

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): June 18, 2020

SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37798
(Commission
File Number)

26-1622110
(IRS Employer
Identification No.)

65 Grove Street, Watertown, MA 02472
(Address of principal executive offices)(Zip Code)

(617) 923-1400
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (Par Value \$0.0001)	SELB	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

Selecta Biosciences, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. A copy of its current corporate slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information in Item 7.01 of this Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Corporate slide presentation of Selecta Biosciences, Inc. dated June 18, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SELECTA BIOSCIENCES, INC.

Date: June 18, 2020

By: /s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President and Chief Executive Officer



Corporate Presentation

June 2020



Safe harbor/disclaimer

Any statements in this presentation about the future expectations, plans and prospects of Selecta Biosciences, Inc. ("the company"), including without limitation, statements regarding the progress of clinical development of SEL-212, the anticipated timing of the head-to-head trial comparing SEL-212 and pegloticase and related data readouts, the potential of ImmTOR™ to reduce AAV vector immunogenicity and enable re-dosing of AAV gene therapy and other gene therapies without neutralizing antibody formation or loss of therapy expression, the anticipated timing of preclinical toxicology studies in AAV gene therapy, other gene therapies and initiation of a clinical trial related thereto, the company's plans to develop product candidates to treat IgA Nephropathy and/or primary biliary cholangitis, the potential of SEL-212 to serve unmet needs in chronic refractory gout patients including sustained sUA reduction, reduced flares, and once monthly dosing, the anticipated timing for advancing into Phase 3 as well as the anticipated design of the Phase 3 program, the ability of the company's ImmTOR technology to induce immune tolerance and mitigate antigen-specific neutralizing antibody formation, scalability of the company's manufacturing processes, the potential of ImmTOR to enable sustained therapeutic activity of biologic therapies, whether current evaluable SEL-212 patients will be predictive of future evaluable SEL-212 patients, whether maintained sUA level reduction correlates with low and/or negative drug-specific antibody titers, the potential of SEL-212 to significantly reduce tophi/heavy burden and/or rapidly eliminate tissue urate burden, whether SEL-212 has the ability to reduce gout flares frequency initially and over time during SEL-212 therapy, anticipated achievement of key milestones for the company's chronic refractory gout and gene therapy programs, the company's ability to execute on its strategic priorities, advance its ImmTOR platform, and grow its strategic partnerships, the potential of ImmTOR to enhance transgene expression, the potential of the company's partnership with Asklepios BioPharmaceutical, Inc. to address unmet medical need in patients with rare disease, the amount of upfront and milestone payments that Selecta is eligible to receive pursuant to its license agreement with Asklepios BioPharmaceutical, Inc., anticipated collaboration with and the receipt of payments from Swedish Orphan Biovitrum AB ("Sobi"), the receipt of payments from Sarepta Therapeutics, Inc., the company's expected cash position and runway, the billion dollar market potential of the chronic refractory gout market, the ability of the company's ImmTOR platform to unlock the full potential of biologic therapies, the potential of SEL-212 to enable sustained efficacy in chronic refractory gout patients and resolve their symptoms, the potential treatment applications for products utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy, the potential of AAV and non-AAV gene therapies to transform the future in a variety of inherited and acquired diseases, the potential of the ImmTOR platform generally, 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 their 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 unproven approach of the company's ImmTOR technology, potential delays in enrollment of patients, or the ability of patients to continue in our clinical trials due to the COVID-19 outbreak, 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, proprietary programs, licenses or contractual relationships, the ability of Asklepios BioPharmaceutical, Inc. to develop products and make milestone payments, the ability of Sobi to make upfront and milestone payments, the ability of Sarepta Therapeutics, Inc. to make upfront payments, the company's 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 possibility that the company's recurring losses from operations and negative cash flows from operations could raise substantial doubt regarding its ability to continue as a going concern, substantial fluctuation in the price of its common stock, including fluctuation in the stock market generally and our stock price specifically due to the COVID-19 outbreak, the company's strategy may change, and the company may not be able to effectively implement its current strategic plan, the size of the company's workforce following the restructuring may not be sufficient, and the company may not be able to effectively attract or retain new employees, risks associated with the restructuring, such as employee claims and the risk that the actual financial and other impacts of the reduction could vary materially from the outcomes anticipated, the impact, if any, of the COVID-19 outbreak on the company's operations, including supply chain and clinical trials, other COVID-19 related risks and other important factors discussed in the "Risk Factors" section of the company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, for the quarter ended March 31, 2020, and in other filings that the company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this presentation 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 obligation to update any forward-looking statements included in this presentation.



