



Sangamo Therapeutics Announces Strategic Update and Reports Third Quarter 2023 Financial Results

November 1, 2023

- *Announced additional progress towards strategic transformation into neurology-focused genomic medicine company.*
- *Focusing resources on proprietary epigenetic regulation therapies treating neurological diseases and novel AAV capsid delivery technologies.*
- *Dosed a total of 25 patients in Phase 1/2 STAAR study in Fabry disease, with promising clinical data continuing to emerge. Deferring additional investments in Phase 3 planning until collaboration partner or Phase 3 trial funding secured.*
- *Actively seeking collaboration partners or direct investors in CAR-Treg cell therapy programs. Deferring new investments until collaboration partner or external investment is secured.*
- *Announced planned shutdown of Brisbane headquarters, restructuring of operations, and US workforce reduction of approximately 40%.*
- *Cost savings expected from the restructuring, workforce reduction and other potential cost reductions anticipated to reduce annual operating expenses by approximately 50%.*
- *Conference call and webcast scheduled for Thursday, November 2, 8:30 a.m. Eastern Time.*

BRISBANE, Calif.--(BUSINESS WIRE)--Nov. 1, 2023-- Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicines company, today announced recent business highlights, including progress on its strategic transformation and a corresponding restructuring of operations and workforce reduction, and reported third quarter 2023 financial results.

"In 2020, we shared our refreshed company strategy which aims to both maximize the potential of our proprietary genomic editing and delivery technology, and to focus on areas where we believe we can apply that technology to be either first-in-class or best-in-class. The process of streamlining Sangamo's pipeline has been accelerated within today's challenging economic environment and we have had to make difficult decisions to defer further investments and seek collaboration partners or direct investment in both our Fabry gene therapy and CAR-Treg cell therapy programs," said Sandy Macrae, Chief Executive Officer of Sangamo. "As we work to unlock value in our clinical programs that is not currently reflected as part of Sangamo, we plan to do everything in our power to get these important assets into the hands of parties with the means to advance them towards patients. At the same time, we will continue to progress our promising epigenetic regulation programs for neurological diseases and hope to soon share a breakthrough in our capsid delivery capabilities, which we believe could open the door for many other high-value and unmet diseases to be addressed with our editing capabilities. We continue to seek ways to raise additional capital to strengthen our financial foundation."

The restructuring announced today represents a further step towards simplifying the Sangamo organization and focusing on our epigenetic regulation therapies treating neurological diseases and our novel AAV capsid delivery technologies. Sangamo is deferring new investments in its Fabry and CAR-Treg programs beyond what is currently committed and is actively seeking collaboration partners or direct investors in both. In addition, Sangamo expects to close its Brisbane, California facility in early 2024 to conserve cash resources, and will transition its headquarters to its Richmond, California facility as of January 1, 2024. As a result of this restructuring, Sangamo is reducing its US workforce by approximately 40%, or approximately 162 roles.

In connection with the restructuring, D. Mark McClung, Executive Vice President, Chief Operating Officer and Jason Fontenot, Senior Vice President, Chief Scientific Officer will be leaving the company on January 2, 2024. In the context of a streamlined and more focused organization, we are eliminating their roles. Until his departure, Mark will continue to lead our search for partners and investors in our Fabry and CAR-Treg programs. Amy Pooler, currently serving as Vice President, Neuroscience and Gregory Davis, currently serving as Vice President, Genome Engineering Design and Technology, have been appointed as Head of Research and Head of Technology, respectively, effective November 17, 2023.

The restructuring and workforce reductions, in combination with other potential cost reductions, are anticipated to reduce our non-GAAP annual operating expenses from approximately \$240 million-\$260 million in 2023 to approximately \$115 million-\$135 million in 2024, a decrease of approximately 50%. Sangamo expects to incur approximately \$8 million-\$10 million in one-time restructuring costs in the fourth quarter of 2023. Sangamo believes its cash, cash equivalents, and marketable securities as of September 30, 2023, in combination with the cost savings expected from the restructuring, workforce reduction and other potential cost reductions, will be sufficient to fund its planned operations into the third quarter of 2024.

Dr. Macrae continued: "I am grateful to all our employees for their commitment to Sangamo's mission and the patients we seek to serve, and have special appreciation to all those who are leaving for their important contributions. Additionally, I would like to personally thank Mark for the wisdom, candor and leadership he has brought to Sangamo. He has been a trusted colleague and will be greatly missed. I would also like to thank Jason for his dedication, passion and leadership. He leaves a strong scientific legacy for which we will always be grateful."

