# Selecta Biosciences Reports Second Quarter 2022 Financial Results and Provides Business Update

August 4, 2022

*– Completed enrollment of DISSOLVE II, triggering a $10 million milestone payment obligation from Swedish Orphan Biovitrum AB (publ.) (Sobi); DISSOLVE I & II studies remain on track for joint topline data readout in Q1 2023 –*

*– Sarepta extends Option and License agreement in exchange for a $2 million payment and notified Selecta of the achievement of certain pre-clinical milestones triggering a $4 million milestone payment obligation –*

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

*– As of June 30, 2022, Selecta had approximately $143.4 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., Aug. 04, 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 second quarter ended June 30, 2022 and provided a business update.

"We continued to make steady progress in the second quarter of 2022, highlighted by the completion of enrollment in DISSOLVE II, triggering a $10 million milestone payment obligation from Sobi, and the completion of an underwritten equity offering raising gross proceeds of $38.7 million," said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. "Building on this momentum, we enter the second half of 2022 with a focused portfolio of proprietary programs and an expected financial runway into mid-2024. We remain on track clinically, with joint topline data from DISSOLVE I and II anticipated in Q1 2023 and the initiation of a Phase 1 trial of SEL-302, our wholly owned gene therapy in combination with ImmTOR for the treatment of MMA, anticipated in Q4 2022. We continue preclinical development across all three pillars of our pipeline: In partnership with Cyrus Bioscience we are progressing in identifying a proprietary IL-2 to combine with ImmTOR; we have progressed to IND-enabling studies and manufacturing scale-up work for Xork, our proprietary IgG protease as a pre-treatment to enable AAV gene therapies; and our collaborations toward the identification of a next-generation IgA protease for the treatment of IgA Nephropathy continue apace with candidate selection anticipated by year-end. We believe that collectively, these advancements bring us one step closer to our mission of re-imagining immunotherapy for autoimmune disease, unlocking the potential of AAV gene therapy and amplifying the efficacy of biologics."

**Recent Program Highlights and Anticipated Upcoming Milestones:**

**Tolerogenic Therapies for Autoimmune Disease:**

- ***ImmTOR with proprietary IL-2 protein agonist (ImmTOR-IL™)****:* Preclinically, Selecta has observed synergistic activity when ImmTOR is combined with engineered IL-2 molecules that are selective for Tregs. 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 is working with its partner, Cyrus Biotechnology, to develop a next generation IL-2 molecule to combine with ImmTOR and 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 the development of 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 expects to initiate a Phase 1 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 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 Gene Therapy:*** Building on our pre-clinical studies of ImmTOR-IL in inhibiting the formation of neutralizing antibodies to AAV gene therapies, we are pleased to announce that we continue to see mitigating effects in mice at gene therapy doses of 10x our prior studies.

**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.
  - Selecta completed enrollment for DISSOLVE II in June 2022, with 153 study participants, triggering a $10 million milestone payment obligation from Sobi which has been received in Q3 2022.
  - DISSOLVE I & II trials are on track for completion in Q4 2022 with joint topline readout expected in Q1 2023.

- ***ImmTOR with IgA1 protease for IgA nephropathy***: Selecta is working with both Ginkgo Bioworks and IGAN Biosciences to identify and develop a next generation IgA protease to combine with ImmTOR.

  - Selecta anticipates enzyme candidate selection by year end 2022.

**Further Corporate and Partnership Updates:**

- Sarepta extended its Research License and Option Agreement for ImmTOR in Duchenne Muscular Dystrophy (DMD) and certain Limb-Girdle Muscular Dystrophies (LGMD) by nine months.
- Additionally, in June 2022 Selecta was informed by Sarepta of the achievement of certain pre-clinical milestones.
  - Selecta expects to receive a $2 million payment for extending Sarepta's option periods under the agreement to Q1 2023, and an additional $4 million payment for achievement of the pre-clinical milestone. Receipt of both payments is expected in Q3 2022.
- At the 25th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT) Selecta showcased six presentations, including three joint presentations with its partner Asklepios BioPharmaceutical, Inc. (AskBio). These presentations highlighted the immunogenic potential of empty AAV and the potential of ImmTOR and ImmTOR-IL in addressing key efficacy and safety challenges in gene therapy.
  - Our CSO, Kei Kishimoto, was awarded an 'Outstanding Poster Presentation Award' for the abstract titled: Combination of ImmTOR Tolerogenic Nanoparticles and IL-2 Mutein Synergistically Inhibits the Formation of Anti-AAV Antibodies.

**Second Quarter 2022 Financial Results:**

**Cash Position**: Selecta had $143.4 million in cash, cash equivalents, marketable securities, and restricted cash as of June 30, 2022, as compared to cash, cash equivalents, marketable securities, and restricted cash of $129.4 million as of December 31, 2021. The increase in cash was primarily due to proceeds from the completion of an equity offering during the second quarter, raising gross proceeds of $38.7 million. Net cash used in operating activities was $24.1 million for the six months ended June 30, 2022, as compared to $18.2 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 second quarter of 2022 was $39.3 million, as compared to $19.7 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 and the shipment of manufactured supply under the Sarepta Agreement.

