Selecta Biosciences Reports First Quarter 2022 Financial Results and Provides Business Update

May 5, 2022

– Phase 1 trial of SEL-302 remains on track to initiate in the second half of 2022 –

– DISSOLVE I & II studies on track for completion in Q4 2022 with joint topline readout in Q1 2023 –

– Completed underwritten offering, raising approximately $38.7 million in gross proceeds, extending runway into mid-2024 –

– As of April 11, 2022, Selecta had approximately $154.2 million in cash, cash equivalents, restricted cash and marketable securities –

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

WATERTOWN, Mass., May 05, 2022 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its clinically validated ImmTOR® platform to develop tolerogenic therapies for autoimmune diseases, enhance gene therapies and mitigate unwanted immune responses to biologics, today reported financial results for the first quarter ended March 31, 2022 and provided a business update.

"In the first quarter of 2022, we executed across our pipeline and proactively took measures to extend our cash runway into mid-2024," said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. "In early April, we successfully completed an underwritten offering, raising an additional $38.7 million in gross proceeds, further strengthening our financial resources which we believe will carry us through key value-driving milestones and help Selecta realize the full potential of our leading precision immune tolerance platform. The synergistic effects of ImmTOR in combination with a Treg-selective IL-2 (ImmTOR-IL™) has the potential to be a first-in-class, antigen-specific immunotherapy, with broad applications across all three pillars of our pipeline. Furthermore, we believe we are well-positioned to deliver on our clinical development strategy across our wholly owned pipeline while continuing to pursue strategic partnerships in gene therapy and biologics. We remain on track to deliver on multiple upcoming catalysts in 2022, including the initiation of a Phase 1 trial of SEL-302, our wholly owned gene therapy in combination with ImmTOR for the treatment MMA, the completion of the Phase 3 DISSOLVE clinical program in chronic refractory gout and several IND-enabling studies that collectively advance our strategy for re-imagining immunotherapy for autoimmune disease, unlocking the potential of AAV gene therapy and amplifying the efficacy of biologics."

Recent Highlights and Anticipated Upcoming Milestones:

Tolerogenic Therapies for Autoimmune Disease

- ***ImmTOR with proprietary IL-2 protein agonist (ImmTOR-IL™)****:* Pre-clinically, Selecta has observed synergistic activity when ImmTOR is combined with engineered IL-2 molecules that are selective for Tregs. When ImmTOR-IL was co-administered with an antigen of interest in a preclinical study, the resulting preclinical data suggest that ImmTOR may have profound synergistic effects in further expanding antigen-specific Tregs when compared to ImmTOR alone, positioning it to be a potential first-in-class antigen-specific therapy for the treatment of autoimmune disease.
    - Selecta is working with its partner, Cyrus Biotechnology, to develop a next generation IL-2 molecule to combine with ImmTOR.
    - Selecta continues work toward identifying suitable target indications and accelerating the development of ImmTOR-IL to the clinic.
- ***Primary biliary cholangitis (PBC):*** Selecta continues IND-enabling work on an ImmTOR platform approach to treating PBC.

Gene Therapies:

- ***SEL-302 for methylmalonic acidemia (MMA)****:* On March 9, 2022, the FDA removed the clinical hold on SEL-302 for the treatment of patients with MMA.
    - Selecta expects initiation of the Phase 1 clinical trial of SEL-302 in the second half of 2022.
- ***SEL-018 IgG Protease (Xork)****:* In collaboration with Genovis, Selecta continues to advance Xork, a next-generation IgG protease, to help address disease in those patients who are ineligible for gene therapies due to pre-existing anti-AAV antibodies. Selecta believes the novel combination of Xork and ImmTOR has the potential to simultaneously address two of the key hurdles in gene therapy today: pre-existing immunity and the inability to re-dose AAV gene therapies.
    - IND-enabling studies are expected to commence in 2022.

Biologic Therapies:

- ***SEL-212 for chronic refractory gout****:* Selecta continues to advance DISSOLVE, the Phase 3 development program of

SEL-212, which has been licensed to Swedish Orphan Biovitrum AB (publ.) (“Sobi”).
    - On December 1, 2021, Selecta announced complete enrollment for DISSOLVE I, currently being run in the United States.
    - DISSOLVE II continues to enroll, with trial sites in the United States and four Eastern European countries. Screening and randomization in both Russia and Ukraine have been temporarily closed to preserve study supplies in these countries for those already enrolled. Moreover, 11 additional sites in the United States have been activated to speed enrollment and help mitigate any potential disruptions from the closure of screening and randomization in Russia and Ukraine, and DISSOLVE II enrollment has been increased to approximately 140 study participants.
    - DISSOLVE I & II studies are on track for completion in Q4 2022 with joint topline readout expected in Q1 2023.

- ***ImmTOR with IgA1 protease for IgA nephropathy***: Selecta is working with both Ginkgo Bioworks and IGAN Biosciences to identify and develop a next generation IgA protease to combine with ImmTOR.
    - Selecta anticipates enzyme candidate selection to be completed in 2022.

Corporate Updates:

- Completed underwritten offering of common stock and warrants, raising approximately $38.7 million in gross proceeds.
- Amended outstanding term loan to defer principal amortization period to April 1, 2023.
- Performed strategic review and portfolio prioritization, pausing SEL-313, OTC-D gene therapy development and increasing focus on providing modality-enabling solutions to AAV gene therapy companies.

