UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 8, 2021

SELECTA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37798**	**26-1622110**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

65 Grove Street, Watertown, MA 02472
(Address of principal executive offices)(Zip Code)

(617) 923-1400
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**SELB**	**The Nasdaq Stock Market LLC**

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.

On November 8, 2021, Selecta Biosciences, Inc. (the "Company") posted a slide presentation in the "Investors & Media" portion of its website at www.selectabio.com containing top-line data for the Phase 1 clinical trial evaluating the potential of the ImmTOR platform in mitigating the formation of neutralizing antibodies against adeno-associated viral serotype 8 (AAV8) vectors used in gene therapies. A copy of the slide presentation is furnished as Exhibit 99.1 to this Current Report.

The information contained in Item 7.01 of this Current Report (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of 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 or the Exchange Act, except as expressly provided by specific reference in such a filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 8.01 Other Events.

On November 8, 2021, the Company announced top-line data from the Phase 1 clinical trial evaluating the potential of the ImmTOR platform in mitigating the formation of neutralizing antibodies against adeno-associated viral serotype 8 (AAV8) vectors used in gene therapies. Top-line results include:

- AAV8 empty capsids elicited peak median anti-AAV8 neutralizing antibody (NAb) titers of 1:6875.
- Median day 30 titers of neutralizing anti-AAV8 antibodies were 1:25 and 1:5 in the 0.15 mg/kg and 0.3 mg/kg ImmTOR cohorts, respectively.
- Median day 30 titers of neutralizing anti-AAV8 antibodies were 50-fold and 250-fold lower in the 0.15 mg/kg and 0.3 mg/kg ImmTOR cohorts respectively compared to the median of control subjects dosed with AAV8 empty capsid alone.
- At 30 days 6 of 6 or 100% of subjects that received 0.3 mg/kg of ImmTOR exhibited an anti-AAV8 neutralizing antibody titer of 1:25 or less. 4 of 6 or 67% of subjects at this dose had a titer of 1:5 or less.
- At 30 days 6 of 9 or 67% of subjects that received 0.15 mg/kg of ImmTOR exhibited an anti-AAV8 neutralizing antibody titer of 1:25 or less. 2 of 9 or 22% of subjects at this dose had a titer of 1:5 or less.
- 1 of 8 or 12.5% of subjects that received AAV8 empty capsid alone had a neutralizing antibody titer of 1:25 or less at 30 days and no subjects (0/8) had a titer of 1:5 or less.
- At 90 days 2 of 6 subjects in the 0.3 mg/kg cohort were observed to have sustained control of neutralizing antibodies with titers of 1:25 or less.
- Consistent with preclinical data, the Company observed that the single dose ImmTOR cohorts saw delayed formation of neutralizing antibodies eventually reaching similar median levels of neutralizing antibodies to the control group by day 90.
- No serious adverse events were reported. The most common treatment-related adverse events included stomatitis and rash.

Forward-looking statements

Any statements in this Current Report on Form 8-K about the future expectations, plans and prospects of the Company, including without limitation, statements regarding the proprietary technology platform of the Company, and the proprietary platform of its partners, the programs and disease indication targets anticipated under this collaboration, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the Company's ability to conduct those clinical trials and studies, the timing or making of any regulatory filings, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human primate and mouse study subjects will translate to studies performed with human beings, the potential of any therapies developed by the Company to fulfill unmet medical needs, the Company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, the potential of the ImmTOR technology platform generally and the Company's ability to grow its strategic partnerships, 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 proof of concept trials, including the uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary or topline 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 ability to predict results of studies performed on human beings based on results of studies performed on non-human primates and mice, the unproven approach of the Company's ImmTOR technology, the Company's partners' ability to re-engineer or develop any protein therapeutics, 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, substantial fluctuation in the price of its common stock, and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this Current Report 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 intention to update any forward-looking statements included in this Current Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
99.1	Slide Presentation of Selecta Biosciences, Inc. dated November 8, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SELECTA BIOSCIENCES, INC.

