

**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): July 24, 2024**

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

**Delaware**  
(State or other jurisdiction of  
incorporation)

**000-30171**  
(Commission  
File Number)

**68-0359556**  
(IRS Employer  
ID Number)

**501 Canal Blvd., Richmond, California 94084**  
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

**Item 8.01 Other Events.**

On July 24, 2024, Sangamo Therapeutics, Inc., or Sangamo, issued a press release reporting on the announcement of Pfizer, Inc., or Pfizer, of positive topline results from the registrational Phase 3 AFFINE clinical trial being conducted by Pfizer evaluating giroctocogene fitelparvovec, an investigational gene therapy product candidate that Sangamo is developing with Pfizer for the treatment of adults with moderately severe to severe hemophilia A. A copy of the press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release of Sangamo dated July 24, 2024.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: July 24, 2024

By: /s/ SCOTT B. WILLOUGHBY  
Name: Scott B. Willoughby  
Title: Senior Vice President, General Counsel and  
Corporate Secretary



## SANGAMO THERAPEUTICS REPORTS ON PFIZER'S ANNOUNCEMENT OF POSITIVE TOPLINE RESULTS FROM PHASE 3 TRIAL OF HEMOPHILIA A GENE THERAPY CANDIDATE

*Giroctocogene fitelparvovec trial meets primary and key secondary objectives of superiority compared to prophylaxis*

**RICHMOND, California, July 24, 2024** - Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicine company, today reported on Pfizer Inc.'s announcement of positive topline results from the Phase 3 AFFINE trial ([NCT04370054](#)) evaluating giroctocogene fitelparvovec, an investigational gene therapy that Sangamo is co-developing with and licensing to Pfizer for the treatment of adults with moderately severe to severe hemophilia A.

Sangamo is eligible to earn from Pfizer up to \$220 million in milestone payments upon the achievement of certain regulatory and commercial milestones for giroctocogene fitelparvovec and product sales royalties of 14% - 20% if giroctocogene fitelparvovec is approved and commercialized, subject to certain reductions.

Pfizer reported that the AFFINE trial achieved its primary objective of non-inferiority, as well as superiority, of total annualized bleeding rate (ABR) from Week 12 through at least 15 months of follow up post-infusion compared with routine Factor VIII (FVIII) replacement prophylaxis treatment. Following a single  $3 \times 10^{13}$  vg/kg dose, giroctocogene fitelparvovec demonstrated a statistically significant reduction in mean total ABR compared to the pre-infusion period (1.24 vs 4.73; one-sided p-value=0.0040).

Key secondary endpoints as defined by the trial protocol were met and also demonstrated superiority compared to prophylaxis. 84% of participants maintained FVIII activity >5% at 15 months post-infusion (one-sided p-value = 0.0086) with the majority of participants having FVIII activity  $\geq 15\%$ , and the mean treated ABR showed a statistically significant 98.3% reduction from 4.08 in the pre-infusion period to 0.07 post-infusion (from Week 12 up to at least 15 months [15-44 months]; one-sided p-value < 0.0001). Throughout the trial, among all dosed participants, one participant (1.3%) returned to prophylaxis post-infusion.

In the AFFINE trial, giroctocogene fitelparvovec was generally well tolerated. Transiently elevated FVIII levels  $\geq 150\%$  were observed in 49.3% of dosed participants, as measured via chromogenic assay, with no impact on efficacy and safety results. Serious adverse events were reported in 15 patients (20%), including 13 events reported by 10 patients (13.3%) assessed as related to treatment. Treatment-related adverse events generally resolved in response to clinical management.

"For people living with hemophilia A, the physical and emotional impact of needing to prevent and treat bleeding episodes through frequent IV infusions or injections cannot be underestimated," said Professor Andrew Leavitt M.D., AFFINE lead investigator, Departments of Laboratory Medicine and Medicine Division of Hematology/Oncology Director, Adult Hemophilia Treatment Center, University of California, San Francisco, CA. "I'm excited by the strength of these positive results from the AFFINE trial that show giroctocogene fitelparvovec was generally well tolerated, and demonstrate the transformative potential of this gene therapy candidate to provide superior bleed protection compared with routine FVIII prophylaxis, while helping relieve the treatment burden for people living with hemophilia A."

