to induce antigen-specific tolerance against the uricase enzyme. In the Phase 1a single ascending dose trial of pegsiticase only (without SVP-Rapamycin), antibodies against the uricase enzyme were formed as expected, curtailing control of uric acid in many patients to no more than 14 days. It is notable that up to 92% of patients treated with a currently marketed version of uricase for gout also develop immune responses, which have been linked to reduced efficacy and safety. Data from the ongoing Phase 1b single ascending dose trial of SVP-Rapamycin plus fixed doses of pegsiticase demonstrate that clinically active doses of SEL-212 are well tolerated and can prevent the formation of antibodies against the uricase enzyme, enabling sustained control of uric acid for at least 30 days after a single dose, supporting monthly dosing in the upcoming Phase 2 trial. At a dose level 65% above the maximum tolerated dose and 5 times above a clinically active dose of SEL-212, two serious adverse events of stomatitis, a known side effect of rapamycin, occurred and resolved without issues. The second of these two cases was initially diagnosed as a sore throat and graded as a non-serious adverse event, but was retrospectively reclassified in July 2016 by the investigator of that subject. Presentation of the clinical data from the Phase 1a and 1b trials is planned at a scientific meeting in the second half of 2016.

Preparations of the Phase 2 trial of SEL-212 in symptomatic gout patients with hyperuricemia remain on track for initiation during the second half of 2016. This study is expected to be conducted at approximately 15 centers across the United States, with initial data expected in the first half of 2017.

- **Advancing Gene Therapy Programs:** Selecta also announced plans to focus its first two gene therapy programs to be developed with the proprietary immunotherapeutic candidate SVP-Rapamycin for two rare genetic disorders of metabolism, Methylmalonic Acidemia (MMA) and Ornithine Transcarbamylase Deficiency (OTC). Both diseases

cause severe developmental issues and lack effective treatments. SVP-Rapamycin has been shown to inhibit antibody responses to AAV vector and has enabled repeat dosing in animals by our collaborator, Dr. Federico Mingozzi of Genethon. Mitigation of undesired immune responses associated with gene therapy vectors would enable earlier and more frequent treatment, which could result in better therapeutic outcomes compared to gene therapies without SVP-Rapamycin.

Selecta entered into an exclusive license agreement with Massachusetts Eye and Ear (MEE) to apply the next generation gene therapy vector Anc80 to MMA and two collaboration agreements, one with the National Institutes of Health and MEE for MMA and one with the International Centre for Genetics and Biotechnology in Trieste, Italy for OTC.

- **Achieved Milestone Payment under Collaboration with Sanofi:** Selecta's two programs with Sanofi for a food allergy and celiac disease continue to progress. In the second quarter of 2016, Selecta achieved a milestone in the celiac disease program leading to a $1 million payment. Under the terms of the collaboration with Sanofi, Selecta is eligible to receive research support and milestones totaling up to $300 million for each program. Additionally, Selecta is entitled to up to double-digit tiered royalties as a percentage of product net sales for any commercialized immunotherapy resulting from these efforts with Sanofi.

- **Published research on mechanism and application potential in Nature Nanotechnology:** Preclinical data has recently been published in Nature Nanotechnology supporting Selecta's lead clinical program, showing that Selecta's SVP-Rapamycin induces antigen-specific immune tolerance and mitigates the formation of anti-drug antibodies (ADAs) to biologic drugs, including pegsiticase (for gout) and adalimumab (for rheumatoid arthritis). It was demonstrated that once tolerance is induced in mice and cynomolgus monkey, the biologic drug could be administered without the SVP-Rapamycin while avoiding subsequent formation of ADAs. The publication elucidates the mechanisms by which SVP-Rapamycin induces tolerance to mitigate the immunogenicity of biologics including induction of tolerogenic dendritic cells; increase in regulatory T cells; reduction in B cell activation and germinal center formation; and inhibition of antigen-specific hypersensitivity reactions.

- **Successfully Completed Initial Public Offering:** In June 2016, Selecta completed its initial public offering of common stock, raising net proceeds of $60.8 million, after deducting underwriting discounts and commissions and offering expenses. In July 2016, Selecta received additional proceeds of $3.7 million, after deducting underwriting discounts, commissions and offering expenses, from the exercise in part of the underwriters' overallotment option.

- **Announced Board Appointments:** Selecta appointed Timothy C. Barabe to its Board of Directors and Audit Committee. Mr. Barabe has extensive experience in the life sciences industry and serves on the Boards of Directors of Arqule, Vigilant Biosciences, Veeva Systems and Opexa Therapeutics. Mr. Barabe retired in June 2013 from his position as Executive Vice President and Chief Financial Officer of Affymetrix, Inc. Previously, he was Senior Vice President and Chief Financial Officer of Human Genome Sciences and Regent Medical Limited and served with Novartis AG from 1982 through 2004 in a succession of senior executive positions in finance and general management, most recently as the Chief Financial Officer of Sandoz GmbH.

