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

# FORM 8-K/A

**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 18, 2020**

# SANGAMO THERAPEUTICS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **000-30171** | **68-0359556** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer ID Number)** |

**7000 Marina Blvd., Brisbane, California 94005**
**(Address of principal executive offices) (Zip Code)**

**(510) 970-6000**
**(Registrant's telephone number, including area code)**

**Not Applicable**
**(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, $0.01 par value per share** | **SGMO** | **Nasdaq Global Select Market** |

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. ☐

**Explanatory Note:**

This amended Current Report on Form 8-K is being filed solely for the purposes of amending and restating Item 9.01 in order to furnish a revised Exhibit 99.2, which contained an error in the version originally furnished. Other than updating Item 9.01 to correct Exhibit 99.2, there are no other changes to the Form 8-K as originally filed.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits.*

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated June 18, 2020 (incorporated by reference to the initial filing) |
| 99.2 | World Federation of Hemophilia Virtual Summit Data Presentation |
| 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.

**SANGAMO THERAPEUTICS, INC.**

Dated: June 18, 2020

By: /s/ Gary H. Loeb
Name: Gary H. Loeb
Title: Executive Vice President and General Counsel

# Updated Follow-up of the High-Dose Cohort in the Alta Study, a Phase 1/2 Study of giroctocogene fitelparvovec (SB-525) Gene Therapy in Adults With Severe Hemophilia A

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Presented at the World Federation of Hemophilia (WFH) Virtual Summit, June 14–19, 2020

# Disclosures for:
# Thomas J. Harrington, MD

| Conflict | Disclosure |
|---|---|
| Research Support | Sangamo/Pfizer Inc. |
| Director, Officer, Employee | none |
| Shareholder | none |
| Honoraria | none |
| Advisory Committee | none |
| Consultant | none |
| | |

# Disclaimer

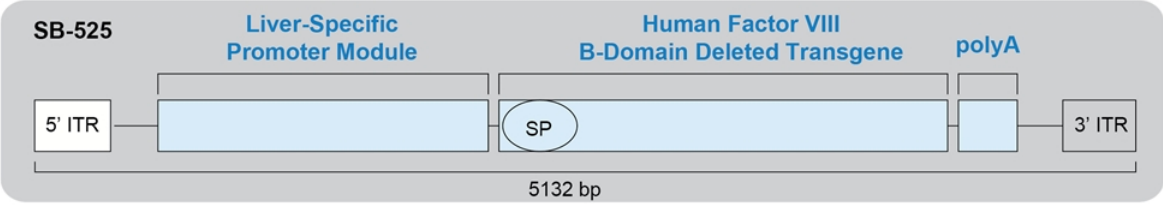
- Data in this presentation are presented “as-is” and potentially subject to change.

# Hemophilia A

- Characterized by increased bleeding caused by low levels of factor VIII (FVIII) activity resulting from mutations in the *F8* gene
- Treatment is currently based on replacement therapy with exogenous FVIII, along with emerging mimetic-based therapy
- Current treatments require frequent dosing to be effective, and involve intravenous (IV) or subcutaneous administration
- Maintenance of FVIII activity in the mild to normal range can improve the outcomes for patients with hemophilia A
- The wide therapeutic window and underlying single gene defect make hemophilia A an ideal candidate for gene therapy

# Giroctocogene fitelparvovec (SB-525) Gene Therapy for Hemophilia A

- Alta is a phase 1/2 dose-ranging, single-dose, multicenter study to assess the safety and tolerability of giroctocogene fitelparvovec (SB-525) in adult subjects (aged ≥18 years) with severe hemophilia A
- Giroctocogene fitelparvovec (SB-525) is a liver-tropic recombinant adeno-associated virus (rAAV6) vector carrying a B-domain–deleted *F8* gene that is delivered through a single IV infusion
- Key exclusion criteria
  - Neutralizing activity to AAV6 capsid and/or inhibitor to FVIII
  - History of hypersensitivity response to FVIII replacement therapy
  - History of liver dysfunction
  - Contraindication to steroids

