

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): August 9, 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 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

Exhibit No.	Description
99.1	Corporate slide presentation of Selecta Biosciences, Inc. dated August 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: August 9, 2018

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



Canaccord Genuity Presentation

Nasdaq: SELB

August 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, statements regarding the progress of the Phase 2 clinical trial of SEL-212, the anticipated timing for reporting further data from the Phase 2 trial and advancing into Phase 3 (if at all), whether the product profile of SEL-212 provides mitigation of ADAs enabling repeat dosing and sustained serum uric acid control, whether 5-monthly combination doses of SEL-212 have the potential to extend efficacy over the entire treatment period, the company's ability to define its design for the Phase 3 program with the FDA at its End-of-Phase 2 meeting or 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, whether patients receiving SEL-212 will be able to complete full therapy cycles over 6 months, whether SEL-212 data will continue to show low incidence of gout flares initially and over time during SEL-212 therapy, whether SEL-212 will continue to be generally well-tolerated, statements regarding the design and potential significance of a head-to-head trial of SEL-212 and Krystexxa, statements regarding the progress and enrollment of the Phase 1 trial for SEL-403 in mesothelioma, the potential Phase 1 study of SEL-403 in patients with pancreatic cancer in cooperation with NCI, the ability of the company's SVP platform, including SVP-Rapamycin, to mitigate unwanted immunogenicity, unlock the full potential of biologic therapies, enable new therapies and improve the efficacy and safety of existing biologics, the potential of SEL-212 to treat severe gout patients, resolve their debilitating symptoms, and to change the chronic severe gout treatment paradigm, the potential of SEL-403 to treat mesothelioma, 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 company's plan to apply its SVP platform to a range of biologics for rare and serious diseases, statements regarding the potential of the company to enter into collaborations and licenses in a range of therapeutic areas, the potential of the company's two gene therapy product candidates to enable repeat administration, whether SEL-212 holds billion dollar potential, the sufficiency of the company's capital resources to fund its operating expenses and capital expenditure requirements through the third quarter of 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 August 8, 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
 - Plan to present Phase 2 data from patients who have received 5 monthly combination doses of SEL-212 at the American College of Rheumatology (ACR) meeting Oct. 19th-24th
- 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

SCIENTIFIC AMERICAN

January 2018 Edition



"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

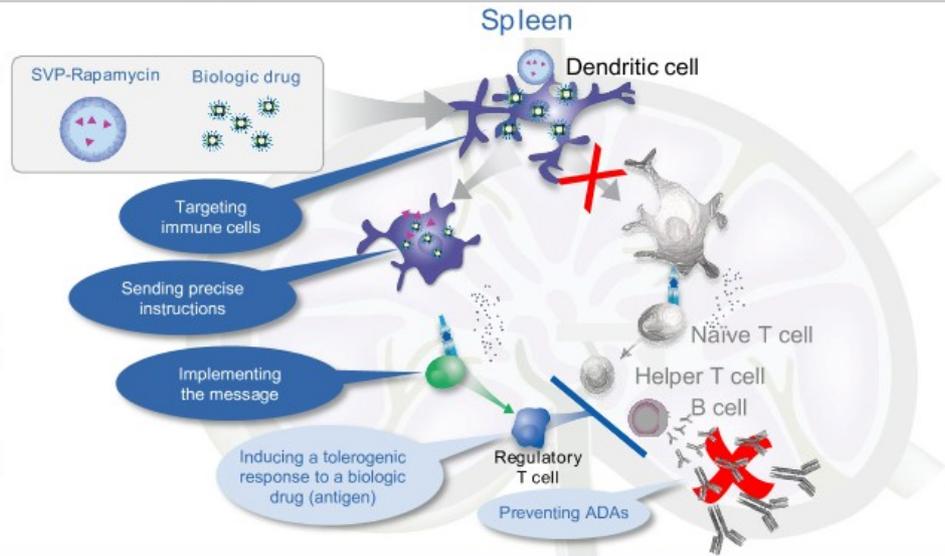


Patients often produce antibodies to the very treatments keeping them alive, sometimes to disastrous effect...

