Selecta Biosciences Reports Recent Business Highlights and Fourth Quarter and Full Year 2020 Financial Results

March 11, 2021

- First-in-human dose-escalation study to evaluate ability of ImmTOR™ to mitigate immunogenicity of AAV capsid initiated with initial data expected in the fourth quarter of 2021 -

- Methylmalonic acidemia (MMA) gene therapy program in collaboration with AskBio expected to enter the clinic in the second quarter of 2021 -

- Pediatric Investigation Plan (PIP) for ornithine transcarbamylase (OTC) deficiency gene therapy program submitted to the EMA pediatric committee -

- Investigational New Drug (IND) application for IgA nephropathy program expected by the end of 2021 -

- SEL-212 Phase 3 DISSOLVE clinical program in chronic refractory gout with Sobi enrolling with topline data expected in the second half of 2022 -

- Cash runway into the second quarter of 2023 -

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

WATERTOWN, Mass., March 11, 2021 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its clinically validated ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses, today reported recent business highlights and financial results for the fourth quarter and year ended December 31, 2020.

“This is a very exciting time in Selecta’s history, having made significant progress across all aspects of the company,” said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. “In 2020, we significantly de-risked the company through a strategic partnership with Sobi for SEL-212, under which we commenced the Phase 3 DISSOLVE program in the third quarter of 2020. We rapidly advanced our pipeline, having recently dosed our first subject with ImmTOR in combination with an AAV capsid, which builds on compelling non-human primate data announced earlier this year.”

“We are very pleased by the continued progress of our gene therapy program. In collaboration with AskBio, our lead program in methylmalonic acidemia, is on track to enter the clinic in the second quarter of this year and we expect initial data by the end of the year. A key objective of 2021 will be to generate human data in our gene therapy programs and to continue to build our extensive pipeline in gene therapies, enzyme therapies—with an expected IND filing by the end of the year in IgA nephropathy—and autoimmune diseases, as we work to deliver on our mission to leverage our pioneering ImmTOR platform to improve the lives of patients and their families,” Dr. Brunn added.

Recent Business Highlights and Anticipated Milestones

Enzyme Therapies:

- *SEL-212 for chronic refractory gout:* The Phase 3 DISSOLVE clinical program for SEL-212 for the treatment of chronic refractory gout, which was licensed to Sobi, is progressing as planned with topline data expected in the second half of 2022.
    - The Phase 3 clinical program consists of two double blind, placebo-controlled trials of SEL-212 (DISSOLVE I and DISSOLVE II) (NCT04513366 and NCT04596540, respectively). Both studies have a 6-month primary endpoint of serum uric acid (SUA) < 6 mg/dL at month 6, and DISSOLVE I has a 6-month safety extension.
- *IgA nephropathy:* Selecta’s second indication is IgA nephropathy, a kidney disease that occurs when immune complexes of an antibody called immunoglobulin A1 (IgA1) accumulates in the kidneys. Leveraging the learnings from SEL-212, Selecta will be researching a novel therapeutic approach by combining ImmTOR with an enzyme, IgA1 protease, which has been shown in animal studies to debulk the IgA1 immune complexes in the kidney, the root cause of IgA nephropathy. Selecta expects to file an Investigational New Drug, or IND, application, for this program by the end of 2021.

Gene Therapies:

- *MMA-101 for methylmalonic acidemia (MMA):* Selecta’s lead gene therapy product candidate, MMA-101 combined with ImmTOR for the treatment of MMA, is expected to enter the clinic in the second quarter of 2021 with preliminary data expected by year-end. The MMA-101 program is being conducted in collaboration with AskBio.
    - Selecta and AskBio received Orphan Designation for MMA-101 from the U.S. Food and Drug Administration (FDA) in November 2020. MMA-101 previously received Rare Pediatric Disease Designation from the FDA in October 2020.
- *First-in-human trial of SEL-399:* In collaboration with AskBio, Selecta recently initiated the first-in-human dose-escalation

trial of SEL-399, an adeno-associated viral serotype 8 (AAV8) empty vector capsid (EMC-101) containing no DNA combined with ImmTOR. The trial aims to determine the optimal dose of ImmTOR to mitigate the formation of antibodies to AAV8 capsids used in gene therapies. Selecta and AskBio expect to report initial data in the fourth quarter of 2021.
    - The dose-escalation trial of SEL-399 is designed to evaluate the safety and preliminary efficacy of ImmTOR in combination with an AAV capsid. Preliminary efficacy will be measured by assessing levels of AAV8-specific neutralizing antibodies.
- *SEL-313 for ornithine transcarbamylase deficiency (OTC deficiency):* Selecta's proprietary gene therapy product candidate, SEL-313, is being developed to treat OTC deficiency, a rare genetic disorder that causes ammonia to accumulate in the blood due to mutations in the OTC gene, which is critical for proper function of the urea cycle. SEL-313 is currently in preclinical development and is expected to enter the clinic in 2022. A Pediatric Investigation Plan (PIP) for SEL-313 was submitted to the European Medicines Agency (EMA) pediatric committee in February 2021.
- *Non-human primate data of ImmTOR in gene therapy*: Selecta's gene therapy programs build on extensive preclinical data that have demonstrated the potential benefits of the ImmTOR platform in AAV gene therapy. Selecta observed that co-administration of AAV vector and ImmTOR in non-human primates (NHP) enabled higher and more durable transgene expression as well as robust inhibition of anti-AAV8 immunoglobulin G (IgG) and neutralizing antibodies.