Selecta well-positioned for success

- Pioneering immune tolerance platform, ImmTOR™
 - Selecta's immune tolerance platform, ImmTOR, could unlock the full potential of biologic therapies by mitigating Neutralizing Antibody (Nab) formation
 - Pipeline focused on therapeutic biologics/enzymes, gene therapies, and novel immunotherapies for autoimmune diseases

- Gene therapy program expected to enter the clinic by early 2021
 - Preclinical results suggest high relevance to diseases which may require re-dosing gene therapies to maintain efficacy
 - MMA program expected to enter clinic by early 2021
 - Several collaborations & licensing agreements for rapid POC
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- Lead program – SEL-212, addressing a \$1B+ chronic refractory gout market with high unmet need
 - COMPARE trial ongoing to evaluate efficacy and safety of SEL-212 vs. pegloticase
 - 170 patients have been enrolled in the study, and top-line data is expected in 3Q 2020
 - Phase 3 pivotal program against placebo to commence in 2H 2020
 - Entered global, excl. China, licensing agreement with Sobi with \$100 million in initial payments and up to \$630 million in milestones

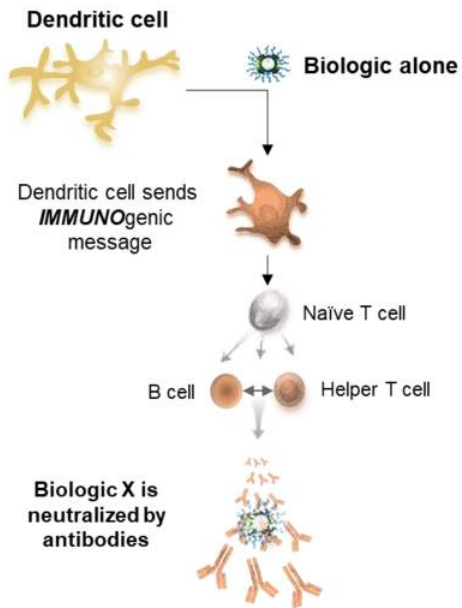
- Antigen-specific immune tolerance is a highly attractive treatment approach for autoimmune diseases
 - Initial focus on two proprietary programs in areas of high unmet need
 - IgA Nephropathy (IgAN) – builds on SEL-212 success: POC of combining an immunogenic enzyme with ImmTOR has been established
 - Primary biliary cholangitis (PBC) – ImmTOR would target the liver; animal models of liver injury and inflammation have shown beneficial effects
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ImmTOR
Pioneering
Immune
Tolerance
Platform

Biologic therapies may trigger NABs that negate their therapeutic benefit

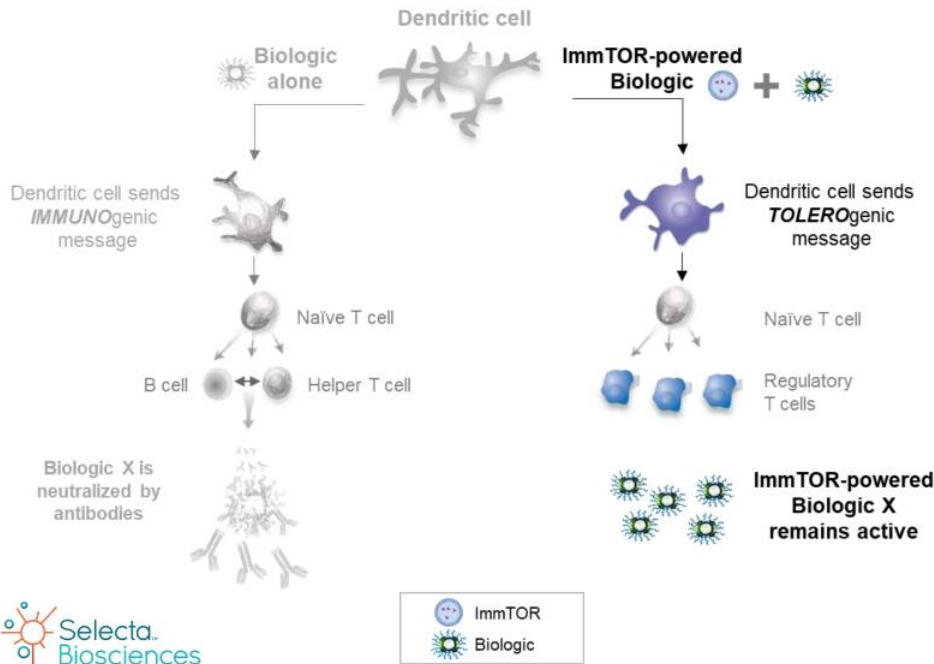


There is a significant unmet need for a technology that selectively induces immune tolerance

