# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

# **FORM 8-K**

CURRENT REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE **SECURITIES EXCHANGE ACT OF 1934** 

Date of report (Date of earliest event reported): October 3, 2011

# SANGAMO BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

68-0359556

(IRS Employer Identification No.)

**Richmond, California 94804** 

(Zip Code)

(Address of Principal Executive Offices)

(510) 970-6000

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) 0
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) 0
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) 0
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

000-30171 (Commission File Number)

501 Canal Blvd, Suite A100

#### Item 7.01-Regulation FD Disclosure.

On October 3, 2011, Sangamo BioSciences, Inc. issued a press release announcing the results of its Phase 2b clinical trial (SB-509-901) in subjects with moderate severity diabetic neuropathy. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits

(c) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

Exhibit No.

99.1 Press Release Issued October 3, 2011.

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DATE: October 3, 2011

SANGAMO BIOSCIENCES, INC.

By: /s/ EDWARD O. LANPHIER II Edward O. Lanphier II President, Chief Executive Officer Company to Discontinue SB-509 Development to Focus on Pipeline of ZFP® Therapeutics for HIV and Monogenic Diseases

#### Company to Hold Conference Call at 8:30 am ET Today to Discuss Data

RICHMOND, Calif., Oct. 3, 2011 /PRNewswire/ -- Sangamo BioSciences, Inc. (Nasdaq: SGMO) today announced that its Phase 2t study (SB-509-901) did not meet its primary or secondary clinical endpoints in subjects with moderate severity diabetic neuropathy (DN) as compared to placebo.

"We are disappointed that this trial did not produce a better outcome in the pre-specified primary and secondary endpoints," said Edward Lanphier, Sangamo's president and CEO. "Based on these results, we will discontinue further development of SB-509 and will focus our attention and resources on our pipeline of ZFP Therapeutics for HIV and monogenic diseases for which our genome editing technology is uniquely well positioned. We would like to thank the patients, investigators and the Juvenile Diabetes Research Foundation (JDRF) for their support and participation in the trial."

### **Phase 2b Trial Results**

- SB-509 treatment did not show statistically significant improvements from baseline compared with placebo at 180 days in the primary endpoint, sural nerve conduction velocity (sNCV), the secondary endpoint, neuropathy impairment score in the lower limb (NIS-LL), or intraepidermal nerve fiber density (IENFD).
- In a pre-specified analysis, a clinically relevant improvement was observed in the mean total LENSE score of 3.4 points in SB-509-treated subjects compared to a 1.9 point improvement in placebo treated subjects from baseline (p=0.11). This trend affected pinprick and touch pressure sensation more than vibration, and was primarily due to improvement seen in subjects with a baseline IENFD score of <9 fibers/mm. In this group the effect on total LENSE score was more prominent at 90 days (mean improvement of 4.3 points in treated subjects compared with a worsening of 0.8 points in placebo subjects; p=0.008) than at 180 days (mean improvement of 4.8 points in treated subjects compared with an improvement of 1.8 points in placebo subjects; p=0.08).
- SB-509 was generally well-tolerated. There were three serious adverse events in the SB-509 treated group compared with three serious adverse events in the placebo group. The remaining adverse events were mild and reversible and were generally equivalent in both groups.

The full clinical data set will be published or presented at an appropriate medical meeting.

"While positive effects on major endpoints in SB-509-treated subjects in this trial were of a similar magnitude to those observed in our earlier Phase 2 trial (SB-509-601), the placebo group in the SB-509-901 study showed an unexpected improvement in these measures over the 180 day test period," stated Dale Ando, M.D., Sangamo's vice president of therapeutic development and chief medical officer. "Although LENSE was only an exploratory endpoint in the trial, the positive outcomes that we observed were scientifically intriguing. LENSE uses assessments routinely applied in clinical neurological examination and provides a measure of patient-reported sensory function, in contrast to current endpoints such as NCV whose clinical relevance is less clear."

