

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): November 19, 2019

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.)

480 Arsenal Way
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, \$0.0001 par value per share	SELB	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 November 2019

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: November 19, 2019

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



Corporate Presentation

November 2019

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 the clinical development of SEL-212, the anticipated timing of the head-to-head trial comparing SEL-212 and Krystexxa® and related data readouts, whether the head-to-head trial with Krystexxa® will demonstrate superiority, provide rapid results or de-risk the Phase 3 trials for SEL-212, the company's ability to enroll patients in its clinical trials, the potential of ImmTOR™ to reduce AAV vector immunogenicity and enable re-dosing of AAV gene therapy without neutralizing antibody formation or loss of therapy expression, the anticipated timing of preclinical toxicology studies in gene therapy and initiation of a clinical trial related thereto, the potential of SEL-212 to serve unmet needs in chronic refractory gout patients including sustained sUA reduction, reduced flares, and once monthly dosing, whether interim data related to the SEL-212 clinical program will be predictive of future data, the anticipated timing for advancing into Phase 3 (if at all), the anticipated timing of the company's plans to meet with the U.S. Food and Drug Administration, the ability of the company's ImmTOR technology to induce immune tolerance and mitigate antigen-specific neutralizing antibody formation, the 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, the potential of SEL-212 to significantly reduce tophi/heavy urate 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 therapy programs, the company's ability to execute on its strategic priorities, advance its ImmTOR platform, and grow its strategic partnerships, the potential of the company's partnership with Asklepios Biopharmaceutical, Inc. to address unmet medical need in patients with rare diseases, the timing of advancing the company's collaboration with CureCN, the impact of the restructuring, the company's ability to achieve its new priorities, the company's ability to reduce its annual cash burn rate in connection with the restructuring, the company's expected cash position and runw, 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 debilitating symptoms, the potential treatment applications for products utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy, the potential of AAV gene therapy 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," "will" 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, 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, and, specifically, to reach an agreement regarding an acceptable amendment of the company's exclusive patent license agreement with the Massachusetts Institute of Technology, 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, 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 results of the reduction could vary materially from the outcomes anticipated, 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, on November 8, 2019, 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

- **ImmTOR™, Selecta's immune tolerance technology platform, could unlock the full potential of biologic therapies by mitigating Neutralizing Antibody (Nab) formation**
 - Focused on therapeutic biologics/enzymes and AAV gene therapies
- **Lead program, SEL-212, addressing a \$1B+ chronic refractory gout market with high unmet need¹**
 - COMPARE trial ongoing to evaluate efficacy and safety of SEL-212 vs. KRYSTEXXA®
 - Interim data expected Q1 2020
 - Full 6-month top-line data, including statistical superiority, planned for mid 2020
 - Ongoing preparation to initiate Phase 3 clinical trial in SEL-212
 - FDA meeting in January 2020 regarding Phase 3 clinical development plan
- **Plan to enter the clinic in gene therapy in 2020¹**
 - Preclinical results suggest high relevance to diseases which may require re-dosing gene therapies to maintain efficacy
 - Currently have collaborations & licensing agreements with AskBio, Spark, and Genethon / CureCN Consortium
- **Purpose-built organization aligned to priorities**
 - Recently appointed Alison Schechter, M.D., as CMO and Brad Dahms as CFO

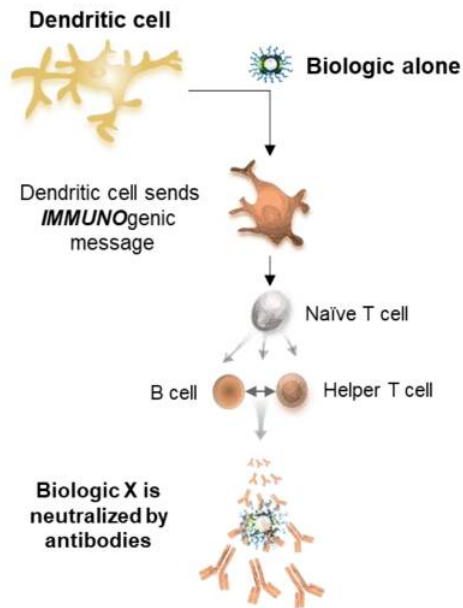


¹ We will require additional sources of capital to complete the COMPARE trial, to initiate the Phase 3 clinical trial of SEL-212, and to conduct the planned clinical program in gene therapy.