Dendritic cells play a key role in immune tolerance providing a promising target to mitigate unwanted antigen-specific immune responses

Inducing selective immune tolerance for biologic therapy considered the *“Holy Grail”*

ImmTOR has the potential ability to enable sustained therapeutic activity of biologic therapies and unlock their potential



Co-administer with biologic therapies to mitigate antigen-specific NAb formation



Induce a tolerogenic message from the dendritic cell to naïve T cells to develop into T regulatory cells



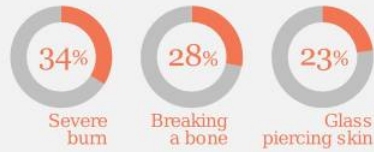
Promote selective immune tolerance of the biologic therapy

A stylized sun graphic in a light orange color, featuring a central circle with several radiating lines of varying lengths. The graphic is positioned on the left side of the slide, partially overlapping the text area.

SEL-212
(ImmTOR+pegadricase)
for Chronic Refractory Gout

Chronic refractory gout is a severe form of inflammatory arthritis with a significant impact on patients

How chronic refractory gout patients describe their flare pain



How long chronic refractory gout flares can last



Annual lost productivity (pts <65)

~25 days

Estimated # of patients diagnosed in US with chronic refractory gout

~160,000

Chronic disease can lead to sequelae including:

- Bone erosions
- Tophi
- Chronic pain
- Joint deformities
- Loss of function
- Disability



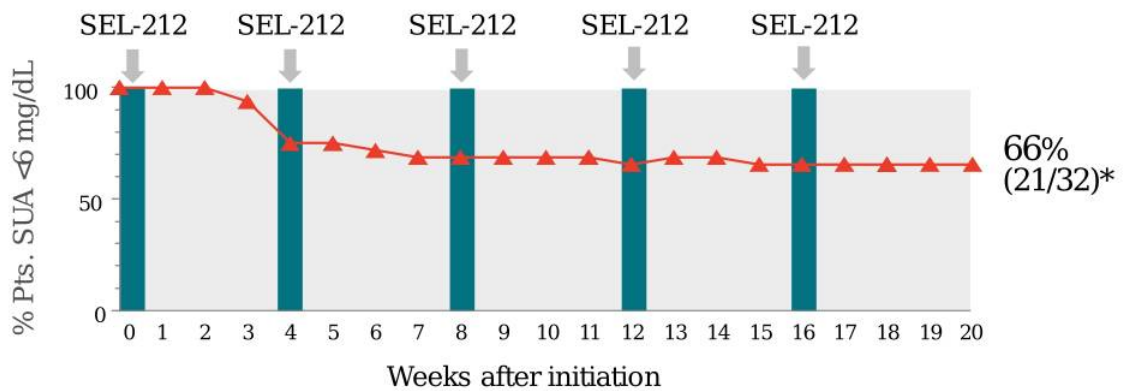
Significant need for effective new therapies in chronic refractory gout

- Improved efficacy, allowing patients to complete full 6-month therapy cycle
 - Persistent reduction in Serum Uric Acid (SUA) levels
 - Elimination of tophi
- Monthly dosing
- Gout flare reduction
- **Avoidance of “off-label” and global immunosuppressive therapies**

SEL-212 has the potential to address these unmet needs and holds \$1B+ market poten

Sustained reduction of SUA with monthly dosing of SEL-212 was observed in Phase 2 dose ranging study

Phase 2 results after 20 weeks of once-monthly SEL-212 treatment:

