

**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): January 7, 2019

**SELECTA BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**001-37798**  
(Commission  
File Number)

**26-1622110**  
(I.R.S. Employer  
Identification No.)

**480 Arsenal Way**  
**Watertown, MA 02472**  
(Address of principal executive offices) (Zip Code)

**(617) 923-1400**  
(Registrant's telephone number, include 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))

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  x

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.  x

**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 (the “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
<a href="#">99.1</a>	<a href="#">Corporate slide presentation of Selecta Biosciences, Inc. dated January 2019</a>

**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: January 7, 2019

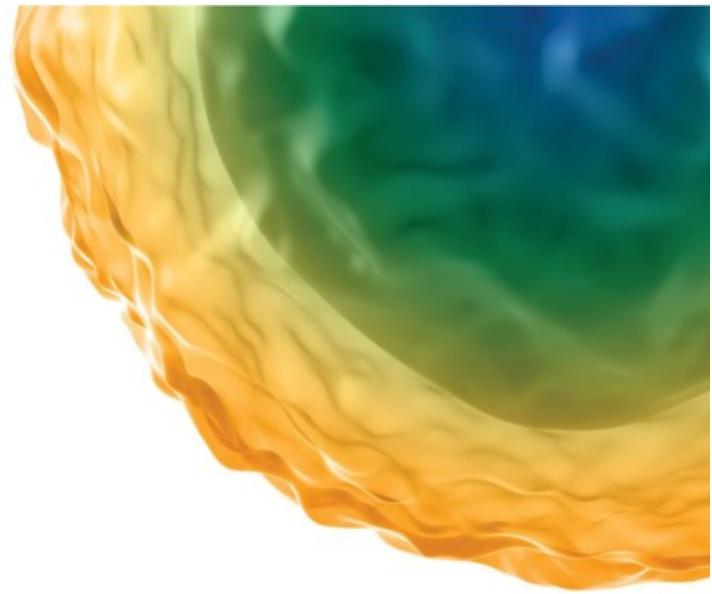
By:           /s/ Carsten Brunn, Ph.D.            
Carsten Brunn, Ph.D.  
President and Chief Executive Officer



# Company Presentation

January 2019

 Nasdaq | SELB



# 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 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 AAV 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 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 gene therapy programs, the company's ability to execute on its strategic priorities, advance its ImmTOR platform, and grow its strategic partnerships, the impact of the restructuring on 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 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," "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, 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, 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, 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, 2018, 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.*

# Investment highlights

---

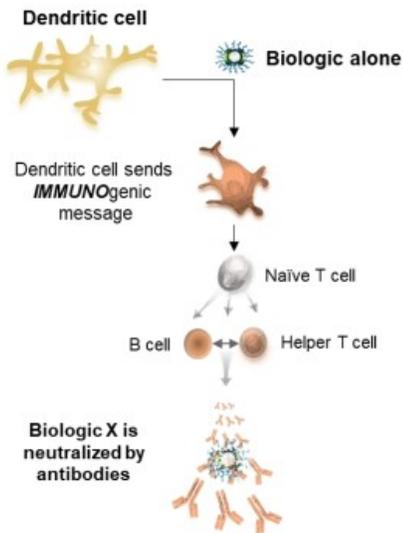
- Biologic therapies are a growth market, but therapeutic potential may be limited by formation of neutralizing antibodies (NAbs)
- Immune tolerance technology ImmTOR (SVP-Rapamycin) has the potential to unlock the full potential of biologic therapies by mitigating NAb formation
  - Focus on therapeutic enzymes and AAV gene therapies
- Committed to realizing potential in \$1B chronic refractory gout market with high unmet need
  - Completed SEL-212 (ImmTOR+pegadricase) Phase 2 trial in chronic refractory gout
  - Plan to initiate SEL-212 vs Krystexxa head-to-head trial in H1 19; interim 6-month data projected for H2 19; full 6-month data analysis, including statistical significance, planned for H1 20
  - Planning to initiate Phase 3 in H2 19
- Exploring partnerships for clinical POC of ImmTOR in gene therapy
  - Preclinical results suggest high relevance to diseases which may require re-dosing gene therapies to maintain efficacy
  - Initiated collaborations, licensing agreements, and proprietary programs (e.g., CureCN, Spark)
- Streamlined organization aligned to priorities

