

**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 8, 2018

**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

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 (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 January 8, 2018, in connection with the presentation and/or distribution of the Presentation, the Company announced that it expects to report initial results for its Phase 2 clinical trial of SEL-212 in chronic severe gout in April 2018 and further expects to hold an End of Phase 2 Meeting with the U.S. Food and Drug Administration in the second quarter of 2018.

The Company also expects to submit an investigational new drug application for SEL-302 in methylmalonic acidemia in 2019.

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

(d) Exhibits

Exhibit No.	Description
<a href="#">99.1</a>	<a href="#">Corporate slide presentation of Selecta Biosciences, Inc. dated January 2018</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 8, 2018

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



# Investor Presentation

Nasdaq: SELB

January 2018



# Safe Harbor / Disclaimer

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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, whether the company participates in an End-of-Phase 2 meeting for SEL-212 in Q2 2018, the potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, the ability of SVP-Rapamycin to avoid unwanted immunogenicity and unlock the full potential of a range of therapeutics, whether higher level doses of SVP-Rapamycin or SEL-212 will show increased clinical activity and durability in line with the Phase 1b, when the company will report further data from the Phase 2 trial, 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 of SEL-212 for the Phase 3, when the company will advance to a Phase 3 for SEL-212 (if at all), whether SEL-212 has the potential to address the unmet needs of gout patients, whether SEL-212 will lower the incidence of flares, whether SEL-212 holds billion dollar potential, the ability of the *company’s* SVP platform, including SVP-Rapamycin, to mitigate immune response and create better therapeutic outcomes or to improve the efficacy or safety of existing biologics, 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, whether the company commences a Phase 1 trial for SEL-403 in Q1 2018, 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 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, a significant portion of the *company’s* total outstanding shares have recently become eligible to be sold into the market, 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 7, 2017, 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

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- Clinical-stage company applying proprietary Synthetic Vaccine Particle (SVP™) platform to avoid 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
- IND just accepted for second product candidate: 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 Now 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

SCIENTIFIC  
AMERICAN  
January 2018 Edition

**WAR  
AGAINST  
OURSELVES**

Many new drugs trigger an immune reaction that stops them, and the race is on to design the attack.

By Michael Sautter

"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

## The New York Times

### When the Immune System Thwarts Lifesaving Drugs

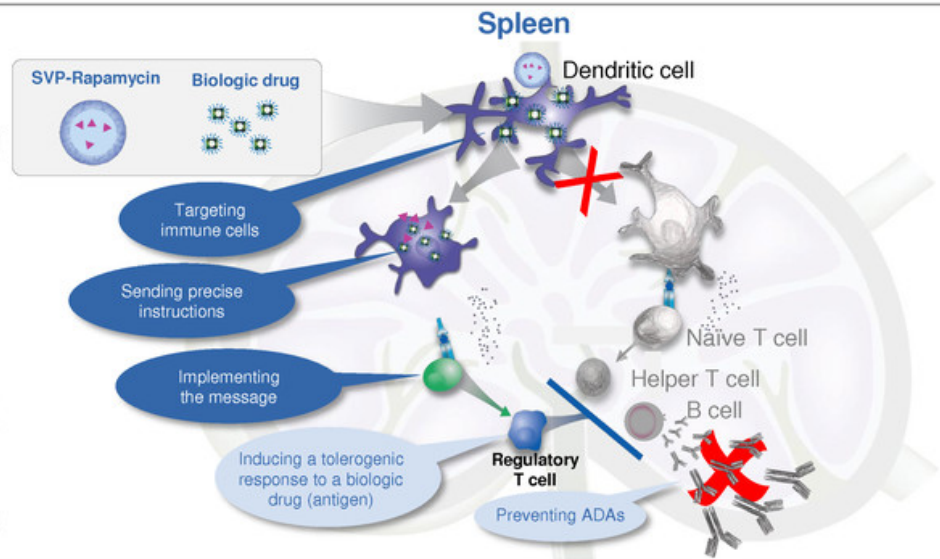


Patients often produce antibodies to the very treatments keeping them alive, sometimes to disastrous effect...

