Sangamo Therapeutics Logo

Sangamo Therapeutics Reports Second Quarter 2019 Financial Results

August 7, 2019

Conference Call and Webcast Scheduled for 5:00 p.m. Eastern Time

BRISBANE, Calif.--(BUSINESS WIRE)--Aug. 7, 2019-- Sangamo Therapeutics, Inc. (NASDAQ: SGMO), a genomic medicine company, today reported second quarter 2019 financial results and recent business highlights.

“We continue to progress our strategy to develop our diversified portfolio of genomic medicine product candidates using our expertise in gene therapy, cell therapy, genome editing and gene regulation,” said Sandy Macrae, CEO of Sangamo. “Last month, we reported updated results for SB-525, our investigational gene therapy for hemophilia A. We are pleased with the emerging clinical profile and competitive positioning of SB-525 and are preparing for a Phase 3 registrational study with our partner Pfizer. The THALES study evaluating ST-400, a gene-edited cell therapy for beta thalassemia being developed with Sanofi, is progressing well and recently enrolled a fourth patient. In the upcoming months, two of our wholly owned programs, ST-920, an investigational gene therapy for Fabry disease, and TX-200, our first CAR-Treg product candidate, are also expected to advance into the clinic.”

“We have observed significant increases in efficacy above a defined vector dose threshold with AAV6, the vector we use in our hemophilia gene therapy and our *in vivo* genome editing clinical programs,” Dr. Macrae continued. “These recent insights into the kinetics of AAV6 suggest rational methods for improving the delivery of zinc finger nucleases, which we believe may substantially enhance the efficacy of *in vivo* genome editing, especially when added to the significantly increased potency that we expect to obtain with our updated gene editing reagents. We believe we can integrate these improvements rapidly and plan to introduce them as the next step forward for our *in vivo* genome editing clinical development programs. Based on current assumptions, including the timelines for manufacturing, we now expect that our next *in vivo* genome editing clinical trial will commence by year end 2020.”

Recent Highlights

Clinical

- In partnership with Pfizer, presented updated Phase 1/2 data for SB-525, an investigational gene therapy for the treatment of adults with hemophilia A. The data showed that SB-525 was generally well-tolerated and demonstrated a dose-dependent increase in Factor VIII (FVIII) activity levels. The first two patients treated at the 3e13 vg/kg dose rapidly achieved normal levels of FVIII activity, with no reported bleeding events or exogenous FVIII usage. The response was durable for at least 24 weeks, the extent of follow-up at the time of the data cut-off. The two patients most recently treated at the 3e13 vg/kg dose level are demonstrating FVIII activity kinetics that appear consistent with the first two patients treated in this dose cohort at similar early time points.
- In July, dosed the fifth patient in the 3e13 vg/kg cohort (Patient 11 in the study), completing enrollment of the Phase 1/2 study evaluating SB-525
- United States Food and Drug Administration granted regenerative medicine advanced therapy (RMAT) designation for SB-525 gene therapy to treat severe hemophilia A
- Preparations have begun to advance SB-525 into a Phase 3 registrational clinical trial, including engagement with regulators and initiating the transfer of the SB-525 manufacturing process to Pfizer
- Enrolled a fourth patient into the Phase 1/2 clinical trial for ST-400, an *ex vivo* gene-edited cell therapy candidate for the treatment of beta thalassemia, which is being developed in partnership with Sanofi. Sanofi is conducting a Phase 1/2 clinical trial evaluating BIVV003, a separate but related gene-edited cell therapy candidate for sickle cell disease.
- Activated the first clinical site for the STAAR study evaluating ST-920, an investigational gene therapy candidate for Fabry disease. Sangamo expects to enroll the first patient by year end 2019.
- Remain on track to file CTA in 2019 for TX200, a CAR-Treg product candidate, in HLA-A2 mismatched kidney transplantation
- Kite, a Gilead Company, is planning to initiate a clinical study of KITE-037, an allogeneic anti-CD19 CAR-T, in 2020.

Research

- Published a manuscript detailing the activity of disease allele-selective zinc finger proteins in preclinical models of Huntington’s disease in the July 2019 issue of *Nature Medicine*
- Published a manuscript detailing two new approaches for optimizing the specificity of genome editing with zinc finger nucleases in the August 2019 issue of *Nature Biotechnology*

Corporate

- Hired Gary Loeb as Executive Vice President and General Counsel

Second Quarter 2019 Financial Results

For the second quarter ended June 30, 2019, Sangamo reported a consolidated net loss of $30.3 million, or $0.26 per share, compared to a net loss of $16.6 million, or $0.17 per share, for the same period in 2018. As of June 30, 2019, the Company had cash, cash equivalents, and investments of

$450.3 million.

Revenues for the second quarter ended June 30, 2019 were $17.5 million, compared to $21.4 million for the same period in 2018. The decrease was primarily due to a decline of $3.7 million in revenues related to the agreement with Pfizer due to a change in estimate resulting from the expansion of the project scope of the hemophilia A collaboration.

