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

November 3, 2022

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

BRISBANE, Calif.--(BUSINESS WIRE)--Nov. 3, 2022-- Sangamo Therapeutics, Inc. (Nasdaq: SGMO), a genomic medicines company, today reported recent business highlights and third quarter 2022 financial results.

“This has been a year marked by progress across our pipeline. In the third quarter, we continued to advance our clinical trials and preclinical activities while maintaining fiscal discipline and operational excellence,” said Sandy Macrae, Chief Executive Officer of Sangamo. “We were proud to present promising updated preliminary data from our wholly owned Fabry study, to resume our partnered Hemophilia A pivotal trial, and to continue dosing in our renal transplant rejection and sickle cell studies. Our pipeline progress is expected to yield additional data in Q4 and into 2023. As we look to next year and beyond, I am confident in Sangamo’s ability to carry out our mission of developing transformational therapies for patients in need.”

Recent Business Highlights

Fabry disease *– Reported data updates from the Phase 1/2 STAAR study’s dose escalation phase; Dose expansion phase underway and dosing commenced; Phase 3 planning progresses.*

- Presented updated preliminary data from the Phase 1/2 STAAR study evaluating isaralgagene civaparvovec, our wholly owned gene therapy product candidate for the treatment of Fabry Disease at three separate conferences, most notably at the 29th Congress of the European Society of Gene & Cell Therapy (ESGCT), presenting updated data as of July 21, 2022.
- Preliminary data showed all nine patients from the dose escalation phase exhibited sustained elevated α-Gal A activity, ranging from nearly 2-fold to 30-fold of mean normal, for up to 23 months post dosing, as of the last date of measurement.
- Four patients were withdrawn from enzyme replacement therapy (ERT) and maintained significantly elevated levels of α-Gal A activity up to 28 weeks post withdrawal. Since the cutoff date, the fifth and final patient in the dose escalation phase who started the study on ERT has been withdrawn from ERT. All patients withdrawn have remained off ERT.
- The Phase 1/2 STAAR study has transitioned into the expansion phase, with the first five expansion patients dosed at the 5e13 vg/kg dose level, including the first two female patients.
- We expect to present additional clinical updates from the STAAR study, including the first data from the expansion cohort, in the first half of 2023.
- We continue to actively prepare for a potential pivotal Phase 3 trial.

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

- We dosed the sixth patient in the Phase 1/2 PRECIZN-1 study of BIVV003, a zinc finger nuclease gene-edited cell therapy candidate for the treatment of sickle cell disease. This is the second 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.
- Received Regenerative Medicine Advanced Therapy (RMAT) designation from the FDA for BIVV003.
- We expect to present updated data from the Phase 1/2 PRECIZN-1 study via a poster presentation at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition on December 10-13, 2022 in New Orleans, Louisiana.
- Phase 3 study design, enabling activities and manufacturing readiness are in progress.

Renal Transplant Rejection *– Dosed the second patient in the Phase 1/2* STEADFAST *study; progressed clinical activities in preparation for patient three.*

- Dosed the second 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 in both patients.
- Progressed clinical activities in preparation for the third patient.
- We plan to provide guidance on timing for dosing for the third patient once the kidney transplant has been scheduled.

Hemophilia A *– Announced, with Pfizer, the resumption of recruitment in the Phase 3 AFFINE trial; dosing is expected to resume shortly; pivotal data read-out expected in the first half of 2024.*

- Pfizer and Sangamo announced that recruitment has re-opened 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.

- Trial sites resumed enrollment in September, and dosing is expected to resume shortly.
- A pivotal readout is expected in the first half of 2024.
- We expect to present updated data from the Phase 1/2 ALTA study via a poster presentation at the ASH Annual Meeting in December.

Third Quarter 2022 Financial Results

Consolidated net loss for the third quarter ended September 30, 2022 was $53.2 million, or $0.34 per share, compared to a net loss of $47.7 million, or $0.33 per share, for the same period in 2021.

Revenues

Revenues for the third quarter ended September 30, 2022 were $26.5 million, compared to $28.6 million for the same period in 2021.

The decrease of $2.1 million in revenues was primarily attributable to a decrease of $1.9 million and $1.6 million related to our collaboration agreements with Novartis and Biogen respectively, and a decrease of $1.1 million due to the termination of our collaboration agreement with Sanofi. These decreases were partially offset by a $1.9 million adjustment to revenue during 2021 related to the collaboration agreement with Sanofi and an increase of $0.5 million in revenue related to our collaboration agreement with Kite.

