Selecta Biosciences Reports Second Quarter 2021 Financial Results and Provides Business Update

August 12, 2021

- *IND filing for wholly owned gene therapy program, SEL-302 (MMA-101, in combination with ImmTOR) in methylmalonic acidemia (MMA) expected during the third quarter of 2021; Manufacturing issue has been resolved, with a new completed lot undergoing final release testing*
- *SEL-399 (empty AAV8 capsid with ImmTOR) study on track with topline data expected in the fourth quarter of 2021*
- *Selecta achieved $3 million milestone payment from Sarepta Therapeutics related to successfully meeting the criteria for a preclinical study*
- *As of June 30, 2021, Selecta had approximately $151.5 million in cash, cash equivalents, and marketable securities which is expected to provide runway into the third quarter of 2023*

WATERTOWN, Mass., Aug. 12, 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 financial results for the second quarter ended June 30, 2021 and provided a business update.

"We are very pleased about our continued progress across all aspects of the company," said Carsten Brunn, Ph.D., president, and chief executive officer of Selecta. "Building on our ongoing empty AAV8 capsid study, we are rapidly advancing our two proprietary gene therapy programs into the clinic and as we enter a critical inflection point in development, we are honored to have gene therapy pioneer, Jude Samulski, Ph.D., join as a special advisor. The recently published preclinical data is encouraging and further supports the advancement of our lead candidate in methylmalonic acidemia (MMA), SEL-302. We will build on this momentum and expect to file an IND in MMA during the third quarter of 2021, bringing us one step closer to addressing immunogenicity constraints in AAV-driven gene therapy and ultimately, providing patients with potentially transformative treatment options. Additionally, we are steadily executing across our enzyme and autoimmune development program. We have a well-defined work plan ahead of us and the financial resources to maximize the value of our innovative ImmTOR platform."

Recent Highlights and Anticipated Upcoming Milestones:

Enzyme Therapies:

- *SEL-212 for chronic refractory gout:* Enrollment for the Phase 3 DISSOLVE clinical program for the treatment of chronic refractory gout, which was licensed to Sobi, is progressing as planned.
  - Topline data is expected in the second half of 2022.
- Investigational New Drug, or IND, enabling studies are underway for a novel therapeutic approach that combines ImmTOR with an enzyme, IgA1 protease for the treatment of IgA nephropathy.
  - Selecta expects to file an IND in IgA nephropathy in 2022 and will provide additional updates later in the year.

Gene Therapies:

- *First-in-human trial of SEL-399:* In collaboration with AskBio, Selecta 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 dose regimen of ImmTOR to mitigate the formation of antibodies to AAV8 capsids used in gene therapies.
  - Topline data is expected in the fourth quarter of 2021.
- *SEL-302 for methylmalonic acidemia (MMA):* Selecta announced publication in the journal *Molecular Therapy Methods & Clinical Development* demonstrating that ImmTOR enhances transgene expression after both initial and repeat dosing of AAV in a mouse model of MMA. The publication further validates use of ImmTOR in Selecta's gene therapy pipeline, including its lead candidate, SEL-302 (MMA-101 in combination with ImmTOR), for the treatment of MMA, a rare metabolic disease in which the body cannot break down certain proteins and fats.
  - The previously disclosed MMA-101 manufacturing issue was resolved. Manufacturing of a new lot has been completed and is currently undergoing final release testing.
  - Selecta expects to file an IND for SEL-302 during the third quarter of 2021.
- *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 urea cycle disorder that causes ammonia to accumulate in the blood due to mutations in the OTC gene.
  - SEL-313 is currently in preclinical development and a clinical trial application, or CTA and/or IND filing are expected

in 2022.

- *Sarepta Therapeutics program in Duchenne Muscular Dystrophy (DMD) and certain Limb-Girdle Muscular Dystrophies (LGMD) subtypes:* Selecta has achieved a $3 million milestone payment related to the completion of a preclinical study under the Research License and Option Agreement.

Restoring Self-Tolerance in Autoimmune Diseases:

- Selecta announced *Frontiers in Immunology* publication showcasing the enhanced hepatic tolerogenic potential of ImmTOR. Data demonstrate that ImmTOR enhances the tolerogenic environment in the liver, shows induction of a tolerogenic phenotype in all major hepatic antigen presenting cell populations and is protective in an acute model of autoimmune hepatitis. The publication further supports development of Selecta's ImmTOR platform for the treatment of liver-specific autoimmune diseases, including primary biliary cholangitis (PBC).
    - Selecta continues IND-enabling work on an ImmTOR-based approach to treating PBC and expects to file an IND in PBC in the second half of 2022.

Corporate Updates:

- Jude Samulski, Ph.D., was appointed as a special advisor to help guide Selecta's gene therapy programs into the clinic. Dr. Samulski is a professor of pharmacology and has been the director of the University of North Carolina Gene Therapy Center for over two decades. He was awarded the first patent for AAV as a viral vector and was the first recipient of the American Society of Gene & Cell Therapy Outstanding Achievement Award for lifetime achievements in gene therapy. Dr. Samulski has advanced gene therapies into human clinical trials for hemophilia, Duchenne muscular dystrophy, giant axonal neuropathy, Pompe disease and heart failure, and is the president, chief scientific officer and co-founder of Asklepios BioPharmaceutical Inc. (AskBio), a biotechnology company focused on AAV-driven gene therapy.