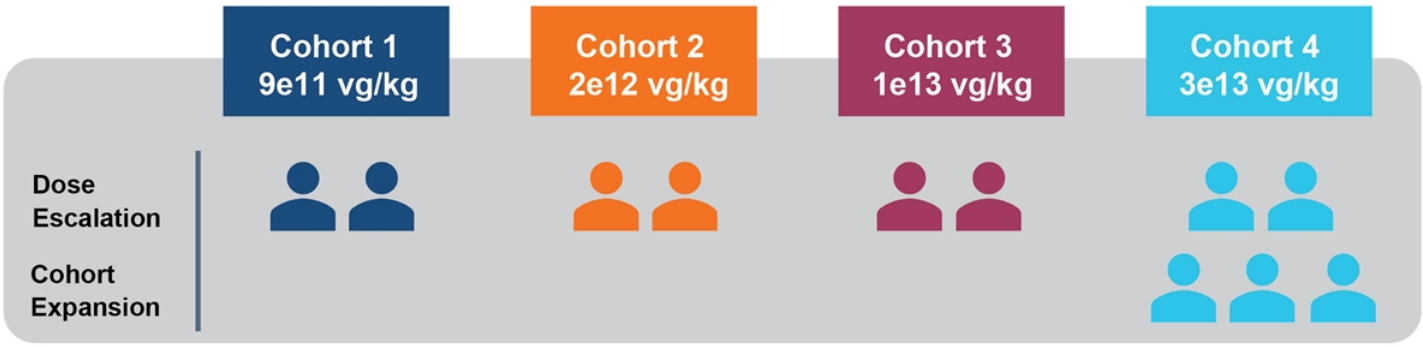


# Study End Points

- Primary end points
  - Safety and tolerability of SB-525, as assessed by the incidence of adverse events (AEs) and serious adverse events (SAEs) and by changes in clinical laboratory assessments, vital signs and electrocardiogram, and liver imaging
  - Changes in circulating FVIII activity
- Secondary end points
  - Change from baseline in the use of FVIII replacement therapy and frequency and severity of bleeding episodes
  - Measurement of FVIII inhibitor levels
  - Vector shedding in bodily fluids

# Study Status

- 4 dose cohorts of 2 subjects each and a high-dose cohort expansion of 3 subjects (total of 11 subjects dosed); no prophylactic steroid use
- Steroid treatment is initiated for alanine aminotransferase (ALT) elevation that exceeds 1.5x baseline value
- The safety and efficacy data of each cohort were reviewed by an independent safety monitoring committee prior to each dose escalation and prior to initiating cohort 4 expansion



# Study Status, cont'd

## Patient Demographics

| Characteristic | | Cohort 1 9e11 vg/kg | Cohort 2 2e12 vg/kg | Cohort 3 1e13 vg/kg | Cohort 4 3e13 vg/kg | All Subjects |
|---|---|---|---|---|---|---|
| Age, years | n | 2 | 2 | 2 | 5 | 11 |
| | Mean (SD) | 30.5 (9.19) | 35.5 (16.26) | 32.0 (1.41) | 26.8 (6.30) | 30.0 (7.94) |
| | Median | 30.5 | 35.5 | 32.0 | 29.0 | 30.0 |
| | Min-max | 24, 37 | 24, 47 | 31, 33 | 18, 34 | 18, 47 |
| Gender, n (%) | Male | 2 (100) | 2 (100) | 2 (100) | 5 (100) | 11 (100) |
| Race, n (%) | Asian | – | 1 (50) | – | – | 1 (9.1) |
| | White | 2 (100) | 1 (50) | 2 (100) | 4 (80.0) | 9 (81.8) |
| | Other | – | – | – | 1 (20.0) | 1 (9.1) |
| Ethnicity, n (%) | Hispanic or Latino | – | – | – | 2 (40.0) | 2 (18.2) |
| | Not Hispanic or Latino | 2 (100) | 2 (100) | 2 (100) | 3 (60.0) | 9 (81.8) |