By HINA KHAJIA
May 15, 2017

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





SEL-212 for Chronic Severe Gout



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

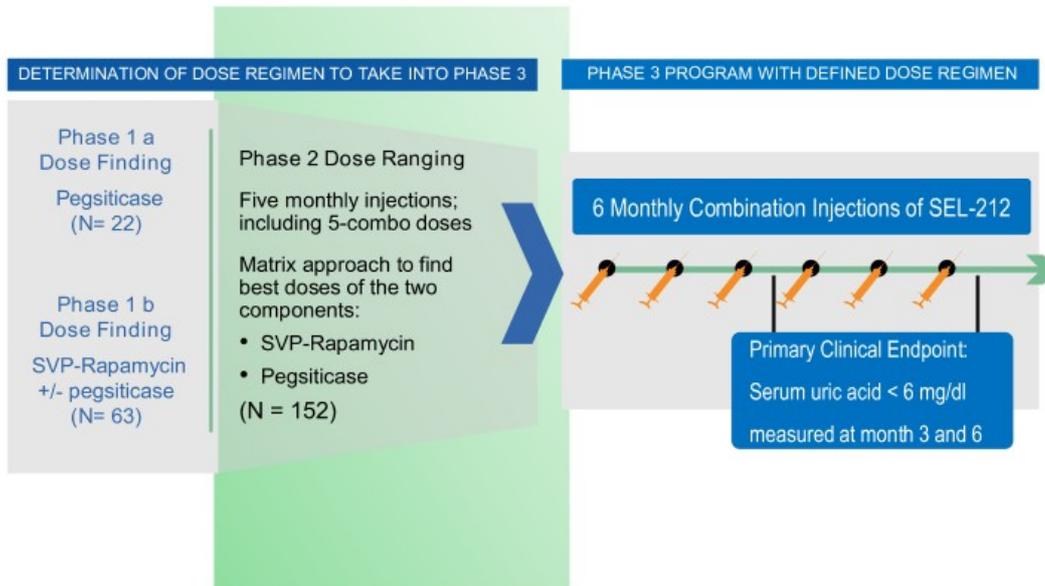
Today's Unmet Needs in Chronic Severe Gout

- 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

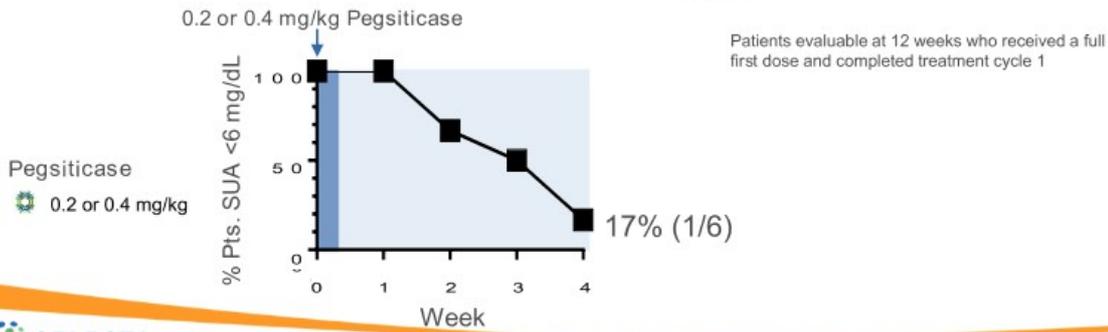
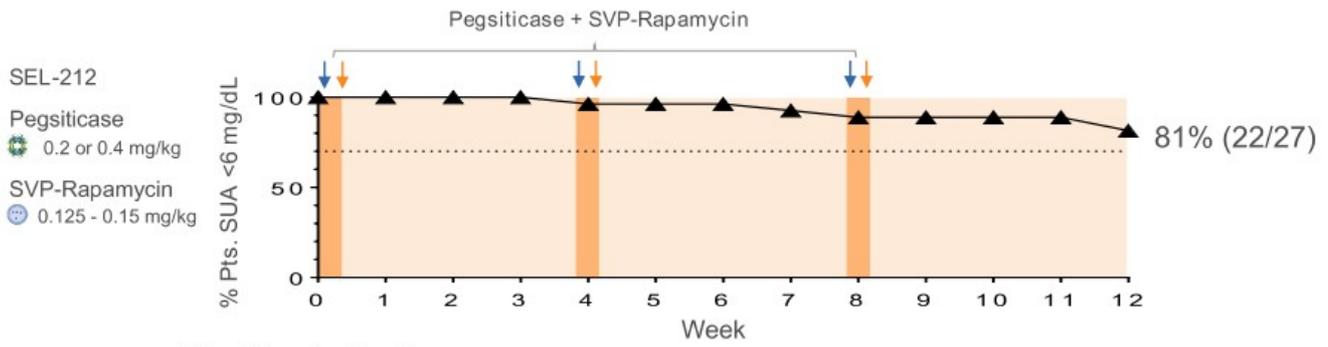
Current Stage of SEL-212 Development