Date: November 8, 2021

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

Exhibit 99.1

Nasdaq | SELB

Selecta Biosciences

AAV8 Empty Capsid plus ImmTOR™ (SEL-399) Human Proof-Of-Concept Study*

Top Line Data Report of a Phase 1 Clinical Study in Healthy Volunteers

November 8, 2021

* Joint study with AskBio

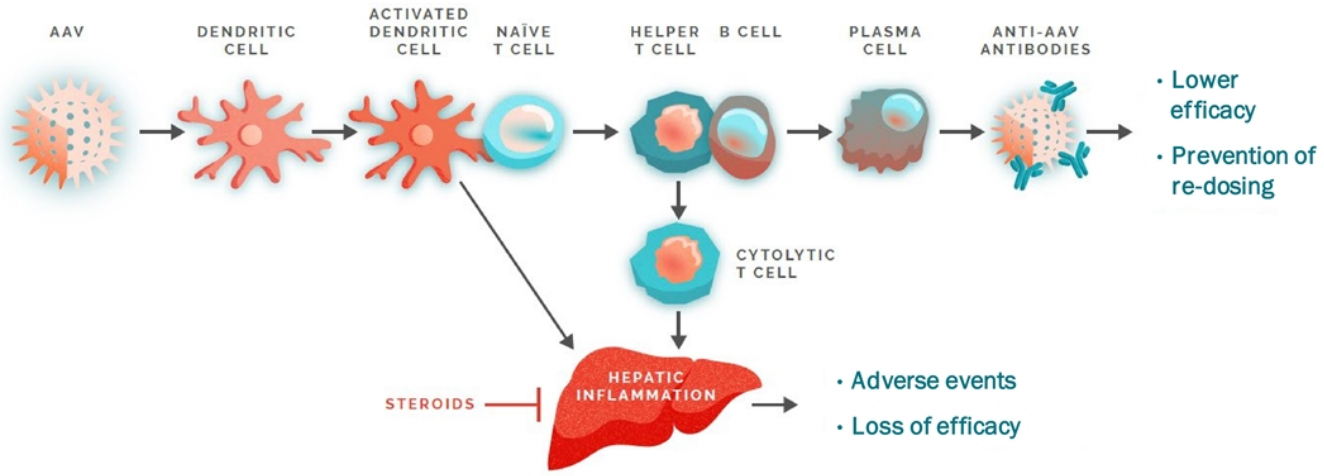
Safe Harbor / Disclaimer

Any statements in this presentation about the future expectations, plans and prospects of Selecta Biosciences, Inc. ("the company"), including without limitation, statements regarding the pre-clinical and clinical development of gene therapy product candidates by the company, including with respect to anticipated geographic markets, the availability and timing of data from any future or planned clinical program, the timing and execution of company's plans to submit any regulatory filings, the potential market opportunity for the company's gene therapy programs, the potential of any company gene therapy product candidate to address unmet medical needs including but not limited to the ability to re-treat gene therapy disease indications or enhance transgene expression, the potential treatment applications and regulatory and clinical development of the company's product candidates utilizing the ImmTOR platform in areas such as enzyme therapy and gene therapy and related timing, the potential of the ImmTOR technology platform generally and the company's ability to grow its strategic collaborations, upcoming events and presentations, including with respect to the presentation of the SEL-399.101 empty capsid full data set, 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 effect of the COVID-19 pandemic on any of the company's planned or ongoing clinical trials, manufacturing activities, supply chain and operations, 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, undesirable side effects of the company's product candidates, the company's reliance on third parties to manufacture its product candidates and to conduct its clinical trials as well as the impact of the COVID-19 pandemic on those third parties and their ability to continue their operations, the company's inability to maintain its existing or future collaborations, licenses or contractual relationships and the inability of the company's licensees to make up-front and milestone payments under these collaborations, its inability to protect its proprietary technology and intellectual property, management's ability to perform as expected, potential delays in regulatory approvals, the company's business development strategy, 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, and other important factors discussed in the "Risk Factors" section of the company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 filed with the U.S. Securities and Exchange Commission (SEC), 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 intention to update any forward-looking statements included in this presentation.

