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Sangamo BioSciences Reports Fourth Quarter And Full Year 2015 Financial Results

Company Begins 2016 in Strong Financial Position with $210 Million in Cash

Poised to Initiate First in vivo Genome Editing Clinical Trials for Hemophilia B and MPS I

RICHMOND, Calif., Feb. 9, 2016 /PRNewswire/ -- Sangamo BioSciences, Inc. (NASDAQ: SGMO), the leader in therapeutic genome editing, today reported its fourth quarter and full year 2015 financial results and accomplishments.

"2015 was an important and very productive year for Sangamo, and we enter 2016 poised to initiate the first human clinical trials of *in vivo* therapeutic genome editing," said Edward Lanphier, Sangamo's president and chief executive officer. "Our zinc finger nuclease (ZFN) technology leads the therapeutic genome editing field and we have established the core competencies necessary to move our ground-breaking genome editing programs through IND enabling studies and into clinical trials. We believe our IVPRP clinical studies will provide fundamental proof-of-concept data and significantly differentiate the technical advantages of our ZFN platform from other genome editing technologies of bacterial origin as well as conventional gene therapy approaches. In addition to our two new open IVPRP INDs we plan to file six more IND applications in 2016 for our other IVPRP-based programs, and our hemoglobinopathies programs which we are developing in collaboration with Biogen. We began the year with approximately $210 million in cash, which puts Sangamo in a strong financial position and will allow us to accomplish all of our goals in 2016."

Recent Highlights

- **Announcement of FDA clearance of IND application for Phase 1/2 clinical trial of MPS I (Hurler syndrome) program.** In February 2016, Sangamo announced that its Investigational New Drug (IND) application for the Company's SB-318 program was cleared by the U.S. Food and Drug Administration (FDA) and is now active. SB-

318 is an application of the Company's proprietary In Vivo Protein Replacement Platform™ (IVPRP™) genome editing approach, for the treatment of MPS I. In December 2015, the NIH Recombinant DNA Advisory Committee (RAC) unanimously approved the clinical protocol for SB-318.

- **Announcement of FDA clearance of IND application for Phase 1/2 clinical trial of hemophilia B program.** In December 2015, Sangamo announced that an IND application for SB-FIX, the Company's IVPRP genome editing approach for the potential cure of hemophilia B, has been cleared by the FDA and is now active.
- **Presentation of Phase 2 clinical data from SB-728-T HIV studies demonstrating superiority of adenoviral delivery of zinc finger nucleases to T-cells for viral load control and reservoir reduction.** In December 2015, Sangamo presented Phase 2 clinical data from ongoing clinical trials of the Company's SB-728-T HIV program, SB-728-1101 Cohort 3* and SB-728mR-1401. The preliminary comparative data suggest that adenoviral delivery of ZFNs to T-cells may be uniquely immune-stimulatory for both acute viral load control and HIV reservoir reduction. The trial is currently ongoing with the accrual of five additional subjects in '1101 Cohort 3*.
- **Presentation of data at the 2015 American Society of Hematology meeting (ASH) highlighting ZFP Therapeutic programs for hemophilia and hemoglobinopathies.** In December 2015, Sangamo presented data at ASH demonstrating the production of therapeutic levels of Factor IX (FIX) clotting protein in non-human primates (NHPs) from its hemophilia B program, and clinical scale manufacturing and engraftment of ZFN-modified hematopoietic stem and progenitor cells (HSPCs) for the treatment of beta-thalassemia.
- **Publication of improved method for efficient targeted integration in HSPCs and T-cells.** In November 2015, Sangamo announced the publication in*Nature Biotechnology* of data demonstrating efficient ZFN-mediated, targeted gene insertion in HSPCs, as well as a study in *Nucleic Acids Research*, demonstrating a similarly efficient process in primary human T-cells.
- **Internal Organization.** Sangamo promoted Stewart Craig, Ph.D., from Vice President to Senior Vice President of Technical Operations. Dr. Craig joined Sangamo in May 2014 and has led the development of the Company's successful and growing manufacturing capabilities. Fyodor Urnov, Ph.D., Senior Scientist, was promoted to Vice President of Discovery & Translational Research. Dr. Urnov is a key contributor to the development of Sangamo's ZFP Therapeutic technology platform and leads Sangamo's hemoglobinopathies research collaboration with Biogen Inc. (Biogen). Nathalie Dubois-Stringfellow, Ph.D. was promoted from Senior Director to Vice President of Product Development & Management. Dr. Dubois-Stringfellow, with extensive experience in pre-clinical drug development and project management, established an effective cross-functional team-based culture at Sangamo, enabling the Company's successful and timely IND submissions.

Upcoming Events in the First Half of 2016

- **Initiation of Phase 1/2 clinical trials for IVPRP-based SB-FIX-1501 (hemophilia B) and SB-318-1502 (MPS I / Hurler syndrome) programs.** The trials will be the first two *in vivo* clinical studies of genome editing in humans and the first clinical programs based on Sangamo's IVPRP approach. Sangamo expects to initiate the

Phase 1/2 trial for hemophilia B in the first half of 2016, and the Phase 1/2 trial for MPS I in mid-2016.