# ImmTOR (SVP-Rapamycin)

Immune Tolerance Technology



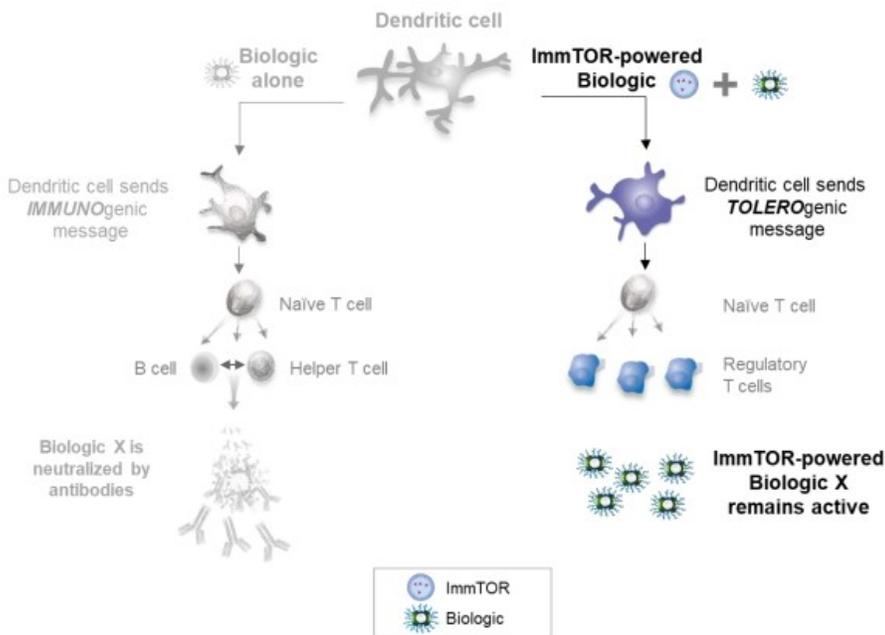
# Biologic therapies may trigger neutralizing antibodies (NABs) that negate their therapeutic benefit



- Current options limited
- Despite unmet need for a technology that selectively induces immune tolerance, there have been few advances in the last 40 years
- Dendritic cells sit at the crossroads of immune stimulation and immune tolerance providing a promising target to mitigate unwanted and antigen-specific immune responses

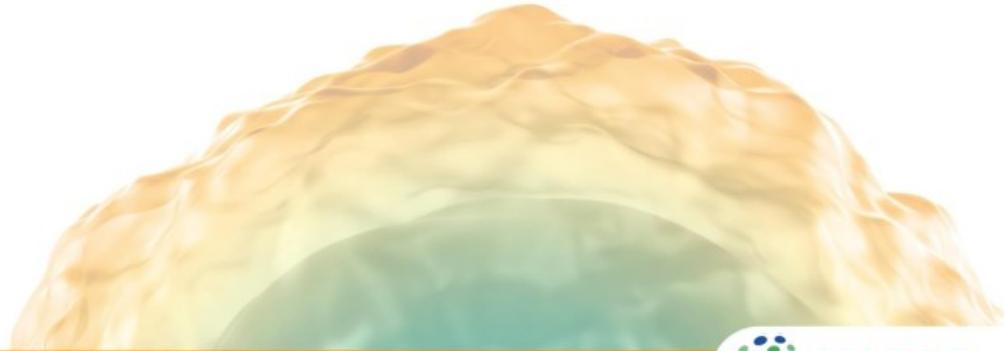
Inducing selective immune tolerance for biologic therapies considered the **“Holy Grail”**

# ImmTOR has the potential to enable sustained therapeutic activity of biologic therapies



- ImmTOR was designed to be co-administered with biologic therapies to mitigate antigen-specific NAb formation
- ImmTOR has the potential to induce a tolerogenic message from the dendritic cell to naïve T cells to develop into T regulatory cells
- T reg cells promote selective immune tolerance of the biologic therapy
- ImmTOR is designed to unlock the potential of biologic therapies

