# Sangamo Therapeutics Announces Strategic Update and Reports Preliminary First Quarter 2023 Financial Results

April 26, 2023

- *Strong clinical momentum continues in Phase 1/2 STAAR study in Fabry disease with 20 patients dosed in total.*
- *Dosed third patient in cohort 1 of Phase 1/2 CAR-Treg STEADFAST study for TX200 in HLA A2 mismatched kidney transplantation.*
- *Unveiled Nav1.7 target to treat chronic neuropathic pain as flagship program of wholly owned neurology epigenetic regulation pipeline, with IND submission expected in 2024.*
- *Announced strategic pipeline prioritization and corporate restructuring, including US workforce reduction of approximately 27%.*
- *Conference call and webcast scheduled for Thursday, April 27 at 8:30 a.m. Eastern Time.*

BRISBANE, Calif.--(BUSINESS WIRE)--Apr. 26, 2023-- Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicines company, today announced recent business highlights, including a strategic pipeline prioritization and restructuring, and reported certain preliminary first quarter 2023 financial results.

“This quarter, Sangamo continued to advance its clinical and pre-clinical pipeline. Our Phase 1/2 Fabry study continues to enroll and dose patients, alongside preparations for a potential Phase 3 trial expected to commence by the end of 2023. We successfully dosed the third patient with TX200, our CAR-Treg therapy in kidney transplantation, and received positive regulatory feedback from the first two European authorities required to accelerate the dose escalation. We are also excited to unveil Nav 1.7 as the prioritized target in our wholly owned neurology epigenetic regulation pipeline,” said Sandy Macrae, Chief Executive Officer of Sangamo. “Today’s environment necessitates careful choices when deciding how many programs to take forward at once. We are therefore announcing a sharpened strategic focus, prioritizing our investments in our most promising programs. This has led to difficult, but necessary, decisions to step away from certain pre-clinical assets, shrink parts of our infrastructure and redeploy investments towards realizing the full potential of what we believe are our most valuable programs.”

The restructuring announced today is the result of a strategic decision to increase focus on three key areas: Nav 1.7 and Prion as cornerstones to the neurology epigenetic regulation portfolio; Fabry Phase 3 readiness; and the TX200 CAR-Treg clinical study, alongside a broader rightsizing of resources and investments across the company. Additionally, Sangamo expects to significantly reduce its internal manufacturing and allogeneic research footprints in California. As a result of this restructuring, Sangamo is reducing its US workforce by approximately 27%, or approximately 120 roles. These actions are in addition to the previously announced portfolio prioritization which resulted in the decision to seek a partner for our sickle cell disease program. In addition, R. Andrew Ramelmeier, Ph.D., Executive Vice President, Technical Operations will be leaving the company on July 10, 2023. Phillip Ramsey, currently serving as Vice President, Technical Development, has been appointed as Head of Technical Operations effective May 29, 2023.

The restructuring plus other planned cost reduction initiatives are expected to result in annualized savings of approximately $31 million. Sangamo believes its available cash, cash equivalents and marketable securities as of March 31, 2023, in combination with the other expected cost reductions, will be sufficient to fund its planned operations for at least the next 12 months. Sangamo expects to incur approximately $5 million - $7 million in one-time restructuring costs in the second and third quarters of 2023. Sangamo is assessing ways to further reduce annual operating expenses, consistent with the prioritized objectives and progress of the company.

“I am grateful to all our employees for their commitment to Sangamo and dedication to patients, and have special gratitude to those who are leaving for all they have done to advance our mission. Additionally, I would like to personally thank Andy for the passion, dedication and leadership he has brought to Sangamo. He leaves a great legacy of technical excellence and I wish him well in the future.”

**Recent Business Highlights**

***Neurology Epigenetic Regulation Programs –*** *Unveiled Nav1.7 program to treat chronic neuropathic pain as flagship program in prioritized wholly owned neurology pipeline; made strategic decision to pause further development of other pre-clinical programs following conclusion of collaborations with Biogen and Novartis.*

- Announced Nav1.7 to treat chronic neuropathic pain as flagship program in Sangamo’s newly prioritized wholly owned neurology pipeline, with an IND submission expected in 2024. First data from this program expected to be published via a platform presentation at the upcoming American Society for Cell and Gene Therapy (ASGCT) 26$^{th}$ Annual Meeting in Los Angeles in May 2023.
- Advanced wholly owned prion disease program, with an IND submission anticipated in 2025.
- Continued to advance identification and selection of engineered AAV capsids for enhanced central nervous system delivery.
- Following a strategic portfolio evaluation, decided to pause further development of programs previously partnered with Biogen and Novartis, pending the identification of a suitable capsid for delivery for those specific indications.