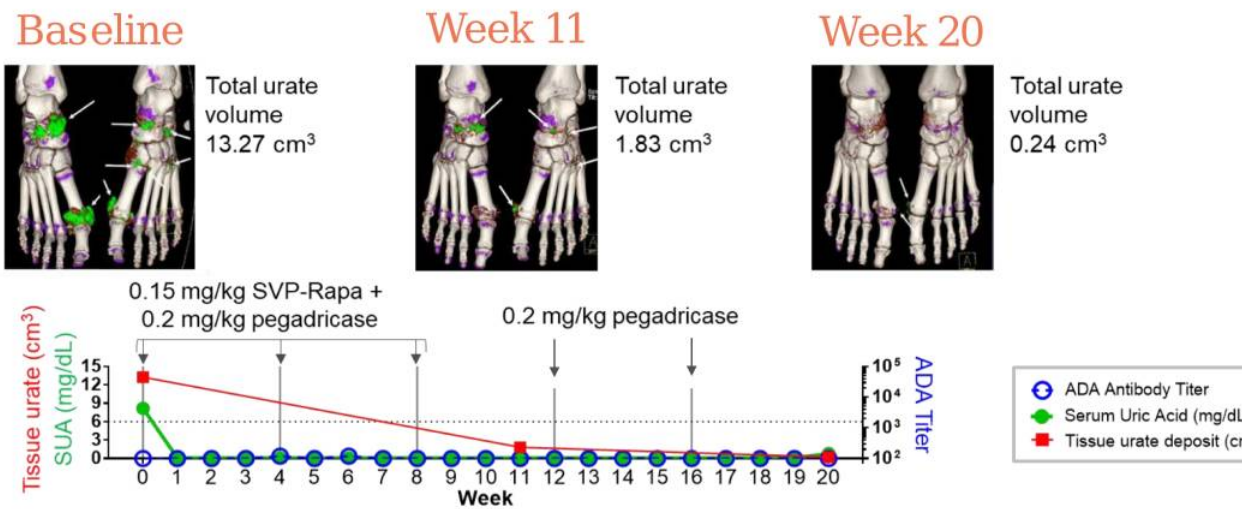


66% of evaluable patients completed the 20-week period with an SUA level < 6 mg/dL



*Week 20 Evaluable patients = patients who received a full first dose and did not discontinue due to any measure other than drug effectiveness or drug related safety

Dual energy computed tomography (DECT) scan images show reduction of tissue urate burden in Phase 2 dose ranging study



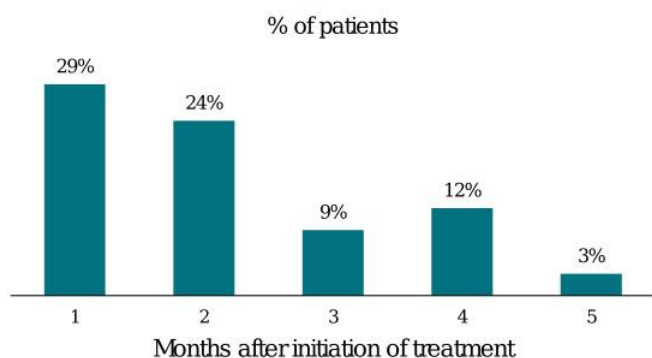
DECT uses a computer algorithm to produce color-coded images that render uric acid green, cortical bone blue, and trabecular bone purple



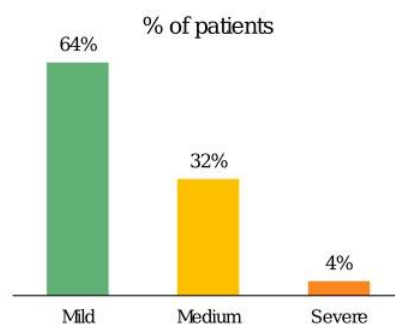
<https://selectabio.com/wp-content/uploads/2018/10/ACR-poster-DECT-2018-FINAL-.pdf>

Phase 2 dose ranging data showed reduced frequency and severity of flares during SEL-212 therapy

Percent of SEL-212 patients who had flares



Severity of flares



- Majority of flares occurred in months 1 & 2, with no new patients who flared after month 2
- 96% of flares were mild or moderate in severity
- No gout flares were classified as SAEs nor resulted in study drug discontinuations

SEL-212 generally well-tolerated in the Phase 2 dose ranging study

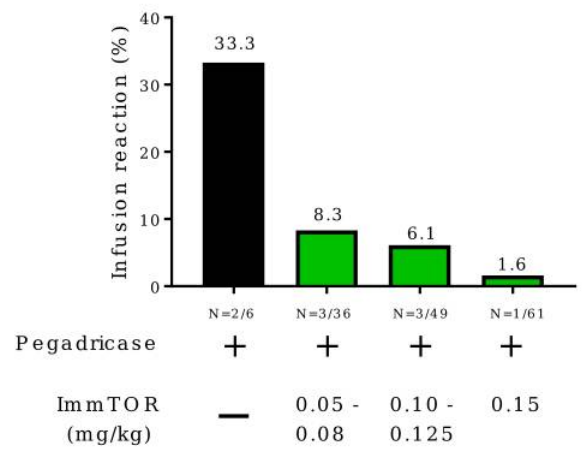
SEL-212 was generally well tolerated at clinically active doses following >470 administrations during the Phase 2 trial