**Research and Development Expenses:** Research and development expenses for the second quarter of 2022 were $19.2 million, as compared to $14.5 million for the same period in 2021. The increase in cost was primarily the result of expenses incurred for the SEL-212 clinical program, stock compensation, and salaries.

**General and Administrative Expenses:** General and administrative expenses for the second quarter of 2022 were $6.2 million, as compared to $4.7 million for the same period in 2021. The increase in costs was primarily the result of expenses incurred for issuance costs for the 2022 equity offering and stock compensation.

**Net Income (loss):** For the second quarter of 2022, Selecta reported net income of $8.6 million, or basic net income per share of $0.06, compared to net income of $4.6 million, or $0.04 basic net income per share, 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 corporate update and review the company's second 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 10157873. 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, the anticipated timing for receipt of payments owed to the Company, and the Company's ability to grow its strategic partnerships, enrollment in the Company's clinical trials and the Company's plans with respect to areas affected by geopolitical conflict 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 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 its 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 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.

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**Financial Tables**

**Selecta Biosciences, Inc. and Subsidiaries**

**Consolidated Balance Sheets**

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| | (Unaudited) | |
| **Assets** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 138,057 | $ 114,057 |
| Marketable securities | 3,999 | 13,998 |

| | | |
|---|---|---|
| Accounts receivable | 23,994 | 9,914 |
| Prepaid expenses and other current assets | 6,522 | 6,474 |
| Total current assets | 172,572 | 144,443 |
| **Non-current assets:** | | |
| Property and equipment, net | 2,833 | 2,142 |
| Right-of-use asset, net | 9,238 | 9,829 |
| Long-term restricted cash | 1,379 | 1,379 |
| Investments | 2,000 | 2,000 |
| Other assets | 46 | 90 |
| Total assets | $ 188,068 | $ 159,883 |
| **Liabilities and stockholders' equity** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 693 | $ 224 |
| Accrued expenses | 12,366 | 10,533 |
| Loan payable | 3,285 | 5,961 |
| Lease liability | 1,125 | 1,049 |
| Income taxes payable | 320 | 601 |
| Deferred revenue | 15,974 | 53,883 |
| Total current liabilities | 33,763 | 72,251 |
| **Non-current liabilities:** | | |
| Loan payable, net of current portion | 22,634 | 19,673 |
| Lease liability | 8,018 | 8,598 |
| Deferred revenue | 7,113 | 11,417 |
| Warrant liabilities | 26,934 | 25,423 |
| Total liabilities | 98,462 | 137,362 |
| **Stockholders' equity:** | | |
| Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2022 and December 31, 2021 | — | — |
| Common stock, $0.0001 par value; 350,000,000 shares authorized; 152,713,211 and 123,622,965 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively | 15 | 12 |
| Additional paid-in capital | 487,008 | 457,391 |
| Accumulated deficit | (392,937) | (430,316) |
| Accumulated other comprehensive loss | (4,480) | (4,566) |
| Total stockholders' equity | 89,606 | 22,521 |
| Total liabilities and stockholders' equity | $ 188,068 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| | (Unaudited) | | | |
| Collaboration and license revenue | $ 39,273 | $ 19,663 | $ 73,272 | $ 30,713 |
| Operating expenses: | | | | |
| Research and development | 19,182 | 14,463 | 36,871 | 27,467 |
| General and administrative | 6,231 | 4,748 | 11,768 | 9,952 |
| Total operating expenses | 25,413 | 19,211 | 48,639 | 37,419 |
| Operating income (loss) | 13,860 | 452 | 24,633 | (6,706) |
| Investment income | 207 | 12 | 222 | 24 |
| Foreign currency transaction, net | (104) | (14) | (76) | (7) |
| Interest expense | (715) | (711) | (1,422) | (1,422) |
| Change in fair value of warrant liabilities | (4,647) | 4,820 | 13,868 | (11,927) |
| Other income, net | — | 6 | 154 | 6 |
| Net income (loss) | $ 8,601 | $ 4,565 | $ 37,379 | $ (20,032) |

Other comprehensive income (loss):

| | | | | |
|---|---|---|---|---|
| Foreign currency translation adjustment | 118 | 12 | 86 | 6 |
| Unrealized gain on marketable securities | — | 1 | — | — |
| Total comprehensive income (loss) | $ 8,719 | $ 4,578 | $ 37,465 | $ (20,026) |
| | | | | |
| Net income (loss) per share: | | | | |
| Basic | $ 0.06 | $ 0.04 | $ 0.27 | $ (0.18) |
| Diluted | $ 0.06 | $ 0.00 | $ 0.17 | $ (0.18) |
| Weighted average common shares outstanding: | | | | |
| Basic | 148,505,729 | 113,524,110 | 136,436,316 | 112,140,815 |
| Diluted | 148,505,729 | 121,177,998 | 136,966,312 | 112,140,815 |

Source: Selecta Biosciences, Inc.