As anticipated, operating expenses increased in the second quarter ended June 30, 2019, reflecting the Company's growth through the acquisition of TxCell, increased U.S. headcount in support of growth of the preclinical pipeline and clinical development programs, and manufacturing-related activities. Total operating expenses for the second quarter ended June 30, 2019 were $51.1 million, compared to $40.6 million for the same period in 2018. Research and development expenses were $36.5 million for the second quarter of 2019, compared to $29.3 million for the same period in 2018. The increase was primarily due to manufacturing and clinical trial expenses related to the progress of the Company's clinical development programs. General and administrative expenses were $14.6 million for the second quarter of 2019, compared to $11.3 million for the same period in 2018. The increase was primarily due to increased compensation costs related to headcount growth and increased facility expenses, primarily related to our new Brisbane facility.

Financial Guidance for 2019

- **Operating Expense:** Sangamo expects operating expense of $210 to $220 million for the year ending December 31, 2019.
- **Cash and Investments:** Sangamo projects that current cash, cash equivalents, and investments should provide funds for operations through year end 2021.

Conference Call

Sangamo will host a conference call today, August 7, 2019, at 5:00 p.m. Eastern Time, which will be open to the public. The call will also be webcast live 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 9582057. 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 9582057.

About Sangamo Therapeutics

Sangamo Therapeutics, Inc. is focused on translating ground-breaking science into genomic medicines with the potential to transform patients' lives using gene therapy, *ex vivo* gene-edited cell therapy, *in vivo* genome editing, and gene regulation. For more information about Sangamo, visit www.sangamo.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding Sangamo's current expectations. These forward-looking statements include, without limitation, statements regarding the Company's ability to develop and commercialize product candidates to address genetic diseases with the Company's proprietary technologies; the anticipated benefit from investingin a diverse pipeline of products; Sangamo's ability to enhance efficacy of in vivo *gene editing, increase potency with Sangamo's updated gene editing reagents and integrate such improvements into its gene editing clinical development programs, as well as the timing of commencement of such programs and the anticipated benefits therefrom; and Sangamo's 2019 financial guidance related to cash, cash equivalents, and investments, anticipated operating expenses and cash runway. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, the outcomes of clinical trials, the uncertain regulatory approval process, uncertainties related to the execution of clinical trials, uncertainties that research outcomes will support clinical programs, Sangamo's reliance on partners and other third-parties to meet their clinical and manufacturing obligations, and the ability to maintain strategic partnerships. Further, there can be no assurance that the necessary regulatory approvals will be obtained or that Sangamo and its partners will be able to develop commercially viable product candidates. Actual results may differ from those projected in forward-looking statements due to risks and uncertainties that exist in Sangamo's operations and business environments. These risks and uncertainties are described more fully in Sangamo's Annual Report on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission and Sangamo's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 that it filed August 7, 2019. Forward-looking statements contained in this announcement are made as of this date, and Sangamo undertakes no duty to update such information except as required under applicable law.*

SELECTED CONDENSED CONSOLIDATED FINANCIAL DATA

(unaudited; in thousands, except per share data)

Statement of Operations Data:

	Three months ended June 30,		**Six Months Ended June 30,**	
	2019	**2018**	**2019**	**2018**
Revenues	$ 17,548	$ 21,416	$ 25,619	$ 34,053

Operating expenses:				
Research and development	36,455	29,255	71,305	52,802
General and administrative	14,597	11,301	31,715	21,388
Total operating expenses	51,052	40,556	103,020	74,190
Loss from operations	(33,504)	(19,140)	(77,401)	(40,137)
Interest and other income, net	3,148	2,500	4,842	3,310
Net loss	(30,356)	(16,640)	(72,559)	(36,827)
Net loss attributable to non-controlling interest	(72)	-	(125)	-
Net loss attributable to Sangamo Therapeutics, Inc. stockholders	$ (30,284)	$ (16,640)	$ (72,434)	$ (36,827)
Basic and diluted net loss per common share attributable to Sangamo Therapeutics Inc. stockholders	$ (0.26)	$ (0.17)	$ (0.67)	$ (0.40)
Shares used in computing basic and diluted net loss per common share attributable to Sangamo Therapeutics, Inc. stockholders	114,382	97,267	108,360	91,831

BALANCE SHEET DATA

	June 30, 2019	**December 31, 2018**
Cash, cash equivalents, marketable securities and interest receivable	$ 450,315	$ 400,508
Total assets	673,481	590,395
Total stockholders' equity	445,748	367,257

View source version on businesswire.com: https://www.businesswire.com/news/home/20190807005805/en/

Source: Sangamo Therapeutics, Inc.

Investor Relations – United States
McDavid Stilwell
510-970-6000, x219
mstilwell@sangamo.com

Media Inquiries – United States
Aron Feingold
510-970-6000, x421
afeingold@sangamo.com

Investor Relations and Media Inquiries – European Union
Caroline Courme
33 4 97 21 27 27
ccourme@sangamo.com