Phase 2 Trial Overview

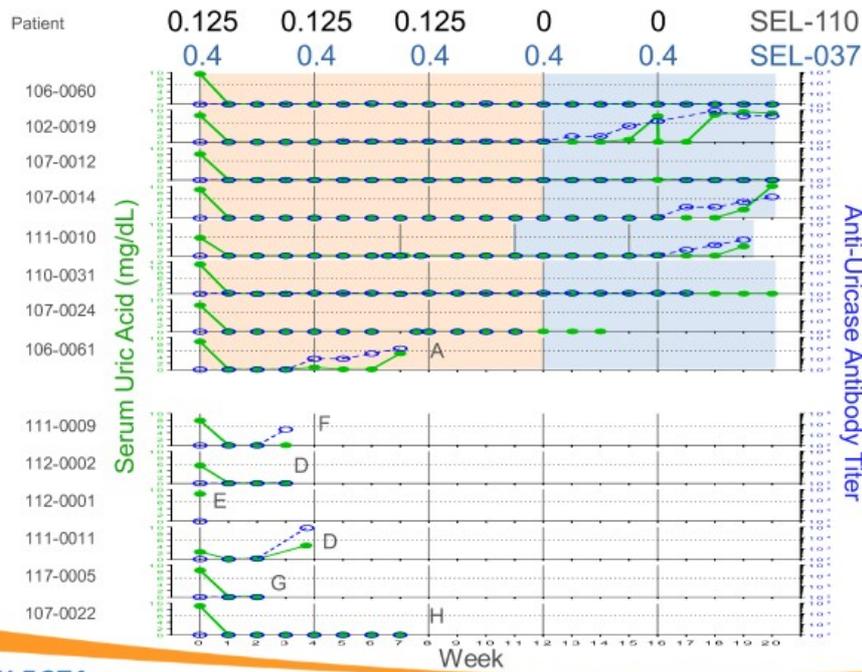
Enrollment Criteria	<ul style="list-style-type: none">• Patients with symptomatic gout and serum uric acid levels >6 mg/dL
Primary/Secondary Endpoints	<ul style="list-style-type: none">• Safety, tolerability and pharmacokinetics of multiple doses of SEL-212 and pegsiticase alone• Reduction of serum uric acid levels• Reduction of ADA levels
Design	<ul style="list-style-type: none">• Multiple ascending dose cohorts
Dosing	<ul style="list-style-type: none">• Control cohorts: pegsiticase alone every 28 days for up to five doses• Cohorts 13,15,17: SEL-212 every 28 days for five doses• Every other cohort: SEL-212 every 28 days for three doses followed by two doses of pegsiticase alone
Stopping Rules	<ul style="list-style-type: none">• Dosing stopped upon loss of sUA control at Days 21 after a dose
As of April 2	<ul style="list-style-type: none">• 152 patients dosed at 15 U.S. clinical sites