The Ability to Inhibit The Development of AAV-Specific Antibodies Has The Potential to Enable Re-Dosing of AAV Gene Therapy

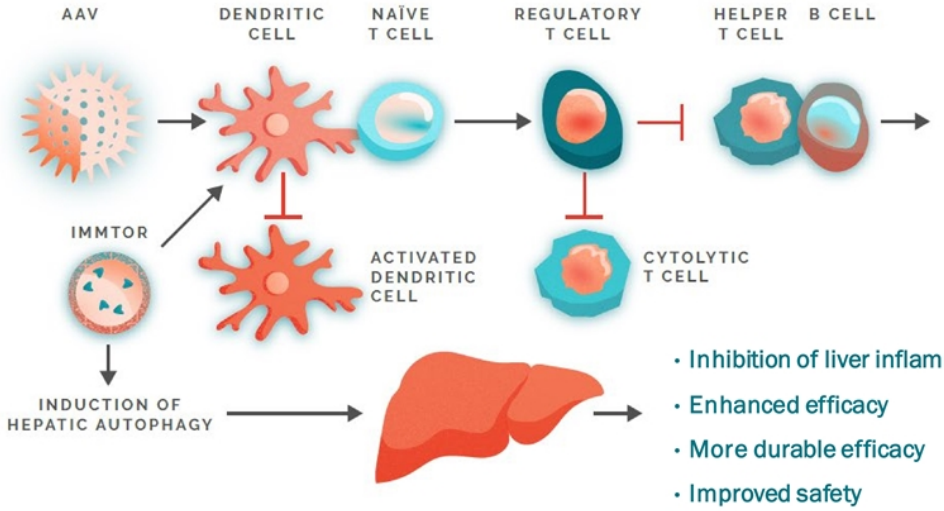
- Adeno-associated virus (AAV) vectors are the most widely used in-vivo gene therapy vectors
- AAV is non-self replicating and over time transgene expression may wane, particularly in growing tissues such as liver in childhood, suggesting that re-dosing of gene therapy may be necessary
- Gene therapy with AAV induces a robust immune response in recipients, resulting in high level anti-AAV neutralizing antibodies (NAb) which precludes re-dosing of the gene therapy
- Because NAb can reduce the efficiency of gene therapy, treatment with AAV gene therapy is restricted to patients with low levels of pre-existing NAb. For example, Zolgensma NAb titers must be ≤1:50 to be eligible for treatment
- In addition to induction of anti-AAV NAb, the immune response to AAV gene therapy may be involved in observed gene therapy associated toxicities such as hepatotoxicity and thrombotic microvascular angiopathy
- As a proof-of-concept study, we studied the ability of ImmTOR, an immune tolerizing drug, to inhibit anti-AAV8 NAb formation in healthy volunteers to evaluate the potential of ImmTOR for gene therapy re-dosing

AAV Gene Therapy Induces an Immune Response That Precludes Redosing, Inhibits Efficacy, And Causes Adverse Events