***Fabry disease*** *– Dosed three additional patients in Phase 1/2 STAAR study; advancing Phase 3 trial design planning in anticipation of FDA meeting in the summer; expect to begin pivotal trial by end of 2023.*

- 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 20 patients dosed to date. We expect dosing to conclude by the end of 2023.
- Plan to meet with the FDA on proposed Phase 3 study design in the summer and anticipate commencement of the pivotal trial in the second half of 2023, with dosing of the first patient expected to start as early as the first part of 2024.

***Renal Transplant Rejection*** *– Dosed third patient in cohort 1; preparations for higher dose cohort underway; efforts to accelerate dose escalation advancing through regulatory reviews; prioritizing near-term autologous portfolio, resulting in the relocation of allogeneic development and manufacturing activities.*

- Dosed third patient in cohort 1 in 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 three patients dosed to date.
- Received positive regulatory feedback for accelerated dose escalation protocol from two European agencies to date.
- Plan to share initial data from cohort 1 by the end of 2023.
- Intend to prioritize near-term autologous portfolio, resulting in decision to transition all remaining allogeneic research activities from Sangamo US to Sangamo France, and to cease cell therapy manufacturing in California.

***Hemophilia A (Pfizer)*** *– Dosing of patients in Phase 3 AFFINE trial to support primary analysis complete; pivotal data read-out expected in mid-2024; BLA and MAA submissions anticipated in second half of 2024.*

- Dosing of patients to support primary analysis 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.

***American Society of Gene and Cell Therapy (ASGCT) 26$^{th}$ Annual Meeting*** *– 14 Sangamo abstracts accepted.*

- A total of 14 Sangamo abstracts were accepted for presentation at ASGCT on May 16-20, 2023, in Los Angeles, California, including pre-clinical updates from our prioritized neurology programs Nav 1.7 and Prion, innovations in our epigenetic regulation platform and advances in our AAV capsid engineering program.

**Preliminary First Quarter 2023 Financial Results**

Sangamo is in the process of completing its customary quarter-end close and review procedures, including the evaluation of non-cash charges related to impairment of long-lived assets, as of and for the quarter ended March 31, 2023, and the final results for this period could materially differ from the preliminary expected results disclosed in this press release. Sangamo's full first quarter 2023 financial results will be reflected in a Quarterly Report on Form 10-Q which is expected to be filed no later than May 10, 2023. The financial performance measures presented in this press release for the first quarter of 2023 are forward-looking statements, preliminary estimates and unaudited, based on management's initial review of the information presented, and are thus inherently uncertain and subject to change as Sangamo completes its end-of-period reporting process and related activities for the first quarter of 2023. During the course of the review of Sangamo's condensed consolidated financial statements and related notes as of and for the quarter ended March 31, 2023, Sangamo's independent registered public accountants may identify items that could cause final reported results to be materially different from the preliminary estimates presented herein. Additional information and disclosures would be required for a more complete understanding of Sangamo's financial position and results of operations as of and for the quarter ended March 31, 2023. Accordingly, undue reliance should not be placed on this preliminary information.

*Revenues*

Revenues for the first quarter ended March 31, 2023, are estimated to be approximately $158.0 million, compared to $28.2 million for the same period in 2022.

The estimated increase of $129.8 million in revenues is primarily attributable to an increase of $121.1 million in revenue relating to our collaboration agreement with Biogen, mainly due to the impact of termination related contract modification, and an increase of $6.0 million in revenue relating to our collaboration agreement with Kite, mainly due to a reduction in the estimated project costs, which resulted in an adjustment to the measure of proportional cumulative performance.

*Operating Expenses*

Total operating expenses on a GAAP basis for the first quarter ended March 31, 2023, are estimated to be in the range of $120 million to $140 million, compared to $73.5 million for the same period in 2022.

The total estimated operating expenses on a GAAP basis for the quarter included certain non-cash charges such as impairment of goodwill of $38.1 million, and impairment of long-lived assets of up to $20 million. These estimated charges are a result of the termination of our collaboration agreements with Biogen and Novartis, a sustained decline in our stock price and related market capitalization and a general decline in equity values in the biotechnology industry.