Expanded Phase 2 Data at 3 Months Show 81% of Patients With Control of SUA <6 mg/dl



Cohort 10:

0.125 mg/kg of SEL-110 + 0.4 mg/kg of SEL-037

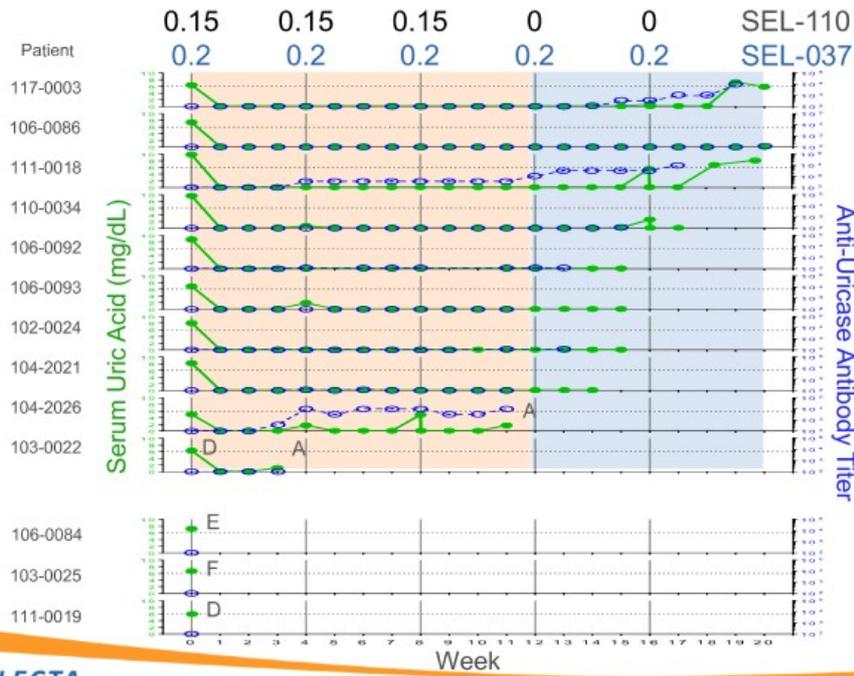


7 of 8 evaluable patients (87.5%) maintained UA control after 3 monthly doses of SEL-110 and SEL-037

- 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



Cohort 11: 0.15 mg/kg of SEL-110 + 0.2 mg/kg of SEL-037



8 of 10 evaluable patients (80%) maintained UA control after 3 monthly doses of SEL-110 and SEL-037

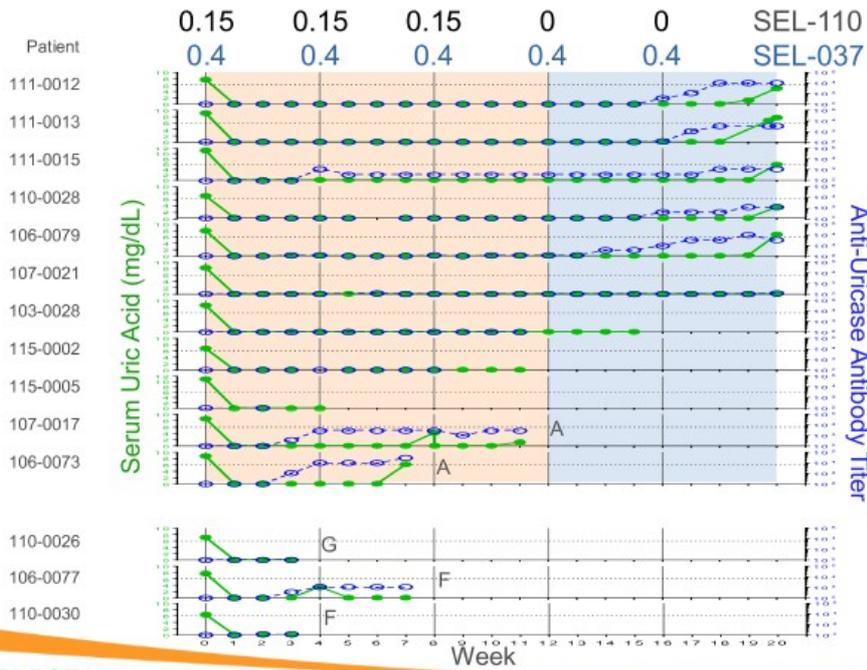
- A Stopping rules met
- D Withdrawn due to protocol deviation
- E Discontinuation due to infusion reaction
- F Withdrawal of Consent



