Sangamo BioSciences Reports First Quarter 2016 Financial Results

May 2, 2016

RICHMOND, Calif., May 2, 2016 /PRNewswire/ -- Sangamo BioSciences, Inc. (NASDAQ: SGMO), the leader in therapeutic genome editing, today reported its first quarter 2016 financial results and accomplishments.



"During the first quarter of 2016 we focused on activities to enable initiation of the first clinical trials of our IVPRP approach in hemophilia B and MPS I, and I am pleased to report that we will meet our stated timelines for the opening of both trials," said Edward Lanphier, Sangamo's president and chief executive officer. "We look forward to generating and presenting clinical data that support the application of this highly leverageable platform while continuing to progress our programs in hemophilia A and several lysosomal storage disorders toward clinical development."

Recent Highlights

- Presentation of new data from Sangamo's proprietary In Vivo Protein Replacement Platform™ (IVPRP) programs for MPS I and MPS II at the 12th Annual WORLDSymposium ™ Meeting. Sangamo scientists and academic collaborators from the University of Minnesota presented new preclinical data in disease models of the Company's IVPRP-based MPS I (Hurler syndrome) and MPS II (Hunter syndrome) programs at the 2016 WORLDSymposium ™ Annual Meeting. In animal models of disease, the data demonstrated the production of stable, therapeutic levels of replacement enzyme from the liver into the circulation and secondary tissues, including the brain, resulting in significant reduction in biomarkers of the disease, and notably, statistically significant improvements in cognitive function in treated animals
- Publication in the New England Journal of Medicine (NEJM) highlighting Sangamo's IVPRP approach for hemophilia B. In March, NEJM published a review authored by Dr. Amit Nathwani, a key opinion leader in the field of gene therapy approaches to hemophilia, highlighting Sangamo's IVPRP-based SB-FIX program for the one-time, permanent treatment of hemophilia B. The article details the significant advantages of Sangamo's ZFN-mediated, targeted integration of the Factor IX (FIX) gene at the albumin locus over conventional non-integrating gene therapy approaches that use adeno-associated virus (AAV) to deliver the FIX gene and other therapeutic genes to liver cells.
- Sangamo augments clinical expertise with the appointment of Matthew Spear, M.D. as Vice President and Head of Clinical Development. Dr. Spear joins Sangamo with more than 20 years of experience in all stages of biopharmaceutical research and development and has led the development of over 15 therapeutic products. Most recently, Dr. Spear served as a Vice President in Clinical Development at Incyte Corp.
- Presentation of immunological data from Sangamo's SB-728-T Phase 2 clinical program in HIV/AIDS at the 2016 Annual Conference on Retroviral and Opportunistic Infections (CROI 2016). Sangamo's collaborators from Case Western Reserve University presented analyses of immunological data from the Company's clinical trials of SB-728-T, a ZFP Therapeutic[®] designed to provide functional control of HIV/AIDS. The presentation outlined potentially interrelated mechanisms for viral load (VL) control in SB-728-T-treated subjects during a treatment interruption (TI) from their antiretroviral therapy. This suggests a model mechanism of action for SB-728-T and enables identification of patients who will most benefit from Sangamo's ZFN-mediated CCR5 knock-out approach.

Upcoming Events in 2016

- Initiation of IVPRP-based Phase 1/2 clinical trials SB-FIX-1501 (hemophilia B) and SB-318-1502 (MPS I / Hurler syndrome) by the end of the second quarter and mid-2016, respectively.
- Presentation of data from several ZFP Therapeutic programs by Sangamo scientists and collaborators at the upcoming 19th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT), which will be held in Washington D.C. from May 4-7, 2016.
- Submission of investigational new drug (IND) applications in the first half of 2016 for Sangamo's IVPRP-based SB-913 program for MPS II (Hunter syndrome), and beta-thalassemia program in collaboration with Biogen Inc. (Biogen).
- Presentation of new clinical data from Cohort 3* of Sangamo's SB-728-1101 Phase 1/2 trial in T-cells for the functional control of HIV/AIDS in the second half of 2016.

First Quarter 2016 Results

For the first quarter ended March 31, 2016, Sangamo reported a consolidated net loss of \$16.5 million, or \$0.23 per share, compared to a net loss of

\$5.3 million, or \$0.08 per share, for the same period in 2015. As of March 31, 2016, the Company had cash, cash equivalents, marketable securities and interest receivable of \$189.0 million.

Revenues for the first quarter of 2016 were \$3.9 million, compared to \$13.5 million for the same period in 2015. First quarter 2016 revenues were generated from the Company's collaboration agreements with Biogen and Shire International GmbH (Shire), enabling technology agreements and research grants. The revenues recognized for the first quarter of 2016 consisted of \$3.7 million from collaboration agreements and \$0.2 million from research grants, compared to \$12.7 million and \$0.8 million, respectively, for the same period in 2015.

The decrease in collaboration agreement revenues was primarily a result of an amendment to the Company's collaboration and license agreement with Shire in the third quarter of 2015, which returned the rights to the hemophilia programs to Sangamo, and a decrease in revenue under the Company's collaboration agreement with Sigma.