Potential for ImmTOR to Enhance AAV Gene Therapy

Potential to enable re-dosing of AAV gene therapy

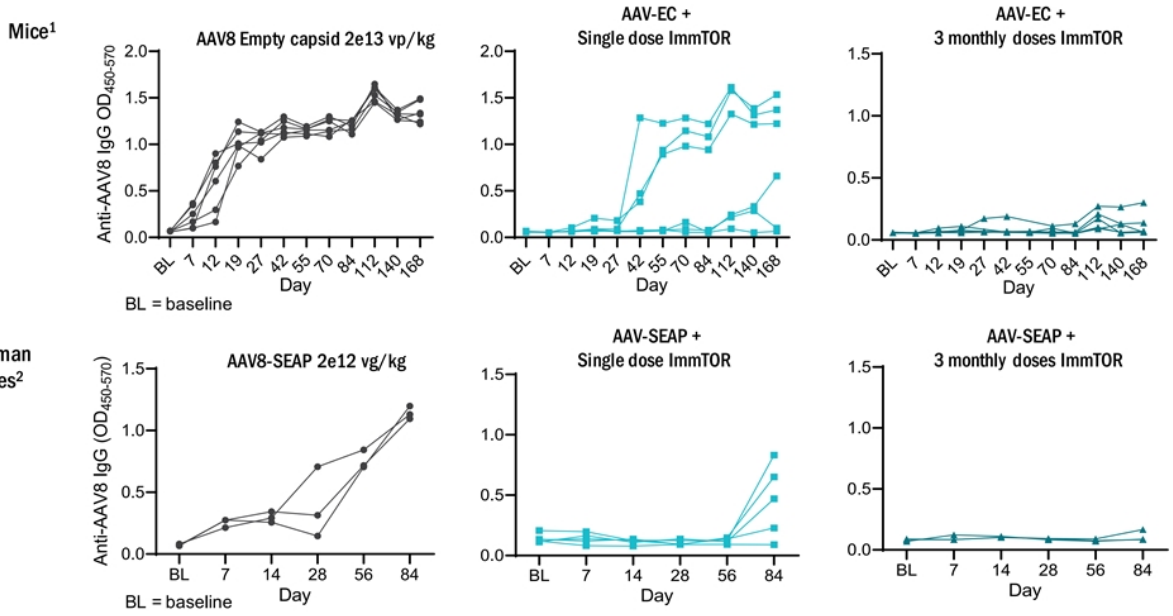


- Prevention of AAV antibody production
- Potential to re-dose

- Inhibition of liver inflammation
- Enhanced efficacy
- More durable efficacy
- Improved safety

Long-Term Inhibition of Anti-AAV8 Antibodies With 3 Monthly Doses of ImmTOR in Animals

Single And Multiple Dose ImmTOR Data



Study Design

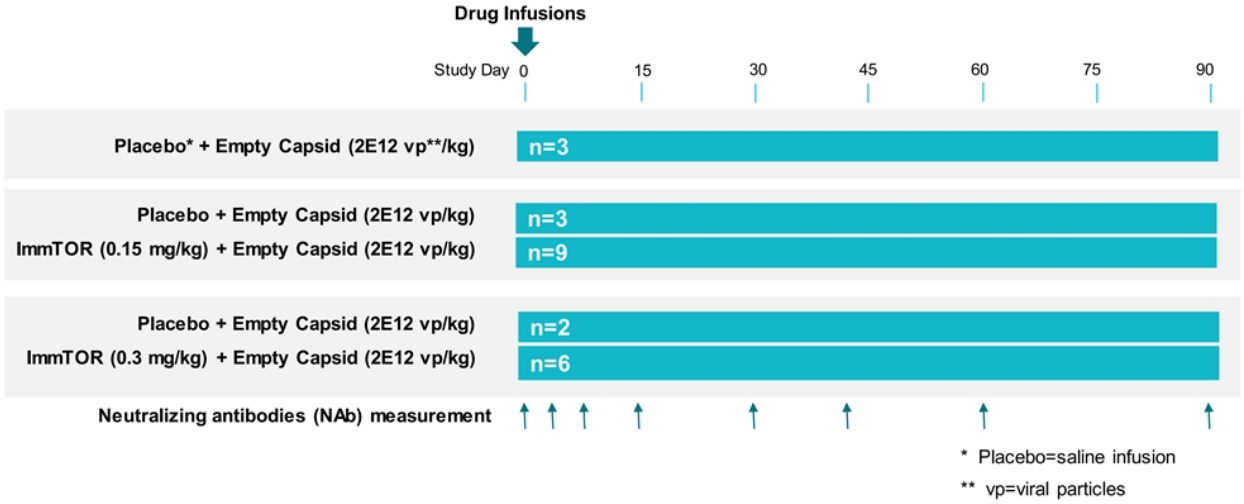
SEL-399 Phase 1 Dose-Escalation Study: Objectives and Endpoints

- General Objectives
  - To determine the immune response to AAV8 empty capsids (EMC-101), which contain no DNA payload, in healthy volunteers
  - To determine whether single escalating doses of ImmTOR can reduce the immune response to AAV8 empty capsids in healthy volunteers

	Specific Objectives	Endpoint Measures
Primary (Top Line)	**Immune activity**	• **Neutralizing anti-AAV8 antibodies (NAb)**
	Safety	• **Adverse events**
Secondary	Effect on T-cell and B-cell responses	• Anti-AAV8 binding antibody kinetics • AAV8 capsid-specific T-cell responses
	Pharmacokinetics of ImmTOR and EMC-101	• ImmTOR (sirolimus) and EMC-101 PK parameters
Exploratory	Mechanisms of immune response and inhibition	• Properties of Anti-AAV8 antibodies • Composition of immune cell populations • Evaluation of serum biomarkers