Restoring Self-Tolerance in Autoimmune Diseases:

- Selecta continues IND-enabling work on an ImmTOR-based approach to treating primary biliary cholangitis (PBC), a chronic, progressive liver disorder that leads to inflammation, damage and scarring of the small bile ducts. PBC has a well-defined target antigen, significant unmet medical need, and is well suited to the application of our ImmTOR immune tolerance platform. Selecta expects to file an IND in PBC in 2022.

Fourth Quarter and Full Year 2020 Financial Results:

Cash Position: Selecta had $140.1 million in cash, cash equivalents, and restricted cash as of December 31, 2020, which compares to cash, cash equivalents, and restricted cash of $147.6 million as of September 30, 2020. Selecta believes its available cash, cash equivalents, and restricted cash will be sufficient to meet its operating requirements into the second quarter of 2023.

Revenue: Revenue recognition for the fourth quarter and fiscal year 2020 was $12.0 million and $16.6 million, respectively, which compares with $6.7 million and $6.7 million for the same periods in 2019.

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 fiscal year 2020 were $15.1 million and $54.5 million, respectively, which compares with $15.2 million and $42.7 million for the same periods in 2019.

During the quarter ended December 31, 2020, there was a reduction in expenses for the SEL-212 clinical programs due to the timing of the initiation of the Phase 3 DISSOLVE clinical program compared to the Phase 2 COMPARE program in the prior period. This reduction was offset by increases in expenses incurred under the AskBio Collaboration combined with internal research and development to support our clinical programs. The annual increase reflects the initiation of the Phase 3 DISSOLVE clinical program. These costs are subject to the cost reimbursement arrangement under the license agreement with Sobi.

General and Administrative Expenses: General and administrative expenses for the fourth quarter and fiscal year 2020 were $4.8 million and $18.9 million, respectively, which compares with $4.1 million and $16.4 million for the same period in 2019. The quarterly and annual increase in expense was the result of increased patent and professional fees and facility and office expenses offset by a decrease in travel expense.

Net Loss: For the fourth quarter and fiscal year 2020, Selecta reported a net loss of $15.4 million, or $0.14 per share and $68.9 million, or $0.68 per share, respectively, compared to a net loss of $14.9 million, or $0.28 per share and $55.4 million, or $1.22 per share, for the same periods in 2019.

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 fourth quarter 2020 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 10147796. 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 leveraging its clinically validated 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. The company's first program aimed at addressing immunogenicity to AAV gene therapies is expected to enter clinical trials in early 2021 in partnership with AskBio for the treatment of methylmalonic acidemia (MMA), a rare metabolic disorder. A wholly-owned program focused on addressing IgA nephropathy driven by ImmTOR and a therapeutic enzyme is also in development among additional product candidates. Selecta recently licensed its Phase 3 clinical product candidate, SEL-212, in chronic refractory gout to Sobi. 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 the unique proprietary platform of its partners, the

potential of ImmTOR to enable re-dosing of AAV gene therapy and to mitigate immunogenicity, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the company's ability to conduct those clinical trials and 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 primate 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 intellectual property 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 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 primates, 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 from operations raise substantial doubt regarding its ability to continue as a going concern, substantial fluctuation in the price of its common stock, and other important factors discussed in the "Risk Factors" section of the company's most recent Annual Report on Form 10-K 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.

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 138,685	$ 89,893
Restricted cash	—	279
Accounts receivable	7,224	5,000
Prepaid expenses and other current assets	5,434	1,495
Total current assets	151,343	96,667
Property and equipment, net	1,395	1,222
Right-of-use asset, net	10,948	301
Long-term restricted cash	1,379	1,379
Other assets	370	—
Total assets	$ 165,435	$ 99,569
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 443	$ 500
Accrued expenses	8,146	$ 13,492
Loan payable	—	18,905
Lease liability	908	372
Deferred revenue	72,050	1,674
Total current liabilities	81,547	34,943
Non-current liabilities:		
Loan payable, net of current portion	24,793	—
Lease liability	9,647	—
Deferred revenue	38,746	14,680
Warrant liabilities	28,708	41,549
Total liabilities	183,441	91,172
Stockholders' (deficit) equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	—	—

Common stock, $0.0001 par value; 200,000,000 shares authorized; 108,071,249 and 86,325,547 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	11	9
Additional paid-in capital	391,175	348,664
Accumulated deficit	(404,629)	(335,753)
Accumulated other comprehensive loss	(4,563)	(4,523)
Total stockholders' (deficit) equity	(18,006)	8,397
Total liabilities and stockholders' (deficit) equity	$ 165,435	$ 99,569

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

(Amounts in thousands, except share data and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Grant and collaboration revenue	$ 11,951	$ 6,654	$ 16,597	$ 6,677
Operating expenses:				
Research and development	15,091	15,152	54,505	42,743
General and administrative	4,758	4,072	18,913	16,389
Total operating expenses	19,849	19,224	73,418	59,132
Loss from operations	(7,898)	(12,570)	(56,821)	(52,455)
Investment income	3	127	260	834
Loss on extinguishment of debt	—	—	(461)	—
Foreign currency transaction gain (loss), net	(27)	(14)	56	(47)
Interest expense	(713)	(335)	(1,556)	(1,519)
Change in fair value of warrant liabilities	(6,837)	(857)	(10,443)	(857)
Other income (expense), net	26	(1,239)	89	(1,306)
Net loss	(15,446)	(14,888)	(68,876)	(55,350)
Other comprehensive loss:				
Foreign currency translation adjustment	21	10	(40)	34
Total comprehensive loss	$ (15,425)	$ (14,878)	$ (68,916)	$ (55,316)
Net loss per share:				
Basic and diluted	$ (0.14)	$ (0.28)	$ (0.68)	$ (1.22)
Weighted average common shares outstanding:				
Basic and diluted	107,855,065	52,321,884	101,202,176	45,548,511

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