GAAP and Non-GAAP operating expenses

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 65.1	$ 62.5	$ 183.7	$ 179.0
General and administrative	16.2	14.5	46.2	47.1
Total operating expenses	81.3	77.0	229.9	226.1
Stock-based compensation expense	(7.8)	(7.9)	(23.4)	(24.9)
Non-GAAP operating expenses	$ 73.5	$ 69.1	$ 206.5	$ 201.2

Total operating expenses on a GAAP basis for the third quarter ended September 30, 2022 were $81.3 million, compared to $77.0 million for the same period in 2021. Non-GAAP operating expenses, which exclude stock-based compensation expense, for the third quarter ended September 30, 2022 were $73.5 million, compared to $69.1 million for the same period in 2021.

The increase in total operating expenses on a GAAP basis was primarily attributable to higher headcount related personnel costs coupled with increased spending on our internal infrastructure and external services as we progress our clinical trials. These increases were partially offset by reimbursement of certain research and development expenses by Sanofi under the termination agreement.

Cash, cash equivalents and marketable securities

Cash, cash equivalents and marketable securities as of September 30, 2022, were $350.3 million, compared to $464.7 million as of December 31, 2021. We have raised approximately $75.1 million in net proceeds under our at-the-market offering program from January 1, 2022 through October 31, 2022.

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

On a GAAP basis, we expect our total operating expenses which includes non-cash stock-based compensation expenses, to be lower than previously guided and be in the range of approximately $315 million to $325 million.

We expect our non-GAAP total operating expenses, excluding estimated non-cash stock-based compensation expenses of approximately $35 million, to be in the range of approximately $280 million to $290 million.

Upcoming Events

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

Scientific / Medical Conferences

- 64th American Society of Hematology (ASH) Annual Meeting & Exposition, December 10-13, New Orleans, Louisiana

Investor Conferences

- 31st Annual Credit Suisse Healthcare Conference, November 8, 2022
- Barclays Gene Editing & Gene Therapy Summit, November 14, 2022
- Stifel Healthcare Conference, November 15, 2022
- Jefferies London Healthcare Conference, November 16, 2022
- EvercoreISI HealthCONxConference, November 29 - December 1, 2022

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

Conference Call to Discuss Third Quarter 2022 Results

The Sangamo management team will discuss these results on a conference call today, Thursday November 3, 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, 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 presentation of updated clinical data from the Phase 1/2 STAAR study, 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, and preparations and plans for dosing the third patient in the STEADFAST study, the anticipated advancement of our product candidates to late-stage development, including potential future Phase 3 trials of isaralgagene civaparvovec and BIVV003, plans and timing regarding the expected resumption of dosing of patients in the Phase 3 AFFINE trial and the availability 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 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 impacts of clinical trial delays, pauses and holds on clinical trial timelines and commercialization of product candidates, including the risk that any necessary conditions to resume dosing of patients in the Phase 3 AFFINE trial are not met in a timely manner, or at all; 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, 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; 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 September 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	**Nine months ended**

	September 30,		September 30,	
	2022	2021	2022	2021
Revenues	$ 26,460	$ 28,563	$ 84,069	$ 82,715
Operating expenses:				
Research and development	65,116	62,498	183,719	179,018
General and administrative	16,238	14,501	46,239	47,135
Total operating expenses	81,354	76,999	229,958	226,153
Loss from operations	(54,894)	(48,436)	(145,889)	(143,438)
Interest and other income, net	1,769	834	5,754	3,010
Loss before income taxes	(53,125)	(47,602)	(140,135)	(140,428)
Income tax expense	30	86	170	373
Net loss	$ (53,155)	$ (47,688)	$(140,305)	$(140,801)
Net loss attributable to non-controlling interest	-	-	-	(11)
Net loss attributable to Sangamo Therapeutics, Inc. stockholders	$ (53,155)	$ (47,688)	$(140,305)	$(140,790)
Basic and diluted net loss per share attributable to Sangamo Therapeutics, Inc. stockholders	$ (0.34)	$ (0.33)	$ (0.93)	$ (0.98)
Shares used in computing basic and diluted net loss per share attributable to Sangamo Therapeutics, Inc. stockholders	158,042	145,399	150,850	144,173

Selected Balance Sheet Data:

	September 30, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 350,268	$ 464,717
Total assets	$ 593,913	$ 721,923
Total stockholders' equity	$ 309,154	$ 375,343

View source version on businesswire.com: https://www.businesswire.com/news/home/20221103005505/en/

Investor Relations & Media Inquiries
Louise Wilkie
ir@sangamo.com
media@sangamo.com

Source: Sangamo Therapeutics, Inc.