SEL-399 Phase 1 Dose-Escalation Study: Subjects and Design

- Total healthy volunteers enrolled: 23 (14 males and 9 females)
- All subjects with anti-AAV8 NAb titers <1:5 at baseline
- Randomized, placebo controlled and double-blind study



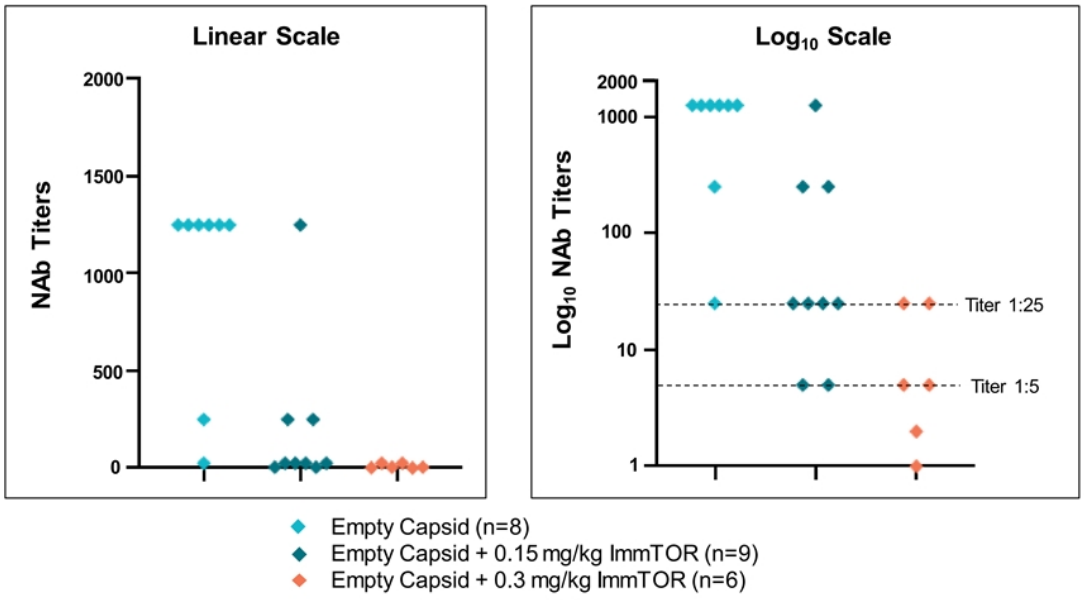
* Placebo=saline infusion

** vp=viral particles

SEL-399 Phase 1 Dose-Escalation Study

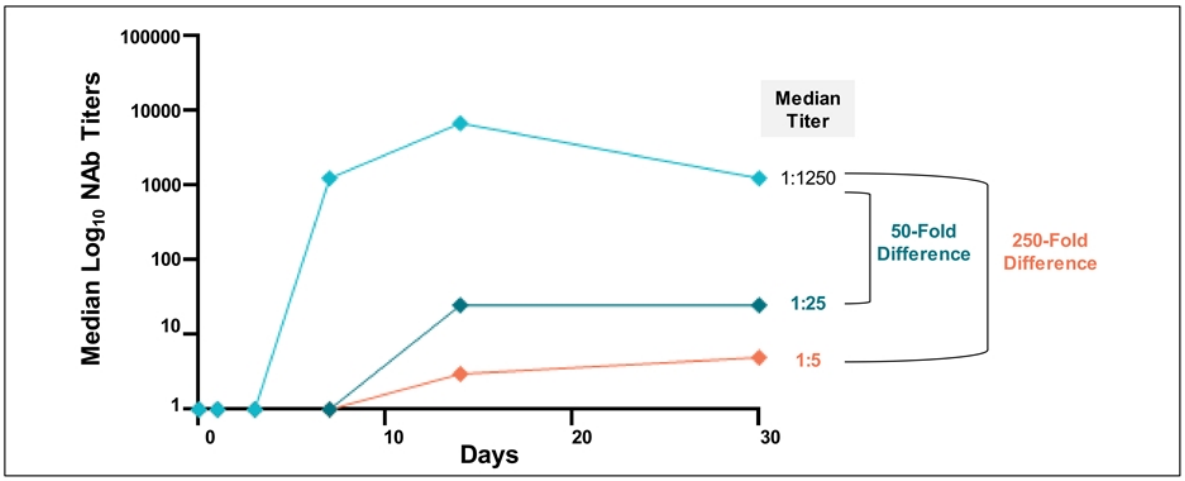
Single Dose ImmTOR Inhibited Formation of Anti-AAV8 NAb at Day 30

