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

November 3, 2022

– DISSOLVE I & II studies of SEL-212 in Chronic Refractory Gout remain on track for joint topline data readout in Q1 2023 –

– SEL-302, Selecta's wholly owned gene therapy in combination with ImmTOR for the treatment of Methylmalonic Acidemia (MMA), remains on track to begin a Phase 1 trial in Q4 2022 –

– As of September 30, 2022, Selecta had approximately $148.0 million in cash, cash equivalents, restricted cash and marketable securities, which is expected to provide runway into mid-2024 –

– Candidate selection for an IL-2 and IgA protease expected by year-end 2022 –

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

WATERTOWN, Mass., Nov. 03, 2022 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company pioneering precision immune tolerance with its clinically validated ImmTOR® platform to develop tolerogenic therapies for autoimmune diseases, unlock the potential of gene therapies and amplify the efficacy of biologic therapies, today reported financial results for the third quarter ended September 30, 2022 and provided a business update.

"We are pleased with the steady progress seen across our clinical and pre-clinical pipelines. With expected financial runway into mid-2024 we believe we are well-positioned to execute on our key priorities and achieve multiple near-term value driving inflection points," said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. "Clinically, we remain on track to initiate the Phase 1 trial of SEL-302, our wholly owned gene therapy in combination with ImmTOR for the treatment of MMA in Q4 2022, and expect to report joint topline data from the Phase 3 DISSOLVE clinical program investigating SEL-212 in chronic refractory gout, in Q1 2023. Preclinically, with our external partners we continue to drive toward candidate selection for an IgA protease to treat IgA nephropathy, as well as progress IND-enabling studies and manufacturing scale-up for Xork, our proprietary IgG protease developed as a pre-treatment to enable AAV gene therapies. Finally, building on the recently presented data at ESGCT, we continue our work in identifying a proprietary IL-2 to combine with ImmTOR, which we anticipate announcing by year-end. We believe ImmTOR- IL™, based on the synergistic effects we have observed preclinically, has the potential to be a generational leap forward for our precision immune tolerance platform."

Recent Program Highlights and Anticipated Upcoming Milestones:

Tolerogenic Therapies for Autoimmune Disease:

- ***ImmTOR-IL****:* Preclinically, Selecta has observed synergistic activity when ImmTOR is combined with engineered IL-2 molecules that are selective for Tregs (ImmTOR-IL™). Furthermore, when ImmTOR-IL was co-administered with an antigen of interest, the resulting data suggested that ImmTOR-IL may have profound synergistic effects in expanding antigen-specific Tregs when compared to ImmTOR alone, positioning ImmTOR-IL as a potential first-in-class antigen-specific therapy for the treatment of autoimmune disease.
    - Selecta continues to work with its partners to develop a next generation IL-2 molecule to combine with ImmTOR and still anticipates selecting an IL-2 candidate by year-end 2022.
    - Selecta continues internal work on identifying additional target indications in autoimmune disease. Selecta plans to adopt a staged development approach, starting first with diseases driven by a single pathogenic antigen, such as Primary Biliary Cholangitis (PBC), then accelerating development across related indications.
- ***Primary biliary cholangitis (PBC):*** Selecta intends to co-administer ImmTOR-IL with PDC-E2, the autoantigen implicated in PBC and continues IND-enabling work for this combination.

Gene Therapies:

- ***SEL-302 for MMA****:* Selecta remains on track to initiate a Phase 1/2 clinical trial of SEL-302, an AAV gene therapy combined with ImmTOR for the treatment of MMA, in the fourth quarter 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 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 address two of the key hurdles in gene therapy today: pre-existing immunity to AAVs and the inability to re-dose AAV gene therapies due to the immune response to AAV capsids.
    - IND-enabling studies and manufacturing scale-up activities are ongoing.

- ***ImmTOR-IL:*** In October 2022, we presented preclinical data at the 29th Annual European Society of Gene and Cell Therapy (ESGCT) Conference further supporting the potential therapeutic utility of ImmTOR in enabling safe repeated vector dosing and mitigating unwanted immune responses. Additionally, we presented data in which we observed the potential of ImmTOR-IL in driving antigen-specific Treg expansion while synergistically inhibiting formation of anti-AAV antibodies at high vector doses.

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 Sobi.
  - In Q3 2022, Selecta received a $10 million milestone payment from Sobi following the completion of enrollment of DISSOLVE II in June 2022.
  - DISSOLVE I & II trials are on track for completion in Q1 2023 with joint topline readout expected in Q1 2023.

- ***ImmTOR with IgA protease for IgA nephropathy***: Selecta continues to work with its partners to identify and develop a next generation IgA protease to combine with ImmTOR, and consistent with prior guidance anticipates selecting an enzyme candidate by year-end 2022.