Giroctocogene fitelparvovec is a novel, investigational gene therapy that contains a bio-engineered AAV6 capsid and a modified B-domain deleted human coagulation FVIII gene. The goal of this investigational treatment for people living with hemophilia A is that a single infusion of giroctocogene fitelparvovec may allow them to produce FVIII themselves for an extended period of time, provide bleed protection and reduce the need for routine prophylaxis with intravenous (IV) infusions or injections.<sup>[i],[ii],[iii],[iv]</sup>

"We are thrilled with the positive topline results from the Phase 3 AFFINE trial, which demonstrated the potential of giroctocogene fitelparvovec as a one-time gene therapy for people with hemophilia A and provide a potential alternative to the current burden of disease management," said Nathalie Dubois-Stringfellow, Ph.D, Chief Development Officer at Sangamo. "These impressive results further validate the power of our genomic technologies and take us one step closer towards what could become Sangamo's first medicine commercially available to patients. We greatly appreciate Pfizer's strong leadership of this important program and look forward to their discussions of these data with regulatory authorities."

In this Phase 3 trial, eligible trial participants were initially enrolled in a lead-in study ([NCT03587116](#)) and upon successful completion, were enrolled into the AFFINE trial where they received a one-time  $3 \times 10^{13}$  vg/kg dose of giroctocogene fitelparvovec by IV infusion. Participants in the AFFINE trial were screened with a validated assay designed to identify individuals who test negative for neutralizing antibodies to the gene therapy vector. Clinical trial participants will be evaluated in AFFINE over the course of five years, and up to a total of 15 years as part of a long-term follow-up trial.

Pfizer reported that analyses of the full Phase 3 dataset from the AFFINE trial are ongoing and additional data will be presented at upcoming medical meetings. Giroctocogene fitelparvovec has been granted Fast Track and Regenerative Medicine Advanced Therapy designations from the U.S. Food and Drug Administration (FDA), as well as Orphan Drug designations in the U.S. and the European Union. Pfizer reported that it will discuss these data with regulatory authorities in the coming months. Pfizer recently received [FDA approval](#) for BEQVEZ™ (fidanocogene elaparvovec), its hemophilia B gene therapy for eligible patients.

### **About the AFFINE Trial**

The Phase 3 AFFINE (NCT04370054) trial is an open-label, multicenter, single-arm trial to evaluate the efficacy and safety of a single infusion of giroctocogene fitelparvovec in adult male participants (n=75 dosed participants) with moderately severe to severe hemophilia A. Trial participants included in the assessments of the key endpoints of the primary efficacy analysis (n=50) completed a minimum six months of routine FVIII replacement prophylaxis therapy during the lead-in study (NCT03587116) providing data to compare with post giroctocogene fitelparvovec treatment.

The primary endpoint measures the total ABR (spontaneous and traumatic bleedings, treated and untreated) from Week 12 through at least 15 months following treatment with giroctocogene fitelparvovec compared to total ABR on prior FVIII prophylaxis replacement therapy. For more information, visit [clinicaltrials.gov](#).

Giroctocogene fitelparvovec is being developed as part of a collaboration agreement for the global development and commercialization of gene therapies for hemophilia A between Sangamo Therapeutics and Pfizer. In late 2019, Sangamo transferred the manufacturing technology and the Investigational New Drug application to Pfizer. Under the agreement, Pfizer assumed responsibility for pivotal studies, any regulatory activities, and potential global commercialization of giroctocogene fitelparvovec.

### **About Hemophilia A**

Hemophilia is an inherited, rare bleeding disorder that causes people to bleed for longer than normal due to a deficiency of a protein required for normal blood clotting, known as clotting factor VIII (FVIII) in hemophilia A. The severity of hemophilia is determined by the amount of the factor in the blood. The lower the amount of the factor, the more likely it is that bleeding will occur, which can lead to serious health problems.<sup>[v]</sup>

Hemophilia A occurs in approximately 25 in every 100,000 male births worldwide.<sup>[vi]</sup> Approximately 55-75% of males with hemophilia A have a moderate to severe form of the disease.<sup>[vii]</sup> For people who live with hemophilia A, there is an increased risk of spontaneous bleeding as well as bleeding following injuries or surgery.<sup>v</sup> It is a lifelong disease that requires constant monitoring and therapy.<sup>[viii]</sup>