23 SAEs reported in the Phase 2 trial

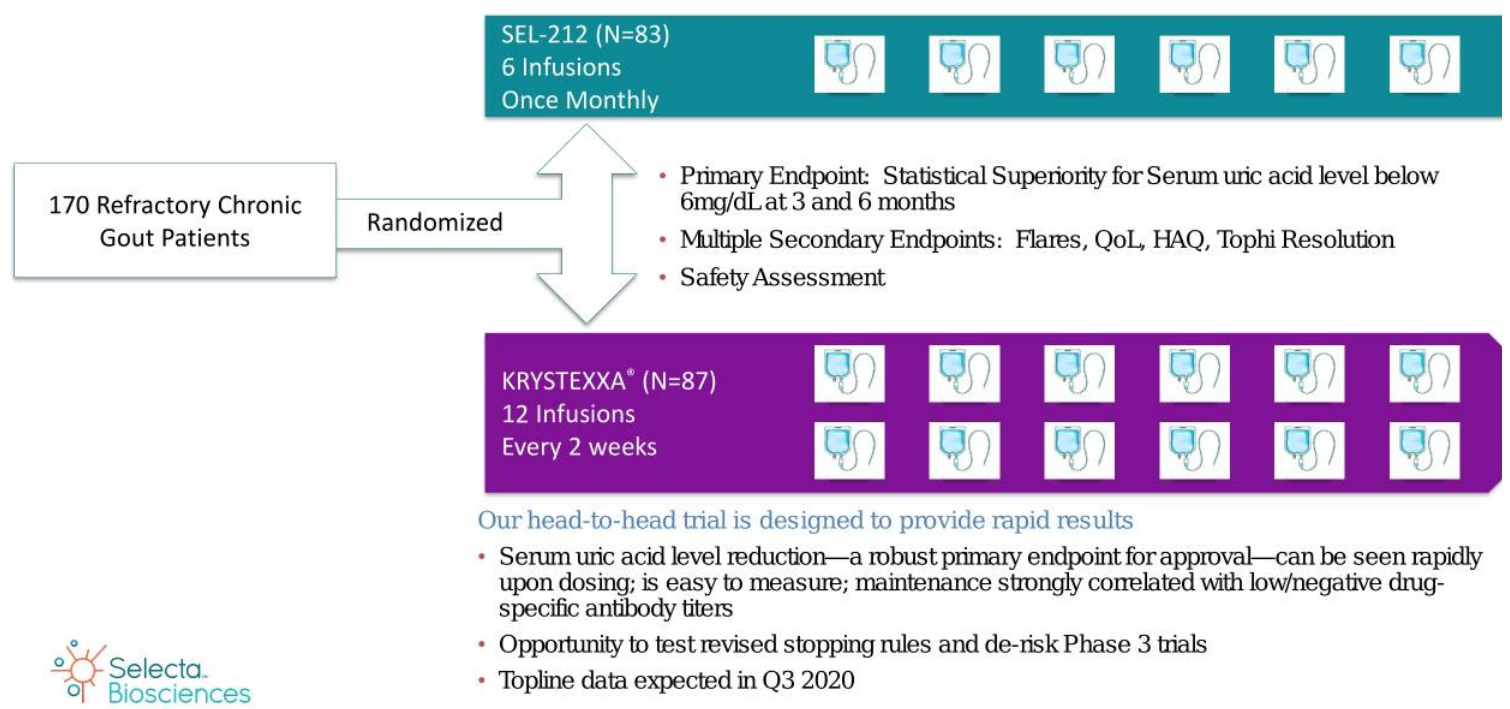
- 14 were reported not to be or unlikely to be related to study drug
- 9 were infusion reactions which decreased in incidence with increasing doses of ImmTOR

All SAEs were successfully treated without further issues

Serious infusion reactions (%)