Min-max, minimum-maximum.
Data cut: March 2020

# Safety Summary: Cohort 4 ($3x10^{13}$ vg/kg)

- 1 subject had a treatment-related serious adverse event (SAE) of grade 3 hypotension and grade 2 fever, with symptoms of headache and tachycardia occurring ≈6 hours after completion of the vector infusion, with resolution ≈12 hours postinfusion
- No additional treatment-related SAEs
- 4/5 subjects in the high dose cohort required corticosteroid treatment for elevations in liver transaminase (ALT/AST), which all resolved with intervention
  - 3 of the 4 subjects had subsequent elevations in liver transaminases after resolution of the initial increase and received a repeat course of corticosteroids, which all resulted in resolution
- FVIII activity levels were sustained in all cases, with no patients experiencing bleeding events or requiring FVIII infusions

# Safety Summary: Treatment-Related Adverse Events Cohort 4 ($3x10^{13}$ vg/kg)

| MedDRA Preferred Term | Cohort 4 3e13 vg/kg (N=5) | |
|---|---|---|
| | Subjects, n (%) | No. of Events |
| Any treatment-related event | 5 (100.0) | 42 |
| Alanine aminotransferase increased* | 3 (60.0) | 9 |
| Pyrexia | 4 (80.0) | 4 |
| Aspartate aminotransferase increased | 1 (20.0) | 2 |
| Tachycardia | 2 (40.0) | 2 |
| Fatigue | 1 (20.0) | 1 |
| Hypotension | 1 (20.0) | 1 |
| Myalgia | 1 (20.0) | 1 |

*One subject had an ALT increase as per central lab results, but Investigator has not reported increase as an Adverse Event
Data cut: March 2020

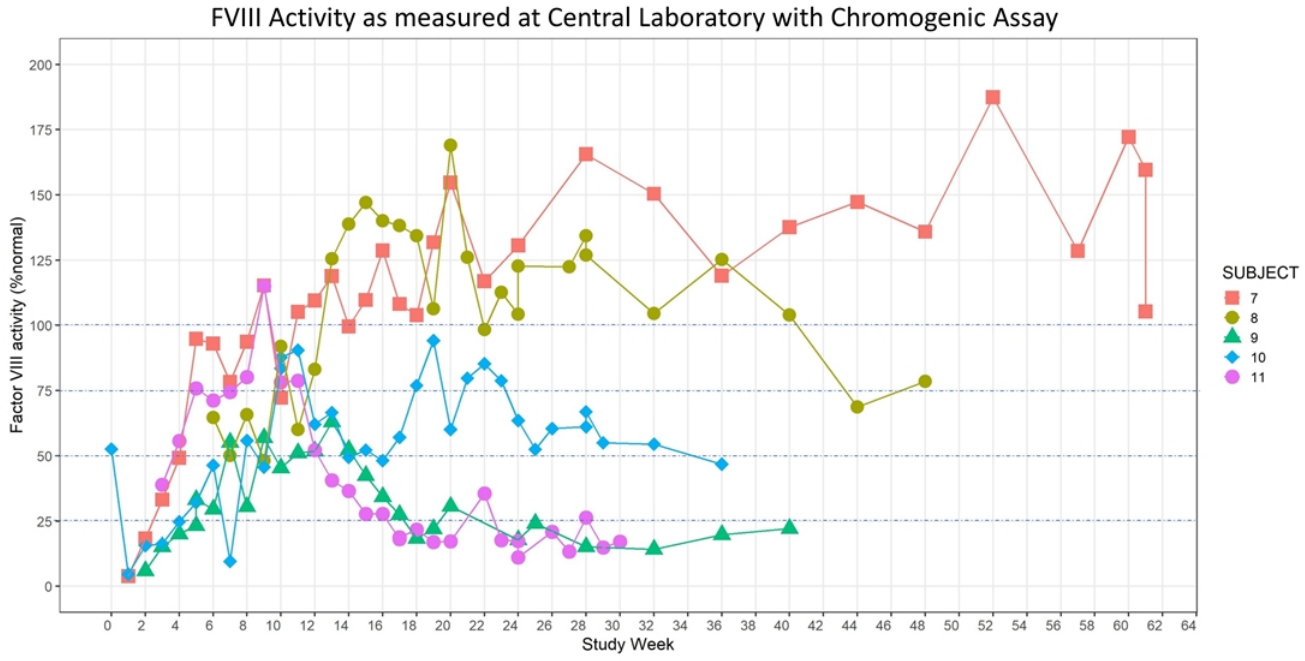
# ALT Elevations: Cohort 4 ($3x10^{13}$ vg/kg)