Recent Business Highlights

Program Highlights

Neurology Epigenetic Regulation Programs – *Progressed IND-enabling activities for Nav1.7; presented updated preclinical data at Prion 2023; presented preclinical data on zinc finger activators at the European Society of Gene and Cell Therapy (ESGCT); made significant progress in identifying new, potentially transformative AAV delivery capsids.*

- Progressed IND enabling activities for the Nav1.7 program to treat chronic neuropathic pain. Continue to expect an IND submission for this program in 2024.
- Presented data from the prion disease program at the Prion 2023 Conference in October 2023, showing in animal models that Sangamo's zinc finger repressors significantly reduce expression of the prion protein in the brain, extend lifespan and limit the formation of toxic prion aggregates.
- Presented an oral presentation at ESGCT in October 2023, showing that our zinc finger activators can be designed to restore normal gene and protein expression of SCN2A *in vitro* and *in vivo* to potentially address neurodevelopmental disorders such as autism spectrum disorder and intellectual disability.
- Presented data on Shank3 gene activation mediated by zinc finger transcriptional activators as a potential therapeutic approach for Phelan-McDermid Syndrome at ESGCT.
- Continued to advance identification and selection of engineered AAV capsids for enhanced central nervous system delivery through both intrathecal and intravenous delivery. Anticipate sharing nonhuman primate data from our capsid development efforts in early 2024.

Fabry Disease – Dosed total of 25 patients in Phase 1/2 STAAR study; all patients dosed to date continue to demonstrate sustained, elevated α -Gal A levels for up to three years for the longest treated patient; received Regenerative Medicine Advanced Therapy (RMAT) Designation from U.S. FDA; enrolled sufficient patients in the Phase 1/2 study believed to provide a preliminary assessment of safety and efficacy; deferring Phase 3 planning investments and actively seeking partners and investment.

- Dosed three additional patients in the dose expansion phase of the Phase 1/2 STAAR study evaluating isaralgagene civaparvovec, our wholly owned gene therapy product for the treatment of Fabry disease, for a total of 25 patients dosed to date, including 14 at the planned Phase 3 dose of 5×10^{13} vg/kg.
- All patients dosed to date continue to demonstrate sustained, elevated α -Gal A levels, with 12 patients having achieved at least one year of follow-up and the longest treated patient having achieved three years of follow-up.
- All 11 patients who were withdrawn from enzyme replacement therapy (ERT) remain off ERT, for up to 24 months for the longest withdrawn patient.
- Treated patients continue to report improvements in their quality of life, some even over and above the benefits they were experiencing on ERT.
- Received U.S. FDA RMAT designation for isaralgagene civaparvovec, which aims to expedite the review of new therapeutics that are intended to address an unmet need in patients with serious conditions. The U.S. FDA has previously granted isaralgagene civaparvovec both Orphan Drug and Fast Track Designations.
- Stopping further screening and enrollment in the Phase 1/2 STAAR study, after successfully enrolling sufficient patients believed to provide a preliminary assessment of efficacy and safety in the Phase 1/2 study.
- Expect to complete dosing of the remaining enrolled patients in the first half of 2024.
- Anticipate presenting updated Phase 1/2 clinical data at a medical meeting in early 2024.
- Deferring additional investments in Phase 3 planning until collaboration partnership or Phase 3 trial financing is secured.

CAR-Tregs – Received approval for accelerated dosing protocol for Phase 1/2 STEADFAST study from European regulatory authorities; dosed the first patient in the second dose cohort; successfully manufactured product candidate for third and new fourth dose levels; presented updated preclinical data at ESGCT; seeking a collaboration partner or direct investment in CAR-Tregs.

- Dosed the first patient in the second cohort of the Phase 1/2 STEADFAST study evaluating TX200, our wholly owned autologous CAR-Treg cell therapy treating patients receiving an HLA-A2 mismatched kidney from a living donor.
- The product candidate continues to be generally well tolerated in all four patients dosed to date.
- Received all necessary regulatory and ethics approvals for an accelerated dose escalation protocol from European regulatory authorities that could allow dosing to advance more quickly through the cohorts and which allows for a new and highest fourth dose cohort, compared to the three cohorts in the previously approved study protocol. The new, fourth cohort dose will be 18-fold higher than the first cohort starting dose.
- Completed manufacturing of the dose for the patient in the third cohort, who recently received a kidney transplant. Dosing of this fifth patient is expected in the fourth quarter of 2023, pending approval from the Safety Monitoring Committee.
- Completed manufacturing of the dose for the first patient in the fourth and highest dose cohort, who recently received a kidney transplant. Dosing of this sixth patient is expected in January 2024, pending approval from the Safety Monitoring Committee – which would accelerate dosing plans by 18 months compared to the previously approved study protocol.
- Presented preclinical data at ESGCT demonstrating the potential of autologous MOG-CAR-Tregs to provide a long-lasting treatment option for multiple sclerosis and updated animal model data demonstrating the promise of IL23R-CAR-Tregs in the potential treatment of Crohn's disease.
- Actively seeking a potential collaboration partner or direct external investment in the CAR-Treg cell therapy programs. Expect to provide an update on these efforts in the first quarter of 2024.
- Deferring new investments until a collaboration partner or external investment is secured.