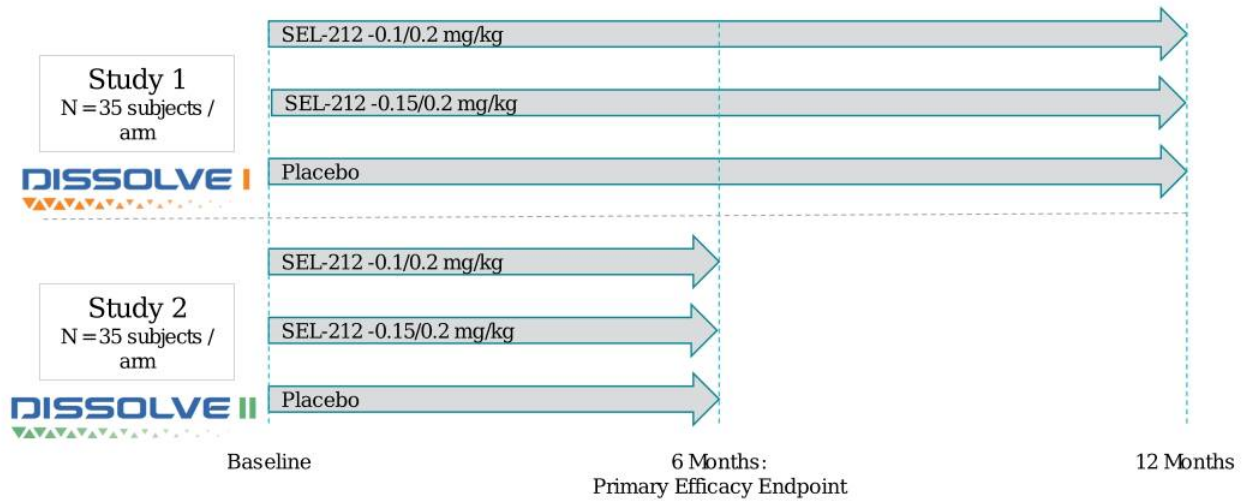


COMPARE Trial: A Study to Compare the Efficacy of SEL-212 to KRYSTEXXA® in Gout Patients Refractory to Conventional Therapy



SEL-212 Phase 3 Study Design

- 2 double blinded placebo-controlled trials of SEL-212 (0.1 mg/kg & 0.15 mg/kg SEL-110)
- Randomized 1:1:1 against Placebo with a total of 210 Treated Subjects
- Enrollment is expected to commence in 2H 2020



Selecta-Sobi Strategic Licensing Agreement

- In June 2020, Selecta and Sobi announced a strategic licensing agreement for SEL-212
 - Sobi takes on SEL-212 development, regulatory, and commercial activities in all markets outside of China
 - Selecta runs the phase 3 on behalf of Sobi, at Sobi's expense
- Supports the strategy for Selecta and Sobi
 - Selecta retains significant upside on SEL-212 without allocating financial resources to the program
 - Selecta to focus its resources on generating near-term value from gene therapy and autoimmune disease programs
 - Builds on Sobi's strategy and expertise to develop and commercialize novel therapies within immunology
 - Sobi's resources in the U.S. and globally could provide meaningful upside potential for SEL-212 in the U.S. and ex-U.S.
- Substantial upfront, significant cost savings, achievable milestones, and attractive royalty
 - Selecta to receive initial payments of \$100 million, including \$75 million upfront license fee and \$25 million equity investment
 - Equity purchased at \$4.62 per share (20% premium to VWAP 10 days prior to signing transaction)
 - Significant cost savings
 - Sobi to fund full phase 3 clinical program and commercial costs, resulting in at least \$150 million in cost savings through 2023
 - Expected to extend Selecta's runway into the first half of 2023
 - Up to \$630 million in potential milestone payments
 - Up to \$80 million in payments upon achievement of various development and regulatory milestones, which can be achieved by 2023
 - Up to \$550 million in payments upon achievement of various sales thresholds for annual net sales of SEL-212 ranging from \$100 million to \$1 billion
 - Royalty payments ranging from low double digits to the high teens



A stylized graphic in the top left corner of the teal header. It features a large central circle with several lines radiating outwards, resembling a sun or a gear. Below this, there is a smaller circle and a vertical line extending downwards.

ImmTOR in Gene Therapy

The ability to re-dose AAV gene therapy is a key goal to unlocking the full therapeutic potential

Dose titration

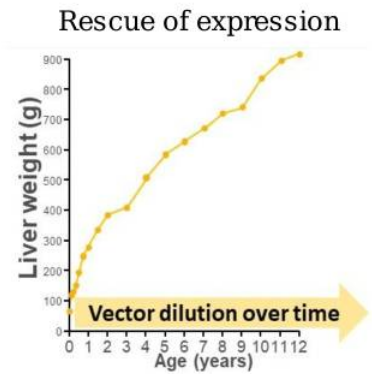
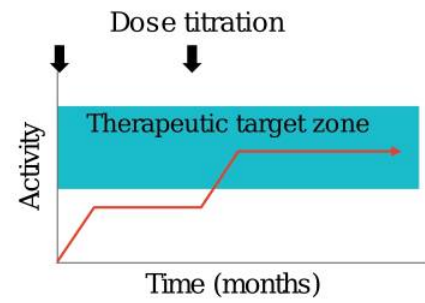
- Potential to increase proportion of patients who achieve therapeutic benefit without risk of overdosing
- Enrollment in clinical trials could be achieved more rapidly

Multiple vector administrations

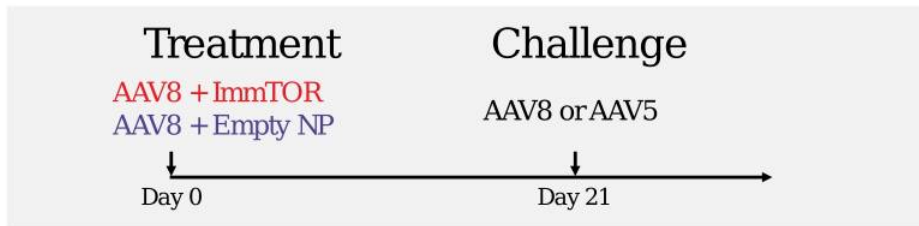
- Provide potential to target systemic diseases in which multiple vector administrations are likely needed to achieve full therapeutic efficacy