By GINA KOLATA  
May 15, 2017

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

- By dosing "free biologic" separate from SVP-Rapamycin, 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)



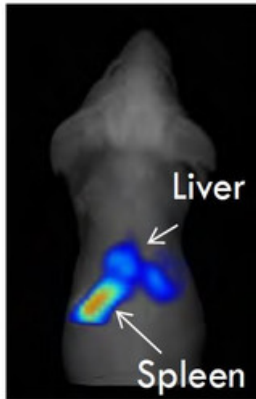
Potential to enable new therapies and improve efficacy/safety of existing biologics



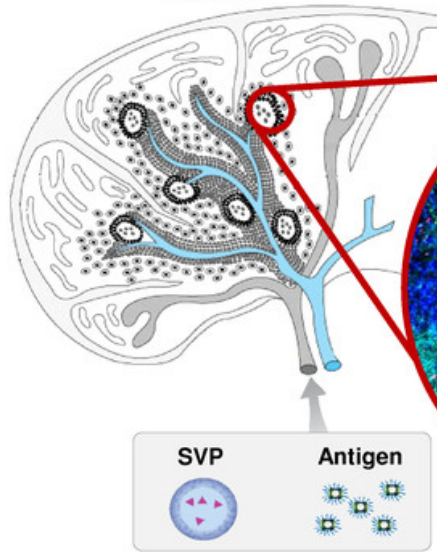


# Leveraging Nanoparticles to Target and Deliver Instructions to the Immune System

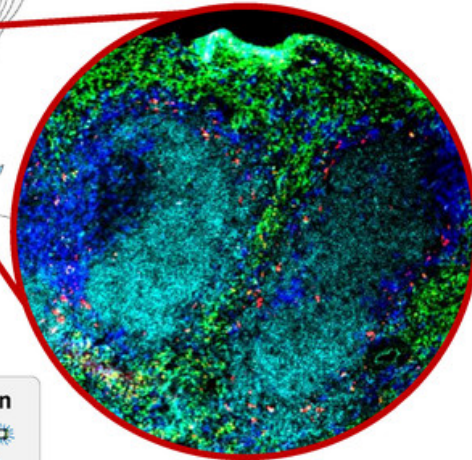
I.V. Injection  
(6hr post-injection)