Unaudited data reported as of June 04, 2018 | Clinicaltrials.gov NCT02959918

Cohort 12:

0.15 mg/kg of SEL-110 + 0.4 mg/kg of SEL-037



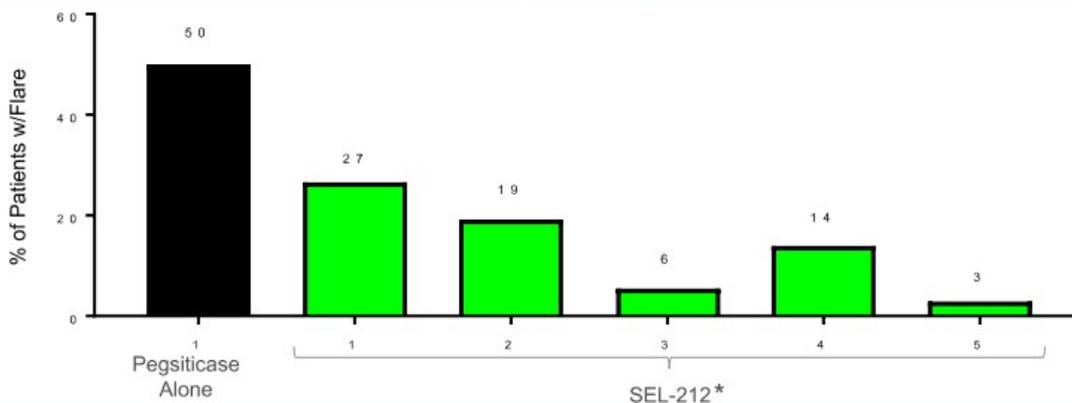
7 of 9 evaluable patients (78%) maintained UA control after 3 monthly doses of SEL-110 and SEL-037. Two still ongoing.

- A Stopping rules met
- F Withdrawal of consent
- G SAE; non-study drug related



Data Continue to Suggest Low Flare Rates During SEL-212 Therapy – All Phase 2 Patients to Date

% of Patients Experiencing Flares in 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

* Patients who received a full first dose and completed treatment cycle; Month 1 N=113, Month 2 N=73, Month 3 N=55, Month 4 N=43, Month 5 N=35

SEL-212 Phase 2 Overview and Summary of New Data Presented at EULAR

Summary of new data presented at EULAR

- 3-month data show SEL-212 product profile may provide:
 - Mitigation of ADAs enabling repeat dosing and sustained serum uric acid control:
~81% of patients with sUA <6 mg/dl
 - Low flare rate in the first month :
33% for new SEL-212 Cohorts; 27% for all SEL-212 Cohorts in the trial
 - Less frequent dosing:
Monthly compared to weekly/bi-weekly dosing for FDA-approved uricase

Next Steps for the SEL-212 Program

- 5-monthly SEL-212 combination doses have potential to extend efficacy over entire treatment period
 - Patient cohorts are now receiving their 4th and 5th of 5 monthly doses of SEL-212 combination therapy
 - Data from patients receiving 5 monthly doses of SEL-212 to be presented at ACR, October 19th -24th