Selecta appointed Timothy A. Springer, Ph.D. to its Board of Directors and Nominating and Governance committee. Dr. Springer is the Latham Family Professor of Biological Chemistry and Molecular Pharmacology and Professor of Medicine at Harvard Medical School and Children's Hospital Boston. He founded LeukoSite in 1993, which developed three drugs approved by the FDA. He has served as Resident Professor at Pfizer. He was an early investor in Selecta and is a founding investor in Moderna and Editas Medicine as well as a founder, investor and board member of Scholar Rock and Morphic Rock Therapeutic.

Unaudited Second Quarter Financial Results:

- **Net Loss:** For the second quarter of 2016, Selecta reported a net loss of $6.9 million, or $(2.75) per share, compared to a net loss of $6.9 million, or $(3.93) per share, for the same period in 2015.

- **Revenue:** For the second quarter of 2016, total revenue of $2.0 million increased by $0.8 million as compared to the same period in the prior year, of which $0.7 million was related to a National Institute of Drug Abuse grant, and $0.3 million was from other grants, offset by $0.2 million lower revenue from collaborations based on the timing of the company's research efforts.

- **Research and Development Expenses:** Research and development expenses for the second quarter of 2016 of $6.0 million increased by $0.7 million as compared to the same period in the prior year. The increase is primarily related to the SEL-212 clinical program, expenses associated with research grants and stock compensation expense, offset by a reduction in license fees.

- **General and Administrative Expenses:** General and administrative expenses of $2.4 million for the second quarter of 2016, increased by $0.2 million compared to the same period in the prior year, primarily due to an increase in patent costs and an increase in accounting fees for quarterly reviews of the company's financial statements, offset by lower depreciation.

- **Cash Position:** Selecta had cash, cash equivalents, investments and restricted cash of $85.3 million at June 30, 2016. In July 2016, Selecta received additional net proceeds of $3.7 million from the exercise in part of the underwriters' over-allotment option.

- **Financial Guidance:** Based on the current operating plan, Selecta expects that its cash, cash equivalents, investments and restricted cash as of June 30, 2016, will fund operating expenses and capital expenditure requirements into the first quarter of 2018.

About Selecta

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company developing targeted therapies that use immunomodulators encapsulated in nanoparticles to induce antigen-specific immune responses to prevent and treat disease. Selecta's proprietary Synthetic Vaccine Particle (SVP) technology is a highly flexible nanoparticle platform, capable of incorporating a wide range of antigens and immunomodulators, allowing the SVP-based products to either induce antigen-specific tolerance or activate the immune system.

Selecta's focus and strategy is to leverage its SVP immune modulating platform to develop and commercialize highly differentiated life-sustaining biologic drugs that are uniquely capable of mitigating the formation of anti-drug antibodies (ADAs). Proprietary programs that use SVP-Rapamycin to enhance efficacy and safety of therapy include SEL-212 for refractory and tophaceous gout and two gene therapies programs for genetic metabolic diseases. Tolerance-inducing SVP biological products also have potential applications in the treatment of allergies and autoimmune diseases.

Selecta is also developing SVP products that activate the immune system to prevent and treat cancer, infections and other diseases.

Selecta is based in Watertown, Massachusetts, USA.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the impact of our initial public offering on our financial position and development of our pipeline, the timing of the Phase 2 clinical trial of SEL-212, including initiation, announcement of data, conference presentations, the number of centers in the Phase 2 clinical trial of SEL-212, the ability of our SVP platform, including SVP-Rapamycin, to mitigate immune response and create better therapeutic