ImmTOR
Immune
Tolerance
Platform

Biologic therapies may trigger NABs that negate their therapeutic benefit

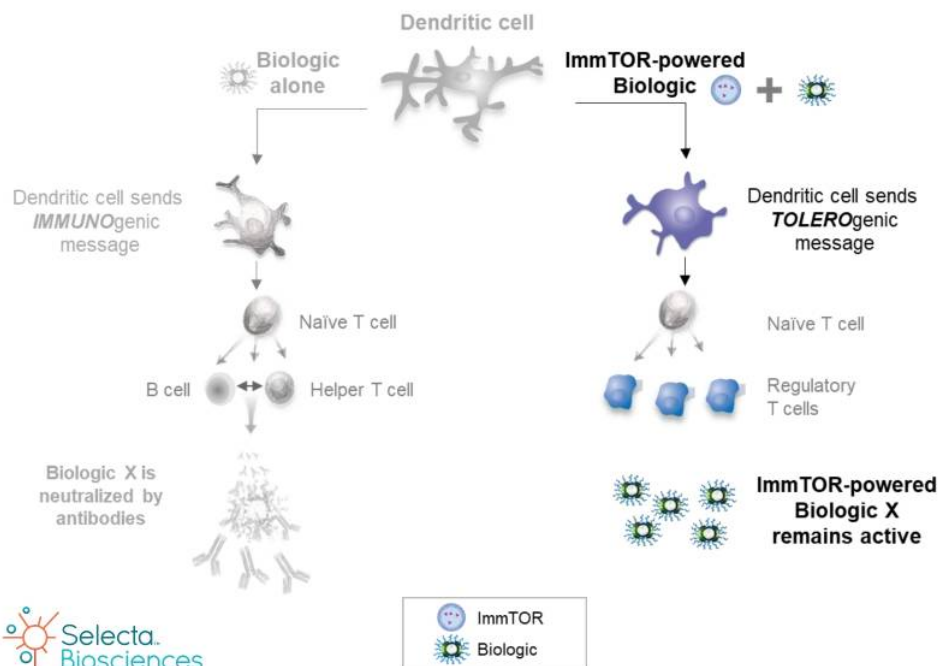


There is a significant unmet need for a technology that selectively induces immune tolerance

Dendritic cells play a key role in immune tolerance, providing a promising target to mitigate unwanted and 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



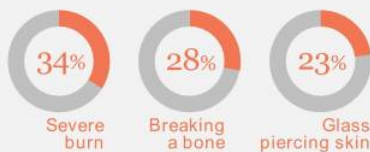
- Co-administer with biologic therapies to mitigate antigen-specific NAb formation
- ↓
- Induce a tolerogenic message from the dendritic cell to naïve T cells to develop into T regulatory cells
- ↓
- Promote selective immune tolerance of the biologic therapy

A large, stylized sun graphic in a light orange color, positioned on the left side of the slide. It features a central circle with several rays extending outwards, and a smaller circle below it. The background is a solid, darker orange color.