Rescue of expression

- Allows for potential rescue in patients with organ damage
- Potential to restore therapeutic expression in pediatric patients as they grow

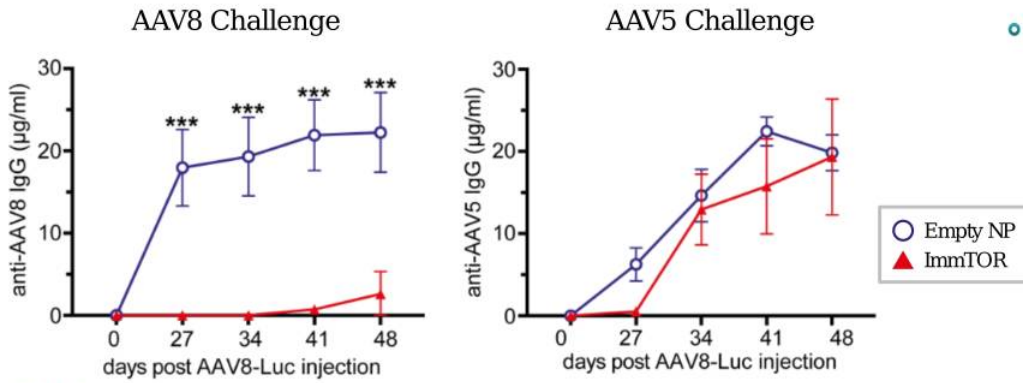


In preclinical studies, ImmTOR induced antigen-specific immune tolerance



ImmTOR provided AAV-specific immune tolerance

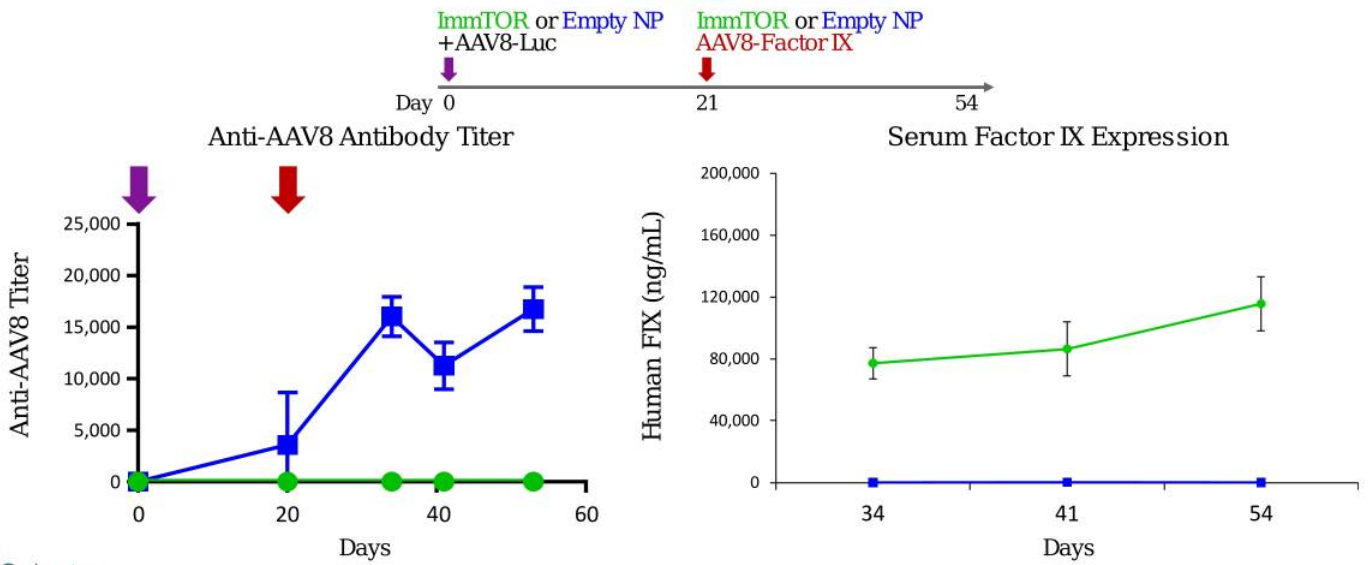
- NAbs did not develop in mice treated with ImmTOR+AAV vector
- Mice treated with empty nanoparticle (NP) AAV vector developed significant IgG response
- When challenged with a different AAV vector both arms mounted an immune response suggesting antigen-specific immune tolerance rather than broad immunosuppression was achieved