Spleen

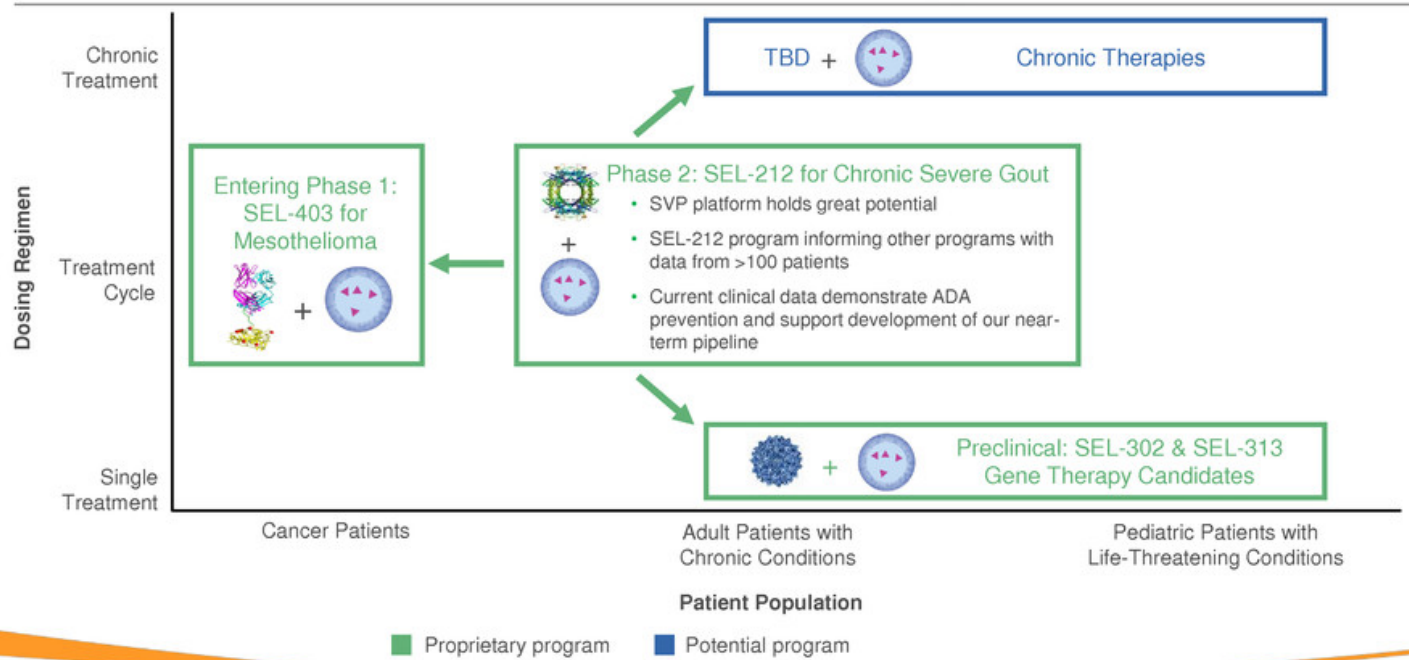


Spleen harvested 24 hr after I.V.  
Injection of fluorescent NPs



- SVP
- Macrophages
- Dendritic cells
- B cells

# Selecta's Pipeline Development Strategy





# SEL-212 for Chronic Severe Gout



# SEL-212: Advancing a Potential New Treatment Option for Chronic Severe Gout Patients Toward Phase 3



## 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

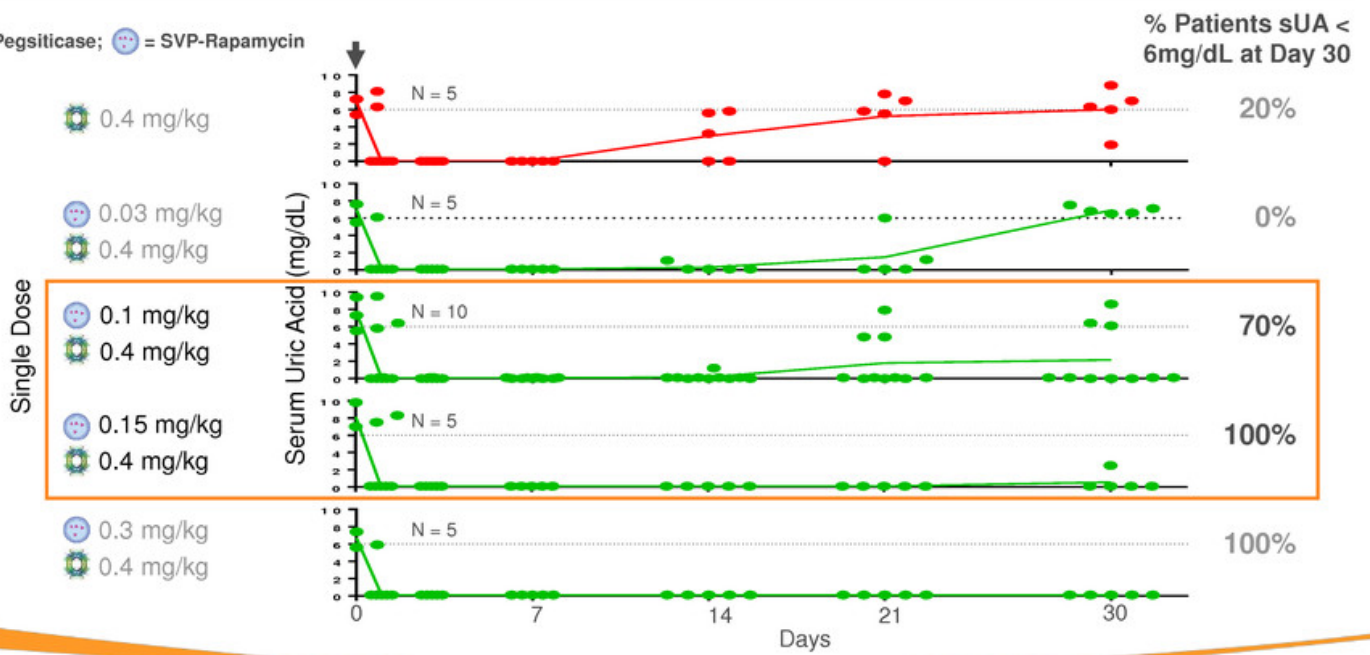
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- Monthly dosing (vs. biweekly for today's approved uricase therapy)
- Ability to complete full therapy cycles
  - Persistent reduction in SUA
  - Elimination of tophi
- Gout flare reduction
- Avoidance of "off-label" and global immunosuppressive therapies

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

# Phase 1b Single Dose Patient Cohorts

 = Pegsiticase; 
  = SVP-Rapamycin



# Phase 2 Trial Overview

## Enrollment Criteria

- Patients with symptomatic gout and SUA levels >6 mg/dL

## Primary/Secondary Endpoints

- Safety, tolerability and pharmacokinetics of multiple doses of SEL-212 and pegsiticase alone
- Reduction of SUA levels
- Reduction of ADA levels