*Cash, Cash Equivalents and Marketable Securities*

Cash, cash equivalents and marketable securities as of March 31, 2023 were $241.0 million, compared to $307.5 million as of December 31, 2022.

Sangamo believes its available cash, cash equivalents and marketable securities as of March 31, 2023, in combination with the other expected cost reductions, will be sufficient to fund its planned operations for at least the next 12 months.

*Financial Guidance for 2023 Updated*

In line with the business announcements outlined, we are revising our full-year operating expense guidance as follows:

- GAAP operating expenses, including goodwill and long-lived assets impairment charges and stock-based compensation expense, are estimated to be in the range of approximately $315 million to $335 million (updated on April 26, 2023). The previous GAAP operating expenses guidance provided on February 22, 2023 was in the range of approximately $310 million to $330 million.
- Non-GAAP operating expenses are estimated to be in the range of approximately $240 million to $260 million (updated on April 26, 2023). Estimated non-GAAP operating expenses exclude impairment of goodwill of $38 million, impairment of long-lived assets of up to $20 million and stock-based compensation expense of $35 million. The previous non-GAAP operating expenses guidance provided on February 22, 2023 was in the range of approximately $275 million to $295 million.

**Upcoming Events**

Sangamo plans to participate in the following events:

*Scientific / Medical Conferences*

- ASGCT 26th Annual Meeting, Los Angeles, California, May 16-20, 2023

*Investor Conferences*

- 2023 Bank of America Global Healthcare Conference, May 9, 2023
- 2023 RBC Global Healthcare Conference, May 17, 2023
- 7th Annual Barclays Gene Editing and Gene Therapy Summit, May 24, 2023
- Stifel 2023 Tailoring Genes: Genetic Medicines Day, May 30, 2023
- Jefferies Global Healthcare Conference, June 8, 2023
- 2023 Wedbush Pacgrow Healthcare Conference, August 8-9, 2023
- 2023 Wells Fargo Healthcare Conference, September 6-8, 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 Business Updates and Preliminary First Quarter 2023 Results**

The Sangamo management team will discuss these business updates and preliminary results on a conference call tomorrow, Thursday, April 27, 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: our preliminary estimated operating results for the quarter ended March 31, 2023, 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 and the potential for acceleration of the study timeline, the anticipated advancement of our product candidates to late-stage development, including potential future Phase 3 trials of isaralgagene civaparvovec and the timing thereof, the availability and presentation of data from the Phase 3 AFFINE trial, and plans for a BLA and MAA submission for giroctocogene fitelparvovec, expectations regarding advancement of our preclinical neurology programs, including announcement of data from, and anticipated IND submissions related to, such programs, the potential for a partner for our sickle cell disease program; expectations concerning our strategic prioritization and restructuring, including plans to reduce our manufacturing and allogenic research footprints and the expected charges and cost savings associated with such restructuring, future cost reductions, our expected cash runway, our 2023 financial guidance related to GAAP and non-GAAP total operating expenses 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 impediments to adjustments to Sangamo's preliminary measures of financial performance resulting from, among other things, the completion of Sangamo's financial close procedures; 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; the effects of macroeconomic factors or financial challenges, including as a result of the ongoing conflict between Russia and Ukraine, the COVID-19 pandemic and current or potential future bank failures, 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, including data from kidney biopsies, and the Phase 1/2 PRECIZN-1 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 civaparvovec, 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; our limited experience manufacturing biopharmaceutical products, including the risks that we may be unable to maintain compliant manufacturing facilities, build additional facilities and manufacture our product candidates as intended; the potential for technological developments that obviate technologies used by Sangamo; our lack of capital resources to fully develop, obtain regulatory approval for and commercialize our product candidates, and our related need for substantial additional funding to execute our operating plan and to continue to operate as a going concern; our reliance on collaborators and our potential inability to secure additional collaborations, including for our sickle cell disease program; 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 March 31, 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 guidance presented in accordance with GAAP, we present non-GAAP total operating expenses financial guidance, which exclude stock-based compensation expense and impairment of goodwill and long-lived assets from GAAP total operating expenses. We believe that these non-GAAP financial measures, 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 and long-lived assets to facilitate a more meaningful evaluation of our current operating performance and comparisons to our operating performance in other periods. These non-GAAP financial measures are 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.*

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