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 improved therapies in chronic refractory gout

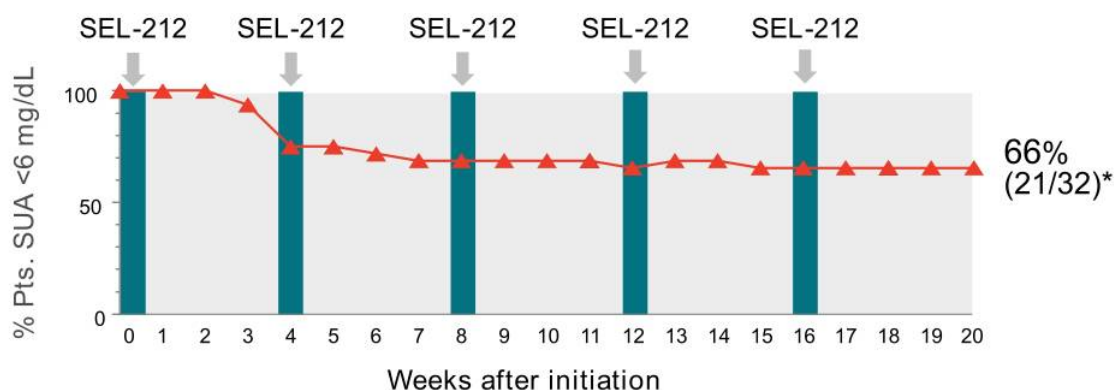
- Improved efficacy, allowing patients to complete full 6-month therapy cycle
 - Persistent reduction in Serum Uric Acid (SUA) levels
 - Elimination of tophi
- Monthly dosing
- Gout flare reduction
- **Avoidance of “off-label” and global immunosuppressive therapies**

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



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:

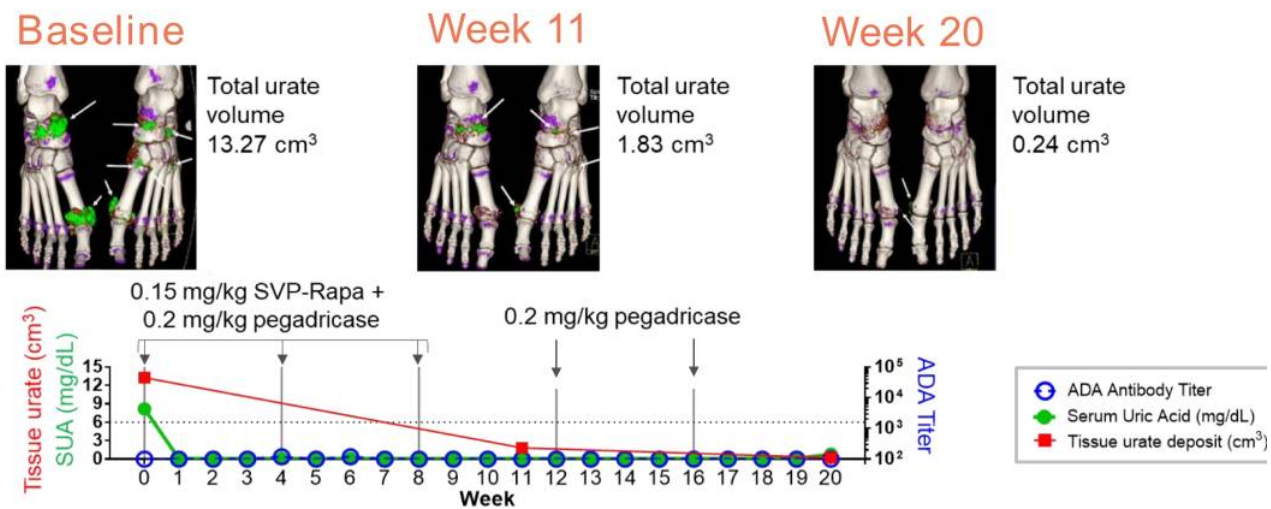


66% of evaluable patients completed the 20-week period with an SUA level <6 mg/dL