### **About Sangamo Therapeutics**

Sangamo Therapeutics is a genomic medicine company dedicated to translating ground-breaking science into medicines that transform the lives of patients and families afflicted with serious neurological diseases who do not have adequate or any treatment options. Sangamo believes that its zinc finger epigenetic regulators are ideally suited to potentially address devastating neurological disorders and that its capsid discovery platform can potentially expand delivery beyond currently available intrathecal delivery capsids, including in the central nervous system. Sangamo's pipeline also includes multiple partnered programs and programs with opportunities for partnership and investment. To learn more, [visit www.sangamo.com](#) and connect with us on [LinkedIn](#) and [Twitter/X](#).

### *Forward-Looking Statements*

*This release contains forward-looking statements regarding Sangamo's current expectations. These forward-looking statements include, without limitation, statements regarding, the potential of giroctocogene fitelparvovec to provide superior bleed protection compared with routine FVIII replacement therapy, that a single infusion of giroctocogene fitelparvovec may allow patients to produce FVIII themselves for an extended period of time, Pfizer's continued advancements of the giroctocogene fitelparvovec program, the potential for Pfizer to complete clinical development, regulatory interactions, manufacturing and global commercialization of any resulting products, the potential for Sangamo to receive development and commercial milestone payments and royalties, and other statements that are not historical fact. These statements are not guarantees of future performance and are subject to risks and uncertainties that are difficult to predict. Sangamo's actual results may differ*

materially and adversely from those expressed in these forward-looking statements. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to: the global business environment, healthcare systems and the business and operations of Sangamo and Pfizer; the research and development process, including the results of preclinical studies and clinical trials; the regulatory approval process for product candidates across multiple regulatory authorities; the manufacturing of products and product candidates; the commercialization of approved products; the potential for technological developments that obviate technologies used by Sangamo and its partners; the potential for Pfizer to breach or terminate its collaboration agreement with Sangamo; the potential for Sangamo to fail to realize its expected benefits from the Pfizer collaboration; and Sangamo's need for substantial additional funding to operate as a going concern. There can be no assurance that Sangamo will earn any milestone or royalty payments under the Pfizer agreement or obtain regulatory approvals for product candidates arising from this agreement. Actual results may also differ from those projected in forward-looking statements due to risks and uncertainties that exist in Sangamo's and Pfizer's operations and businesses. These risks and uncertainties are described more fully in Sangamo's Securities and Exchange Commission, or SEC, filings and reports, including in its Annual Report on Form 10-K for the year ended December 31, 2023, as supplemented by its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, each filed with the SEC, and future filings and reports that Sangamo makes from time to time with the SEC. Forward-looking statements contained in this release are made as of July 24, 2024, and Sangamo undertakes no duty to update such information except as required under applicable law.

#### Investor Relations & Media Inquiries

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[iii] Centers for Disease Control and Prevention. What is hemophilia? October 2023. Available at: <https://www.cdc.gov/ncbddd/hemophilia/facts.html#:~:text=Hemophilia%20is%20usually%20an%20inherited,can%20help%20to%20stop%20bleeding>. Last accessed: July 2024.

[iv] Pfrepper, Christian, et al. "Emicizumab for the Treatment of Acquired Hemophilia A: Consensus Recommendations from the GTH-AHA Working Group." *Hämostaseologie* (2023).

[v] Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia, 3rd Edition; 2020. *Haemophilia*, 26(S6), 1–158.

[vi] Iorio A, Stonebraker JS, Chambost H, et al. Establishing the Prevalence and Prevalence at Birth of Hemophilia in Males: A Meta-analytic Approach Using National Registries. *Ann Intern Med* 2019;171(8):540-546.

[vii] WFH. World Federation of Hemophilia Report on the Annual Global Survey 2022. October 2023. (<https://www1.wfh.org/publications/files/pdf-2399.pdf>).

[viii] Brod M, Bushnell DM, Neergaard JS, et al. Understanding treatment burden in hemophilia: development and validation of the Hemophilia Treatment Experience Measure (Hemo-TEM). *J Patient Rep Outcomes*. 2023;7(1):17.