outcomes, the potential treatment applications for SVP products, and the sufficiency of our cash, cash equivalents, investments, and restricted cash.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we have incurred significant losses and may never become profitable; our need for additional funding, which may not be available; our limited operating history; operating and financial restrictions from our credit facility and the charter of our Russian subsidiary; limitations on our ability to use our net operating loss and research and development tax credit carryforwards; the early stage of clinical development for our product candidates; the unproven approach of our SVP technology; our failure to capitalize on more profitable candidates or indications; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; potential delays in enrollment of patients, which could affect the receipt of necessary regulatory approvals; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; our potential inability to obtain orphan drug designation; any fast track or Breakthrough Therapy designation may not lead to faster development, or regulatory or marketing approval; undesirable side effects of our product candidates, which could negatively impact regulatory approval or commercialization; our reliance on third parties to manufacture our product candidates and to conduct our clinical trials; our inability to maintain our existing or future collaborations or licenses; our lack of experience in manufacturing our product candidates on a commercial scale; failure of our product candidates to achieve market acceptance; our inability to establish effective sales, marketing and distribution capabilities; failure of our product candidates to offer material commercial advantages over other treatments; failure to compete successfully against other drug companies; unfavorable pricing regulations, third-party coverage, or reimbursement policies; product liability lawsuits; failure to obtain marketing approval internationally; compliance with healthcare laws and regulations; recently enacted or future legislation; post-marketing restrictions or withdrawal from the market; compliance with export and import controls, sanctions, embargoes, anti-corruption and anti-money laundering laws and regulations; strict price controls imposed by foreign governments; compliance with environmental, health, and safety laws and regulations; negative public opinion or increased regulatory scrutiny of gene therapy and genetic research; our inability to protect our proprietary technology and intellectual property; our inability to protect the confidentiality of our trade secrets and know-how; changes in United States patent law; intellectual property infringement lawsuits; our patents being found invalid or unenforceable; claims challenging the inventorship or ownership of our patents and other intellectual property; failure to comply with intellectual property licenses and funding arrangements; claims that we or our employees misappropriated intellectual property or claiming ownership of our intellectual property; adequate protection of our trademarks and tradenames; ability to obtain FDA approval of product names; competition from biosimilars; ability to attract and retain key executives and qualified personnel; inability to manage our growth; risks associated with operating in Russia and internationally; potential system failures; misconduct of our employees or contracted third parties; impact of acquisitions or joint ventures; substantial fluctuation in the price of our common stock; our executive officers, directors, and principal stockholders have the ability to control or significantly influence matters submitted to stockholders; a significant portion of our total outstanding shares are eligible to be sold into the market in the near future; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against us.

These and other important factors discussed under the caption "Risk Factors" in our final prospectus filed with the Securities and Exchange Commission, or SEC, on June 23, 2016 relating to our Registration Statement on Form S-1, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

(In thousands, except for shares and par value)

	June 30, 2016 (unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 82,648	$ 32,337
Short term deposits and investments	1,900	4,125
Restricted cash	407	133
Accounts receivable	1,961	824
Prepaid expenses and other current assets	2,131	1,494
Total current assets	89,047	38,913
Property and equipment, net	1,954	2,029
Restricted cash and other deposits	316	316
Other assets	—	1,566
Total assets	$ 91,317	$ 42,824
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 943	$ 2,179
Accrued expenses	4,715	3,378
Loans payable, current portion	1,781	—
Deferred revenue, current portion	1,242	1,313
Contingently repayable grant funding	258	420
Total current liabilities	8,939	7,290
Non-current liabilities:		
Deferred rent and lease incentive	—	105
Loans payable, net of current portion	10,128	11,855
Deferred revenue, net of current portion	3,474	2,295
Other long-term liabilities	—	290
Total liabilities	22,541	21,835
Commitments and contingencies (Notes 7 and 12)		
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 June 30, 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	—	21,448

7,437,325 shares issued and outstanding; as of June 30, 2016 and December 31, 2015 respectively.		
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 June 30, 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 June 30, 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 June 30, 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 June 30, 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 and 0 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively.	—	—
Common stock, $0.0001 par value; 200,000,000 and 62,164,377 shares authorized at June 30, 2016 and December 31, 2015 respectively; 17,900,547 and 2,180,976 shares issued, 17,895,824 and 2,173,399 shares outstanding as of June 30, 2016 and December 31, 2015, respectively	1	—
Additional paid-in capital	203,125	1
Accumulated deficit	(129,765)	(111,508)
Accumulated other comprehensive loss	(4,585)	(4,986)
Total stockholders' equity (deficit)	68,776	(116,493)
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 91,317	$ 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 June 30,	
	2016	**2015**
Grant and collaboration revenue	$ 2,017	$ 1,236
Operating expenses:		

Research and development	6,000		5,314	
General and administrative	2,418		2,238	
Total operating expenses	8,418		7,552	
Loss from operations	(6,401	)	(6,316	)
Investment income	10		62	
Foreign currency transaction gain (loss), net	(158	)	(246	)
Interest expense	(310	)	(330	)
Other expense, net	(64	)	(37	)
Net loss	(6,923	)	(6,867	)
Other comprehensive loss:				
Foreign currency translation adjustment	170		245	
Comprehensive loss	$ (6,753	)	$ (6,622	)
Net loss	(6,923	)	(6,867	)
Accretion of redeemable convertible preferred stock	(2,210	)	(1,562	)
Net loss attributable to common stockholders	$ (9,133	)	$ (8,429	)
Net loss per share attributable to common stockholders				
Basic and diluted	$ (2.75	)	$ (3.93	)
Weighted average common shares outstanding				
Basic and diluted	3,322,546		2,147,184	

Media contact:
Kathryn Morris
The Yates Network
+1-845-635-9828
kathryn@theyatesnetwork.com

Investor contact:
Stephanie Ascher
Stern Investor Relations, Inc.
+1-212-362-1200
stephanie@sternir.com

Selecta Biosciences Inc