### Phase 2b Trial Design (SB-509-901)

The double blind, repeat-dosing, placebo controlled Phase 2b study, SB-509-901, was designed to finalize dose, schedule, and primary and secondary endpoints for pivotal Phase 3 trials. The trial accumulated data on endpoints including nerve conduction velocity in the sural nerve (sNCV, the primary endpoint), Neurological Impairment Score in the Lower Limb (NIS-LL, the secondary endpoint), as well as exploratory endpoints of Lower Extremity Neurological Sensory Examination (LENSE), quality of life assessments (QOL) and intraepidermal nerve fiber density (IENFD). The study involved a total of 170 subjects who were randomized 1:1 between placebo and treatment groups.

### About SB-509

SB-509 is an injectable plasmid encoding a zinc finger DNA-binding protein (ZFP) transcription factor (ZFP TF) designed to upregulate the endogenous expression of the gene encoding vascular endothelial growth factor (VEGF-A). In pre-clinical studies, VEGF-A has been demonstrated to have direct angiogenic, neurotrophic and neuroprotective properties.

### **About Diabetic Neuropathy**

The Centers for Disease Control estimate that from 1980 through 2010, the number of Americans with diabetes has more than quadrupled from 5.6 million to 25.8 million and that of those about 60 to 70 percent have mild to severe forms of neuropathy. Diabetic neuropathy is a progressive degenerative disease that is one of the most frequent complications of diabetes, affecting between 15.8 and 18 million Americans in 2010. High blood glucose levels lead to nerve damage over time, primarily affecting

peripheral nerves. Symptoms include numbness, tingling sensations and pain particularly in the toes or feet, which gradually evolve to loss of sensation and motor function as nerve damage progresses. Ulcers and sores may appear on numb areas of the foot as pressure wounds or injuries go unnoticed. Despite palliative treatment, these areas of trauma frequently become infected and this infection may spread to the bone, necessitating amputation of the leg or foot. More than 60 percent of non-traumatic lower-limb amputations in the United States occur among people with diabetes.

## **Conference Call**

Sangamo will host a conference call to discuss these results today, October 3, 2011 at 8:30 a.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. The webcast replay will also be available for two weeks after the call.

The conference call dial-in numbers are (877) 377-7553 for domestic callers and (678) 894-3968 for international callers. The passcode for the call is 15507481. 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 11:30 am ET on October 3, 2011 to midnight ET on October 10, 2011. 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 15507481.

## **About Sangamo**

Sangamo BioSciences, Inc. is focused on research and development of novel DNA-binding proteins for therapeutic gene regulation and modification. The most advanced ZFP Therapeutic® development program is SB-509, which recently reported Phase 2b clinical trial data in patients with diabetic neuropathy. Sangamo also has a Phase 1/2 clinical trial and two ongoing Phase 1 clinical trials to evaluate safety and clinical effect of a treatment for HIV/AIDS as well as a Phase 1 trial of a treatment for recurrent glioblastoma multiforme. Other therapeutic development programs are focused on Parkinson's disease, monogenic diseases, neuropathic pain and nerve regeneration. Sangamo's core competencies enable the engineering of a class of DNA-binding proteins called zinc finger DNA-binding proteins (ZFPs). By engineering ZFPs that recognize a specific DNA sequence, Sangamo has created ZFP transcription factors (ZFP TFs) that can control gene expression and, consequently, cell function. Sangamo is also developing sequence-specific ZFP Nucleases (ZFNs) for gene modification. Sangamo 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 may contain forward-looking statements based on Sangamo's current expectations. These forward-looking statements include, without limitation, references relating to research and development of novel ZFP TFs and ZFNs and therapeutic applications of Sangamo's ZFP technology platform for the treatment of diabetic neuropathy, HIV/AIDS and monogenic diseases. Actual results may differ materially from these forward-looking statements due to a number of factors, including uncertainties relating to the initiation and completion of stages of our clinical trials, whether the clinical trials will validate and support the tolerability and efficacy of ZFNs, technological challenges, Sangamo's ability to develop commercially viable products and technological developments by our competitors. For a more detailed discussion of these and other risks, please see Sangamo's SEC filings, including the risk factors described in its Annual Report on Form 10-K and its most recent Quarterly Report on Form 10-Q. Sangamo BioSciences, Inc. assumes no obligation to update the forward-looking information contained in this press release.

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