Phase 3 program initiation in a couple of clinical trial sites expected in 2018

SEL-212 Safety For the Total Phase 2 Patient Population

- SEL-212 has been generally well tolerated at clinically active doses following >380 administrations
- Seventeen SAEs reported in the ongoing Phase 2 trial:
 - Nine 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 EULAR-Cohort Data Compared to KRYSTEXXA® ACR Data

<u>Category</u>	<u>SEL-212 (12 weeks)</u>	<u>KRYSTEXXA® (16 weeks)⁺</u>
sUA control	81% ⁺⁺	44%
Gout flare %	33%	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

- Phase 2 data will be presented from patients receiving five combination doses of SEL-212 at ACR October 19th-24th
- Phase 3 program expected to begin in 2018

SEL-212 PHASE 3 PROGRAM

6 Monthly Combination Injections of SEL-212 against placebo



Primary Clinical Endpoint:
Serum uric acid < 6 mg/dl
measured at month 3 and 6

Additional possible studies include:

- Head to Head versus Krystexxa
- Krystexxa Failures

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. diagnoses¹) 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

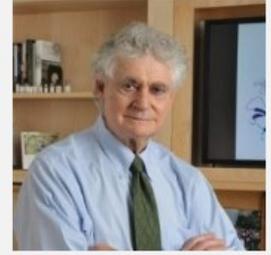
LMB-100



- 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%)

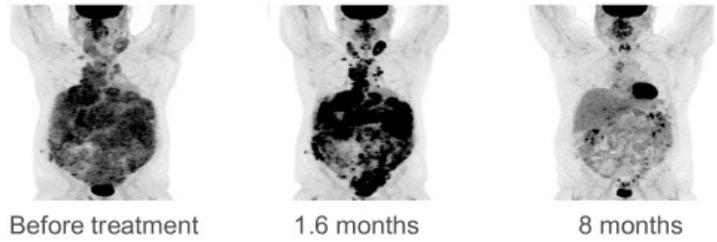
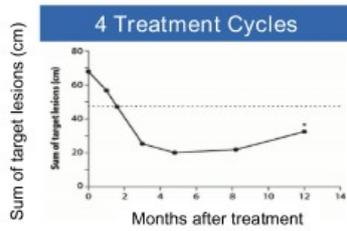


Ira Pastan, M.D.
Head, Molecular
Biology Section
National Cancer
Institute

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

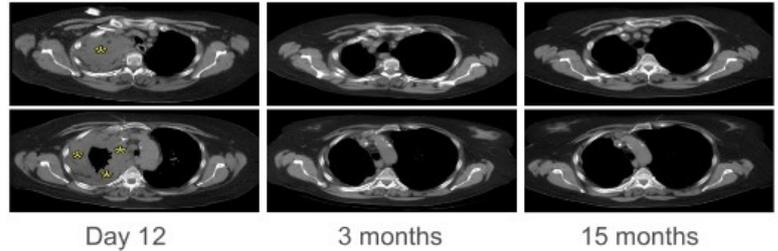
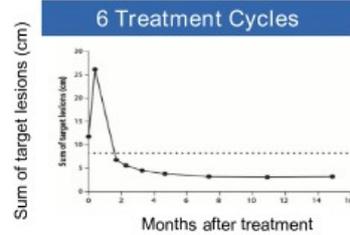
Patient 1