First Quarter 2022 Financial Results

Cash Position: Selecta had $118.8 million in cash, cash equivalents, marketable securities, and restricted cash as of March 31, 2022, as compared to cash, cash equivalents, marketable securities, and restricted cash of $129.4 million as of December 31, 2021. With the approximately $36.0 million in net proceeds raised from the April underwritten offering, Selecta believes its available cash, cash equivalents, restricted cash, and marketable securities will be sufficient to meet its operating requirements into mid-2024. Net cash used in operating activities was $11.9 million for the quarter ended March 31, 2022, as compared to $12.1 million of cash used in operating activities for the same period in 2021.

Collaboration and License Revenue: Collaboration and license revenue for the first quarter of 2022 was $34.0 million, as compared to $11.1 million for the same period in 2021. 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 2022 were $17.7 million, as compared to $13.0 million for the same period in 2021. The increase in cost was primarily the result of expenses incurred for the preclinical programs, salaries and contract license and milestone payments.

General and Administrative Expenses: General and administrative expenses for the first quarter of 2022 were $5.5 million, as compared to $5.2 million for the same period in 2021. The increase in costs was primarily the result of stock compensation expenses.

Net Income (loss): For the first quarter of 2022, Selecta reported net income of $28.8 million, or basic net income per share of $0.23, compared to net loss of $(24.6) million, or $(0.22) per share, for the same period in 2021.

Conference Call and Webcast Reminder
Selecta management will host a conference call at 8:30 AM ET today to provide a corporate update and review the company’s first quarter 2022 financial results. 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 10157872. 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 cash runway, the unique proprietary technology platform of the Company, and the unique proprietary platform of its partners, the potential of ImmTOR to enable re-dosing of AAV gene therapy and to mitigate immunogenicity, the potential of ImmTOR and the Company’s product pipeline to treat chronic refractory gout, MMA, IgAN, other autoimmune diseases, lysosomal storage disorders, 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 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, whether the observations made in non-human study subjects will translate to studies performed with human beings, 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 Company’s technology to enable repeat administration in gene therapy product candidates and products, the ability to re-dose patients

and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, the potential of the ImmTOR technology platform generally and the Company's ability to grow its strategic partnerships, enrollment in the Company's clinical trials and the Company's plans with respect to areas affected by geopolitical conflict 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 the 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 or 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 its 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 Quarterly Report on Form 10-Q to be filed after this release, 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.

For investors:
Bruce Mackle
LifeSci Advisors, LLC
+1-929-469-3859
bmackle@lifesciadvisors.com

For media:
Brittany Leigh, Ph.D.
LifeSci Communications, LLC
+1-813-767-7801
bleigh@lifescicomms.com

Financial Tables

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

(Amounts in thousands, except share data and par value)

	March 31, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 113,437	$ 114,057
Marketable securities	3,997	13,998
Accounts receivable	7,153	9,914
Prepaid expenses and other current assets	5,420	6,474
Total current assets	130,007	144,443
Non-current assets:		
Property and equipment, net	2,689	2,142
Right-of-use asset, net	9,536	9,829
Long-term restricted cash	1,379	1,379
Investments	2,000	2,000
Other assets	85	90
Total assets	$ 145,696	$ 159,883
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 264	$ 224
Accrued expenses	8,889	10,533
Loan payable	696	5,961
Lease liability	1,087	1,049
Income taxes payable	320	601
Deferred revenue	27,990	53,883
Total current liabilities	39,246	72,251
Non-current liabilities:		

Loan payable, net of current portion	25,042	19,673
Lease liability, net of current portion	8,316	8,598
Deferred revenue	10,420	11,417
Warrant liabilities	6,908	25,423
Total liabilities	89,932	137,362
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 124,380,844 and 123,622,965 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	12	12
Additional paid-in capital	461,888	457,391
Accumulated deficit	(401,538)	(430,316)
Accumulated other comprehensive loss	(4,598)	(4,566)
Total stockholders' equity	55,764	22,521
Total liabilities and stockholders' equity	$ 145,696	$ 159,883

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,	
	2022	**2021**
	(Unaudited)	
Collaboration and license revenue	$ 33,999	$ 11,050
Operating expenses:		
Research and development	17,689	13,004
General and administrative	5,537	5,204
Total operating expenses	23,226	18,208
Operating income (loss)	10,773	(7,158)
Investment income	15	12
Foreign currency transaction, net	28	7
Interest expense	(707)	(711)
Change in fair value of warrant liabilities	18,515	(16,747)
Other income, net	154	—
Net income (loss)	$ 28,778	$ (24,597)
Other comprehensive income (loss):		
Foreign currency translation adjustment	(32)	(6)
Unrealized loss on marketable securities	—	(1)
Total comprehensive income (loss)	$ 28,746	$ (24,604)
Net income (loss) per share:		
Basic	$ 0.23	$ (0.22)
Diluted	$ 0.08	$ (0.22)
Weighted average common shares outstanding:		
Basic	124,232,799	110,742,150
Diluted	127,573,485	110,742,150

Source: Selecta Biosciences, Inc.