



Selecta Biosciences Reports First Quarter 2023 Financial Results and Provides Business Update

May 4, 2023

- Company to implement capital prioritization initiative, extending cash runway to 2H-2025 -

- \$127.5 million in cash, cash equivalents, restricted cash, and marketable securities as of March 31, 2023 -

- Reported positive data from Phase 3 DISSOLVE program of SEL-212 in chronic refractory gout; BLA filing expected in 1H 2024 -

- Selecta to host conference call today at 8:30 AM ET -

WATERTOWN, Mass., May 04, 2023 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its clinically validated ImmTOR™ platform to develop tolerogenic therapies for autoimmune diseases and gene therapies, today reported financial results for the first quarter ended March 31, 2023 and provided a business update.

The Company also announced a program prioritization and capital allocation strategy that is expected to extend its cash runway into the second half of 2025.

"As the only immune tolerance platform with positive Phase 3 data, we firmly believe in the potential of our pipeline of candidates powered by our ImmTOR technology," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta. "As we continue to navigate the current market environment, we have undertaken the strategic decision to focus our resources in the areas where we believe we have the highest potential to succeed in delivering meaningful therapies to the patients we aim to serve. In the near term, we look forward to continuing to work with our partner, Sobi®, to advance SEL-212 (ImmTOR in combination with pegadricase) toward a Biologics License Application (BLA), which we continue to expect in the first half of 2024, while also advancing our ImmTOR-IL combination for diseases of the liver."

Strategic Initiative Overview

Following a comprehensive review of its portfolio and capital resources, Selecta, in consultation with the Company's Board of Directors, plans to streamline operations and prioritize investments in select programs. As part of this initiative, the Company plans to:

- **Advance SEL-212 in Patients with Chronic Refractory Gout in Partnership with Sobi.** In March 2023, Selecta and its SEL-212 development partner, Sobi, reported positive Phase 3 data from the Phase 3 DISSOLVE I & II placebo controlled randomized clinical trials. Both trials met their primary endpoint, and SEL-212 was observed to be safe and well-tolerated. A BLA submission remains on track for the first half of 2024. In June 2020, Sobi licensed SEL-212 from Selecta and is responsible for development, regulatory, and commercial activities in all markets outside of China.
- **Prioritize Development of the Combination of ImmTOR and Company's Proprietary Treg-Selective IL-2 (ImmTOR-IL).** The combination of ImmTOR and IL-2 (ImmTOR-IL) represents an evolution of Selecta's precision immune tolerance platform. The Company remains on track to initiate Investigational New Drug (IND)-enabling studies in 2023, while also exploring multiple autoimmune indications that may be suitable for study with ImmTOR-IL, with an initial focus on diseases of the liver.
- **Develop SEL-018 IgG Protease (Xork) for LOPD in Partnership with Astellas Gene Therapies.** In January 2023, the Company announced an exclusive licensing and development agreement for IdeXork (Xork), a next-generation immunoglobulin G (IgG) protease, to be developed for use with AT845, Astellas Gene Therapies' investigational adeno-associated virus (AAV)-based treatment for Late-Onset Pompe disease (LOPD) in adults. Xork is designed to be differentiated by its low-cross reactivity to pre-existing antibodies in human serum, which the Company believes has the potential to expand access to life-changing gene therapies for more patients.
- **Advance Gene Therapy Programs through Potential Partnerships.** Selecta will pause further development of its wholly-owned gene therapy programs, including the ongoing Phase 1/2 clinical trial of SEL-302, an AAV gene therapy combined with ImmTOR for the treatment of methylmalonic acidemia (MMA). The Company is currently assessing ways to support further development of these programs through potential partnerships.
- **Reduction in Force.** The Company reduced its headcount by approximately 25% in order to align its workforce with its updated priorities. As a result of the reduction in force, the Company expects to incur a cash charge of approximately \$1.0 million related to severance and benefit-related expenses.

Dr. Brunn added, "The decision to enact these measures was extremely difficult, as we are losing many valued colleagues who helped advance

Selecta to where it is today. I would like to express my sincere gratitude to all of these individuals.”

First Quarter 2023 Financial Results:

Cash Position: Selecta had \$127.5 million in cash, cash equivalents, restricted cash, and marketable securities as of March 31, 2023, as compared to cash, cash equivalents, restricted cash, and marketable securities of \$136.2 million as of December 31, 2022. Selecta believes that following the capital efficiencies expected to be realized through its strategic reprioritization, its available cash, cash equivalents, restricted cash, and marketable securities, as well as the next anticipated milestone payment related to SEL-212 development activities, will be sufficient to meet its operating requirements into the second half of 2025.

Collaboration and License Revenue: Revenue for the first quarter of 2023 was \$5.9 million, as compared to \$34.0 million for the same period in 2022. Revenue was primarily driven by the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program under the license agreement with Sobi.

Research and Development Expenses: Research and development expenses for the first quarter of 2023 were \$18.6 million, as compared to \$17.7 million for the same period in 2022. The increase was primarily the result of expenses incurred for contract license and milestone payments and personnel expenses partially offset by a decrease in expenses incurred for the SEL-212 clinical program.

General and Administrative Expenses: General and administrative expenses for the first quarter of 2023 were \$5.7 million, as compared to \$5.5 million for the same period in 2022. The increase was primarily the result of increased personnel expenses.

