Sangamo Therapeutics Logo

Sangamo Therapeutics Reports Fourth Quarter And Full Year 2018 Financial Results

February 28, 2019

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

BRISBANE, Calif., Feb. 28, 2019 /PRNewswire/ -- Sangamo Therapeutics, Inc. (NASDAQ: SGMO), a genomic medicine company, today reported fourth quarter and full year 2018 financial results and recent business highlights.

Recent Highlights

- **ST-920 IND acceptance:** The U.S. Food and Drug Administration (FDA) accepted the Investigational New Drug application (IND) for ST-920, a gene therapy candidate being evaluated for the treatment of adults with Fabry disease. Sangamo expects to initiate the Phase 1/2 clinical trial evaluating ST-920 later this year.
- **WORLD*Symposium* presentations:** At the WORLD*Symposium* earlier in February, Sangamo presented interim results from the Phase 1/2 CHAMPIONS and EMPOWERS studies evaluating SB-913 and SB-318, zinc finger nuclease (ZFN) *in vivo* genome editing product candidates for the treatment of Mucopolysaccharidosis Type II (MPS II) and MPS I, respectively. Sangamo believes data from these two studies provide complementary evidence supportive of a favorable safety profile and of the activity of the ZFN *in vivo* genome editing approach used in both SB-913 and SB-318.
- **EVP of R&D appointment:** Sangamo appointed Adrian Woolfson, BM BCh, PhD, as Executive Vice President of Research and Development.
- **Completion of acquisition of TxCell:** In the fourth quarter of 2018, Sangamo completed the acquisition of TxCell, SA. The acquisition positions Sangamo as a leader in the development of CAR-Tregs, which the Company plans to evaluate for solid organ transplant rejection and for autoimmune diseases.

"The enrollment of patients last year into our five active clinical trials has laid the foundation for a steady flow of data readouts in 2019," said Sandy Macrae, CEO of Sangamo. "In the remainder of the year, we anticipate providing important data that will help us understand the potential clinical benefit of our MPS I and MPS II programs, as well as clinical results and analyses from three clinical hematology assets for hemophilia A, hemophilia B and beta thalassemia. We also expect four additional programs to progress into clinical development, including our wholly owned gene therapy for Fabry disease and CAR-Treg therapy for the prevention of solid organ transplant rejection, as well as partnered programs in sickle cell disease and oncology being developed in collaboration with Sanofi and Kite, respectively. I'm excited for what lies ahead as we continue to push forward the development of our genomic medicines."

Anticipated Milestones in 2019

In Vivo Genome Editing

- SB-913: Nine patients are enrolled in the CHAMPIONS Study evaluating SB-913 for MPS II, including three patients who recently entered the study in the expanded high-dose cohort. In 2019, Sangamo expects to report longer-term safety and biochemical measurements, as well as analyses of liver biopsies and enzyme replacement therapy withdrawal experience.
- SB-318: Three patients are enrolled in the EMPOWERS Study evaluating SB-318 for MPS I. In 2019, Sangamo expects to report longer-term safety and biochemical measurements, as well as analyses of liver biopsies and enzyme replacement therapy withdrawal experience.
- SB-FIX: One patient is currently enrolled in the FIXtendz Study evaluating SB-FIX for hemophilia B. Sangamo expects to enroll a second subject in the study and later in 2019 to report data including safety and factor expression levels.
- Second-generation reagents for *in vivo* genome editing platform: Sangamo has developed second-generation albumin locus ZFN constructs for potential use in the ongoing *in vivo* genome editing development programs. The Company plans to initiate a clinical trial this year using these second-generation ZFNs that should enable a Phase 3 decision for the MPS II program in 2020.

Gene Therapy

- SB-525: Eight patients are enrolled in the Alta Study evaluating SB-525 gene therapy for hemophilia A, being developed in collaboration with Pfizer. In 2019, Sangamo expects to report data including safety and factor expression levels, as well as information regarding factor replacement use and bleeding events.
- ST-920: In 2019, Sangamo anticipates activating sites for the Phase 1/2 clinical trial evaluating ST-920 gene therapy for the treatment of Fabry disease.

Ex Vivo Cell Therapy

- ST-400 and BIVV003: ST-400 and BIVV003 are gene-edited cell therapies being developed in collaboration with Sanofi for the treatment of beta thalassemia and sickle cell disease. Sangamo has enrolled two patients in the Thales Study evaluating ST-400 for the treatment of beta thalassemia and in 2019 expects to report initial safety and efficacy data including levels of fetal hemoglobin and total hemoglobin. BIVV003 is being evaluated for the treatment of sickle cell disease in the Phase 1/2 PRECIZN-1 trial run by Sanofi.
- TX200: In 2019, Sangamo anticipates filing a clinical trial application in Europe for TX200, an autologous CAR-Treg cell therapy for the prevention of solid organ transplant rejection. The Company expects to activate clinical sites by year-end.
- KITE-037: Kite, a Gilead Company, has announced the intention to file an IND for KITE-037, an allogeneic anti-CD19 CAR-T cell therapy, in the latter half of 2019.