In the first quarter of 2016, Sangamo recognized \$2.0 million of revenues related to research services performed under the collaboration agreement with Biogen, and \$0.4 million of revenues related to research services performed under the collaboration agreement with Shire. In addition, Sangamo received upfront payments of \$13.0 million and \$20.0 million pursuant to the agreements entered into with Shire in 2012 and Biogen in 2014, respectively. The Shire payment is being recognized as revenue on a straight-line basis over the initial six-year research term. Beginning in January 2016, the Biogen payment will be recognized over approximately 42 months which reflects the revised service period related to Sangamo's deliverables under the Biogen agreement. The Company recognized \$0.5 million of the Shire upfront payment and \$0.6 million of the Biogen upfront payment as revenue for the first quarter of 2016.

Research and development expenses were \$15.3 million for the first quarter of 2016, compared to \$15.0 million for the same period in 2015. Research and development expenses were primarily comprised of manufacturing expenses, research expenses associated with Sangamo's clinical and preclinical programs, and personnel-related expenses, including stock-based compensation.

General and administrative expenses were \$5.4 million for the first quarter of 2016, compared to \$4.7 million for the same period in 2015.

Total operating expenses for the first quarter of 2016 were \$20.6 million, compared to \$19.7 million for the same period in 2015.

Financial Guidance for 2016

The Company reiterates its earlier guidance as follows:

- Cash and Investments: Sangamo expects that its cash, cash equivalents and marketable securities will be at least \$150 million at the end of 2016, inclusive of research funding from existing collaborators but exclusive of funds arising from any additional new collaborations or partnerships, equity financings or other new sources.
- Revenues: Sangamo expects that revenues will be in the range of \$20 million to \$25 million in 2016, inclusive of research funding from existing collaborations.
- Operating Expenses: Sangamo expects that operating expenses will be in the range of \$85 million to \$95 million for 2016.

Conference Call

Sangamo will host a conference call today, May 2, 2016, at 5:00 p.m. ET, which will be open to the public. The call will be webcast live and can be accessed via a link on the Sangamo BioSciences website in the Investor Relations section under "Events and Presentations" http://investor.sangamo.com/events.cfm. A replay of the webcast will be available for two weeks after the call. During the conference call, the Company will review these results, discuss other business matters and provide guidance with respect to 2016.

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 93178464. A conference call replay will be available for one week following the conference call, from approximately 8:00 p.m. ET on May 2, 2016 to 11:59 p.m. ET on May 9, 2016. 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 93178464.

About Sangamo

Sangamo BioSciences, Inc. is focused on Engineering Genetic Cures[®] for monogenic and infectious diseases by deploying its novel DNA-binding protein technology platform in therapeutic genome editing and gene regulation. The Company's proprietary In Vivo Protein Replacement Platform™ (IVPRP) approach is focused on monogenic diseases, including hemophilia and Iysosomal storage disorders. Based on its proprietary IVPRP approach, Sangamo is initiating Phase 1/2 clinical trials for hemophilia B, the first *in vivo* genome editing application cleared by the FDA, and MPS I. In addition, Sangamo has a Phase 2 clinical program to evaluate the safety and efficacy of novel ZFP Therapeutics[®] for the treatment of HIV/AIDS (SB-728). The Company has also formed a strategic collaboration with Biogen Inc. for hemoglobinopathies, such as sickle cell disease and beta-thalassemia, and with Shire International GmbH to develop therapeutics for Huntington's disease. It has established strategic partnerships with companies in non-therapeutic applications of its technology, including Dow AgroSciences and Sigma-Aldrich Corporation. For more information about Sangamo, visit the Company's website at www.sangamo.com.

ZFP Therapeutic[®] is a registered trademark of Sangamo BioSciences, Inc.

This press release contains forward-looking statements regarding Sangamo's current expectations. These forward looking statements include, without limitation, references to expected timing of initiating clinical trials, presentation of clinical trial data and submission of INDs, anticipated cash and investment balance, operating expenses, revenue and potential milestone and royalty payments under Sangamo's agreements with Shire and Biogen, the research and development of ZFNs and ZFP TFs, clinical trials and therapeutic applications of Sangamo's ZFP technology platform and achievement of research milestones and objectives under collaboration agreements with Shire and Biogen. 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 early stage of ZFP Therapeutic development, the lengthy and uncertain regulatory approval process, uncertainties related to the timing of initiation and completion of clinical trials, whether clinical trial results will validate and support the safety and efficacy of ZFP Therapeutics, and the ability to establish 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 gene-based therapeutics. 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 Reports on Form 10-K and Quarterly Reports on Form 10-Q as filed with the Securities and Exchange Commission. 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:

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	Three Months Ended			
	March 31,			
	2016		2015	
Revenues:				
Collaboration agreements	\$	3,711	\$	12,671
Research grants	231		820	
Total revenues	3,942		13,491	
Operating expenses:				
Research and development	15,266		14,980	
General and administrative	5,357		4,732	
Total operating expenses	20,623		19,712	
Loss from operations	(16,681)		(6,221)	
Interest and other income, net	187		154	
Loss before taxes	(16,494)		(6,067)	
Benefit from income taxes	-		748	
Net loss	\$	(16,494)	\$	(5,319)
Basic and diluted net loss per common share	\$	(0.23)	\$	(80.0)
Shares used in computing basic and diluted net loss per common share 70.373				

70,373 69,283

SELECTED BALANCE SHEET DATA

(Unaudited)

Cash, cash equivalents, marketable securities and interest receivable \$ 188,986 \$ 209,307

Total assets 197,048 217,235

Total stockholders' equity 179,407 192,439

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To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/sangamo-biosciences-reports-first-quarter-2016-financial-results-300261011.html

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