## Design

- Multiple ascending dose cohorts

## Stopping Rules

- Dosing stopped upon loss of SUA control at Day 21 after each dose

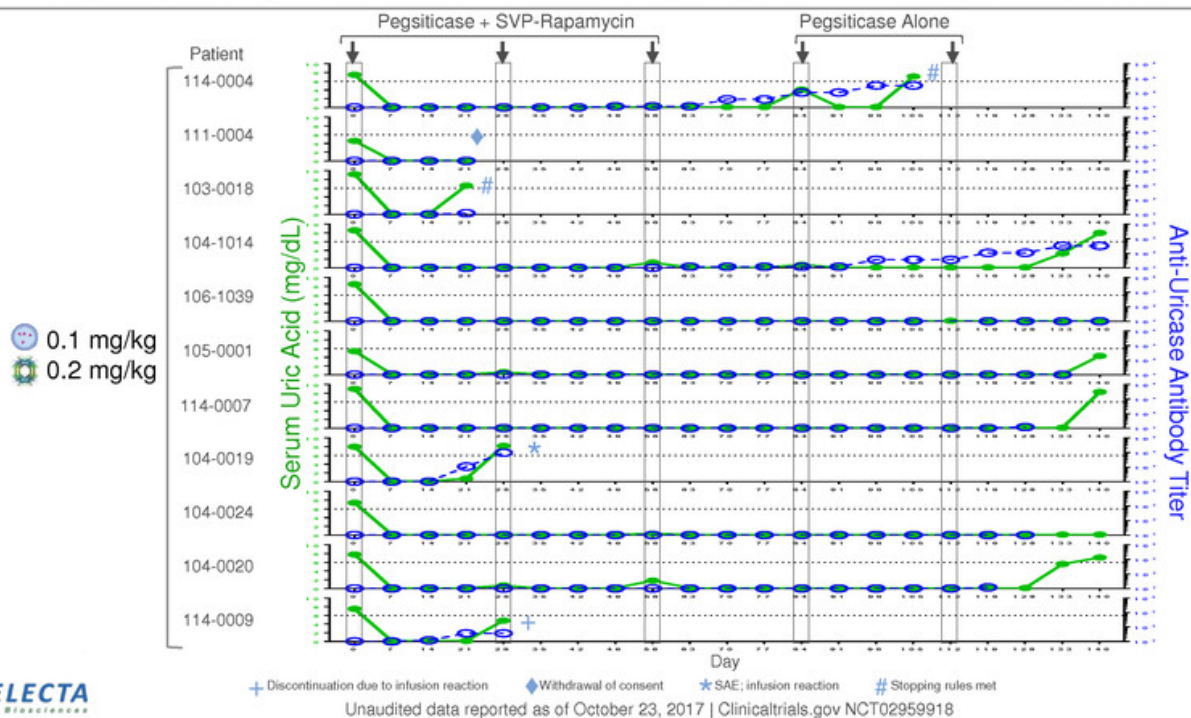
## As of October 23

- 79 patients dosed at 15 active U.S. clinical sites

## Dosing

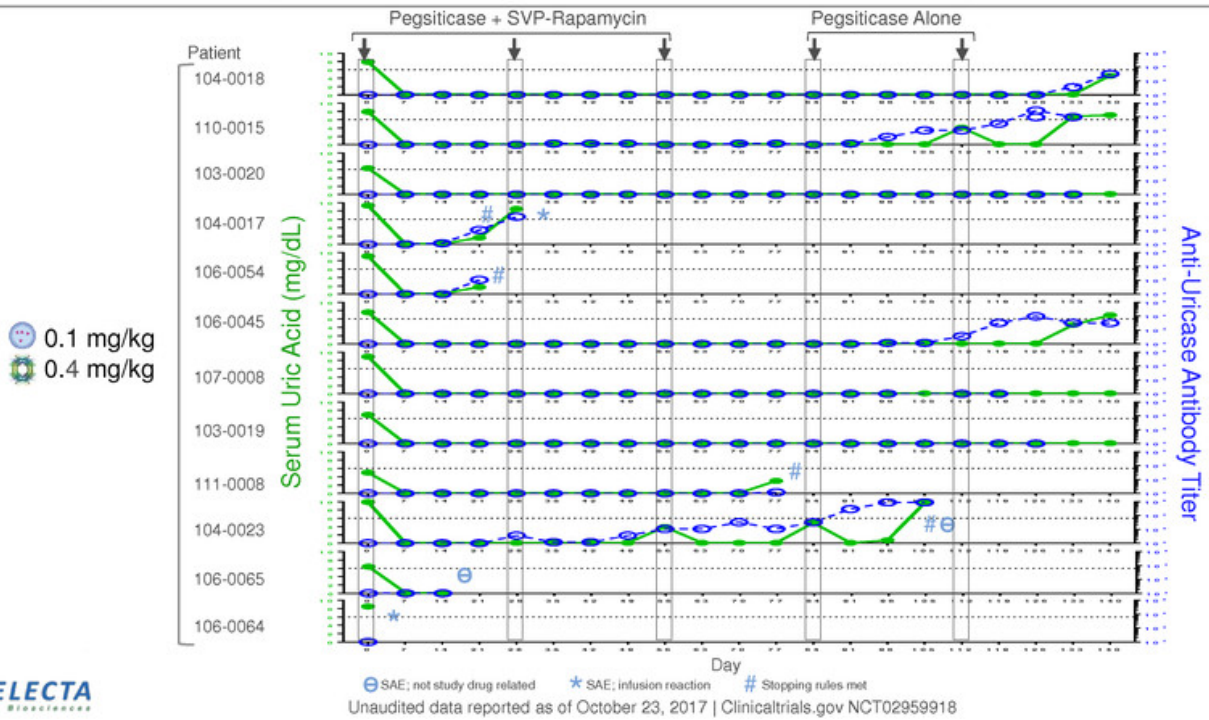
- Control cohorts: pegsiticase alone every 28 days for up to five doses
- Other cohorts: currently testing three combination doses of SEL-212 every 28 days followed by 2 doses of pegsiticase alone
- Preparations now underway to enable five combination doses