Hemophilia A (Pfizer) – dosing complete in Phase 3 AFFINE trial; pivotal data read-out expected in mid-2024; BLA and MAA submissions anticipated in second half of 2024.

- Pfizer has advised us that dosing is complete in the Phase 3 AFFINE trial of giroctocogene fitelparvovec, an investigational gene therapy we are developing with Pfizer for patients with moderately severe to severe hemophilia A.
- A pivotal readout is expected in mid-2024, with Pfizer anticipating BLA and MAA submissions in the second half of 2024 if the pivotal readout is supportive.
- Expect to present updated data with Pfizer from the Phase 1/2 ALTA study of giroctocogene fitelparvovec in an oral presentation at the 65th American Society for Hematology Annual Meeting and Exposition on December 11, 2023.

Third Quarter 2023 Financial Results

Consolidated net loss for the third quarter ended September 30, 2023 was \$104.2 million, or \$0.59 per share, compared to a net loss of \$53.2 million, or \$0.34 per share, for the same period in 2022, primarily due to a non-cash charge relating to impairment of long-lived asset of \$44.8 million, which was a result of continued decline in our stock price and related market capitalization, initiation of actions to seek external financing and reprioritize certain research and development programs, and continued decline in equity values in the biotechnology industry.

Revenues

Revenues for the third quarter ended September 30, 2023 were \$9.4 million, compared to \$26.5 million for the same period in 2022.

The decrease of \$17.1 million in revenues was primarily attributed to a decrease of \$9.6 million and \$9.1 million in revenue relating to our collaboration agreements with Novartis and Biogen, respectively, due to the termination of these collaboration agreements in June 2023, and a decrease of \$1.4 million in revenue relating to our collaboration agreement with Kite, reflecting a reduction in collaboration activities during the quarter. These decreases were partially offset by an increase of \$3.0 million in revenue relating to our other license agreements.

GAAP and Non-GAAP Operating Expenses

(In millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Research and development	\$ 57.1	\$ 65.1	\$ 183.4	\$ 183.7
General and administrative	13.9	16.2	48.1	46.2
Impairment of goodwill and indefinite-lived intangible assets	-	-	89.5	-
Impairment of long-lived assets	44.8	-	65.2	-
Total operating expenses	115.8	81.3	386.2	229.9
Impairment of goodwill and indefinite-lived intangible assets	-	-	(89.5)	-
Impairment of long-lived assets	(44.8)	-	(65.2)	-
Stock-based compensation expense	(6.2)	(7.8)	(21.3)	(23.4)
Non-GAAP operating expenses	\$ 64.8	\$ 73.5	\$ 210.2	\$ 206.5

Total operating expenses on a GAAP basis for the third quarter ended September 30, 2023 were \$115.8 million, compared to \$81.3 million for the same period in 2022. GAAP operating expenses for the third quarter ended September 30, 2023 included a non-cash charge relating to impairment of long-lived asset of \$44.8 million, as described above. Non-GAAP operating expenses, which exclude impairment charges and stock-based compensation expense, for the third quarter ended September 30, 2023 were \$64.8 million, compared to \$73.5 million for the same period in 2022.

The decrease in total operating expenses on a non-GAAP basis was primarily attributable to lower compensation and other personnel costs mainly due to lower headcount as a result of restructuring of operations and corresponding reduction in workforce announced in April 2023, and decrease in manufacturing and lab supply expenses due to deferral and reprioritization of certain research and development programs. These decreases were partially offset by higher facilities and infrastructure related costs, and higher external expenses as we advance our clinical and preclinical pipeline.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities as of September 30, 2023 were \$132.1 million, compared to \$307.5 million as of December 31, 2022. As of September 30, 2023, we have raised approximately \$15.1 million in net proceeds under our at-the-market offering program since January 1, 2023. We believe that our available cash, cash equivalents and marketable securities as of September 30, 2023, in combination with the cost savings expected from the restructuring, workforce reduction and other potential cost reductions, will be sufficient to fund our planned operations into the third quarter of 2024.