100% *of subjects dosed with 0.3 mg/kg ImmTOR had NAb titers ≤1:25 at Day 30*
67% *of subjects dosed with 0.3 mg/kg ImmTOR had NAb titers ≤1:5 at Day 30*



Single Dose ImmTOR Inhibited Formation of Median Anti-AAV8 NAb in a Dose-Dependent Manner at Day 30

1:5 *Median NAb titers in subjects dosed with 0.3 mg/kg ImmTOR at Day 30*
250-fold *lower median NAb titers in subjects dosed with 0.3 mg/kg ImmTOR at Day 30*

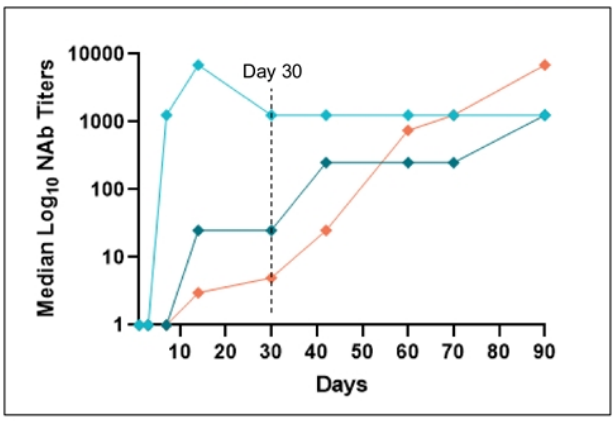


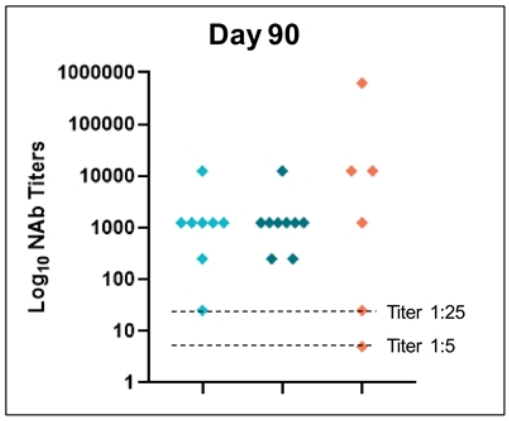
- Empty Capsid (n=8)
- Empty Capsid + 0.15 mg/kg ImmTOR (n=9)
- Empty Capsid + 0.3 mg/kg ImmTOR (n=6)

Subjects Treated With a Single Dose of ImmTOR Developed Delayed NAb Formation by Day 90