# Cohort 7: 0.2 mg/kg Pegsiticase + 0.1 mg/kg SVP-Rapamycin



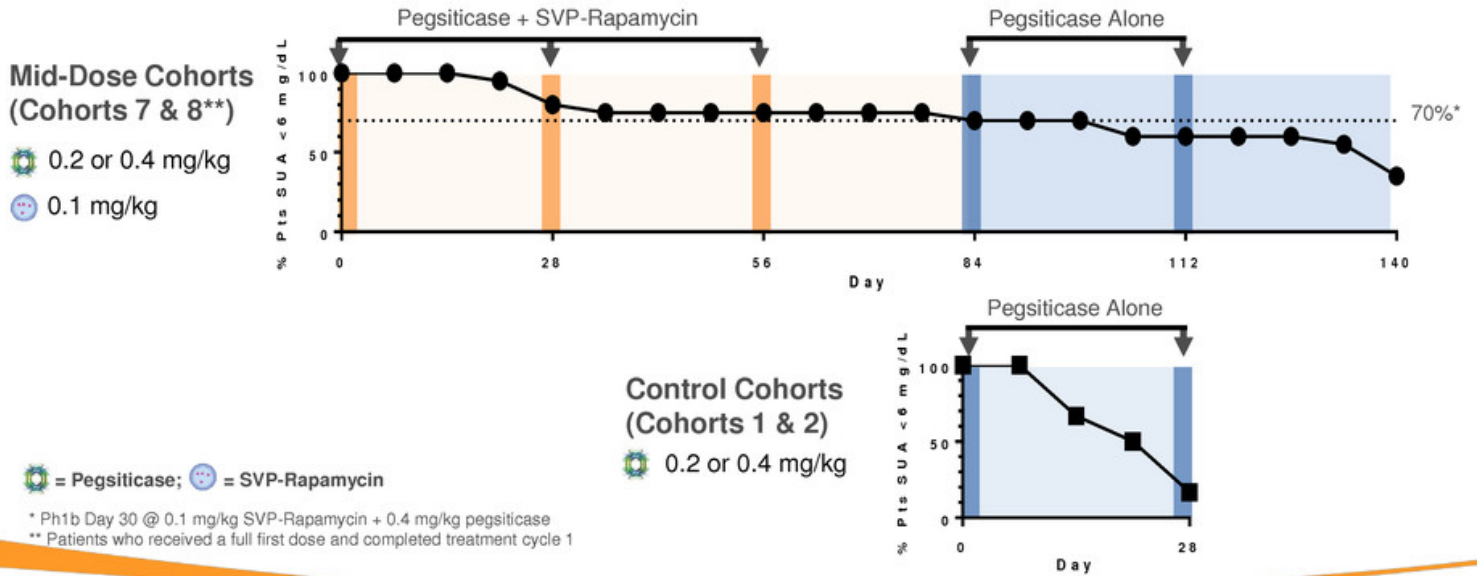


# Cohort 8: 0.4 mg/kg Pegsiticase + 0.1 mg/kg SVP-Rapamycin



# Comparison of Clinical Activity and Immune Tolerance Between Mid-Dose and Control Cohorts

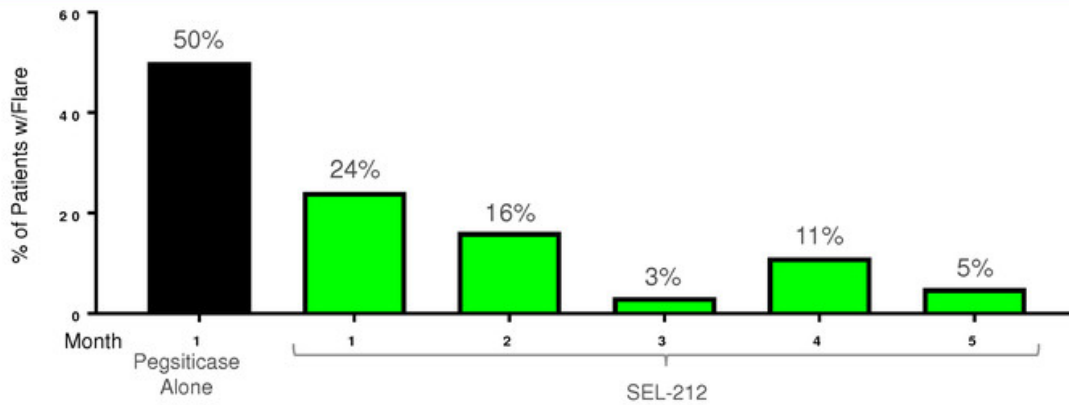
**% of Patients With SUA <6 mg/dL**



Unaudited data reported as of October 23, 2017 | Clinicaltrials.gov NCT02959918

# Low Frequency of Gout Flares Observed with SEL-212 Treatment

% of Patients Experiencing Flares by Month



- Data indicate SEL-212 lowers flares initially and over time during treatment
- Urate lowering therapies typically increase the incidence of flares at the beginning of therapy

## SEL-212 Generally Well Tolerated at Clinically Active Doses

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- SEL-212 has been generally well tolerated at clinically active doses following >200 administrations
- SAEs reported in the Phase 2 trial:
  - Four were reported not to be or unlikely to be related to study drug
  - Seven 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
    - One during a repeat dose of SEL-212 in a higher dose cohort
    - Each of these SAEs occurred prior to Selecta's June data report
    - None occurred after treatment period 2
- All SAEs were successfully treated and resolved without further issues

