# 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 4, 2018

# SELECTA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-37798** | **26-1622110** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (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

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 8.01. Other Events.**

On May 30, 2018, the Company commenced the fourth combination dose in patients in the cohorts expected to receive five doses of SEL-212 in its Phase 2 clinical trial of SEL-212 in chronic severe gout.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Corporate slide presentation of Selecta Biosciences, Inc. dated June 2018 |

**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.

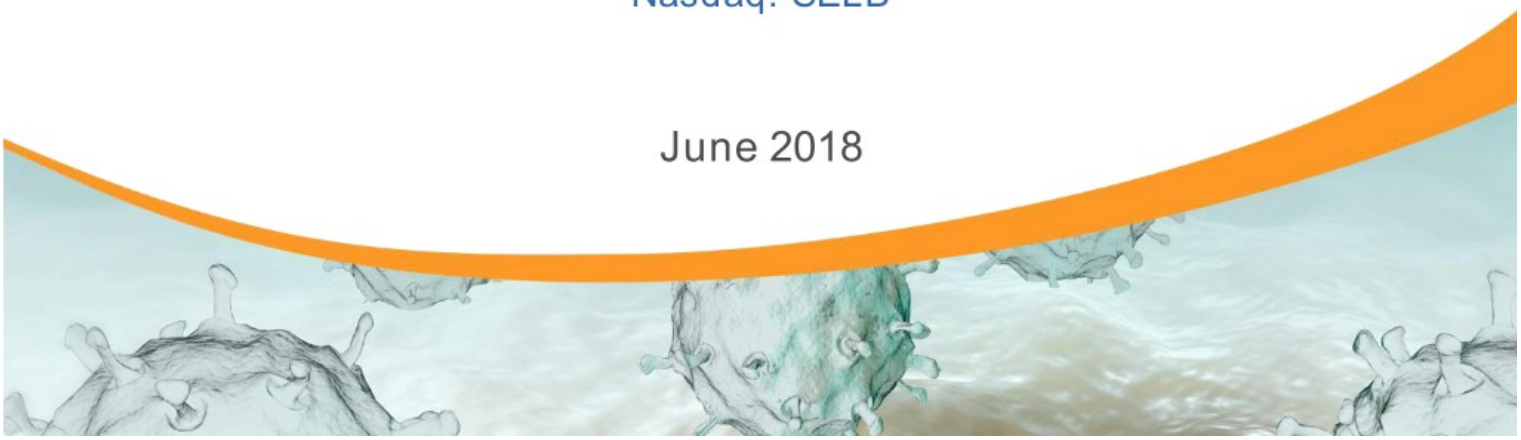
Date: June 4, 2018

By: /s/ Werner Cautreels, Ph.D.
Werner Cautreels, Ph.D.
President and Chief Executive Officer

SELECTA Biosciences

# Jefferies Presentation

Nasdaq: SELB



June 2018

# Safe Harbor / Disclaimer

Any statements in this presentation about the future expectations, plans and prospects of Selecta Biosciences, Inc. *("the company"),* including without limitation, the progress of the Phase 1/2 clinical program of SEL-212, the ability of SVP-Rapamycin to mitigate unwanted immunogenicity and unlock the full potential of biologic therapies, when the company will advance to Phase 3 for SEL-212 (if at all), the ability of SEL-212 to provide better and more sustained serum uric acid control, fewer flares, and less frequent dosing compared with recent data reported with the current FDA-approved uricase therapy, the ability of the *company's* SVP platform, including SVP-Rapamycin, to enable new therapies or to improve the efficacy or safety of existing biologics by mitigating immune response, when the company will conduct an End-of-Phase 2 meeting for SEL-212 if at all, the potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, whether the FDA approves the *company's* plan to provide combination therapy of SEL-212 for the entire treatment period, whether the company will determine an appropriate dose regimen of SEL-212 for the Phase 3, whether SEL-212 has the potential to address the unmet needs of gout patients, whether patients receiving SEL-212 will be able to complete full therapy cycles over 6 months, whether SEL-212 holds billion dollar potential, whether SEL-212 will continue to show low overall incidence of gout flares and continue to be generally well-tolerated, when the company will report further data from the Phase 2 trial, whether the data from patients receiving five monthly combination doses of SEL-212 will support the *company's* plans for its Phase 3 trial, whether the SVP platform enables the biologic to be distributed broadly to desired sites of action, the potential treatment applications for products utilizing the SVP platform in areas such as enzyme therapy, gene therapy, oncology therapy, vaccines and treatments for allergies and autoimmune diseases, the potential of future collaborations or licenses based on the ability of SVP-Rapamycin, the potential of the SVP-Rapamycin platform, generally, statements regarding progress of the Phase 1 trial for SEL-403, whether mesothelioma patients would benefit from a combination therapy consisting of LMB-100 and SVP-Rapamycin, the *company's* ability to locate and enroll a sufficient number of eligible patients to participate in the SEL-403 Phase 1 trial, whether preclinical data regarding SVP-Rapamycin and LMB-100 will be predictive of clinical trial results for SEL-403, whether the company files an IND for SEL-302 in 2019, the company's expectations about receiving additional payments from Spark Therapeutics, Inc. under the license agreement and/or the stock purchase agreement, the sufficiency of the *company's* cash, cash equivalents, investments, and restricted cash into mid-2019 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* SVP 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 or licenses, 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, substantial fluctuation in the price of its common stock, 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 May 9, 2018, and in other filings that the company makes with the SEC. 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.

