



Sangamo Therapeutics Reports Recent Business Highlights and Second Quarter 2022 Financial Results

August 4, 2022

Conference Call and Webcast Scheduled for 4:30 p.m. Eastern Time

BRISBANE, Calif.--(BUSINESS WIRE)--Aug. 4, 2022-- Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicines company, today reported recent business highlights and second quarter 2022 financial results.

"We made meaningful progress advancing our clinical-stage programs in the second quarter," said Sandy Macrae, Chief Executive Officer of Sangamo. "We are engaging in pivotal study-enabling activities in two of our clinical stage programs and are preparing to complete dosing of the first cohort in our TX200 program, which recently received Orphan Medicinal Product Designation from the European Commission. Coupled with strong advances in our preclinical pipeline, we believe this progress positions us well to advance the development of potentially transformational genomic medicines for patients in need and to generate long-term value for our shareholders."

Recent Business Highlights

Fabry disease – *Received endorsement to progress into the Ph1/2 study's expansion phase; continued to recruit patients and activate sites; Phase 3 planning progresses.*

- In June, the Safety Monitoring Committee endorsed progressing the Phase 1/2 STAAR study evaluating isaralgagene civaparvovec, our wholly owned gene therapy product candidate for the treatment of Fabry disease, from the dose escalation phase into the expansion phase at the dose level of 5×10^{13} vg/kg.
- We expect to dose two additional patients imminently, and have multiple patients in screening, including both male and female candidates.
- Enzyme replacement therapy (ERT) withdrawal was completed for an additional two patients previously dosed in the STAAR study, achieving a total of four patients to date who have successfully been withdrawn.
- A total of 16 study sites are now open and recruiting, including the first sites in Canada, Italy and Australia.
- We plan to provide updated results from the STAAR study in the second half of 2022, including at the Society for the Study of Inborn Errors of Metabolism (SSIEM) Annual Symposium, taking place August 30-September 2, 2022.
- We continue to actively prepare for a potential pivotal Phase 3 trial.

Sickle cell disease – *Completed transition of program back to Sangamo; advanced manufacturing activities in anticipation of dosing in Q3; Phase 3 planning progresses.*

- We completed the transition of Sanofi's rights and obligations under the collaboration developing BIVV003, formerly known as SAR445136, our zinc finger nuclease gene-edited cell therapy candidate for the treatment of sickle cell disease, back to Sangamo on June 28, 2022.
- Manufacturing of product candidates using improved methods progressed in the Phase 1/2 study. These improved manufacturing methods have been shown in internal experiments to increase the number of long-term progenitor cells in the final product.
- Dosing of the next patient is anticipated in the third quarter of 2022.
- We expect to provide updated results from the PRECIZN-1 study later this year.
- Phase 3 enabling activities and manufacturing readiness are in progress.

Hemophilia A – *Pfizer advised us that it continues to expect resumption of dosing in Q3 2022; pivotal data read-out expected in late 2023 or early 2024.*

- Pfizer advised us that it continues to anticipate resuming the dosing of additional patients 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, in the third quarter of 2022.
- A pivotal data readout is estimated in late 2023 or early 2024.
- Over 50% of the patients have been enrolled in the Phase 3 AFFINE trial.

Renal Transplant Rejection – *Received Orphan Medicinal Product Designation from the European Commission; progressed manufacturing and clinical activities ahead of anticipated Q3 dosing.*

- Since we dosed the first patient 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, with no treatment related adverse events.

- We completed manufacturing of the dose for the second patient, who recently received a kidney transplant. Dosing of this second patient is expected later in the third quarter of 2022.
- We plan to complete dosing of the first cohort, comprised of three patients, by the end of 2022.
- The European Commission granted Orphan Medicinal Product Designation to TX200, for treatment in solid organ transplantation, following a positive opinion from the European Medicines Agency's Committee for Orphan Medicinal Products.

American Society of Gene and Cell Therapy (ASGCT) – Profiled significant pre-clinical progress across Sangamo's innovative pipeline and platform.

- Presented seven posters and one oral presentation at ASGCT on May 16-19, 2022, including pre-clinical updates across our CAR-Treg autoimmune cell therapy platform, innovations in our genome engineering platform and advances in our AAV capsid engineering program.

Second Quarter 2022 Financial Results

Consolidated net loss for the second quarter ended June 30, 2022, was \$43.2 million, or \$0.29 per share, compared to a net loss of \$47.2 million, or \$0.33 per share, for the same period in 2021.

Revenues

Revenues for the second quarter ended June 30, 2022, were \$29.4 million, compared to \$27.9 million for the same period in 2021.

The increase of \$1.5 million in revenues was primarily attributed to an increase of \$1.3 million in revenue related to our collaboration agreement with Novartis and an increase of \$0.8 million in revenue related to our collaboration agreement with Sanofi. These increases were partially offset by a decrease of \$0.7 million in revenue related to our collaboration agreement with Biogen.

GAAP and Non-GAAP operating expenses

(In millions)	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2022	2021	2022	2021
Research and development	\$ 60.0	\$ 60.1	\$ 118.6	\$ 116.6
General and administrative	15.1	16.5	30.0	32.6
Total operating expenses	75.1	76.6	148.6	149.2
Stock-based compensation expense	(7.9)	(9.5)	(15.6)	(17.1)
Non-GAAP operating expenses	\$ 67.2	\$ 67.1	\$ 133.0	\$ 132.1

Total operating expenses on a GAAP basis for the second quarter ended June 30, 2022, were \$75.1 million, compared to \$76.6 million for the same period in 2021. Non-GAAP operating expenses, which exclude stock-based compensation expense, for the second quarter ended June 30, 2022, were \$67.2 million, compared to \$67.1 million for the same period in 2021.