- Widely metastatic peritoneal mesothelioma
- Survived 32 months



Patient 2

- Extensive pleural mesothelioma
- Survived >6 years



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

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

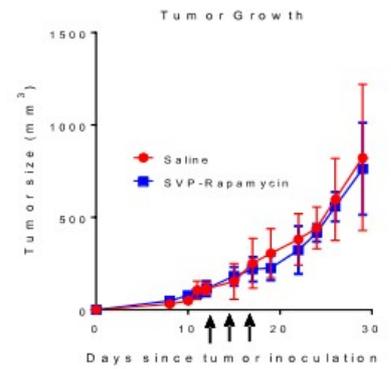
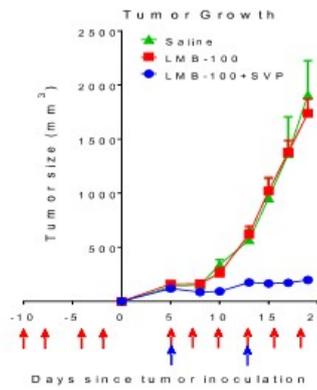
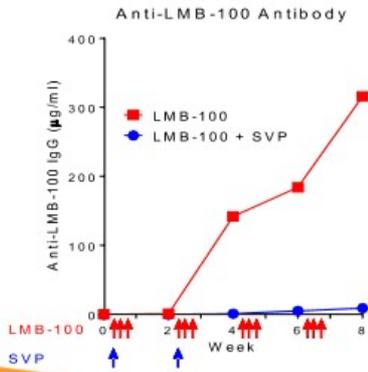
SEL-403



Prevents formation of anti-drug antibodies

Restores LMB-100's anti-tumor response

SVP alone does not accelerate tumor growth



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
- Company working with NCI to potentially conduct Phase 1 study in patients with pancreatic cancer





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

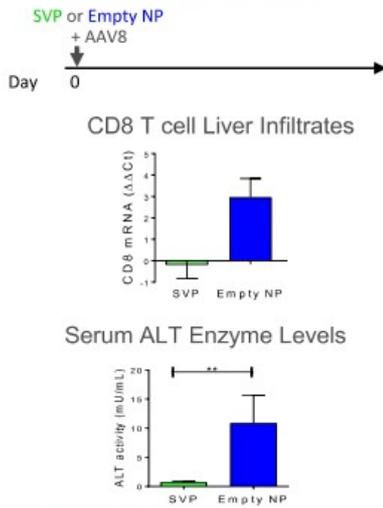


Clear Clinical Path

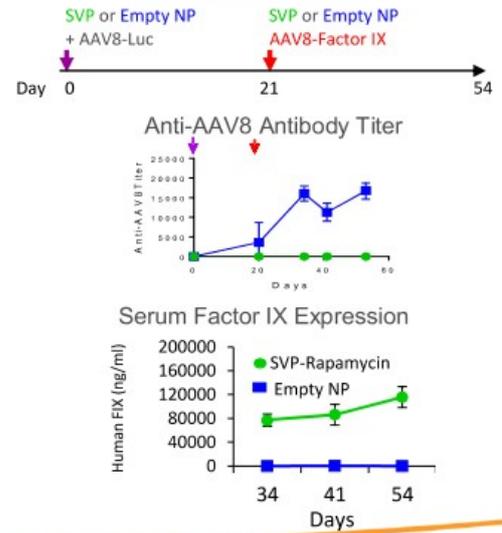
- Lead gene therapy program is SEL-302 for MMA
- Clinical endpoints include: Methylmalonyl-CoA mutase and MMA levels
- Expect to file IND in 2019

