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

May 5, 2022

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

BRISBANE, Calif.--(BUSINESS WIRE)--May 5, 2022-- Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicines company, today reported recent business highlights and first quarter 2022 financial results.

"This quarter, we have continued to progress multiple programs through clinical development and demonstrated, once again, Sangamo's track record of advancing groundbreaking therapies in genomic medicine," said Sandy Macrae, Chief Executive Officer of Sangamo. "We dosed a total of five patients across three programs, including the first patient in our study for the treatment of kidney transplant rejection, in what we believe was the first in human dosing of an engineered CAR-Treg cell therapy product candidate. We believe this progress positions us well to advance transformational genomic medicines for patients in need and to generate long-term value for our shareholders."

Recent Business Highlights

Fabry disease – Dosed three additional patients, resulting in a total of nine patients dosed to date, thereby completing dose escalation for the Phase 1/2 study; Phase 3 planning progresses.

- We dosed two patients in Cohort 4 in the Phase 1/2 STAAR study evaluating isaralgagene civaparvovec, our wholly owned gene therapy product candidate for the treatment of Fabry disease, at a dose level of 5e13 vg/kg.
- In addition, we dosed a third patient in Cohort 3, at the dose level of 3e13 vg/kg.
- In total, we have successfully dosed a total of nine patients across four cohorts to complete the dose escalation portion of the study.
- Enzyme replacement therapy (ERT) withdrawal was completed for a second patient, with no reports to date that the resumption of ERT is required in either patient.
- We expect to provide updated results from the STAAR study in the second half of 2022.
- We continue to actively prepare for the expansion cohorts, as well as a potential pivotal Phase 3 trial.

Sickle cell disease – Dosed fifth patient, the first with a product candidate manufactured using improved methods; Phase 3 planning progresses.

- We dosed the fifth patient in the Phase 1/2 PRECIZN-1 study of SAR445136, a zinc finger nuclease gene-edited cell therapy candidate for the treatment of sickle cell disease, which is under development with Sanofi. This is the first patient in the study to receive a product candidate manufactured using improved methods that have been shown in internal experiments to increase the number of long-term progenitor cells in the final product.
- We plan to dose the remaining patients in this study by the end of the third quarter of 2022.
- We expect to provide updated results from the PRECIZN-1 study in the second half of 2022.
- Phase 3 enabling activities and manufacturing readiness are in progress.
- We continue to collaborate with Sanofi on an orderly transition of Sanofi's rights and obligations under this program back to Sangamo on June 28.

Hemophilia A – FDA lifted clinical hold; Trial remains voluntarily paused; Pfizer expects to resume trial in Q3 2022.

- Pfizer announced that, in March 2022, the FDA lifted the clinical hold that had been placed on 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. Pfizer previously paused this trial when some of the patients experienced FVIII activity greater than 150% following treatment.
- Pfizer also announced that the voluntary pause remains in place until all necessary conditions are met, including approval of updated trial protocols by regulatory authorities.
- In addition, Pfizer announced that a patient with elevated FVIII levels reported a below-the-knee deep vein thrombosis. The patient had a history of thrombotic events prior to participation in the trial, which is a known risk factor for subsequent events and an exclusion criterion for participation in the AFFINE trial. The case was assessed to understand all potential contributing factors, including missed doses of investigator-prescribed direct oral anti-coagulants. The patient is reported to be doing well. The information was shared with trial investigators, health authorities and the independent external Data Monitoring Committee and Pfizer responded to queries from health authorities.
- Pfizer announced that it anticipates resuming this trial in the third quarter of 2022, with a pivotal data readout estimated in the second half of 2023.
- Over 50% of the patients have been enrolled in the Phase 3 AFFINE trial.

Renal Transplant Rejection – Believed to be first-ever in human dosing with an engineered CAR-Treg cell therapy candidate.

- We dosed the first patient in our 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 patient continues to do well, and no adverse events related to treatment have been reported.
- Dosing of the second patient is expected around the middle of 2022, based on their transplant schedule.
- We expect to complete dosing of the first cohort, comprised of three patients, by the end of 2022.

American Society of Gene and Cell Therapy (ASGCT) – Eight abstracts accepted.

- A total of eight Sangamo abstracts were accepted for 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.

