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

November 9, 2021

-Established four strategic collaborations to advance next generation therapeutics and maximize the potential of ImmTOR platform-

-Reported topline data from SEL-399 (empty AAV8 capsid in combination with ImmTOR); Selecta intends continued expansion of ImmTOR platform across gene therapy pipeline-

-Continued execution of multiple preclinical programs toward IND-

-Further strengthened leadership team with the appointment of Kevin Tan as CFO-

-As of September 30, 2021, Selecta had approximately $140.0 million in cash, cash equivalents, restricted cash and marketable securities which is expected to provide runway into the second quarter of 2023-

WATERTOWN, Mass., Nov. 09, 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 third quarter ended September 30, 2021 and provided a business update.

"The third quarter of 2021 was filled with many significant advancements that further validated the value and breadth of our innovative ImmTOR platform, including important milestones across our pipeline and the establishment of numerous collaborations that will continue to propel us forward in the year ahead," said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. "We recently presented topline data from the empty AAV8 capsid study, SEL-399 in healthy volunteers. We believe this pioneering proof-of-concept study showed for the first time ImmTOR's potential to address one of the biggest limitations in gene therapy: preventing the formation of anti-AAV8 neutralizing antibodies after ImmTOR treatment with AAVs and enabling re-dosing of life-saving gene therapies. We are excited to build on these exciting findings, which will inform our clinical development strategy and bring hope to those patients suffering from monogenic disease. We continue to prosecute our clinical pipeline, execute value accretive business development with world class partners and add talent and depth to our leadership team."

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.
- *ImmTOR with IgA1 protease for IgA nephropathy*: Immunoglobulin A nephropathy (IgAN) is a leading cause of chronic kidney disease (CKD) and renal failure. Current treatments fail to address the root cause of the disease.
    - Investigational New Drug, or IND, enabling studies are underway. Selecta expects to file an IND in IgA nephropathy in 2022 and will provide additional updates.

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 key objective was to determine the dose regimen of ImmTOR to effectively mitigate the formation of antibodies to AAV8 capsids used in gene therapies. Data was released on November 8, 2021. Key findings included:
    - No Serious Adverse Events were reported. All treatment-related adverse events were expected for ImmTOR, readily monitorable, and transient
    - At 30 days 6 of 6 or 100% of subjects that received 0.3 mg/kg of ImmTOR exhibited an anti-AAV8 neutralizing antibody titer of 1:25 or less. 4 of 6 or 67% of subjects at this dose had a titer of 1:5 or less
    - At 30 days 6 of 9 or 67% of subjects that received 0.15 mg/kg of ImmTOR exhibited an anti-AAV8 neutralizing antibody titer of 1:25 or less. 2 of 9 or 22% of subjects at this dose had a titer of 1:5 or less
    - At 90 days 2 of 6 subjects in the 0.3 mg/kg cohort were observed to have sustained control of neutralizing antibodies with titers of 1:25 or less
    - Consistent with preclinical data, we observed that the single dose ImmTOR cohorts saw delayed formation of neutralizing antibodies eventually reaching similar median levels of neutralizing antibodies to the control group by day 90

While most subjects treated with ImmTOR showed increases in antibody titers by Day 90, preclinical studies in mice and nonhuman primates

indicate that if antibodies can be controlled at Day 30, we can maintain control with additional two monthly doses of ImmTOR.

- *SEL-302 for methylmalonic acidemia (MMA):* IND filed for 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.
    - IND filed in Q3 2021, 30-day FDA review period has expired.
    - FDA has orally communicated they are still considering certain aspects of the submission related to chemistry, manufacturing and control, or CMC.
    - Formal FDA decision on IND expected by the end of November.

- *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.

Restoring Self-Tolerance in Autoimmune Diseases:

- Selecta continues IND-enabling work on an ImmTOR-based approach to treating primary biliary cholangitis (PBC) and expects to file an IND in PBC in the second half of 2022.

Corporate Updates:

- *Strategic Collaborations*:
    - Gene Therapies
        - Takeda Pharmaceutical Company Limited ("Takeda"): Strategic licensing agreement to develop next-generation gene therapies in two lysosomal storage disorders. The collaboration leverages Selecta ImmTOR platform to enable redosing of transformative therapies.
        - Genovis: Strategic licensing agreement to advance a next-generation IgG protease. This partnership leverages Genovis' proprietary and differentiated immunoglobulin G (IgG) protease, IdeXork (Xork), and Selecta's ImmTOR platform to enable the dosing of transformative gene therapies in patients with pre-existing adeno-associated virus (AAV) immunity and treat certain IgG-mediated autoimmune diseases. Xork shows low crossreactivity to pre-existing antibodies in human sera. The combination of Xork with ImmTOR has the potential to address two of the biggest immunological challenges to gene therapy – expanding access to gene therapies by overcoming pre-existing antibodies to AAV and enabling vector re-dosing.
    - Enzymes
        - Ginkgo Bioworks ("Ginkgo"): Partnership to design novel enzymes and proteins with transformative therapeutic potential to advance treatments for orphan and rare diseases. This partnership leverages Ginkgo's cell programing platform and Selecta's ImmTOR platform to create transformative biologic and enzymatic therapies.
    - Autoimmune
        - Cyrus Biotechnology ("Cyrus"): Established protein engineering collaboration combining Selecta's ImmTOR platform with Cyrus' ability to radically redesign protein therapeutics. The lead program in the collaboration is a proprietary interleukin-2 (IL-2) protein agonist designed to selectively promote expansion of regulatory T cells (Treg) for the treatment of patients with autoimmune diseases and other deleterious immune conditions. The combination of ImmTOR with a Treg-selective IL-2 agonist has the potential to be a best-in-class therapeutic profile.
- *Leadership Expansion*:
    - Kevin Tan was appointed as chief financial officer. Mr. Tan brings deep financial expertise and experience in the gene therapy and rare disease landscape. His impressive track record in capital management and financings, in both the biotech and investment sectors, will be invaluable as Selecta continues to pursue new partnership opportunities and advance multiple assets through the clinic.
    - Matthew Bartholomae was appointed as General Counsel, Board Secretary and transitioned from his previous role at Selecta as Associate General Counsel, Board Secretary.