## SEL-212 Expected to Enter Phase 3 in 2018

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- SEL-212 (SVP-Rapamycin + pegsiticase) designed to be the first non-immunogenic uricase treatment for chronic severe gout
- Phase 2 trial ongoing:
  - SEL-212 has been demonstrated to be clinically active and generally well tolerated
  - Cohorts receiving 0.125 and 0.15 mg/kg doses of SVP-Rapamycin ongoing; plan to report initial data for these cohorts in the first half of April 2018
  - Plan to begin enrolling patients in Q1 2018 that would receive combination therapy for the entire treatment period; preparing supporting preclinical FDA submission
- Plan to participate in End-of-Phase 2 meeting in Q2 2018
- Plan to enter Phase 3 in 2018

# SEL-403 for Mesothelioma



# 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<sup>1</sup>) 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 preclinical activity
- Initial repeat dose data from ongoing SEL-212 Phase 2 bodes well for this application



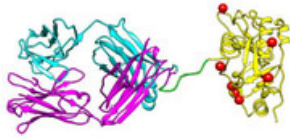
## Clear Clinical Path

- 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; expect Phase 1 mesothelioma trial to be underway in Q1 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.**

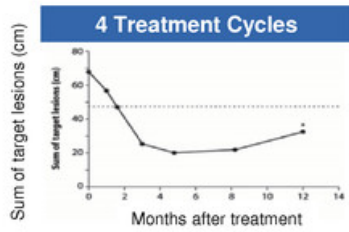
Head, Molecular  
Biology Section  
National Cancer  
Institute



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

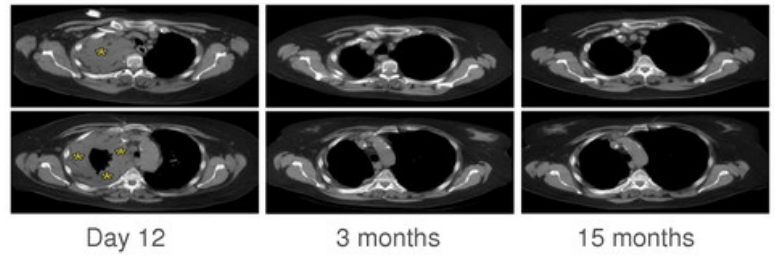
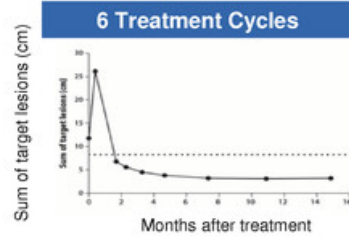
## Patient 1