- 4 of 5 subjects in cohort 4 had an ALT elevation

| Subject ID Number | Time of First ALT Elevation (Week) | Maximum ALT Value, U/L (Grade) | Steroids, >60mg (Weeks) | Steroids, Taper (Weeks) | FVIII levels (Chromo, IU/dL) at Start of Steroids | FVIII Levels (Chromo, IU/dl) at End of Taper | Time of Second ALT Elevation (Week) | Weeks of Steroids After Second Elevation |
|---|---|---|---|---|---|---|---|---|
| 7 | 4.5 | 91 (gr 1) | 3 | 11 | 94.8 | 108.2 | 48# | 16# |
| 8 | 12 | 66 (gr 1) | 1 | 16 | 83.1 | 112.6 | N/A | N/A |
| 10 | 5.5 | 63 (gr 1) | N/A* | 6 | 46.4 | 57.1 | 20 | 9 |
| 11 | 8 | 192 (gr 2) | 1.5 | 4 | 80.2 | 27.7 | 16 | 18 |

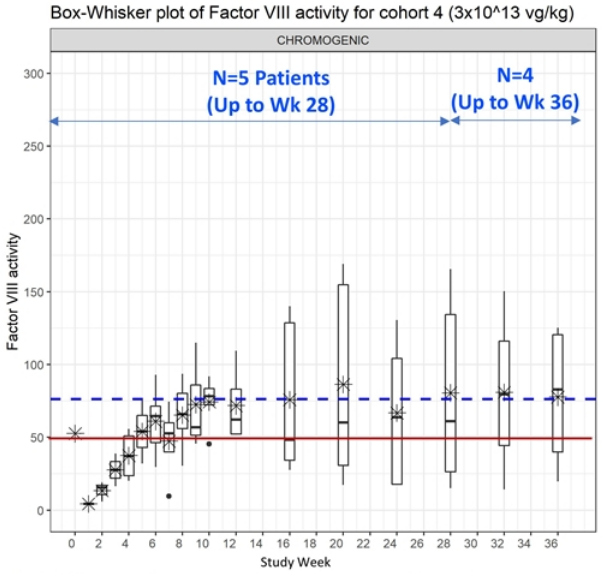
N/A: not applicable
*: Subject started at 60mg.
#: Subject had an additional isolated elevation of ALT at week 28 that was treated with corticosteroids for 1 week and then discontinued. Treatment was ongoing at the time of data cut.
Data cut March 2020

# Efficacy: Cohort 4 ($3x10^{13}$ vg/kg)




Latest available FVIII values from March 2020 data cut

# Efficacy: Cohort 4 ($3x10^{13}$ vg/kg)




50% Factor VIII activity (Lower bound of Normal)

Mean Factor VIII activity value from Week 9 to Week 36 (based on group mean)

* Mean (Box-Whisker plot)

Data cut: March 2020

# Efficacy: Cohort 4 ($3x10^{13}$ vg/kg)

- Steady-state FVIII activity achieved by week 9 post infusion
- Subjects have been followed for 33-65 weeks, FVIII activity values available up to week 30 and up to week 61
- Median steady-state (of geometric means since week 9) FVIII activity level 64.2% via central laboratory chromogenic assay (CA; previously reported that CA tends to correlate better with FVIII antigen level than one-stage clotting assay (OS))
- No bleeding events
- No FVIII infusions beyond initial use of prophylactic factor

# Conclusions

- Cohort 4 ($3x10^{13}$ vg/kg):
  - With follow-up ranging 33 to 65 weeks, data continues to show that giroctocogene fitelparvovec (SB-525) is generally well tolerated
  - Sustained FVIII activity levels in the mild to normal range
  - No use of exogenous FVIII beyond week 3 post infusion
  - No bleeding events
  - 1 treatment related SAE during vector infusion, no additional treatment related SAEs
- Follow-up for Cohorts 1-3 extends up to over 2 years with no safety signals
- The Ph1/2 study is ongoing and supports further development of giroctocogene fitelparvovec (SB-525)
- Phase 3 lead-in study is ongoing