The decrease in total operating expenses on a GAAP basis was primarily due to the timing of certain research and development activities.

Cash, cash equivalents and marketable securities

Cash, cash equivalents and marketable securities as of June 30, 2022, were \$363.7 million, compared to \$464.7 million as of December 31, 2021. Since the beginning of the second quarter, we have raised approximately \$43.1 million in net proceeds under our previously announced at the market offering program.

Financial Guidance for 2022 Reiterated (initial guidance provided on February 24, 2022)

On a GAAP basis, we continue to expect total operating expenses in the range of approximately \$320 million to \$350 million in 2022, which includes non-cash stock-based compensation expense.

We continue to expect non-GAAP total operating expenses, excluding estimated non-cash stock-based compensation expense of approximately \$40 million, in the range of approximately \$280 million to \$310 million in 2022.

Upcoming Events

Sangamo plans to participate in the following events in the third quarter:

Scientific / Medical Conferences

- Society for the Study of Inborn Errors of Metabolism (SSIEM), August 30-September 2, 2022, Freiburg, Germany
- Prion 2022, September 13-16, 2022, Gottingen, Germany

Investor Conferences

- Wedbush PacGrow Healthcare Conference, August 9-10, 2022 [9:10-9:40am EDT]
- H.C. Wainwright 24th Annual Global Investment Conference, September 12-14, 2022

- Jefferies Cell and Genetic Medicine Summit, September 29-30, 2022

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

Conference Call to Discuss Second Quarter 2022 Results

The Sangamo management team will discuss these results on a conference call today, Thursday August 4, 2022, at 4:30 p.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.

The link to access the live webcast can also be found on the Sangamo Therapeutics website in the Investors and Media section under [Events and Presentations](#).

A replay will be available following the conference call, accessible under [Events and Presentations](#).

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 and their ability to generate value for our shareholders, 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 plans to dose patients in the expansion phase of, and the presentation of updated clinical data from, the Phase 1/2 STAAR study and updates regarding the PRECIZN-1 study, the dosing of patients with product candidates using improved manufacturing methods in the PRECIZN-1 study and the potential impacts thereof, as well as the timing and expectations for completion of dosing in such study, the expected timeline for dosing additional patients in the STEADFAST study, the anticipated advancement of our product candidates to late-stage development including potential future Phase 3 trials, plans and timing regarding the expected resumption of dosing of patients in the Phase 3 AFFINE trial and the presentation of data from such trial, our 2022 financial guidance related to GAAP and non-GAAP total operating expenses and stock-based compensation, 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 the effects of the evolving COVID-19 pandemic and the impacts of the pandemic and other macroeconomic factors, including as a result of the ongoing conflict between Russia and Ukraine, 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 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 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, or BIVV003 (formerly known as SAR44513); the unpredictable regulatory approval process for product candidates across multiple regulatory authorities, including the potential that health authorities will not issue the required protocol amendment approvals in the Phase 3 AFFINE trial in a timely manner, or at all; 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; the potential that Sangamo will not be able to identify and secure options or new collaborators for the BIVV003 program; the potential for Sangamo to cease development of the BIVV003 program, whether due to its inability to secure options to advance the program or otherwise; our lack of resources to fully develop, obtain regulatory approval for and commercialize our product candidates; 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 filings and reports, including in our Annual Report on Form 10-K for the year ended December 31, 2021 as supplemented by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022. 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 total operating expenses, which exclude stock-based compensation expense from GAAP total 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. 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		Six months ended	
	June 30,		June 30,	
	2022	2021	2022	2021
Revenues	\$ 29,378	\$ 27,872	\$ 57,609	\$ 54,152
Operating expenses:				
Research and development	60,019	60,086	118,603	116,520
General and administrative	15,093	16,486	30,001	32,634
Total operating expenses	75,112	76,572	148,604	149,154
Loss from operations	(45,734)	(48,700)	(90,995)	(95,002)
Interest and other income, net	2,643	1,550	3,985	2,176
Loss before income taxes	(43,091)	(47,150)	(87,010)	(92,826)
Income tax (benefit) expense	82	24	140	287
Net loss	\$ (43,173)	\$ (47,174)	\$ (87,150)	\$ (93,113)
Net loss attributable to non-controlling interest	-	(5)	-	(11)
Net loss attributable to Sangamo Therapeutics, Inc. stockholders	\$ (43,173)	\$ (47,169)	\$ (87,150)	\$ (93,102)
Basic and diluted net loss per share attributable to Sangamo Therapeutics, Inc. stockholders	\$ (0.29)	\$ (0.33)	\$ (0.59)	\$ (0.65)
Shares used in computing basic and diluted net loss per share attributable to Sangamo Therapeutics, Inc. stockholders	148,158	143,984	147,194	143,550

Selected Balance Sheet Data:

	June 30, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	\$ 363,688	\$ 464,717
Total assets	\$ 617,126	\$ 721,923
Total stockholders' equity	\$ 318,281	\$ 375,343

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