- **Presentation of clinical data from Sangamo's HIV program at the 2016 Annual Conference on Retroviruses and Opportunistic Infections (CROI).** Sangamo's collaborator, Rafick Pierre Sekaly, Ph.D., will present further immunologic and viral reservoir analyses of clinical data from the Company's SB-728-1101 study, suggesting potential mechanisms of viral control post-treatment with SB-728-T.
- **Preclinical data presentation from Sangamo's MPS I and MPS II programs at the 2016 Annual WORLD*Symposium* Meeting.** Sangamo expects to present data from its animal model studies for the Company's IVPRP-based MPS I and MPS II (Hunter syndrome) programs for lysosomal storage disorders (LSDs). The meeting is being held in San Diego, CA from February 29 to March 4, 2016.
- **Submission of IND applications for Sangamo's SB-913 (MPS II) program and beta-thalassemia program.** Sangamo expects to file both IND applications in the first half of 2016. SB-913, for the treatment of MPS II, is the second LSD application of the Company's proprietary IVPRP approach. The beta-thalassemia program, which is being developed in collaboration with Biogen, employs Sangamo's ZFN-mediated *ex vivo* genome editing approach to knockout the BCL11A Enhancer.

Fourth Quarter 2015 Results

For the fourth quarter ended December 31, 2015, Sangamo reported a consolidated net loss of $14.0 million, or $0.20 per share, compared to a net loss of $4.3 million, or $0.06 per share, for the same period in 2014. As of December 31, 2015, the Company had cash, cash equivalents, marketable securities and interest receivable of $209.3 million.

Revenues for the fourth quarter of 2015 were $9.1 million, compared to $15.0 million for the same period in 2014. Fourth quarter 2015 revenues were generated from the Company's collaboration agreements with Biogen, Shire International GmbH (Shire), and Dow AgroSciences, enabling technology agreements and research grants. The revenues recognized for the fourth quarter of 2015 consisted of $9.0 million in collaboration agreements and approximately $0.2 million in research grants, compared to $14.5 million and approximately $0.4 million, respectively, for the same period in 2014.

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, returning the rights to the hemophilia programs to Sangamo. In the fourth quarter of 2015, Sangamo recognized $1.9 million of revenues related to research services performed under the collaboration agreement with Shire, and $1.9 million of revenues related to research services performed under the collaboration agreement with Biogen. In addition, pursuant to the agreements entered into with Shire in January 2012 and Biogen in January 2014, Sangamo received upfront payments of $13.0 million and $20.0 million, respectively. These payments are being recognized as revenue on a straight-line basis over the initial six-year research term for Shire and approximately 40 months for Biogen. The Company recognized $0.5 million of the Shire upfront payment and $1.6 million of the Biogen upfront payment as revenue for the fourth quarter of 2015.

Research and development expenses were $19.9 million for the fourth quarter of 2015,

compared to $15.1 million for the same period in 2014. The increase was primarily due to increases in manufacturing expenses, external research expenses associated with our preclinical programs, and personnel-related expenses, including stock-based compensation. General and administrative expenses were $4.9 million for the fourth quarter of 2015, compared to $4.3 million for the same period in 2014.

Total operating expenses for the fourth quarter of 2015 were $24.8 million, compared to $19.4 million for the same period in 2014.

Full Year 2015 Results

For the year ended December 31, 2015, the consolidated net loss was $40.7 million, or $0.58 per share, compared to a consolidated net loss of $26.4 million, or $0.39 per share, for the year ended December 31, 2014. Revenues were $39.5 million for the year ended December 31, 2015, compared to $45.9 million for the same period in 2014. Total operating expenses were $86.4 million for the year ended December 31, 2015, compared to $72.7 million for the same period in 2014.

Financial Guidance for 2016

- **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:** In light of the amendment to our collaboration and licensing agreement with Shire, that returned the rights of the hemophilia programs to Sangamo, the Company 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, February 9, 2016, at 5:00 p.m. ET, which will be open to the public. The call will also 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 also 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 39287479. 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 9, 2016 to 11:59 p.m. ET on February 16, 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 39287479.

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 lysosomal storage disorders. 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 filing 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

(in thousands, except per share data)

Statement of Operations Data:

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
Revenues:				
Collaboration agreements	$ 8,966	$ 14,546	$ 37,844	$ 43,880
Research grants	155	406	1,695	1,990
Total revenues	9,121	14,952	39,539	45,870
Operating expenses:				
Research and development	19,906	15,091	67,198	56,974
General and administrative	4,888	4,330	19,197	15,677
Total operating expenses	24,794	19,421	86,395	72,651
Loss from operations	(15,673)	(4,469)	(46,856)	(26,781)
Interest and other income, net	25	150	431	364
Loss before taxes	(15,648)	(4,319)	(46,425)	(26,417)

Benefit from income tax	1,635	0	5,722	0
Net loss	$ (14,013)	$ (4,319)	$ (40,703)	$ (26,417)
Basic and diluted net loss per common share	$ (0.20)	$ (0.06)	$ (0.58)	$ (0.39)
Shares used in computing basic and diluted net loss per common share	70,157	68,607	69,757	67,022

SELECTED BALANCE SHEET DATA

	December 31, 2015	December 31, 2014
Cash, cash equivalents, marketable securities and interest receivable	$ 209,307	$ 226,645
Total assets	217,235	243,212
Total stockholders' equity	192,439	206,633

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