# Corporate Overview

- Clinical-stage company applying proprietary Synthetic Vaccine Particle (SVP™) platform to mitigate unwanted immunogenicity and unlock the full potential of biologic therapies
- Expect to begin Phase 3 in 2018 with SEL-212 (SVP-Rapamycin + pegsiticase) for chronic severe gout; current data suggest product profile may provide: 1) Better and more sustained serum uric acid control; 2) Fewer flares; and 3) Once monthly dosing; versus FDA approved uricase
- Ongoing Phase 1 trial of SEL-403 (SVP-Rapamycin + LMB-100) for mesothelioma
- Proprietary gene therapy candidates in preclinical development
- License agreement in place with Spark Therapeutics, with additional potential for collaborations and licenses in a range of therapeutic areas

# Immunogenicity is Well Recognized as a Serious Challenge for Biologic Therapies

## IMMUNOGENICITY'S IMPACT

**COMPROMISED EFFICACY**
Anti-drug antibodies (ADAs) neutralize therapeutic benefit

**SAFETY RISK**
Hypersensitivity reactions can impact patients

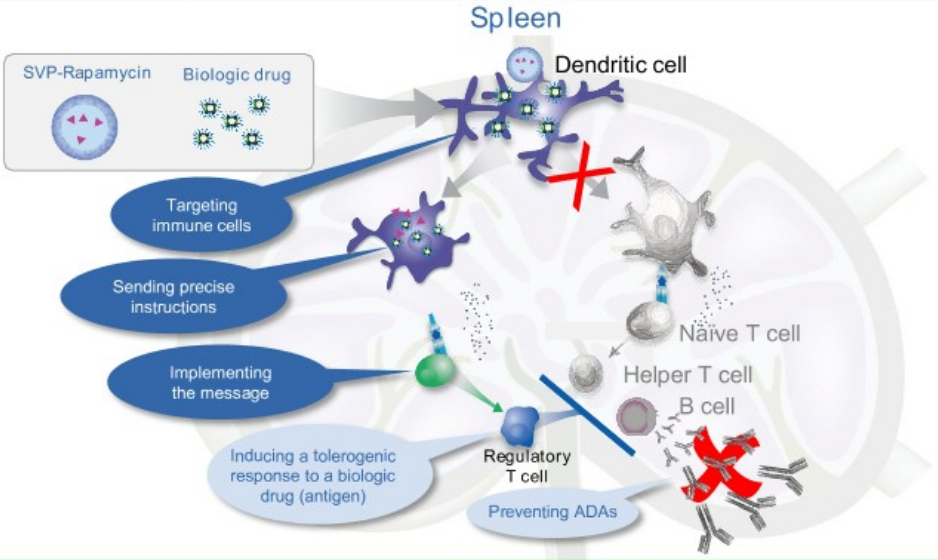
**UNPREDICTABLE RESPONSE**
Changed PK/PD through drug-ADA interaction


"With the explosion of biologic products on the market and in *research pipelines, we've* become very concerned about the effectiveness and safety of *these drugs."*

– Amy Rosenberg, MD, Director, Division of Biotechnology Products Review and Research, FDA

# Mitigating Unwanted Immunogenicity via Selecta's SVP-Rapamycin Technology Platform

- By dosing the "free biologic" it distributes broadly to desired sites of action
- Some of the biologic co-localizes with dendritic cells that have taken up SVP-Rapamycin
- The dendritic cells then induce regulatory T cells that circulate throughout the body and suppress immune responses against the biologic (i.e. ADAs)




Potential to enable new therapies and improve efficacy/safety of existing biologics



Kishimoto et al., Improving the efficacy and safety of biologic drugs with tolerogenic nanoparticles, Nature Nanotechnology, Aug. 2016


SEL-212 for Chronic
Severe Gout
SELECTA

# SEL-212: Advancing a Potential New Treatment Option for Chronic Severe Gout Patients

## Ownership

- In-licensed pegsiticase in 2014; combined with SVP-Rapamycin to form SEL-212

## Rare and Serious Disease

- ~160,000 adults with chronic severe gout treated by U.S. rheumatologists
- Debilitating flares and joint-damaging arthritis caused by uric acid deposits; risk of renal and cardiovascular disease

## Immunogenicity Barrier

- Uricases are highly effective in breaking down uric acid deposits, but are foreign to the human immune system, causing immunogenicity in nearly all patients that can negate efficacy and present safety risks

## Clear Clinical Path

- Serum uric acid level reduction – a robust FDA/EMA primary endpoint for approval – can be seen rapidly upon dosing; easy to measure; maintenance strongly correlated with low/negative ADA titers
- Adult patient population with rapid enrollment potential

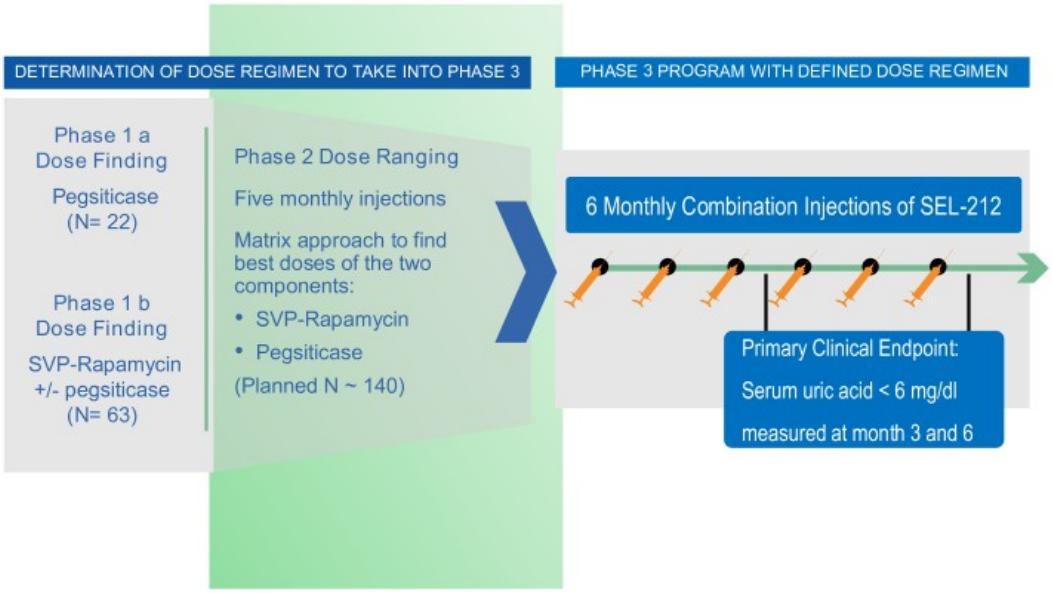
# Today's Unmet Needs in Chronic Severe Gout

