Selecta Biosciences Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

March 2, 2023

- Topline data for Phase 3 DISSOLVE I & II clinical trials of SEL-212 in chronic refractory gout remains on track for Q1 2023 -

- Continue to enroll patients in ReiMMAgine, the Phase 1/2 clinical trial of SEL-302 for the treatment of methylmalonic acidemia (MMA) -

- IND enabling studies expected to commence in 2023 for interleukin-2 (IL-2) candidate to be studied in combination with ImmTOR™, as well as IgA protease candidate for the treatment of IgA Nephropathy -

- As of December 31, 2022, Selecta had approximately $136.2 million in cash, cash equivalents, restricted cash and marketable securities, which is expected to provide runway into mid-2024 -

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

WATERTOWN, Mass., March 02, 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 fourth quarter and full year ended December 31, 2022 and provided a business update.

“2022 was a successful year for Selecta. We delivered on key milestones across our pipeline and established strategic collaborations that have allowed us to drive forward our development programs,” said Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta. “The Phase 3 DISSOLVE I and II clinical trials investigating SEL-212 in chronic refractory gout remains on track, and we expect to deliver topline data later this quarter. We look forward to the potential for SEL-212 to address the unmet needs of patients suffering from chronic refractory gout. In addition, we are currently enrolling patients in ReiMMAgine, our Phase 1/2 clinical trial of SEL-302 for the treatment of MMA. We intend to continue to leverage learnings from our clinical experience and growing safety database to propel our next-generation programs toward multiple IND filings and advance our wholly owned pipeline using ImmTOR in combination with a proprietary IL-2 (ImmTOR-IL), which we believe has the potential to address the unmet need for precision immunotherapy for autoimmune diseases.”

Recent Program Highlights and Anticipated Upcoming Milestones:

Tolerogenic Therapies for Autoimmune Disease:

ImmTOR-IL: In December 2022, the Company selected an identified IL-2 candidate.

- The combination of ImmTOR and IL-2 (ImmTOR-IL) represents an evolution of the precision immune tolerance platform, and an opportunity to further advance and expand the Company’s wholly-owned pipeline.
- The Company plans to initiate 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.

Gene Therapies:

SEL-302 for MMA: In December 2022, the Company initiated ReiMMAgine, the Phase 1/2 clinical trial of SEL-302, an adeno-associated virus (AAV) gene therapy combined with ImmTOR for the treatment of MMA.

- The ReiMMAgine trial is now enrolling patients and aims to evaluate the safety, tolerability and efficacy of SEL-302.

SEL-018 IgG Protease (Xork) for Late-Onset Pompe Disease: 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 Pharma Inc.’s investigational AAV-based treatment for Late-Onset Pompe disease (LOPD) in adults.

- Xork is differentiated by its low cross reactivity to pre-existing antibodies in human serum, which the Company believes has the potential to expand access of life-changing gene therapies to more patients.
- Under the terms of the agreement, Selecta received a $10M upfront payment and is eligible to receive up to $340M upon the achievement of certain additional development and commercial milestones plus royalties on commercial sales. Selecta is responsible for the early development activities and manufacturing of Xork and will maintain rights to the development of additional indications beyond LOPD.

Biologic Therapies:

SEL-212 for chronic refractory gout: The DISSOLVE I & II Phase 3 clinical trials for SEL-212, which has been licensed to Swedish Orphan Biovitrum

AB (publ.) (Sobi), are on track with topline data expected in Q1 2023.

- Selecta has been responsible for executing the Phase 3 clinical trials, with reimbursement from Sobi, and Sobi will be responsible for biologics license application filing and commercialization.

ImmTOR with IgA Protease for IgA Nephropathy (IgAN): In December 2022, the Company selected a next generation Immunoglobulin A (IgA) protease from IGAN Biosciences, Inc. to develop in combination with ImmTOR for the treatment of IgAN.

- ImmTOR in combination with this new class of IgA protease, which is derived from a commensal bacteria and has low levels of baseline anti-drug antibodies, is designed to address the underlying pathophysiology of IgAN.
- The Company plans to initiate IND enabling studies in 2023.

Further Corporate and Partnership Updates:

In November 2022, Blaine Davis was appointed as Chief Financial Officer. Mr. Davis brings more than 25 years of experience in investor relations, business development, corporate affairs and sales and marketing at life sciences companies, with a particular focus on rare diseases.