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

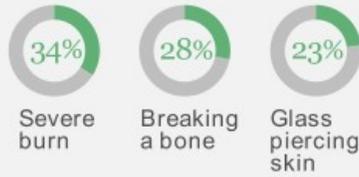


7



# Chronic refractory gout, a severe form of inflammatory arthritis, significant impact on patients

How chronic refractory gout pts describe flare pain



How long chronic refractory gout flares can last



Annual lost productivity (pts < 65)

~25 days

Est # pts 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**



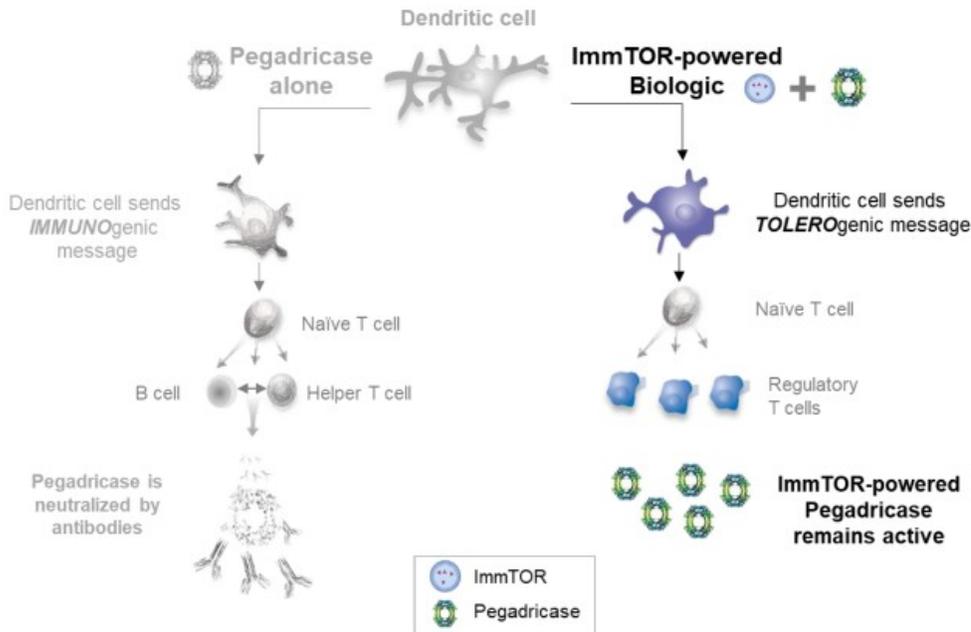
# Today's unmet needs in chronic refractory gout

---

- Monthly dosing
- Ability to complete full therapy cycles (6 months)
  - Persistent reduction in Serum Uric Acid levels (SUA)
  - Elimination of tophi
- Gout flare reduction
- Avoidance of “off-label” and global immunosuppressive therapies

We believe SEL-212 has the potential to address these unmet needs and holds billion-dollar potential

# SEL-212 is designed to be co-administered with uricase to enable sustained efficacy in chronic refractory gout



- SEL-212 has the potential to induce dendritic cells to send tolerogenic message to naïve T cells
- May result in development of regulatory T cells and mitigation of NAb formation, thus unlocking pegadricase's efficacy