- Monthly dosing (vs. biweekly for today's FDA approved uricase therapy)
- 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 Clinical Development Plan

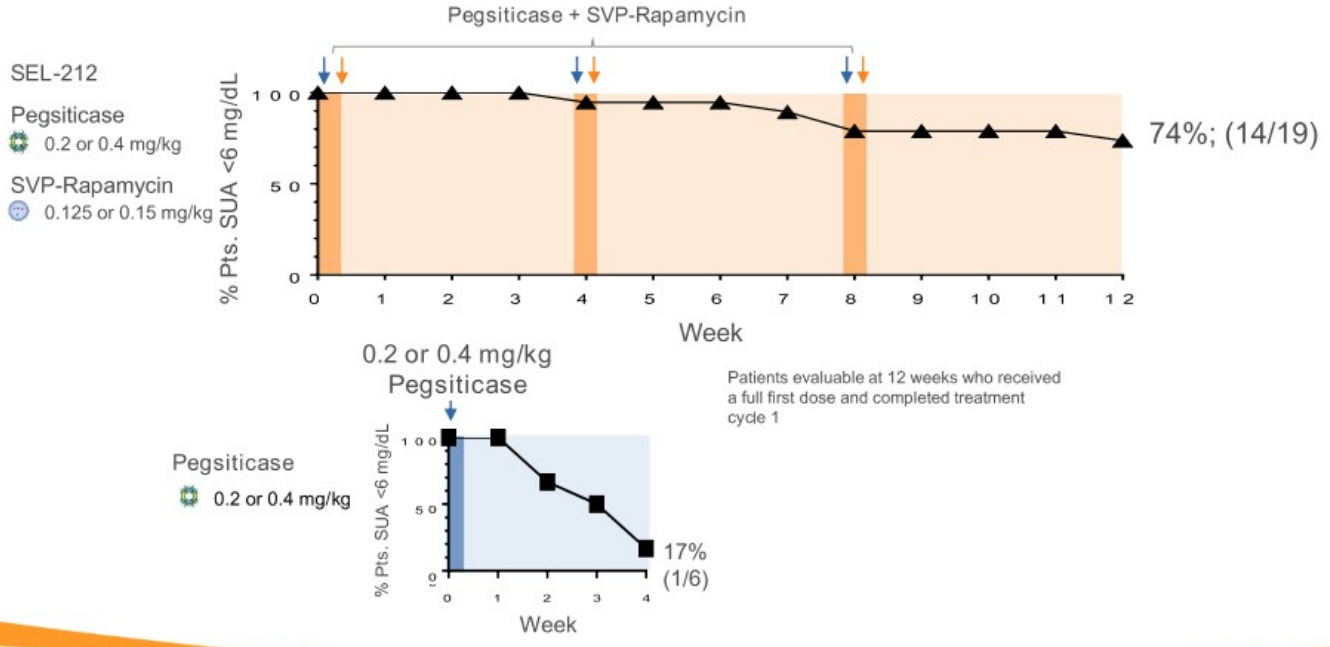




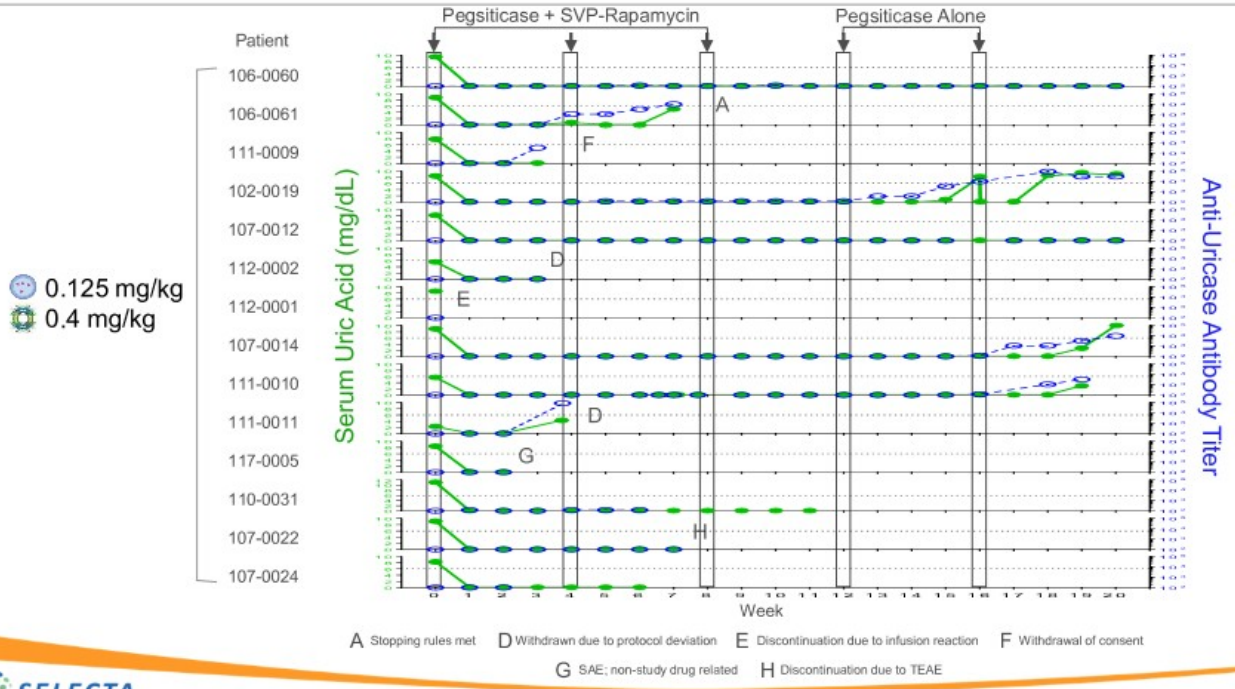
# Phase 2 Trial Overview

| | |
|---|---|
| Enrollment Criteria | • Patients with symptomatic gout and serum uric acid levels >6 mg/dL |
| Primary/Secondary Endpoints | • Safety, tolerability and pharmacokinetics of multiple doses of SEL-212 and pegsiticase alone<br>• Reduction of serum uric acid levels<br>• Reduction of ADA levels |
| Design | • Multiple ascending dose cohorts |
| Dosing | • Control cohorts: pegsiticase alone every 28 days for up to five doses<br>• Cohorts 13,15,17: SEL-212 every 28 days for five doses<br>• Every other cohort: SEL-212 every 28 days for three doses followed by two doses of pegsiticase alone |
| Stopping Rules | • Dosing stopped upon loss of sUA control at Days 21 after a dose |
| As of April 2 | • 117 patients dosed at 15 U.S. clinical sites |