Net (Loss) Income: For the first quarter of 2023, Selecta reported net loss of \$21.7 million, or basic net loss per share of \$(0.14). For the first quarter of 2022, Selecta reported net income of \$28.8 million, or \$0.23 per share.

Conference Call and Webcast Reminder

Selecta's management will host a conference call at 8:30 AM ET today to provide a corporate update and review the Company's first quarter 2023 financial results and strategic initiatives. Individuals may 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 6836582. Investors and the public can access the live and archived webcast of this call and a copy of the presentation via the Investors & Media section of the Company's website, www.selectabio.com.

About Selecta Biosciences, Inc.

Selecta Biosciences Inc. (NASDAQ: SELB) is a clinical stage biotechnology company leveraging its ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses. With a proven ability to induce tolerance to highly immunogenic proteins, ImmTOR has the potential to amplify the efficacy of biologic therapies, including redosing of life-saving gene therapies, as well as restore the body's natural self-tolerance in autoimmune diseases. Selecta has several proprietary and partnered programs in its pipeline focused on enzyme therapies, gene therapies, and autoimmune diseases. Selecta Biosciences is headquartered in the Greater Boston area. For more information, please visit www.selectabio.com.

Selecta 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 Company's expected cash runway; the Company's strategic prioritization of SEL-212 and its collaborations with Sobi and Astellas, the unique proprietary technology platform of the Company and its partners, the potential of ImmTOR to enable re-dosing of therapies and to mitigate immunogenicity, the potential of ImmTOR and the Company's product pipeline to treat chronic refractory gout, MMA, liver diseases, other autoimmune diseases, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's and its partners' ability to conduct its and their clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the ability of the Company to consummate any expected agreements and licenses, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, gout and autoimmune disease, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, the potential of any therapies developed by the Company to fulfill unmet medical needs, the Company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the potential of the ImmTOR technology platform generally, the Company's ability to grow and maintain its strategic partnerships, and enrollment in the Company's clinical trials 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 proof of concept trials, including uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's ImmTOR technology, potential delays in enrollment of patients, 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, the Company's recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. 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 intention to update any forward-looking statements included in this press release, except as required by law.

For Investors and Media:

Blaine Davis
Chief Financial Officer

Financial Tables
Selecta Biosciences, Inc. and Subsidiaries
Consolidated Balance Sheets
(Amounts in thousands, except share data and par value)

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
	<u>(Unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 125,925	\$ 106,438
Marketable securities	—	28,164
Accounts receivable	6,839	6,596
Unbilled receivables	1,843	3,162
Prepaid expenses and other current assets	3,785	3,778
Total current assets	<u>138,392</u>	<u>148,138</u>
Non-current assets:		
Property and equipment, net	2,765	2,794
Right-of-use asset, net	11,201	11,617
Long-term restricted cash	1,311	1,311
Investments	2,000	2,000
Other assets	24	26
Total assets	<u>\$ 155,693</u>	<u>\$ 165,886</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,063	\$ 316
Accrued expenses	9,347	14,084
Loan payable	10,218	8,476
Lease liability	1,671	1,608
Deferred revenue	4,232	593
Total current liabilities	<u>26,531</u>	<u>25,077</u>
Non-current liabilities:		
Loan payable, net of current portion	16,228	17,786
Lease liability, net of current portion	9,617	10,055
Deferred revenue	5,519	—
Warrant liabilities	23,219	19,140
Total liabilities	<u>81,114</u>	<u>72,058</u>
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 153,426,983 and 153,042,435 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	15	15
Additional paid-in capital	495,733	493,308
Accumulated deficit	(416,600)	(394,937)
Accumulated other comprehensive loss	(4,569)	(4,558)
Total stockholders' equity	<u>74,579</u>	<u>93,828</u>
Total liabilities and stockholders' equity	<u>\$ 155,693</u>	<u>\$ 165,886</u>

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

	Three Months Ended	
	March 31,	
	<u>2023</u>	<u>2022</u>
	<u>(Unaudited)</u>	
Collaboration and license revenue	\$ 5,938	\$ 33,999
Operating expenses:		
Research and development	18,624	17,689
General and administrative	5,695	5,537

Total operating expenses	24,319	23,226
Operating (loss) income	(18,381)	10,773
Investment income	1,331	15
Foreign currency transaction, net	19	28
Interest expense	(808)	(707)
Change in fair value of warrant liabilities	(4,079)	18,515
Other income, net	255	154
Net (loss) income	<u>\$ (21,663)</u>	<u>\$ 28,778</u>
Other comprehensive income (loss):		
Foreign currency translation adjustment	(22)	(32)
Unrealized gain on marketable securities	11	—
Total comprehensive income (loss)	<u>\$ (21,674)</u>	<u>\$ 28,746</u>
Net (loss) income per share:		
Basic	<u>\$ (0.14)</u>	<u>\$ 0.23</u>
Diluted	<u>\$ (0.14)</u>	<u>\$ 0.08</u>
Weighted average common shares outstanding:		
Basic	<u>153,345,554</u>	<u>124,232,799</u>
Diluted	<u>153,345,554</u>	<u>127,573,485</u>



Source: Selecta Biosciences, Inc.