Further Corporate and Partnership Updates:

- In Q3 2022, and as previously disclosed, Selecta received a $2 million payment from Sarepta relating to the extension of its Research License and Option Agreement for ImmTOR in Duchenne Muscular Dystrophy (DMD) and certain Limb-Girdle Muscular Dystrophies (LGMD) for an additional nine months to Q1 2023, and an additional $4 million payment from Sarepta for achievement of certain preclinical milestones.

Third Quarter 2022 Financial Results

Cash Position: Selecta had $148.0 million in cash, cash equivalents, marketable securities, and restricted cash as of September 30, 2022, as compared to cash, cash equivalents, marketable securities, and restricted cash of $129.4 million as of December 31, 2021. Net cash used in operating activities was $19.8 million for the nine months ended September 30, 2022, as compared to $28.9 million of cash used in operating activities for the same period in 2021. Selecta believes its available cash, cash equivalents, restricted cash, and marketable securities will be sufficient to meet its operating requirements into mid-2024.

Collaboration and License Revenue: Collaboration and license revenue for the third quarter of 2022 was $20.7 million, as compared to $24.4 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 third quarter of 2022 were $16.5 million, as compared to $21.0 million for the same period in 2021. The decrease in cost was primarily the result of a decrease in expenses incurred for the SEL-212 clinical program, preclinical programs, and the AskBio collaboration.

General and Administrative Expenses: General and administrative expenses for the third quarter of 2022 were $5.8 million, as compared to $5.4 million for the same period in 2021. The increase in costs was primarily the result of expenses incurred for stock compensation and personnel expenses.

Net loss: For the third quarter of 2022, Selecta reported net loss of $7.9 million, or basic net loss per share of $0.05, compared to net loss of $17.9 million, or basic net loss per share of $0.16, 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 business update and review the company's third quarter 2022 financial results. Individuals may participate in the live call via telephone by dialing (844) 845-4170 (domestic) or +1 (412) 717-9621 (international) and may access a teleconference replay for one week by dialing (877) 344-7529 (domestic) or +1 (412) 317-0088 (international) and using confirmation code 10157874. 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 anticipated timing or outcome of selection of developmental product candidates, 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 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 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 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 subsequent 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.

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Financial Tables

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

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

	September 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 112,843	$ 114,057
Marketable securities	33,599	13,998
Accounts receivable	6,925	9,914
Prepaid expenses and other current assets	6,310	6,474
Total current assets	159,677	144,443
Non-current assets:		
Property and equipment, net	2,904	2,142
Right-of-use asset, net	12,056	9,829
Long-term restricted cash	1,600	1,379
Investments	2,000	2,000
Other assets	28	90
Total assets	$ 178,265	$ 159,883
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 214	$ 224
Accrued expenses	12,263	10,533

Loan payable	5,879	5,961
Lease liability	1,552	1,049
Income taxes payable	—	601
Deferred revenue	3,820	53,883
Total current liabilities	23,728	72,251
Non-current liabilities:		
Loan payable, net of current portion	20,215	19,673
Lease liability, net of current portion	10,506	8,598
Deferred revenue	5,436	11,417
Warrant liabilities	33,473	25,423
Total liabilities	93,358	137,362
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 350,000,000 and 200,000,000 shares authorized as of September 30, 2022 and December 31, 2021, respectively; 153,028,822 and 123,622,965 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	15	12
Additional paid-in capital	490,252	457,391
Accumulated deficit	(400,830)	(430,316)
Accumulated other comprehensive loss	(4,530)	(4,566)
Total stockholders' equity	84,907	22,521
Total liabilities and stockholders' equity	$ 178,265	$ 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited)			
Collaboration and license revenue	$ 20,710	$ 24,427	$ 93,982	$ 55,140
Operating expenses:				
Research and development	16,539	20,951	53,410	48,418
General and administrative	5,770	5,445	17,538	15,397
Total operating expenses	22,309	26,396	70,948	63,815
Operating income (loss)	(1,599)	(1,969)	23,034	(8,675)
Investment income	710	11	932	35
Foreign currency transaction, net	15	2	(61)	(5)
Interest expense	(802)	(711)	(2,224)	(2,133)
Change in fair value of warrant liabilities	(6,539)	592	7,329	(11,335)
Other income, net	1	9	155	15
Income (loss) before income taxes	(8,214)	(2,066)	29,165	(22,098)
Income tax (expense) benefit	321	(15,828)	321	(15,828)
Net income (loss)	$ (7,893)	$ (17,894)	$ 29,486	$ (37,926)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(21)	(1)	65	5
Unrealized loss on marketable securities	(29)	(1)	(29)	(1)
Total comprehensive income (loss)	$ (7,943)	$ (17,896)	$ 29,522	$ (37,922)
Net income (loss) per share:				
Basic	$ (0.05)	$ (0.16)	$ 0.21	$ (0.34)
Diluted	$ (0.05)	$ (0.16)	$ 0.15	$ (0.34)
Weighted average common shares outstanding:				
Basic	152,849,992	115,169,949	141,969,449	113,161,622
Diluted	152,849,992	115,169,949	143,792,060	113,161,622

Source: Selecta Biosciences, Inc.