# New Phase 2 Data at 12-weeks show 74% of Patients with Control of SUA <6 mg/dl

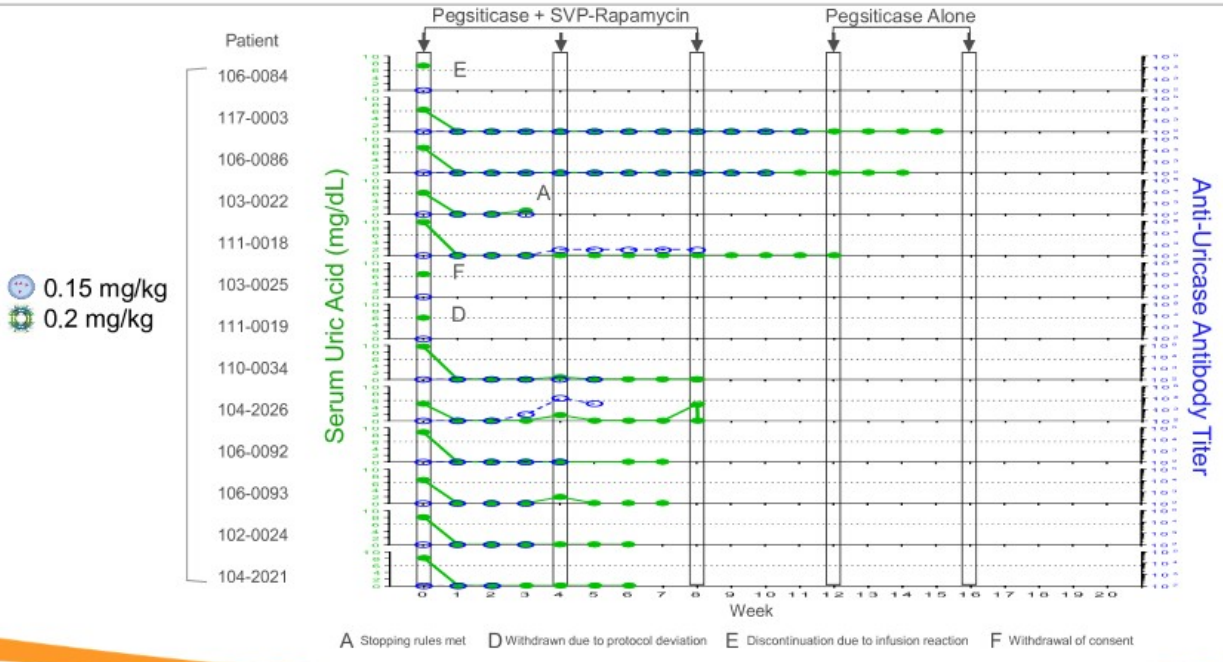


# Patients Dosed With 0.125 mg/kg of SEL-110 + 0.4 mg/kg of SEL-037

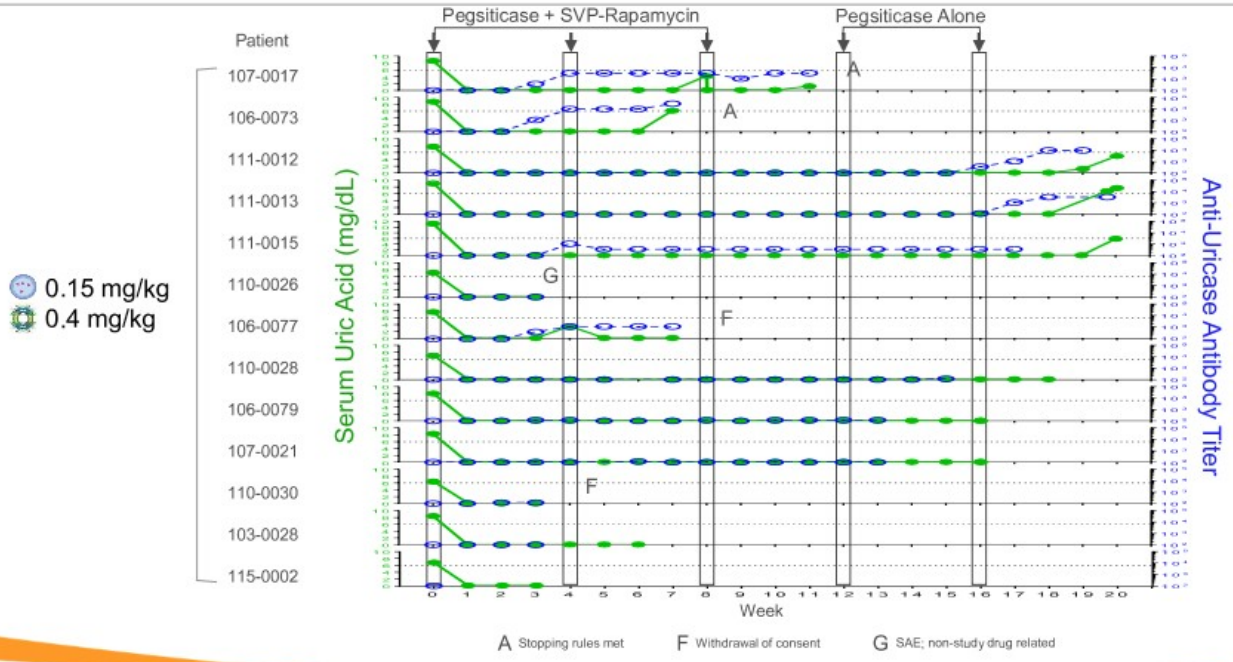



A Stopping rules met D Withdrawn due to protocol deviation E Discontinuation due to infusion reaction F Withdrawal of consent G SAE; non-study drug related H Discontinuation due to TEAE

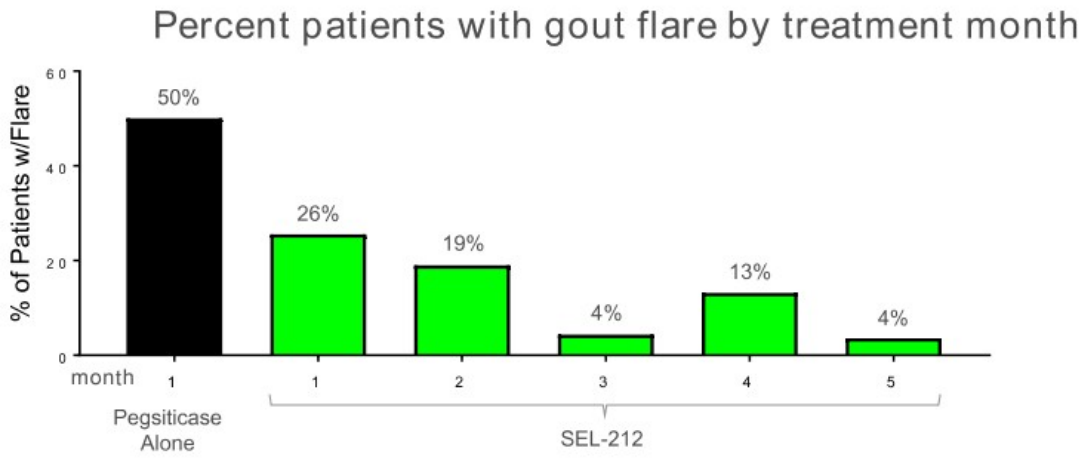
# Patients Dosed With 0.15 mg/kg of SEL-110 + 0.2 mg/kg of SEL-037



# Patients Dosed With 0.15 mg/kg of SEL-110 + 0.4 mg/kg of SEL-037



# SEL-212 Continues to Show Low Overall Incidence of Gout Flares In Total Phase 2 Patient Population



# SEL-212 Safety For Total Phase 2 Patient Population

- SEL-212 has been generally well tolerated at clinically active doses following >300 administrations
- Fifteen SAEs reported in the ongoing Phase 2 trial:
  - Seven were reported not to be or unlikely to be related to study drug
  - Eight infusion reactions:
    - Four in cohorts receiving pegsiticase alone or pegsiticase in combination with the lowest dose of SVP-Rapamycin, as anticipated
    - Two due to protocol deviations related to dosing errors
    - Two 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

# SEL-212 PANLAR Data Compared to KRYSTEXXA® Data

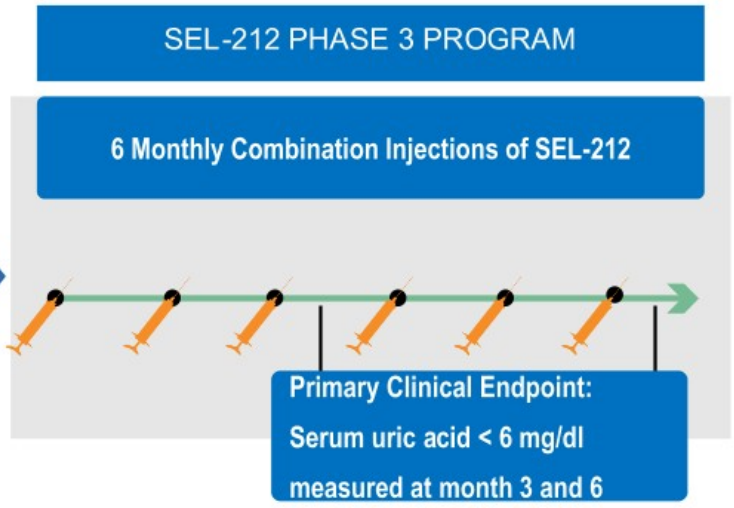
| Category | SEL-212 (12 weeks) | KRYSTEXXA® (16 weeks)+ |
|---|---|---|
| sUA control | 74%++ | 44% |
| Gout flare % | 42% | 52% |
| Dosing regimen | 3 monthly injections | 3 weekly followed by 7 bi-weekly injections |

*+Krystexxa results from "Initial Clinical Study to determine whether a tolerizing regimen of pegloticase can increase frequency* of subjects having sustained *lowering of serum urate." Kenneth E. Saag, Mitchell Finemann, Alan Kivitz, Herbert Baraf, Roy Fleishmann, Arthur Kavanaugh,* and Peter Lipsky; ACR Poster 2017

++ Defined as % of evaluable patients at 12 weeks with sUA <6 mg/dl who received a full first dose and completed treatment cycle 1