- Widely metastatic peritoneal mesothelioma
- Survived 32 months



## Patient 2

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



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

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

SEL-403

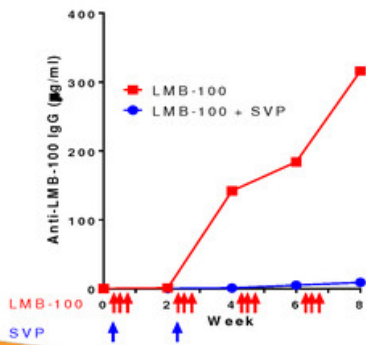


Prevents formation of anti-drug antibodies

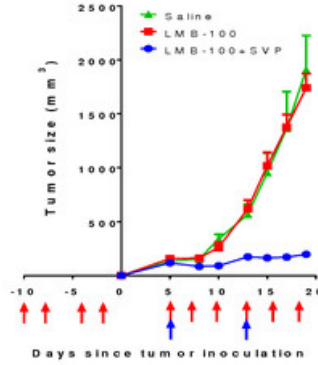
Restores LMB-100's anti-tumor response

SVP alone does not accelerate tumor growth

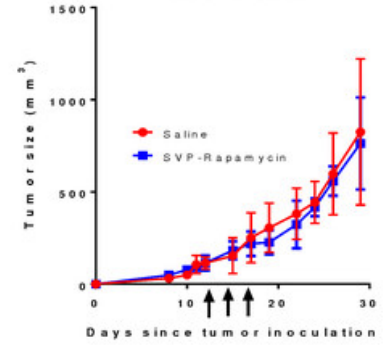
Anti-LMB-100 Antibody



Tumor Growth



Tumor Growth



Data generated in collaboration with Dr. Ira Pastan, NCI

# SEL-403 Entering the Clinic at NCI

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- IND acceptance announced on January 2, 2018
- Expect to commence a dose-escalating Phase 1 trial in Q1 2018 under a CRADA at NCI
- 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'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

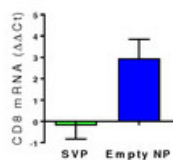
- Lead gene therapy program is SEL-302 for MMA
- Clinical endpoints include: Methylmalonyl-CoA mutase and MMA levels
- Expect to file IND in 2019

# Benefits of ADA Avoidance in Gene Therapy

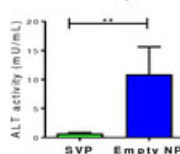
## Inhibiting Liver Inflammation from First Dose



CD8 T cell Liver Infiltrates



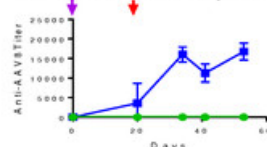
Serum ALT Enzyme Levels



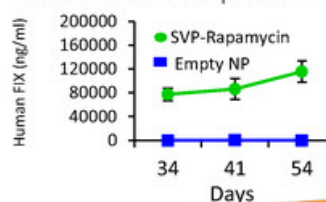
## Allowing for Repeat Dosing And Dose Titration



Anti-AAV8 Antibody Titer

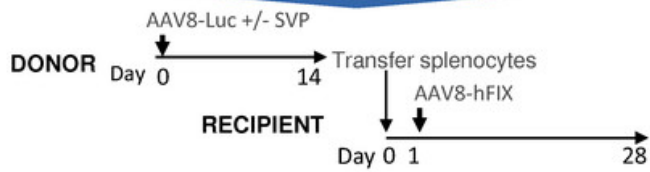


Serum Factor IX Expression

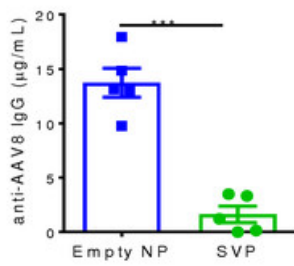


# Demonstration of the Role of Regulatory T Cells

## Effect can be Transferred to a Recipient

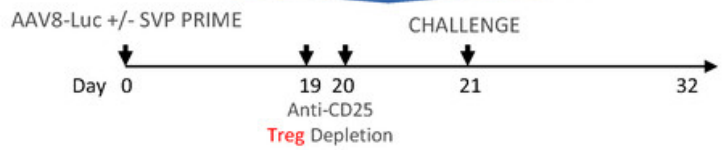


Anti-AAV8 IgG levels in recipient mice (Day +14)