Two additional doses of ImmTOR may be required to maintain control beyond Day 30

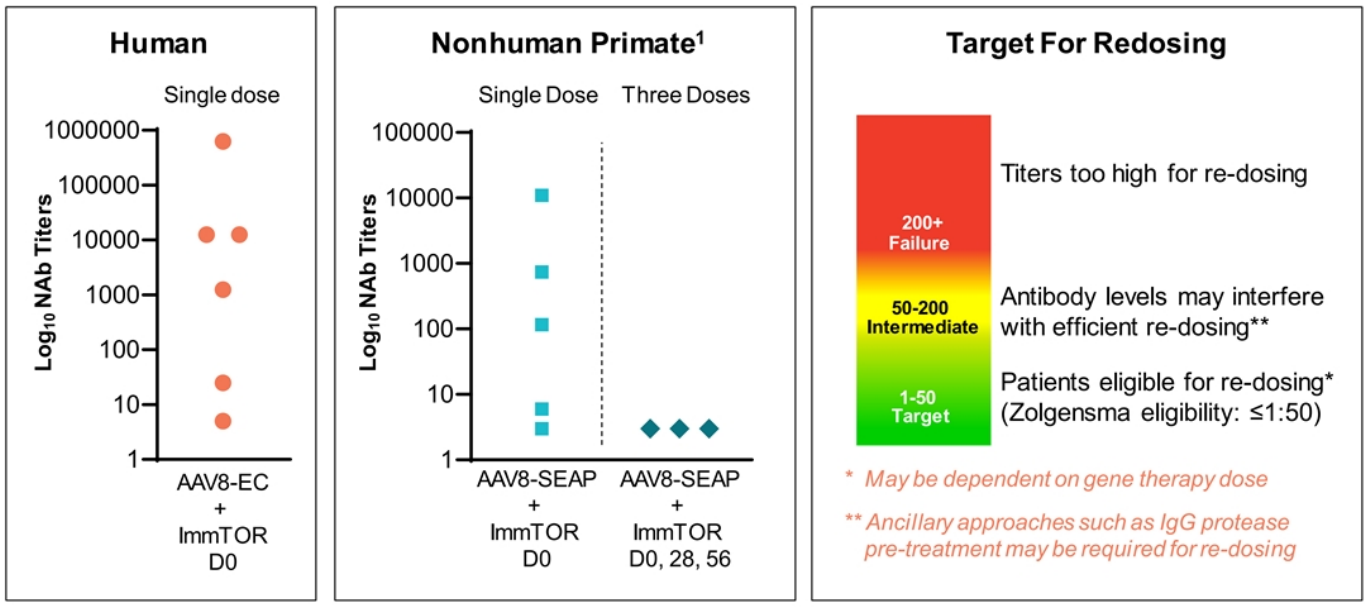
2 of 6 subjects dosed with 0.3 mg/kg ImmTOR had NAb titers ≤1:25 at Day 90
1 of 6 subjects dosed with 0.3 mg/kg ImmTOR had NAb titers ≤1:5 at Day 90





- Empty Capsid (n=8)
- Empty Capsid + 0.15 mg/kg ImmTOR (n=9)
- Empty Capsid + 0.3 mg/kg ImmTOR (n=6)

Empty Capsid Data In-Line With Single Dose ImmTOR NHP Data at Day 90



Safety

All treatment-related adverse events were expected for ImmTOR, readily monitorable, and transient

- There were no Serious Adverse Events (SAEs)
- Adverse events related to ImmTOR were expected based on previous clinical trials
- Stomatitis (mouth ulcers, redness, or pain) was most common
  - 3 of 9 subjects in 0.15 mg/kg group and 6 of 6 subjects in 0.3 mg/kg group, all mild to moderate
  - Average start of stomatitis was on day 11 with an average duration of 8 days
  - Symptoms were ameliorated with steroid mouth wash
- Rash was next most common
  - 3 of 9 subjects in 0.15 mg/kg group and 3 of 6 subjects in 0.3 mg/kg group, all mild to moderate
  - Average start of rash was day 12 and resolved after an average of 23 days
  - No therapy was required
- Asymptomatic and transient laboratory AEs in subjects receiving ImmTOR were seen in 2 subjects with mild to moderate thrombocytopenia and 1 subject with grade 3 hypertriglyceridemia

Summary

Summary and Conclusions

- AAV8 empty capsids elicited a strong immune response with peak median anti-AAV8 NAb titers of 1:6875
- ImmTOR inhibited the formation of anti-AAV8 NAb in a dose-dependent manner at Day 30

ImmTOR Dose	Subjects ≤ 1:5 NAb titer	Subjects ≤ 1:25 NAb titer	Median titers	Fold difference from control
0.15 mg/kg	22%	67%	1:25	50
0.30 mg/kg	**67%**	**100%**	**1:5**	**250**

- After Day 30, 2 of 6 subjects treated with 0.3 mg/kg ImmTOR maintained NAb titers ≤ 1:25, while remaining ImmTOR-treated subjects showed delayed formation of NAb reaching control levels by Day 90
- Animal studies suggest that, if NAb are inhibited at Day 30, administration of two additional monthly doses of ImmTOR may maintain control of NAb beyond 90 days
- Safety findings included AEs previously observed with ImmTOR
- This promising study in healthy volunteers provides support for the potential use of ImmTOR for the inhibition of neutralizing antibodies to AAV8 in gene therapy clinical trials

Q&A