# Next Step for SEL-212 in 2018

- Expansion of PANLAR data set to be presented at EULAR (June 15th)
- Data expected in third quarter from patients receiving five combination doses of SEL-212
  - Patients now receiving 4th of 5 expected combination doses
- Phase 3 trial expected to begin in 2018



# SEL-403 for Mesothelioma

SELECTA Biosciences

# SEL-403: A Highly Potent Recombinant Pseudomonas Immunotoxin Targeting Mesothelin

## Ownership

- In-licensed LMB-100 from NCI in April 2017; up to $9.25 million in milestones; low single-digit royalties
- Combination with SVP-Rapamycin now known as SEL-403

## Rare and Serious Disease

- Mesothelin expressed in virtually all mesotheliomas (~3,000 annual U.S. diagnoses[1]) and pancreatic cancers (~50,000); high percentage of ovarian, lung, breast cancers
- Certain solid tumors are particularly hard to treat and have remained evasive to immunotherapy approaches

## Immunogenicity Barrier

- LMB-100 induces inhibitory antibodies upon first dose in almost all patients, limiting dosing to one or two administration cycles; insufficient to control tumor
- Global immunosuppressants ineffective in preventing ADAs in a vast majority of patients
- SVP allowed 3+ treatment cycles in pre-clinical models, restoring LMB-100 anti-tumor activity
- Initial repeat dose data from ongoing SEL-212 Phase 2 encouraging for this application

## Clear Clinical Path

- Both components of SEL-403 (SVP-Rapamycin and LMB-100) have been in the clinic in separate trials
- FDA acceptance of IND for combination treatment announced in January; First patient dosed in March 2018

1. Beebe-Dimmer et al., Mesothelioma in the United States: a Surveillance, Epidemiology, and End Results (SEER) – Medicare investigation of treatment patterns and overall survival, Clin Epidemiol., Oct. 2016

# Immunotoxin LMB-100

## LMB-100

- LMB-100: Pseudomonas exotoxin A linked to antibody Fab targeting mesothelin
- Technology was licensed to Roche but later returned to NCI
- Efficacy was limited by immunogenicity after one or two cycles in most patients
- Currently in Phase 1 clinical trials

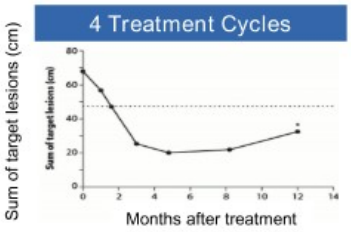
## Mesothelin is overexpressed on many solid tumors

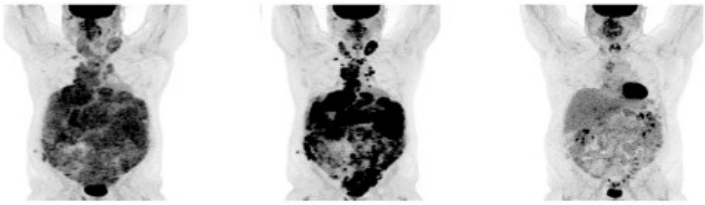
- Mesothelioma (>90%)
- Pancreatic cancer (>90%)
- Ovarian cancer (70%)
- Lung cancer (50%)
- Breast cancer (34%)

Ira Pastan, M.D.
Head, Molecular Biology Section
National Cancer Institute

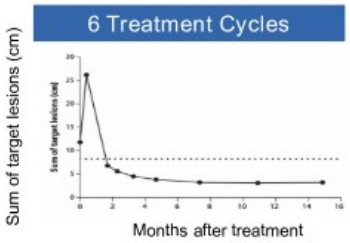
# Clinical Activity of SS1P (LMB-100 Precursor) in Mesothelioma

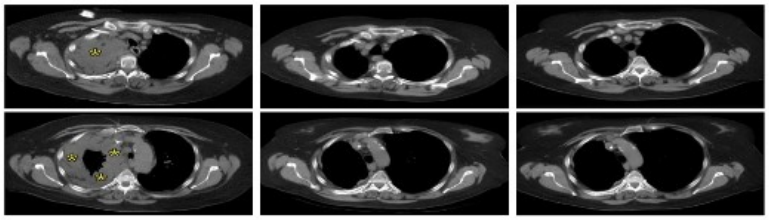
**Patient 1**
- Widely metastatic peritoneal mesothelioma
- Survived 32 months




**Patient 2**
- Extensive pleural mesothelioma
- Survival >6 years (still alive)




**While patients receiving ≥4 cycles showed major anti**-tumor response, immunogenicity limited treatment to 1 or 2 cycles for most patients despite use of immunosuppressive therapy

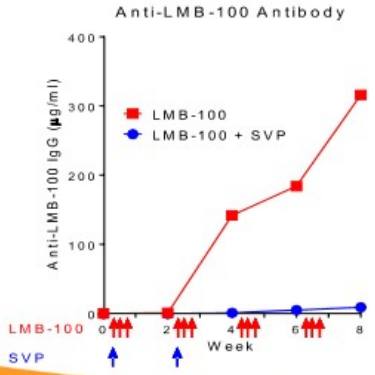


Science Translational Medicine. 2013 Oct 23;5(208).