Fourth Quarter and Full Year 2022 Financial Results:

Cash Position: Selecta had $136.2 million in cash, cash equivalents, marketable securities, and restricted cash as of December 31, 2022, as compared to cash, cash equivalents, marketable securities, and restricted cash of $129.4 million as of December 31, 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: Revenue for the fourth quarter and full year 2022 was $16.8 million and $110.8 million, respectively, as compared to $29.9 million and $85.1 million for the same periods in 2021. Revenue was primarily driven by the license agreement with Sobi resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program.

Research and Development Expenses: Research and development expenses for the fourth quarter and full year 2022 were $19.0 million and $72.4 million, respectively, as compared to $20.3 million and $68.7 million for the same periods in 2021. The quarterly decrease was primarily driven by a decrease in expenses incurred for the SEL-212 clinical program. The annual increase was primarily driven by expenses incurred for preclinical programs, increased personnel expense and stock compensation expense.

General and Administrative Expenses: General and administrative expenses for the fourth quarter and full year 2022 were $6.3 million and $23.9 million, respectively, as compared to $5.5 million and $20.9 million for the same periods in 2021. The quarterly and annual increases were primarily driven by increases in stock compensation and personnel expenses.

Net Income (loss): For the fourth quarter and full year 2022, Selecta reported net income of $5.9 million, or basic net income per share of $0.04, and net income of $35.4 million, or basic net income per share of $0.24, respectively. For the fourth quarter and full year 2021, Selecta reported net income of $12.2 million, or $0.10 per share, and a net loss of $(25.7) million, or $(0.22) per share, respectively.

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 fourth quarter and full year 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 8768458. 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 unique proprietary technology platform of the Company and 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, liver diseases, 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 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 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, 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 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)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 106,438	$ 114,057
Marketable securities	28,164	13,998
Accounts receivable	6,596	9,914
Unbilled receivables	3,162	—
Prepaid expenses and other current assets	3,778	6,474
Total current assets	148,138	144,443
Non-current assets:		
Property and equipment, net	2,794	2,142
Right-of-use asset, net	11,617	9,829
Long-term restricted cash	1,311	1,379
Investments	2,000	2,000
Other assets	26	90
Total assets	$ 165,886	$ 159,883
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 316	$ 224
Accrued expenses	14,084	10,533
Loan payable	8,476	5,961
Lease liability	1,608	1,049
Income taxes payable	—	601
Deferred revenue	593	53,883
Total current liabilities	25,077	72,251
Non-current liabilities:		
Loan payable, net of current portion	17,786	19,673
Lease liability, net of current portion	10,055	8,598
Deferred revenue	—	11,417
Warrant liabilities	19,140	25,423
Total liabilities	72,058	137,362
Stockholders' equity:		

Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 350,000,000 and 200,000,000 shares authorized as of December 31, 2022 and December 31, 2021, respectively; 153,042,435 and 123,622,965 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	15	12
Additional paid-in capital	493,308	457,391
Accumulated deficit	(394,937)	(430,316)
Accumulated other comprehensive loss	(4,558)	(4,566)
Total stockholders' equity	93,828	22,521
Total liabilities and stockholders' equity	$ 165,886	$ 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 December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
	(Unaudited)			
Collaboration and license revenue	$ 16,795	$ 29,937	$ 110,777	$ 85,077
Operating expenses:				
Research and development	18,967	20,318	72,377	68,736
General and administrative	6,324	5,541	23,862	20,938
Total operating expenses	25,291	25,859	96,239	89,674
Operating income (loss)	(8,496)	4,078	14,538	(4,597)
Investment income	1,141	9	2,073	44
Foreign currency transaction gain (loss), net	39	5	(22)	—
Interest expense	(807)	(711)	(3,031)	(2,844)
Change in fair value of warrant liabilities	13,553	8,996	20,882	(2,339)
Other income, net	175	—	330	15
Income (loss) before income taxes	5,605	12,377	34,770	(9,721)
Income tax (expense) benefit	288	(138)	609	(15,966)
Net income (loss)	$ 5,893	$ 12,239	$ 35,379	$ (25,687)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(47)	(7)	18	(2)
Unrealized gain (loss) on marketable securities	19	—	(10)	(1)
Total comprehensive income (loss)	$ 5,865	$ 12,232	$ 35,387	$ (25,690)
Net income (loss) per share:				
Basic	$ 0.04	$ 0.10	$ 0.24	$ (0.22)
Diluted	$ 0.04	$ 0.03	$ 0.10	$ (0.22)
Weighted average common shares outstanding:				
Basic	153,034,925	117,792,406	144,758,555	114,328,798
Diluted	153,034,925	124,058,955	145,874,889	114,328,798

Source: Selecta Biosciences, Inc.