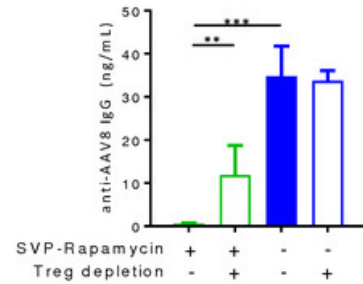


\*\* P < 0.01, \*\*\* P < 0.001

## T Reg Depletion Negates Effect

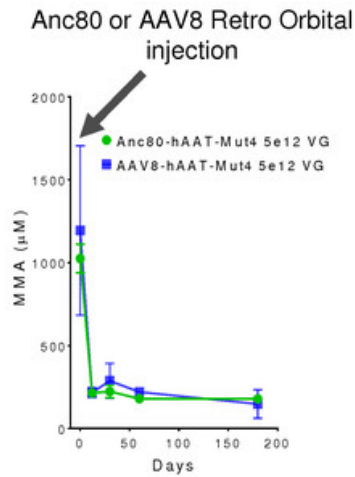


Anti-AAV8 IgG levels (Day 32)

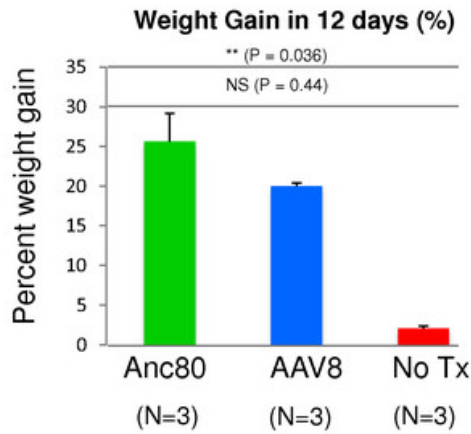


# Anc80/synMUT Proof of Concept in Mouse Model of MMA at ASGCT 2017

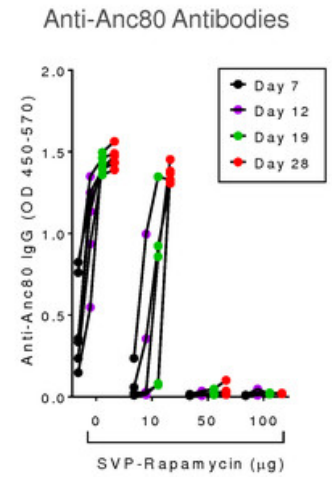
Reducing MMA Levels With  
Anc80 and AAV8



Increasing Weight Gain  
Following Treatment



Preventing Anti-Anc80  
Antibodies via SVP-Rapamycin






# Spark Therapeutics License Agreement

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- 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
<b>Proprietary ADA Mitigation Programs</b>				
Chronic Severe Gout SEL-212	██████████	██████████	██████	
Mesothelioma & Pancreatic Cancer SEL-403*	██████████	██████		
Methylmalonic Acidemia (MMA) SEL-302	██████			
Ornithine Transcarbamylase Deficiency (OTC) SEL-313	██████			
<b>ADA Mitigation Program License</b>				
Hemophilia A	██████			

\* LMB-100 is currently being investigated in two Phase 1 clinical trials at the National Cancer Institute (NCI): one of LMB-100 alone in Mesothelioma and one of LMB-100 in combination with nab-paclitaxel in Pancreatic Cancer. Phase 1 trial of SEL-403 in Mesothelioma is expected to begin in Q1 2018.

# Financial Overview

	For the Quarter Ended	
	September 30, 2017	September 30, 2016
(In thousands, except share and per share data)		
Grant & Collaboration Revenue	\$27	\$1,048
Research & Development Expenses	9,504	6,021
General & Administrative Expenses	4,377	2,495
Net Loss Attributable to Common Stockholders	\$(14,676)	\$(7,728)
Net Loss Per Basic & Diluted Share	\$(0.66)	\$(0.43)
Wtd. Avg. Common Shares Outstanding – Basic & Diluted	22,082,207	18,108,014
	As of	
	September 30, 2017	June 30, 2017
(In thousands)		
Cash, Cash Equivalents, Marketable Securities, Restricted Cash	\$104,780	\$113,045

Cash runway into mid-2019

# Thank You