# Sustained reduction of SUA with monthly dosing of SEL-212 was observed in Phase 2

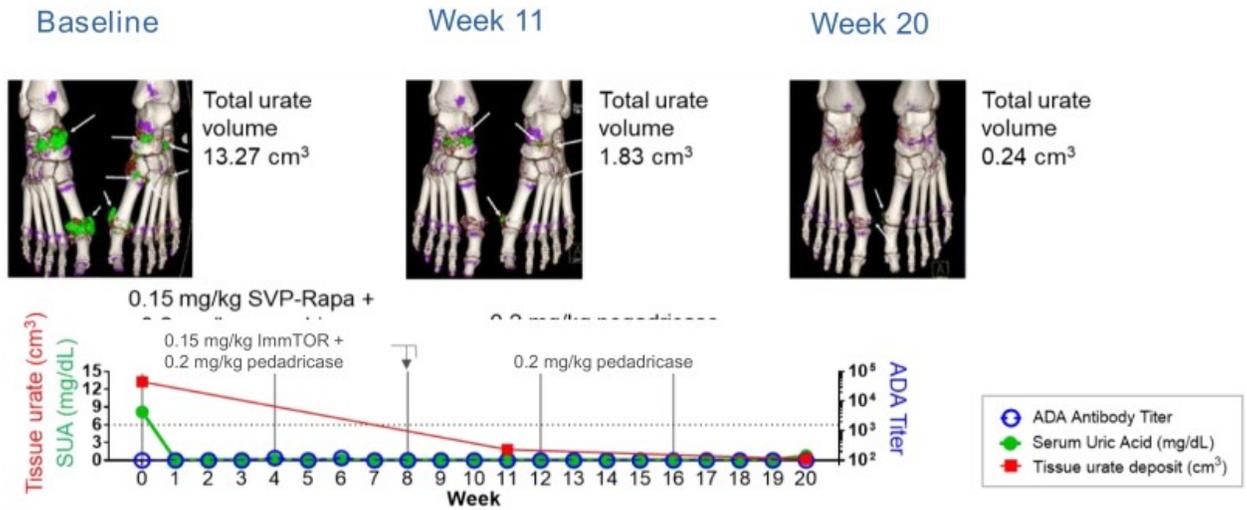
Phase 2 results after 20 weeks of once-monthly SEL-212 treatment:



66% of evaluable patients have 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

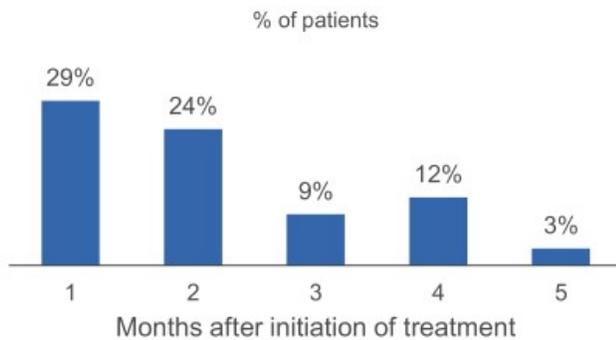
# Dual energy computed tomography (DECT) scan images show reduction of tissue urate burden



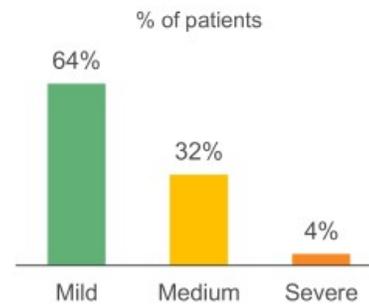
DECT uses a computer algorithm to produce color-coded images that render uric acid green, cortical bone blue, and trabecular bone purple

# Interim data show reduced frequency and severity of flares during SEL-212 therapy

Percent of SEL-212 patients who had flares



Severity of flares



- Majority of flares have occurred in months 1 & 2, and there have been no new patients who flare after second month
- 96% of flares have been mild or moderate in severity
- No gout flares have been 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 >380 administrations

17 SAEs reported in the ongoing Phase 2 trial

- 9 were reported not to be or unlikely to be related to study drug
- 8 infusion reactions:
  - 4 in cohorts receiving pegadricase alone or pegadricase as part of the lowest dose of SEL-212
  - 2 due to protocol deviations related to dosing errors
  - 2 during a repeat dose of SEL-212 in higher (0.1 – 0.15 mg/kg) dose cohorts
  - None occurred after treatment period 2