- Nishan de Silva, M.D. was appointed to Selecta's Board of Directors. Dr. de Silva has extensive leadership experience, most relevantly in gene therapy development, manufacturing, and regulatory activities. Dr. de Silva brings over 20 years of experience in biotechnology operations, biopharmaceutical venture capital and healthcare management consulting. He is currently chief executive officer and director of AFYX Therapeutics, a private venture-backed biotechnology company focused on addressing unmet needs in mucosal diseases. Previously Dr. de Silva served as president, chief operating officer and director of Poseida Therapeutics, a cell and gene therapy-focused biopharmaceutical company, where he oversaw clinical development, regulatory, manufacturing, finance, and business development activities.

Second Quarter 2021 Financial Results:

Cash Position: Selecta had $151.5 million in cash, cash equivalents, marketable securities, and restricted cash as of June 30, 2021, which compares to cash, cash equivalents, and restricted cash of $149.2 million as of March 31, 2021. Selecta believes its available cash, cash equivalents, marketable securities, and restricted cash will be sufficient to meet its operating requirements into the third quarter of 2023.

- Net cash used in operating activities was $18.2 million for the six months ended June 30, 2021, as compared to $23.5 million for the same period in 2020.

Revenue: Revenue recognition for the second quarter of 2021 was $19.7 million, compared to no revenue recognition for the same period in 2020. Revenue was recognized under the license agreement with Sobi which began in July 2020 resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program. Additionally, during the second quarter, Selecta recognized less than $0.1 million for shipments under the license agreement with Sarepta and $0.1 million resulting from the expiration of the contractual audit term under the Skolkovo Foundation grant.

Research and Development Expenses: Research and development expenses for the second quarter 2021 were $14.5 million, which compares with $10.7 million for the same period in 2020. During the quarter ended June 30, 2021, there was an increase in expenses incurred for consulting, salaries, and the discovery and preclinical programs, offset by a decrease of AskBio collaboration costs.

General and Administrative Expenses: General and administrative expenses for the second quarter 2021 were $4.7 million, which compares with $5.6 million for the same period in 2020. The decrease in costs was primarily the result of reduced expense for salaries, professional fees and patent expense, offset by increased consulting and stock compensation expenses.

Net Income (loss): For the second quarter 2021, Selecta reported net income of $4.6 million, or basic net income per share of $0.04, compared to a net loss of $24.1 million, or basic net loss per share of $0.25 for the same period in 2020.

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 second quarter 2021 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 10147802. 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 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, IgA nephropathy, PBC, MMA or OTC, 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 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.

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

	June 30, 2021	December 31, 2020
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 125,749	$ 138,685
Marketable securities	24,389	—
Accounts receivable	8,464	7,224
Prepaid expenses and other current assets	8,210	5,434
Total current assets	166,812	151,343
Non-current assets:		
Property and equipment, net	1,778	1,395
Right-of-use asset, net	10,399	10,948
Long-term restricted cash	1,379	1,379
Other assets	154	370
Total assets	$ 180,522	$ 165,435
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 154	$ 443
Accrued expenses	8,861	8,146
Loan payable	2,291	—
Lease liability	977	908
Deferred revenue	75,013	72,050
Total current liabilities	87,296	81,547
Non-current liabilities:		

Loan payable, net of current portion	22,931	24,793
Lease liability	9,143	9,647
Deferred revenue	24,739	38,746
Warrant liabilities	40,635	28,708
Total liabilities	184,744	183,441
Stockholders' (deficit) equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 115,079,292 and 108,071,249 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	12	11
Additional paid-in capital	424,984	391,175
Accumulated deficit	(424,661)	(404,629)
Accumulated other comprehensive loss	(4,557)	(4,563)
Total stockholders' (deficit) equity	(4,222)	(18,006)
Total liabilities and stockholders' (deficit) equity	$ 180,522	$ 165,435

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)			
Grant and collaboration revenue	$ 19,663	$ —	$ 30,713	$ —
Operating expenses:				
Research and development	14,463	10,730	27,467	25,454
General and administrative	4,748	5,637	9,952	9,735
Total operating expenses	19,211	16,367	37,419	35,189
Operating income (loss)	452	(16,367)	(6,706)	(35,189)
Investment income	12	13	24	253
Foreign currency transaction, net	(14)	(42)	(7)	40
Interest expense	(711)	(205)	(1,422)	(478)
Change in fair value of warrant liabilities	4,820	(7,539)	(11,927)	(8,385)
Other income, net	6	59	6	58
Net income (loss)	4,565	(24,081)	(20,032)	(43,701)
Other comprehensive income (loss):				
Foreign currency translation adjustment	12	31	6	(29)
Unrealized gains on marketable securities	1	—	—	—
Total comprehensive income (loss)	$ 4,578	$ (24,050)	$ (20,026)	$ (43,730)
Net income (loss) per share:				
Basic	$ 0.04	$ (0.25)	$ (0.18)	$ (0.46)
Diluted	$ 0.00	$ (0.25)	$ (0.18)	$ (0.46)
Weighted average common shares outstanding:				
Basic	113,524,110	96,785,915	112,140,815	95,754,714
Diluted	121,177,998	96,785,915	112,140,815	95,754,714

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