Benefits of ADA Mitigation in Gene Therapy

Inhibiting Liver Inflammation from First Dose

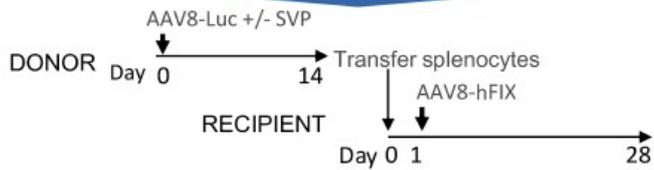


Allowing for Repeat Dosing And Dose Titration

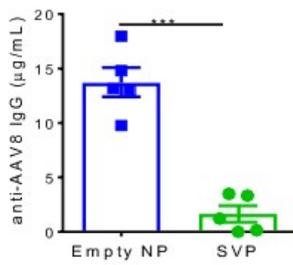


Demonstration of the Role of Regulatory T Cells

Effect can be Transferred to a Recipient

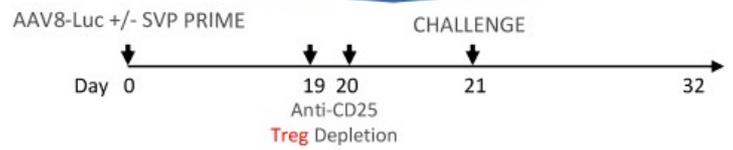


Anti-AAV8 IgG levels in recipient mice (Day +14)

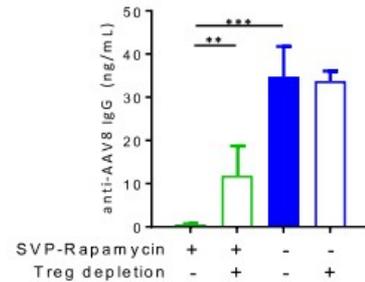


** P < 0.01, *** P < 0.001

T Reg Depletion Negates Effect



Anti-AAV8 IgG levels (Day 32)



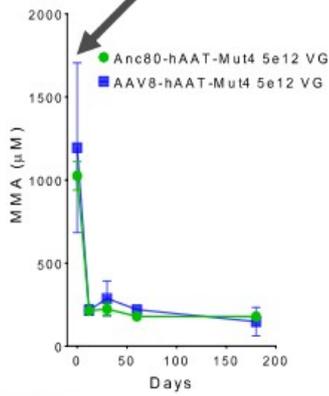
Anc80/synMUT Proof of Concept in Mouse Model of MMA at ASGCT 2017

Reducing MMA Levels With
Anc80 and AAV8

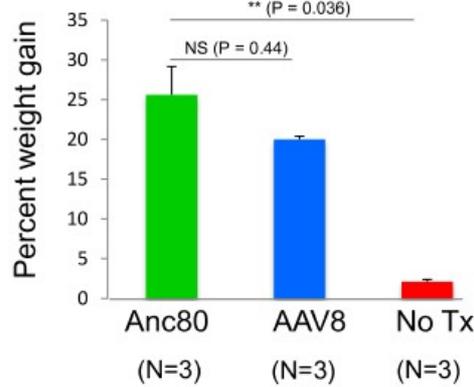
Increasing Weight Gain
Following Treatment

Preventing Anti-Anc80
Antibodies via SVP-Rapamycin

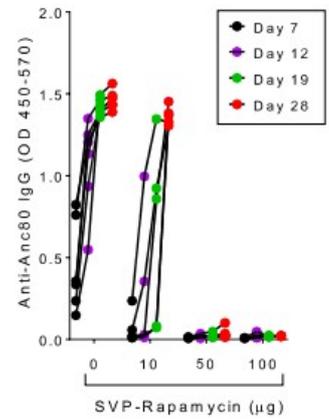
Anc80 or AAV8 Retro Orbital
injection



Weight Gain in 12 days (%)



Anti-Anc80 Antibodies



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				

Financial Overview

	For the Quarter Ended	
	June 30, 2018	March 31, 2018
(In thousands, except share and per share data)		
Grant & Collaboration Revenue	\$ -	\$-
Research & Development Expenses	14,407	11,139
General & Administrative Expenses	4,362	4,674
Net Loss Attributable to Common Stockholders	\$(18,874)	\$(15,866)
Net Loss Per Basic & Diluted Share	\$(0.84)	\$(0.71)
Wtd. Avg. Common Shares Outstanding – Basic & Diluted	22,355,603	22,345,523
	As of	
	June 30, 2018	March 31, 2018
(In thousands)		
Cash, Cash Equivalents, Marketable Securities, Restricted Cash	\$66,228	\$83,472

Cash runway through Q3 2019