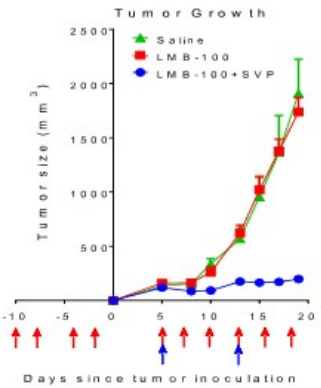
# Preclinical Data Supports the Benefits of SVP-Rapamycin + LMB-100 Combination Therapy

SEL-403

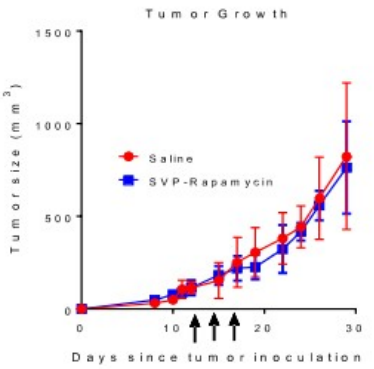
**Prevents formation of anti-drug antibodies**




**Restores LMB-100's anti-tumor response**




**SVP alone does not accelerate tumor growth**






Proc Natl Acad Sci U S A. 2018 Jan 23;115(4):E733-E742

# SEL-403 In Clinical Phase 1 at NCI

- Enrolled the first patient of a dose-escalating Phase 1 trial in March 2018 under a CRADA at NCI (NCT03436732)
- Enrolling up to 18 patients with malignant pleural or peritoneal mesothelioma who have undergone at least one regimen of chemotherapy
- Patients to receive four treatment cycles of the combination product candidate
- Primary objective: Evaluate the safety and tolerability of the combination therapeutic candidate in the study population
- Additional measurements: Objective Response Rates and ADA titers

# Proprietary & Licensed Gene Therapy Programs

SELECTA

# Selecta's Proprietary Gene Therapy Programs

## Ownership
- Two proprietary gene therapies utilizing Anc80 and AAV + SVP-Rapamycin (SEL-302 & SEL-313)

## Rare and Serious Disease
- Two rare inborn error of metabolism: Methylmalonic Acidemia (MMA) and Ornithine Transcarbamylase (OTC) Deficiency
- Onset in early infancy; significantly reduces life expectancy

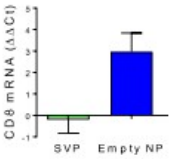
## Immunogenicity Barrier
- Infants require treatment prior to metabolic crisis to avoid CNS effects; retreatment likely needed as patients grow
- Repeat systemic gene therapy dosing currently not possible due to neutralizing antibodies to viral capsid
- Cellular immune responses to the liver are an additional potential barrier

## Clear Clinical Path
- Lead gene therapy program is SEL-302 for MMA
- Clinical endpoints include: Methylmalonyl-CoA mutase and MMA levels
- Expect to file IND in 2019

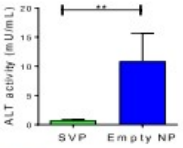
# Benefits of ADA Mitigation in Gene Therapy

## Inhibiting Liver Inflammation from First Dose

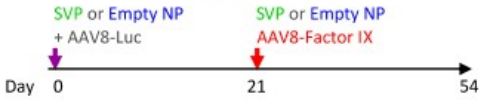

CD8 T cell Liver Infiltrates



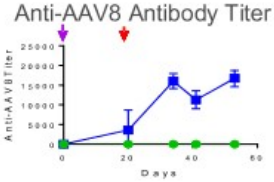

Serum ALT Enzyme Levels



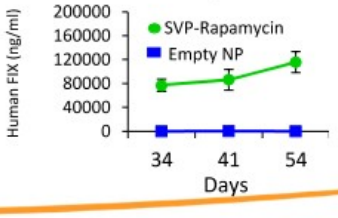

## Allowing for Repeat Dosing And Dose Titration




Anti-AAV8 Antibody Titer

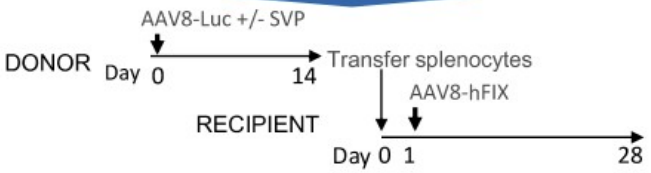



Serum Factor IX Expression

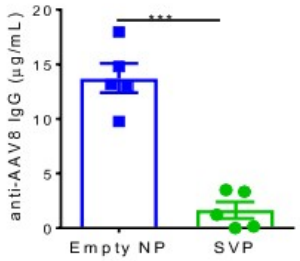


# Demonstration of the Role of Regulatory T Cells

## Effect can be Transferred to a Recipient

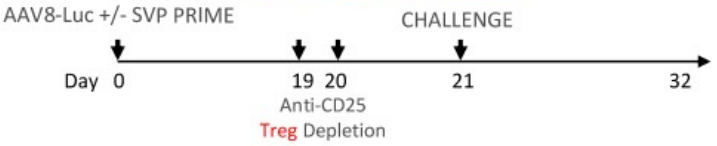



Anti-AAV8 IgG levels in recipient mice (Day +14)