*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

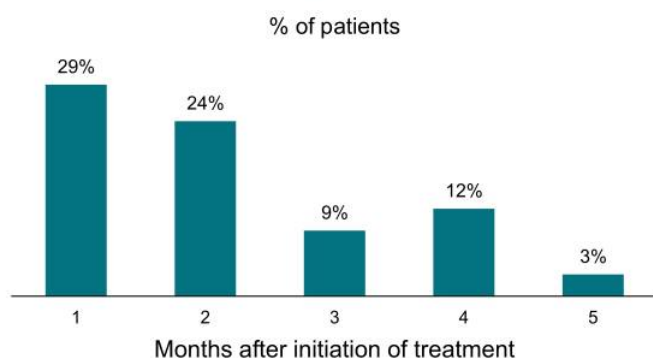
Dual energy computed tomography (DECT) scan images show reduction of tissue urate burden



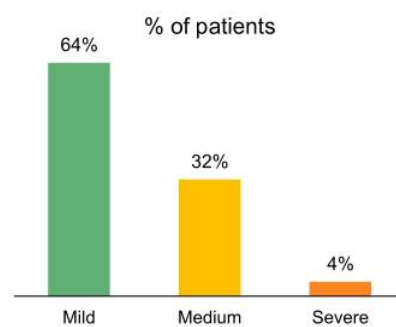
DECT uses a computer algorithm to produce color-coded images that render uric acid green, cortical bone blue, and trabecular bone purple

Phase 2 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 has been generally well tolerated

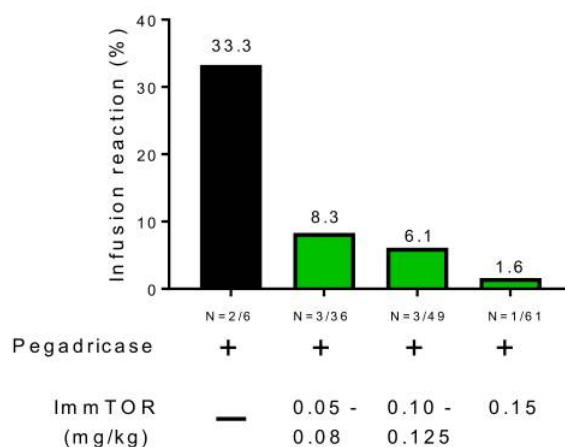
SEL-212 was generally well tolerated at clinically active doses following >470 administrations

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 (%)



Comparing the efficacy of SEL-212 to KRYSTEXXA® in gout patients refractory to conventional therapy

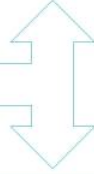


SEL-212 (N=~75)
6 Infusions
Once Monthly
0.15 mg/kg ImmTOR + 0.2 mg/kg of pegadricase



~150 Refractory
Chronic Gout Patients

Randomized



- Primary Endpoint: Statistical superiority for SUA level < 6mg/dL at 6 months
- Multiple Secondary Endpoints: Flares, QoL, HAQ, tophi resolution
- Safety Assessment

KRYSTEXXA® (N=~75)
12 Infusions
Every 2 weeks
8mg



Head-to-head trial is designed to provide objective, comparative results

- SUA level reduction, a robust primary endpoint for approval, can be seen soon after dosing
 - Easy to measure
 - Maintenance strongly correlated with low/negative drug-specific antibody titers
- Adult patient population with two active arms
- Opportunity to test revised stopping rules and de-risk Phase 3 trials





ImmTOR in Gene Therapy

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

Dose titration

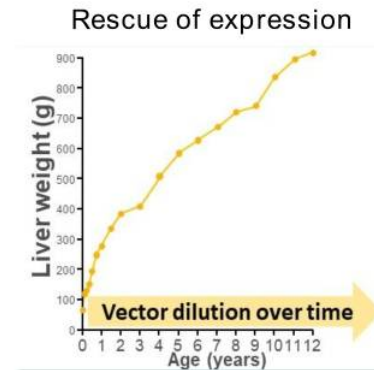
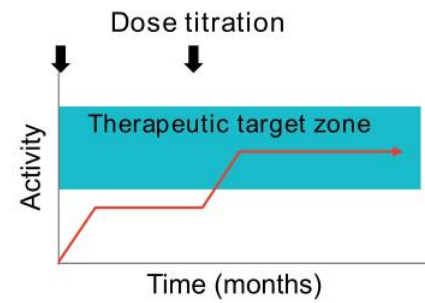
- Potential to increase proportion of patients who achieve therapeutic benefit without risk of overdosing
- Goal of improving enrollment in clinical trials