Meliani et al., Nature Communications, In Oct. 2018

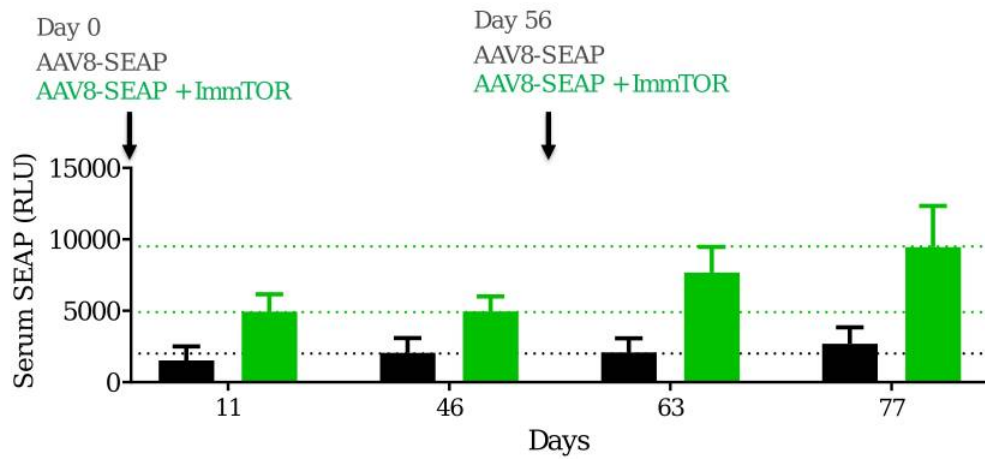
Preclinical data indicates potential of ImmTOR-powered re-dosing in gene therapy

ImmTOR-powered AAV8 gene therapy has potential to be re-dosed without NAb formation or loss of therapy expression



Melani et al., Nature Communications, In Oct. 2018

First dose benefit of ImmTOR on liver-directed transgene expression



First dose benefit is immediate and independent of effect on adaptive immune response
Cumulative benefit of first dose and repeat dose provides up to 4-fold increase in transgene expression



Ilyinskii et al., Tolerogenic ImmTOR™ nanoparticles enhance vector transduction, mRNA synthesis and transgene expression after initial and repeated administrations of AAV-based gene therapy vectors, Nov. 2019

Opportunities for clinical POC in gene therapy

Collaboration

- AskBio
 - Development pipeline and human trials planned for repeat dosing of AAV-based gene therapies to address the unmet medical need for patients with rare and orphan genetic diseases
 - Lead indication is MMA (Methylmalonic Acidemia)
 - Expect to enter the clinic under this collaboration by early 2021

Proprietary Program

- OTC (Omithine Transcarbamylase deficiency)

License Agreements

- AskBio
 - Licensed ImmTOR for Pompe disease in December 2019
- Sarepta Therapeutics
 - Research license and option agreement for DMD and certain LGMD subtypes
- Spark Therapeutics
 - Licensed ImmTOR for hemophilia










Strategic Collaborations

Enhancing Value Through Collaborations

- Selecta has entered into strategic transactions with leading biopharmaceutical companies to further unlock the value of the ImmTOR platform

					
Year	2016	2019	2019	2020	2020
ImmTOR Approach	Enable re-dosing of life-saving gene therapy	Enable re-dosing of life-saving gene therapy	Enable re-dosing of life-saving gene therapy	Improving the efficacy of biologics	Enable re-dosing of life-saving gene therapy
Agreement	License Agreement (Global)	50/50 Collaboration Agreement	License Agreement (Global)	License Agreement (Global, excluding China)	Research Option and License Agreement (Global)
Indications	Hemophilia A	Methylmalonic acidemia and other undisclosed indications	Pompe disease	Chronic refractory gout	Duchenne Muscular Dystrophy and certain Limb Girdle Muscular Dystrophy subtypes

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Summary

Projected upcoming milestones

● SEL-212

- Report top-line data in head-to-head (COMPARE) trial of SEL-212 against pegloticase in chronic refractory gout (3Q 2020)
- Commence Phase 3 clinical program against placebo (2H 2020)

● Gene Therapy Program

- Commence human POC trial under AskBio collaboration in MMA (early 2021)
- POC data (2H 2021)

● Autoimmune diseases

- IND filing in 2021



Strong cash position

- Company well-capitalized with funding, pro forma for the strategic license agreement with Sobi, into the first half of 2023
- Potential for significant additional non-dilutive funding through milestone and royalty payments from 2023 onward

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OUR PURPOSE

Relentlessly committed to overcoming
IMMUNOGENICITY with
our pioneering ImmTOR immune
tolerance platform to transform the lives
of patients and their families