All SAEs were successfully treated without further issues

# Current efficacy and safety data support further development and registration

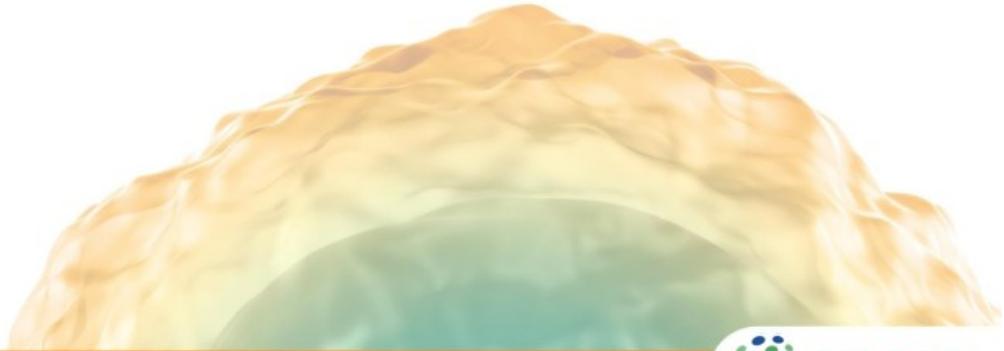
Q1 2019: Planning to initiate head-to-head SEL-212 vs Krystexxa trial



Our head-to-head trial is designed to provide rapid results

- Serum uric acid level reduction—a robust primary endpoint for approval—can be seen rapidly upon dosing; is easy to measure; maintenance strongly correlated with low/negative drug-specific antibody titers
- Adult patient population with rapid enrollment potential
- 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 its therapeutic potential

## Dose titration

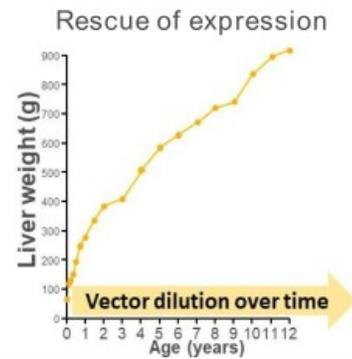
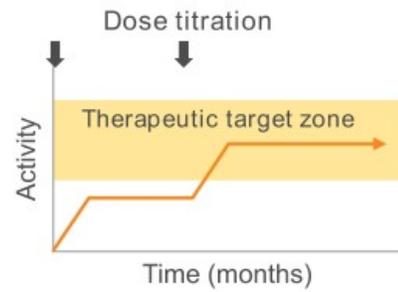
- Potential to increase proportion of patients that achieve therapeutic benefit without risk of overdosing
- Goal of improving enrollment in clinical trials

## Multiple vector administrations

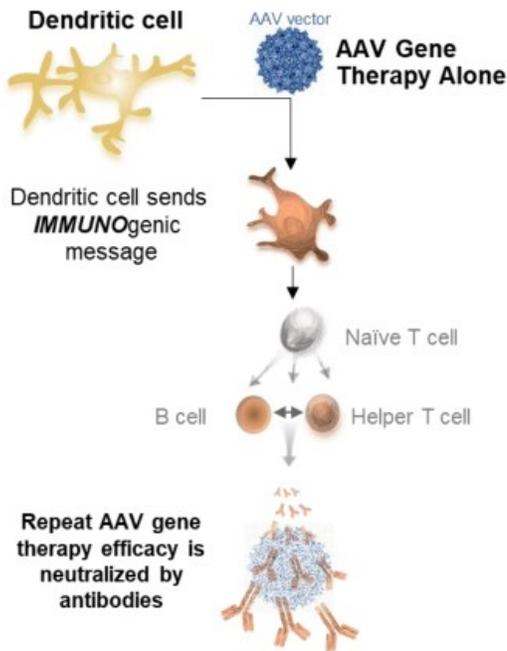
- Provide potential to target systemic diseases in which multiple vector administrations are likely needed to achieve full therapeutic efficacy

## Rescue of expression

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



# Strategies to reduce immunogenicity are an unmet need for re-dosing of AAV gene therapy



AAV gene therapy holds potential to transform the future in a variety of inherited and acquired diseases

- Cystic fibrosis, classic hemophilia, cancer, and cardiovascular disease

Immunogenicity represents a significant barrier to re-administration of AAV vectors

- NABs are triggered following vector administration reducing benefit of repeated AAV-based treatments
- Unmet need: Strategies to reduce AAV vector immunogenicity with goal of allowing for re-dosing