First Quarter 2022 Financial Results

Consolidated net loss for the first quarter ended March 31, 2022 was $44.0 million, or $0.30 per share, compared to a net loss of $45.9 million, or $0.32 per share, for the same period in 2021.

Revenues

Revenues for the first quarter ended March 31, 2022 were $28.2 million, compared to $26.3 million for the same period in 2021.

The increase of $2.0 million in revenues was primarily attributed to an increase of $1.0 million related to our collaboration agreement with Novartis, an increase of $0.7 million related to our collaboration agreement with Biogen, and an increase of $0.4 million related to our collaboration agreement with Sanofi.

GAAP and Non-GAAP operating expenses

	Three Months Ended March 31,	
(In millions)	2022	2021
Research and development	$ 58.6	$ 56.5
General and administrative	14.9	16.1
Total operating expenses	73.5	72.6
Stock-based compensation expense	(7.7)	(7.5)
Non-GAAP operating expenses	$ 65.8	$ 65.1

Total operating expenses on a GAAP basis for the first quarter ended March 31, 2022 were $73.5 million, compared to $72.6 million for the same period in 2021. Non-GAAP operating expenses, which exclude stock-based compensation expense, for the first quarter ended March 31, 2022 were $65.8 million, compared to $65.1 million for the same period in 2021.

The increase in total operating expenses on a GAAP basis was primarily driven by our higher preclinical, clinical and lab supply and other R&D expenses along with our increased headcount to support the advancement of our clinical trials and our ongoing collaborations. Manufacturing and overhead costs also increased as we ramp up our internal manufacturing operations.

Cash, cash equivalents and marketable securities

Cash, cash equivalents and marketable securities as of March 31, 2022 were $400.3 million, compared to $464.7 million as of December 31, 2021.

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.

Conference Call

Sangamo will host a conference call today, May 5, 2022, at 4:30 p.m. Eastern Time, which will be open to the public. The call will also be webcast with live Q&A and can be accessed via a link on the Sangamo Therapeutics website in the Investors and Media section under Events and Presentations.

The conference call dial-in numbers are (877) 377-7553 for domestic callers and (678) 894-3968 for international callers. The conference ID number for the call is 3090098. Participants may access the live webcast via a link on the Sangamo Therapeutics website in the Investors and Media section under Events and Presentations. A conference call replay will be available for one week following the conference call. The conference call replay numbers for domestic and international callers are (855) 859-2056 and (404) 537-3406, respectively. The conference ID number for the replay is 3090098.

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. For more information about Sangamo,

visit www.sangamo.com.

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 plans for cohort expansion in, 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, plans and timing for the transition of the SAR445136 program from Sanofi to Sangamo, 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 submission of a protocol amendment in the Phase 3 AFFINE trial and the resumption of dosing of patients in and 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 factors 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; 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 isaralgagene civaparvovec; 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 for Sanofi and Sangamo to fail to come to agreement on appropriate transition agreements or to execute an orderly transition under their collaboration agreement; the potential that Sangamo will not be able to identify and secure options or new collaborators for the SAR445136 program; the potential for Sangamo to cease development of the SAR445136 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 March 31, 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 Measure

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 March 31,	
	2022	2021
Revenues	$ 28,231	$ 26,280
Operating expenses:		
Research and development	58,584	56,434
General and administrative	14,908	16,148
Total operating expenses	73,492	72,582
Loss from operations	(45,261)	(46,302)
Interest and other income, net	1,342	625
Loss before income taxes	(43,919)	(45,677)
Income tax (benefit) expense	58	262
Net loss	$ (43,977)	$ (45,939)
Net loss attributable to non-controlling interest	-	(6)
Net loss attributable to Sangamo Therapeutics, Inc. stockholders	$ (43,977)	$ (45,933)
Basic and diluted net loss per share attributable to Sangamo Therapeutics, Inc. stockholders	$ (0.30)	$ (0.32)

Shares used in computing basic and diluted net loss per share attributable to Sangamo Therapeutics, Inc. stockholders	146,218	143,112

Selected Balance Sheet Data:

	March 31, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 400,311	$ 464,717
Total assets	$ 654,310	$ 721,923
Total stockholders' equity	$ 334,522	$ 375,343

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