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

Treatment

AAV8 + ImmTOR
AAV8 + Empty NP

Challenge

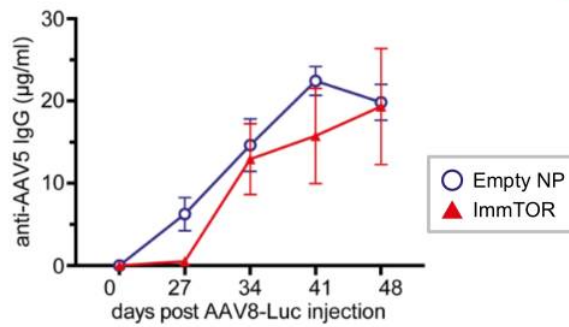
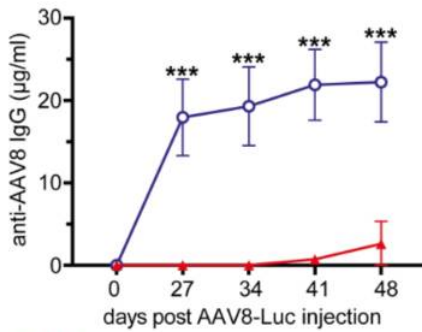
AAV8 or AAV5

Day 0

Day 21

AAV8 Challenge

AAV5 Challenge

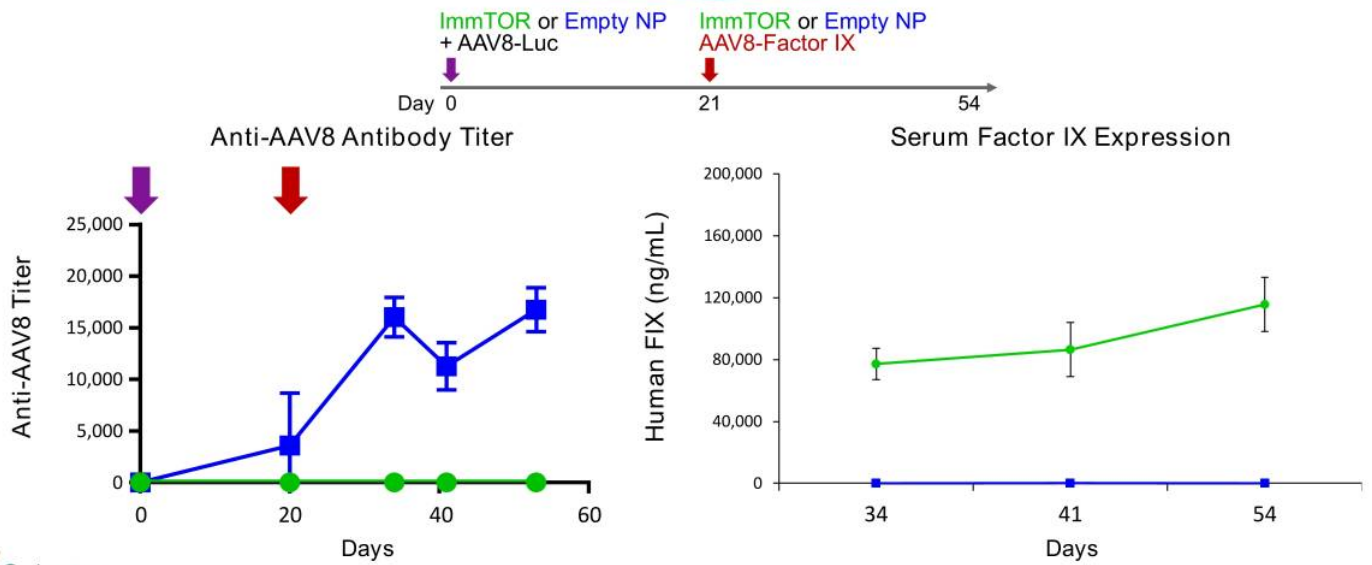


ImmTOR provided AAV-specific immune tolerance

- 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

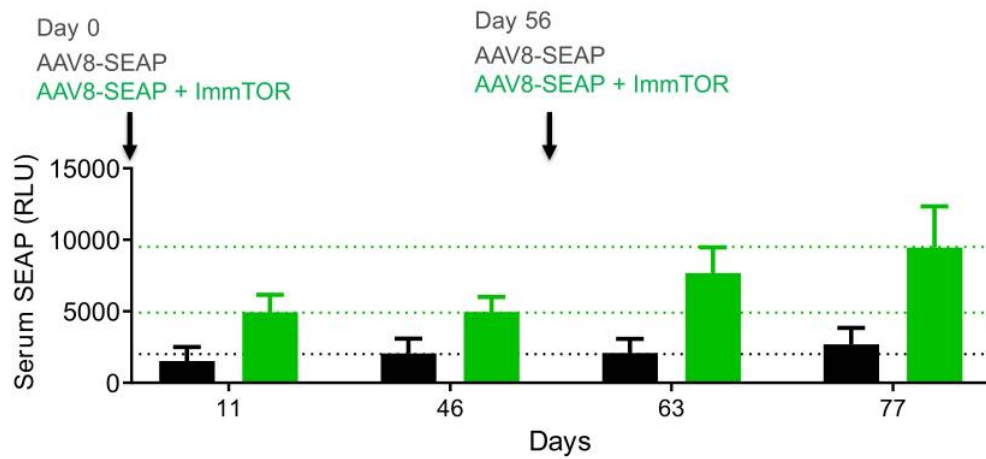
Preclinical data indicates potential of ImmTOR-powered re-dosing in gene therapy

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



Meliani 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

Collaborations

- 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
 - Expect to enter the clinic in 2020
- Genethon and the CureCN consortium
 - AAV gene therapy–sponsored program for treatment of Crigler Najjar Syndrome
 - Expect to obtain scientific advice from the German Health Regulators



Proprietary Programs

- MMA (Methylmalonic Acidemia)
- OTC (Ornithine Transcarbamylase deficiency)

License Agreement

- Spark Therapeutics
 - Licensed ImmTOR for hemophilia as well as exclusive options for up to four additional undisclosed genetic targets



Financial Overview and Projected Milestones

Financial snapshot

For the Quarter Ended
September 30, 2019

(In thousands)

Research & Development Expenses	\$8,104
General & Administrative Expenses	\$3,690
Total Operating Expenses	\$11,794
Net Loss	\$(11,994)

As of
September 30, 2019

(In thousands, except shares outstanding)

Cash, Cash Equivalents, Marketable Securities, Restricted Cash	\$35,892
Shares Outstanding	48,196,387



Projected upcoming milestones

- Report interim data from SEL-212 vs. KRYSTEXXA® COMPARE trial in chronic refractory gout (Q1 2020)¹
- COMPARE full 6-month top-line data analysis, including statistical superiority (mid 2020)¹
- Guidance from FDA meeting regarding Phase 3 clinical development plan (January 2020)
- Planning to commence clinical trial of ImmTOR in gene therapy (2020)¹



¹ We will require additional sources of capital to complete the COMPARE trial, to initiate the Phase 3 clinical trial of SEL-212, and to conduct the planned clinical program in gene therapy.



OUR PURPOSE

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