# In preclinical studies, ImmTOR induced antigen-specific immune tolerance

## Treatment

AAV8 + ImmTOR  
AAV8 + Empty NP

Day 0

## Challenge

AAV8 or AAV5

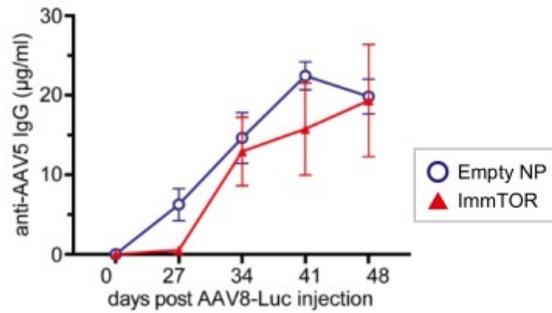
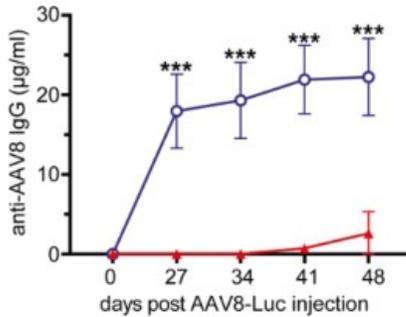
Day 21

## 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

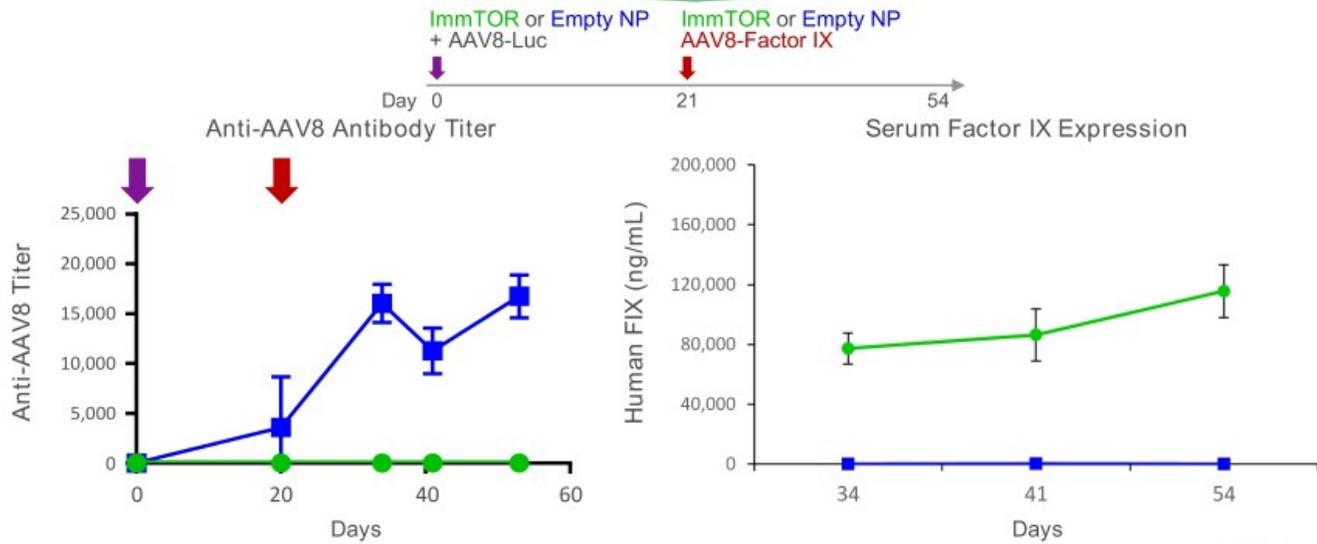
AAV8 Challenge

AAV5 Challenge



# 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



# Opportunities for clinical POC in gene therapy

---

## Collaborations

- Genethon and the CureCN consortium
  - AAV gene therapy–sponsored program for treatment of Crigler Najjar Syndrome
  - Potential for clinical combination therapy with ImmTOR to start 2H 2019; after preclinical toxicology