Updated Financial Guidance for 2023

- GAAP operating expenses, including impairment of goodwill, indefinite-lived intangible assets, and long-lived assets, and stock-based compensation expense, for the full year 2023 are now estimated to be in the range of approximately \$422 million to \$442 million, reflecting the additional non-cash impairment charges recorded in the third quarter. The previous GAAP operating expenses guidance provided on August 8, 2023 was in the range of approximately \$378 million to \$398 million.
- We continue to estimate non-GAAP operating expenses to be in the range of approximately \$240 million to \$260 million, which remains unchanged from the last update on April 26, 2023. Estimated non-GAAP operating expenses exclude impairment of goodwill of \$38.1 million, impairment of indefinite-lived intangible assets of \$51.3 million, impairment of long-lived assets of \$65.2 million, and stock-based compensation expense of \$28.0 million.

Upcoming Events

Sangamo plans to participate in the following events:

Investor Conferences

- Truist Securities BioPharma Symposium, November 8-9, 2023
- Jefferies London Healthcare Conference, November 14-16, 2023
- EvercoreISI HealthCONx, November 28-30, 2023

Access links for available webcasts for these investor conferences will be available on the Sangamo website in the Investors and Media section under [Events](#). Available materials will be found on the Sangamo website after the event under [Presentations](#).

Conference Call to Discuss Third Quarter 2023 Results

The Sangamo management team will discuss these results on a conference call tomorrow, Thursday, November 2, 2023, at 8:30 a.m. Eastern Time.

Participants should register for, and access, the call using [this link](#). While not required, it is recommended you join 10 minutes prior to the event start. Once registered, participants will be given the option to either dial into the call with the number and unique passcode provided or to use the dial-out option to connect their phone instantly.

An updated corporate presentation is available in the Investors and Media section under [Presentations](#).

The link to access the live webcast can also be found on the Sangamo website in the Investors and Media section under [Events](#). A replay will be available following the conference call, accessible at the same link.

About Sangamo Therapeutics

Sangamo Therapeutics is a clinical-stage biopharmaceutical company with a robust genomic medicines pipeline. Using ground-breaking science, including our proprietary zinc finger genome engineering technology and manufacturing expertise, Sangamo aims to create new genomic medicines for patients suffering from diseases for which existing treatment options are inadequate or currently don't exist. To learn more, visit www.sangamo.com and connect with us on [LinkedIn](#) and [Twitter](#).

Forward-Looking Statements

This press release contains forward-looking statements regarding our current expectations. These forward-looking statements include, without limitation, statements relating to: the therapeutic and commercial potential of our product candidates, the anticipated plans and timelines of Sangamo and our collaborators for screening, enrolling and dosing patients in and conducting our ongoing and potential future clinical trials and presenting clinical data from our clinical trials, including expectations regarding the conclusion of dosing in our Phase 1/2 STAAR study, preparations and plans for patient dosing in the STEADFAST study, the potential for acceleration of the study timeline and the availability of data therefrom, the anticipated advancement of our product candidates to late-stage development, including Sangamo's plans to seek a potential partner or additional financing to proceed with potential future Phase 3 trials of isaralgagene civaparovec and the timing thereof, the timeline to present data from the Phase 3 AFFINE trial and to make BLA and MAA submissions for giroctocogene fitelparovec, expectations regarding advancement of our preclinical neurology programs, including announcement of data from, and anticipated IND submissions related to, such programs, plans to seek a partner for or investor in our CAR-Treg program, expectations concerning our strategic prioritization and restructuring, including plans to close our Brisbane facility and the expected charges and cost savings associated with such restructuring, future potential cost reductions, our expected cash runway, our 2023 financial guidance related to GAAP and non-GAAP total operating expenses, impairments and stock-based compensation, our plans to participate in industry and investor conferences, and other statements that are not historical fact. These statements are not guarantees of future performance and are subject to certain risks and uncertainties that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to Sangamo's ability to execute its strategic prioritization and restructuring as currently contemplated; the actual charges associated with the restructuring being higher than anticipated or changes to the assumptions on which the estimated charges associated with the restructuring are based; Sangamo's ability to achieve projected cost savings in connection with the restructuring and to further reduce operating expenses; unintended consequences from the restructuring that impact Sangamo's business; our lack of capital resources to fully develop, obtain regulatory approval for and commercialize our product candidates, including our ability to secure the funding required to initiate a potential Phase 3 trial of isaralgagene civaparovec in a timely manner or at all; our need for substantial additional funding to execute our operating plan and to continue to operate as a going concern; the potential of our preclinical programs utilizing zinc finger technology to address neurological health disorders; the effects of macroeconomic factors or financial challenges, including as a result of the ongoing overseas conflict, current or potential future bank failures, inflation and rising interest rates, on the global business environment, healthcare systems and business and operations of Sangamo and our collaborators, including the initiation and operation of clinical trials; the research and development process, including the enrollment, operation and results of clinical trials and the presentation of clinical data; the impacts of clinical trial delays, pauses and holds on clinical trial timelines and commercialization of product candidates; the uncertain timing and unpredictable nature of clinical trial results, including the risk that therapeutic effects in the Phase 3 AFFINE trial will not be durable in patients as well as the risk that the therapeutic effects observed in the latest preliminary clinical data from the Phase 1/2 STAAR study will not be durable in patients and that final clinical trial data from the study will not validate the safety and efficacy of isaralgagene civaparovec, and that the patients withdrawn from ERT will remain off ERT; the unpredictable regulatory approval process for product candidates across multiple regulatory authorities; reliance on results of early clinical trials, which results are not necessarily predictive of future clinical trial results, including the results of any Phase 3 trial of our product candidates; the potential for technological developments that obviate technologies used by Sangamo; our reliance on collaborators and our potential inability to secure additional collaborations, and our ability to achieve expected future financial performance.