Third Quarter 2021 Financial Results:

Cash Position: Selecta had $140.0 million in cash, cash equivalents, marketable securities, and restricted cash as of September 30, 2021, which compares to cash, cash equivalents, and restricted cash of $140.1 million as of December 31, 2020. Selecta believes its available cash, cash equivalents, marketable securities, and restricted cash will be sufficient to meet its operating requirements into the second quarter of 2023.

- Net cash used in operating activities was $28.9 million for the nine months ended September 30, 2021, as compared to $42.1 million of cash provided by operating activities for the same period in 2020.

Revenue: Revenue for the third quarter of 2021 was $24.4 million, compared to $4.6 million for the same period in 2020. Revenue of $24.3 million was recognized under 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. The significant revenue increase is the result of the continued enrollment of the Phase 3 DISSOLVE clinical program that was initiated in the third quarter of 2020. Additionally, during the third quarter, Selecta recognized $0.2 million for shipments under the license agreement with Sarepta.

Research and Development Expenses: Research and development expenses for the third quarter 2021 were $21.0 million, which compares with $14.0 million for the same period in 2020. During the quarter ended September 30, 2021, there was an increase in expenses incurred for preclinical programs, salaries, headcount, and AskBio collaboration costs.

General and Administrative Expenses: General and administrative expenses for the third quarter 2021 were $5.4 million, which compares with $4.4 million for the same period in 2020. The increase in costs was primarily the result of salaries, professional fees, and stock compensation expenses.

Net loss: For the third quarter 2021, Selecta reported net loss of $17.9 million, or net loss per share of $0.16, compared to a net loss of $9.7 million, or net loss per share of $0.09 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 third 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 10147803. 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 anticipated timing or the outcome of the FDA's review of the Company's IND and other regulatory filings, 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)

	September 30, 2021	December 31, 2020

	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 114,645	$ 138,685
Marketable securities	24,018	—
Accounts receivable	7,324	7,224
Prepaid expenses and other current assets	5,781	5,434
Total current assets	151,768	151,343
Non-current assets:		
Property and equipment, net	1,807	1,395
Right-of-use asset, net	10,117	10,948
Long-term restricted cash	1,379	1,379
Investments	2,000	—
Other assets	91	370
Total assets	$ 167,162	$ 165,435
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 1,593	$ 443
Accrued expenses	10,742	8,146
Loan payable	4,125	—
Lease liability	1,013	908
Income taxes payable	15,828	—
Deferred revenue	62,315	72,050
Total current liabilities	95,616	81,547
Non-current liabilities:		
Loan payable, net of current portion	21,304	24,793
Lease liability	8,873	9,647
Deferred revenue	20,057	38,746
Warrant liabilities	40,043	28,708
Total liabilities	185,893	183,441
Stockholders' (deficit) equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized; 115,443,500 and 108,071,249 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	12	11
Additional paid-in capital	428,371	391,175
Accumulated deficit	(442,555)	(404,629)
Accumulated other comprehensive loss	(4,559)	(4,563)
Total stockholders' (deficit) equity	(18,731)	(18,006)
Total liabilities and stockholders' (deficit) equity	$ 167,162	$ 165,435

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
			(Unaudited)	
Grant and collaboration revenue	$ 24,427	$ 4,646	$ 55,140	$ 4,646
Operating expenses:				
Research and development	20,951	13,960	48,418	39,414
General and administrative	5,445	4,420	15,397	14,155
Total operating expenses	26,396	18,380	63,815	53,569
Operating loss	(1,969)	(13,734)	(8,675)	(48,923)
Investment income	11	4	35	257
Loss on extinguishment of debt	—	(461)	—	(461)
Foreign currency transaction, net	2	43	(5)	83
Interest expense	(711)	(365)	(2,133)	(843)
Change in fair value of warrant liabilities	592	4,779	(11,335)	(3,606)

Other income, net	9	5	15	63
Loss before income taxes	(2,066)	(9,729)	(22,098)	(53,430)
Income tax expense	(15,828)	—	(15,828)	—
Net loss	(17,894)	(9,729)	(37,926)	(53,430)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(1)	(32)	5	(61)
Unrealized loss on marketable securities	(1)	—	(1)	—
Total comprehensive loss	$ (17,896)	$ (9,761)	$ (37,922)	$ (53,491)
Net loss per share:				
Basic and diluted	$ (0.16)	$ (0.09)	$ (0.34)	$ (0.54)
Weighted average common shares outstanding:				
Basic and diluted	115,169,949	105,325,788	113,161,622	98,968,359

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

For Media:
Brittany Leigh, Ph.D.
LifeSci Communications, LLC
+1-646-751-4366
bleigh@lifescicomms.com

Source: Selecta Biosciences, Inc.