## Proprietary programs

- MMA (MethylMalonic Acidemia); IND projected 2H 2019
- OTC (Ornithine TransCarbamylase deficiency)

## License Agreement

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

## Projected 2019 milestones

---

- Report interim 6-month data from SEL-212 vs. Krystexxa Head-to-Head trial in chronic refractory gout (H2 19)
- Initiate SEL-212 Phase 3 program (H2 19)
- Initiate trial with CureCN for first-in-human combination of ImmTOR + AAV gene therapy (H2 19)
- Announce new partnership and/or collaboration in gene therapy (H2 19)
- Extend corporate cash runway with restructured company aligned to new priorities (H1 19)

# Financial Overview

	For the Quarter Ended	
	September 30, 2018	June 30, 2018
(In thousands, except share and per share data)		
Grant & Collaboration Revenue	\$ -	\$-
Research & Development Expenses	11,885	14,407
General & Administrative Expenses	4,056	4,362
Net Loss Attributable to Common Stockholders	\$(16,042)	\$(18,874)
Net Loss Per Basic & Diluted Share	\$(0.71)	\$(0.84)
Wtd. Avg. Common Shares Outstanding – Basic & Diluted	22,403,954	22,355,603
	As of	
	September 30, 2018	June 30, 2018
(In thousands)		
Cash, Cash Equivalents, Marketable Securities, Restricted Cash	\$50,485	\$66,228

Cash runway through Q3 2019

Thank you

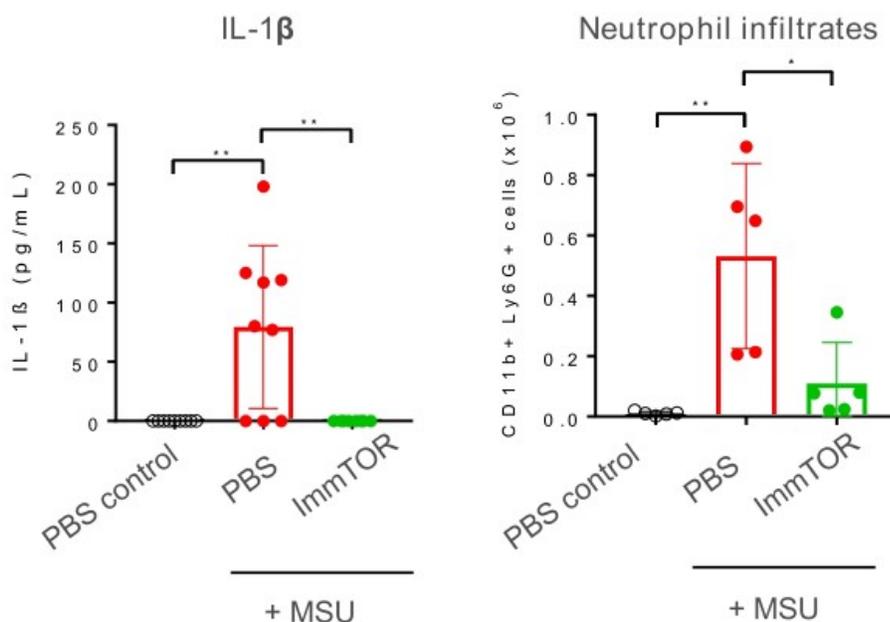


# Appendix



# Mitigation of IL-1 $\beta$ Production by ImmTOR in a Preclinical Model of MSU-Induced Inflammation

- Monosodium urate crystals (MSU) are known to cause inflammation by activating the NLRP3-inflammasome pathway resulting in IL-1 $\beta$  production<sup>1</sup>
- In preclinical study in mice ImmTOR inhibited IL-1 $\beta$  production and neutrophil infiltrates<sup>2</sup>



<sup>1</sup>Liu-Bryan R. et al., Immunol Cell Biol. 2010, 88:20-23

<sup>2</sup>Ko JH, et al., Oncotarget. 2017, 8:40817-40831

<sup>3</sup>Kolte P. et al., Abstract 2250, ACR 2018