There can be no assurance that we and our collaborators will be able to develop commercially viable products. Actual results may differ materially from those projected in these forward-looking statements due to the risks and uncertainties described above and other risks and uncertainties that exist in the operations and business environments of Sangamo and our collaborators. These risks and uncertainties are described more fully in our Securities and Exchange Commission, or SEC, filings and reports, including in our Annual Report on Form 10-K for the year ended December 31, 2022, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 to be 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 announcement are made as of this date, and we undertake no duty to update such information except as required under applicable law.

Non-GAAP Financial Measures

To supplement our financial results and guidance presented in accordance with GAAP, we present non-GAAP operating expenses, which excludes stock-based compensation expense and impairment of goodwill, indefinite-lived intangible assets and long-lived assets from GAAP operating expenses. We believe that this non-GAAP financial measure, when considered together with our financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare our results from period to period and to our forward-looking guidance, and to identify operating trends in our business. We have excluded stock-based compensation expense because it is a non-cash expense that may vary significantly from period to period as a result of changes not directly or immediately related to the operational performance for the periods presented, and we have excluded impairment of goodwill, indefinite-lived intangible assets and long-lived assets to facilitate a more meaningful evaluation of our current operating performance and comparisons to our operating performance in other periods. This non-GAAP financial measure is in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. We encourage investors to carefully consider our results under GAAP, as well as our supplemental non-GAAP financial information, to more fully understand our business.

SELECTED CONSOLIDATED FINANCIAL DATA

(unaudited; in thousands, except per share data)

Statement of Operations Data:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Revenues	\$ 9,398	\$ 26,460	\$ 174,190	\$ 84,069
Operating expenses:				
Research and development	57,089	65,116	183,351	183,719
General and administrative	13,918	16,238	48,068	46,239
Impairment of goodwill and indefinite-lived intangible assets	-	-	89,485	-
Impairment of long-lived assets	44,799	-	65,232	-
Total operating expenses	115,806	81,354	386,136	229,958
Loss from operations	(106,408)	(54,894)	(211,946)	(145,889)
Interest and other income, net	3,515	1,769	9,610	5,754
Loss before income taxes	(102,893)	(53,125)	(202,336)	(140,135)
Income tax expense (benefit)	1,270	30	(4,800)	170
Net loss	\$ (104,163)	\$ (53,155)	\$ (197,536)	\$ (140,305)
Basic and diluted net loss per share	\$ (0.59)	\$ (0.34)	\$ (1.14)	\$ (0.93)
Shares used in computing basic and diluted net loss per share	177,171	158,042	173,375	150,850

Selected Balance Sheet Data:

	September 30,	
	2023	December 31, 2022
Cash, cash equivalents, and marketable securities	\$ 132,111	\$ 307,477
Total assets	\$ 219,697	\$ 562,509
Total stockholders' equity	\$ 134,922	\$ 294,958

View source version on [businesswire.com](https://www.businesswire.com/news/home/20231101893355/en/): <https://www.businesswire.com/news/home/20231101893355/en/>

Investor Relations & Media Inquiries

Louise Wilkie

ir@sangamo.com

media@sangamo.com

Source: Sangamo Therapeutics, Inc.