Fourth Quarter 2018 Financial Results
For the fourth quarter ended December 31, 2018, Sangamo reported a consolidated net loss of $18.7 million, or $0.18 per share, compared to a net loss of $13.1 million, or $0.15 per share, for the same period in 2017. As of December 31, 2018, the Company had cash, cash equivalents, marketable securities and interest receivable of $400.5 million.

Revenues for the fourth quarter ended December 31, 2018 were $26.8 million, compared to $13.1 million for the same period in 2017. The increase came primarily from approximately $11.5 million in revenues related to the collaboration agreements with Pfizer for hemophilia A, and $9.0 million in revenues related to the collaboration with Kite, a Gilead Company, which included reimbursement of $2.7 million in research services. Fourth quarter 2018 revenues were primarily generated from Sangamo's collaboration agreements with Pfizer, Kite, Sanofi, and Dow Agrosciences.

Total operating expenses for the fourth quarter ended December 31, 2018 were $47.6 million, compared to $26.8 million for the same period in 2017. Research and development expenses were $33.3 million for the fourth quarter of 2018, compared to $19.4 million for the same period in 2017. 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 $14.4 million for the fourth quarter of 2018, compared to $7.5 million for the same period in 2017. This increase was primarily due to increased headcount in general support of growth for the Company's pipeline and clinical programs.

Full Year 2018 Results
For the year ended December 31, 2018, the consolidated net loss was $68.3 million, or $0.70 per share, compared to a consolidated net loss of $54.6 million, or $0.70 per share, for the year ended December 31, 2017. Revenues were $84.5 million for the year ended December 31, 2018, compared to $36.6 million for the same period in 2017. The increase in revenues was primarily related to our collaboration and license agreements with Kite and Pfizer. Total operating expenses were $161.6 million for the year ended December 31, 2018, compared to $92.9 million for the same period in 2017. The increase in operating expenses was primarily related to overall Company growth and manufacturing and R&D expenses related to the advancement of Sangamo's therapeutic pipeline.

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, marketable securities and interest receivable position should last at least two years.

Conference Call
Sangamo will host a conference call today, February 28, 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 6875578. For those unable to listen in at the designated time, a conference call replay will be available for one week following the conference call, from approximately 8:00 p.m. ET on February 28, 2019 to 11:59 p.m. ET on March 7, 2019. 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 6875578.

About Sangamo Therapeutics
Sangamo Therapeutics, Inc. is focused on translating ground-breaking science into genomic medicines with the potential to transform patients' lives using the Company's platform technologies in genome editing, gene therapy, gene regulation and cell therapy. 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 initiation of clinical trials and activation of clinical trial sites in 2019, the expected disease targets for our product candidates, the presentation of clinical trial data from clinical trials in 2019, enrollment expectations in 2019, the filing of a clinical trial application in the European Union, and Sangamo's 2019 financial guidance related to cash, cash equivalents, marketable securities and interest receivable and operating expense. 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 dependence on the success of clinical trials, the lengthy and uncertain regulatory approval process, uncertainties related to the initiation, enrollment and completion of clinical trials, whether the final results from a study will validate and support interim safety and efficacy data, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 as filed with the Securities and Exchange Commission and Sangamo's Annual Report on Form 10-K that it intends to file this week. 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 CONSOLIDATED FINANCIAL DATA
(unaudited; in thousands, except per share data)

Statement of Operations Data:

	Three months ended December 31,		For the Year Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Collaboration agreements	$ 26,687	$ 12,918	$ 84,065	$ 35,960
Research grants	150	159	387	607
Total revenues	26,837	13,077	84,452	36,567
Operating expenses:				
Research and development	33,254	19,377	114,866	65,728
General and administrative	14,355	7,466	46,736	27,200
Total operating expenses	47,609	26,843	161,602	92,928
Loss from operations	(20,772)	(13,766)	(77,150)	(56,361)
Interest and other income, net	1,553	675	8,261	1,793
Net loss	(19,219)	(13,091)	(68,889)	(54,568)
Net loss attributable to non-controlling interest	(555)	—	(555)	—
Net loss attributable to Sangamo Therapeutics, Inc. stockholders	$ (18,664)	$ (13,091)	$ (68,334)	$ (54,568)
Basic and diluted net loss per common share	$ (0.18)	$ (0.15)	$ (0.70)	$ (0.70)
Shares used in computing basic and diluted net loss per common share	102,057	84,820	96,941	78,084

SELECTED BALANCE SHEET DATA

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Cash, cash equivalents, marketable securities and interest receivable	$ 400,508	$ 244,560
Total assets	590,395	286,741
Total stockholders' equity	366,518	187,900

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