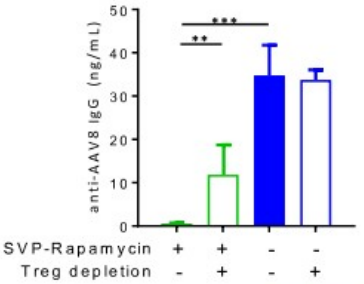



** P < 0.01, *** P < 0.001

## T Reg Depletion Negates Effect

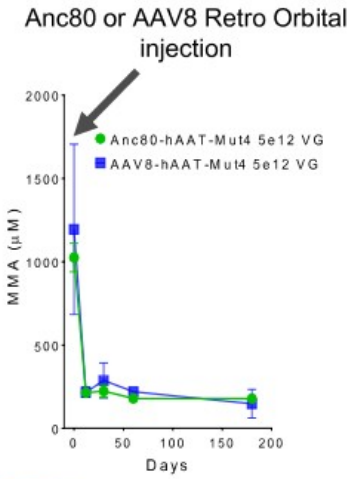



**Anti-AAV8 IgG levels (Day 32)**

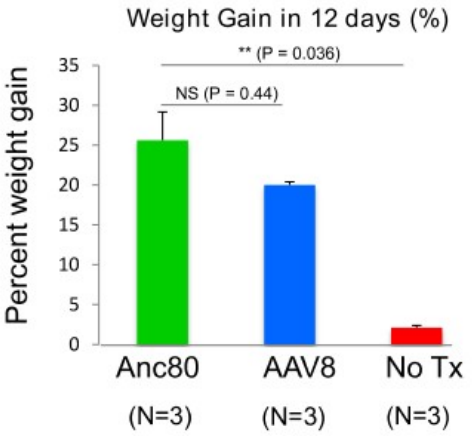


# Anc80/synMUT Proof of Concept in Mouse Model of MMA at ASGCT 2017

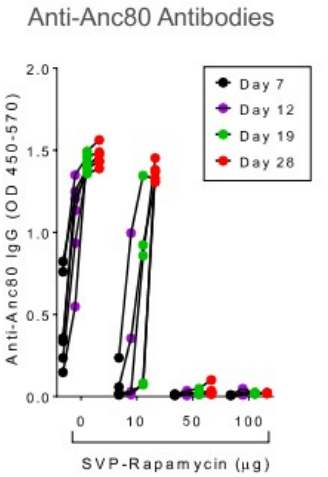
## Reducing MMA Levels With Anc80 and AAV8




## Increasing Weight Gain Following Treatment




## Preventing Anti-Anc80 Antibodies via SVP-Rapamycin



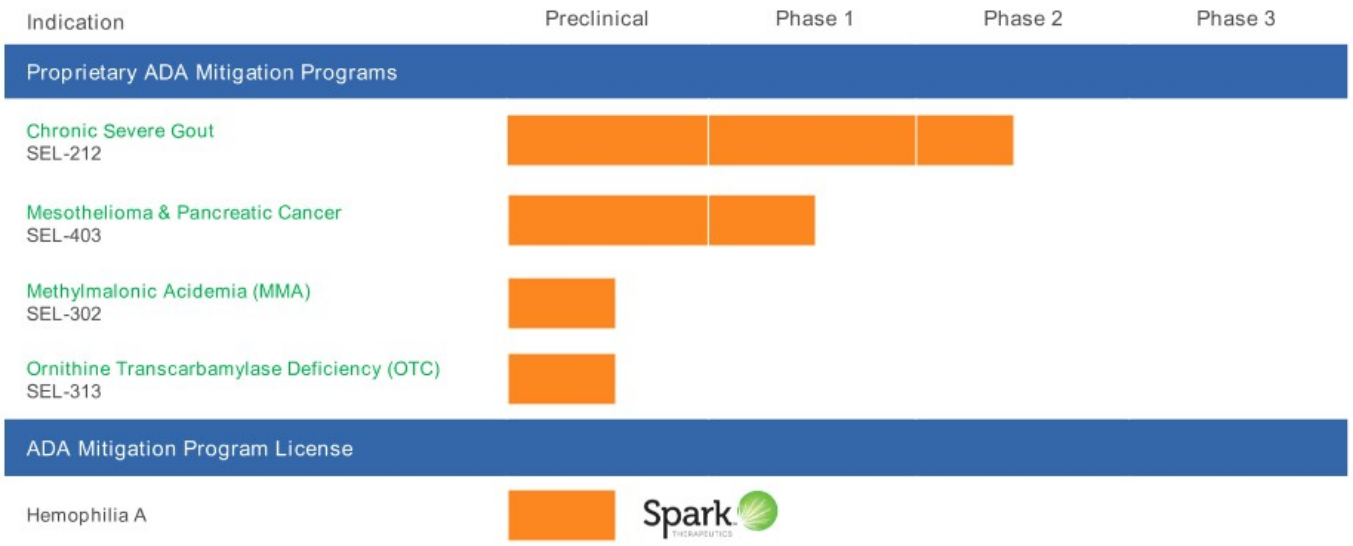



Preclinical data generated in mice in collaboration with Dr. Charles Venditti, NIH, and Dr. Luk Vandenberghe, Mass Eye & Ear

# Spark Therapeutics License Agreement

- December 2016 agreement provides Spark Therapeutics with exclusive worldwide rights to Selecta's SVP technology for up to five gene therapy targets
- Among the largest gene therapy and SMID-cap to SMID-cap biotech deals announced to date
- Initial focus on combination of SVP with Spark's Hemophilia A gene therapy
- Received $30 million of initial cash payments and investments in Selecta equity
- Subject to the terms of the license agreement, Spark also agreed to pay to Selecta:
  - Up to $430 million in milestone payments for each target
  - Mid-single to low-double-digit royalties on worldwide annual net sales of any resulting commercialized gene therapy

# Pipeline


Indication
Preclinical
Phase 1
Phase 2
Phase 3
Proprietary ADA Mitigation Programs
Chronic Severe Gout
SEL-212
Mesothelioma & Pancreatic Cancer
SEL-403
Methylmalonic Acidemia (MMA)
SEL-302
Ornithine Transcarbamylase Deficiency (OTC)
SEL-313
ADA Mitigation Program License
Hemophilia A
Spark
THERAPEUTICS

# Financial Overview

| (In thousands, except share and per share data) | For the Quarter Ended March 31, 2018 | For the Quarter Ended December 31, 2017 |
|---|---|---|
| Grant & Collaboration Revenue | $ - | $17 |
| Research & Development Expenses | 11,139 | 13,623 |
| General & Administrative Expenses | 4,674 | 5,671 |
| Net Loss Attributable to Common Stockholders | $(15,866) | $(19,544) |
| Net Loss Per Basic & Diluted Share | $(0.71) | $(0.89) |
| Wtd. Avg. Common Shares Outstanding – Basic & Diluted | 22,345,523 | 20,425,050 |

| (In thousands) | As of March 31, 2018 | As of December 31, 2017 |
|---|---|---|
| Cash, Cash Equivalents, Marketable Securities, Restricted Cash | $83,472 | $96,967 |

Cash runway into mid-2019