

SANGAMO BIOSCIENCES INC  
Form 10-Q  
August 03, 2009  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2009

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-30171

**SANGAMO BIOSCIENCES, INC.**

(exact name of registrant as specified in its charter)

Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**68-0359556**  
(IRS Employer  
Identification No.)

**501 Canal Blvd, Suite A100**  
**Richmond, California 94804**  
(Address of principal executive offices)

**(510) 970-6000**  
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by section 13 or 15(d) of the Securities Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of July 31, 2009, 41,166,541 shares of the issuer's common stock, par value \$0.01 per share, were outstanding.

**Table of Contents**

**INDEX**

**SANGAMO BIOSCIENCES, INC.**

<b>PART I. FINANCIAL INFORMATION</b>	3
Item 1. <u>Financial Statements (Unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets at June 30, 2009 and December 31, 2008</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2009 and 2008</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2009 and 2008</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	16
Item 4. <u>Controls and Procedures</u>	16
<b>PART II. OTHER INFORMATION</b>	16
Item 1. <u>Legal Proceedings</u>	16
Item 1A. <u>Risk Factors</u>	16
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	28
Item 6. <u>Exhibits</u>	28
<b>SIGNATURES</b>	29

**CERTIFICATIONS**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Some statements contained in this report are forward-looking with respect to our operations, research and development activities, operating results and financial condition. Statements that are forward-looking in nature should be read with caution because they involve risks and uncertainties, which are included, for example, in specific and general discussions about:

our strategy;

product development and commercialization of our products;

clinical trials;

revenues from existing and new collaborations;

our research and development and other expenses;

sufficiency of our cash resources;

our operational and legal risks; and

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

our plans, objectives, expectations and intentions and any other statements that are not historical facts. Various terms and expressions similar to them are intended to identify these cautionary statements. These terms include: anticipates, believes, continues, could, estimates, expects, intends, may, plans, seeks, should and will. Actual results may differ materially from those implied in those statements. Factors that could cause these differences include, but are not limited to, those discussed under Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations. Sangamo undertakes no obligation to publicly release any revisions to forward-looking statements to reflect events or circumstances arising after the date of this report. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q.

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****SANGAMO BIOSCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share amounts)**

	<b>June 30, 2009 (unaudited)</b>	<b>December 31, 2008 (audited)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,774	\$ 19,409
Marketable securities	37,487	45,422
Interest receivable	325	194
Accounts receivable	13	500
Prepaid expenses	536	327
Total current assets	53,135	65,852
Property and equipment, net	1,791	1,986
Other assets	12	12
Total assets	\$ 54,938	\$ 67,850
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 2,544	\$ 3,848
Accrued compensation and employee benefits	983	388
Deferred revenues	4,180	7,395
Total current liabilities	7,707	11,631
Deferred revenues, non-current portion	55	823
Total liabilities	7,762	12,454
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value; 80,000,000 shares authorized, 41,149,521 and 41,057,077 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	411	410
Additional paid-in capital	232,041	228,764
Accumulated deficit	(185,397)	(174,054)
Accumulated other comprehensive income	121	276
Total stockholders' equity	47,176	55,396
Total liabilities and stockholders' equity	\$ 54,938	\$ 67,850

*See accompanying notes.*



**Table of Contents****SANGAMO BIOSCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share amounts)****(Unaudited)**

	<b>Three months ended June 30,</b>		<b>Six months ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
<b>Revenues:</b>				
Collaboration agreements	\$ 4,213	\$ 2,378	\$ 7,370	\$ 4,462
Research grants	513	464	513	1,145
Total revenues	4,726	2,842	7,883	5,607
<b>Operating expenses:</b>				
Research and development	6,877	8,286	14,133	16,929
General and administrative	3,007	2,545	5,933	5,472
Total operating expenses	9,884	10,831	20,066	22,401
Loss from operations	(5,158)	(7,989)	(12,183)	(16,794)
Interest and other income, net	647	570	840	1,406
Net loss	\$ (4,511)	\$ (7,419)	\$ (11,343)	\$ (15,388)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.18)	\$ (0.28)	\$ (0.38)
Shares used in computing basic and diluted net loss per share	41,123	40,858	41,094	40,673

*See accompanying notes.*

**Table of Contents****SANGAMO BIOSCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)****(Unaudited)**

	<b>Six months ended June 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Operating activities:</b>		
Net loss	\$ (11,343)	\$ (15,388)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	291	244
Amortization of premium / discount on marketable securities	(70)	(776)
Stock-based compensation	3,002	2,990
Foreign currency remeasurement (gains) / losses	(493)	3
Changes in operating assets and liabilities:		
Interest receivable	(131)	76
Accounts receivable	487	(8,769)
Prepaid expenses and other assets	(209)	(90)
Accounts payable and accrued liabilities	(1,304)	(927)
Accrued compensation and employee benefits	595	(358)
Deferred revenues	(3,983)	4,828
<b>Net cash used in operating activities</b>	<b>(13,158)</b>	<b>(18,167)</b>
<b>Investing activities:</b>		
Purchases of investments	(28,650)	(41,047)
Maturities of investments	36,500	51,125
Proceeds from sales of investments	3,975	3,975
Purchases of property and equipment	(96)	(534)
<b>Net cash provided by investing activities</b>	<b>7,754</b>	<b>13,519</b>
<b>Financing activities:</b>		
Proceeds from issuance of common stock	328	1,034
Repurchase of common stock	(52)	-
<b>Net cash provided by financing activities</b>	<b>276</b>	<b>1,034</b>
Effect of exchange rate changes on cash	493	(3)
<b>Net decrease in cash and cash equivalents</b>	<b>(4,635)</b>	<b>(3,617)</b>
Cash and cash equivalents, beginning of period	19,409	12,275
<b>Cash and cash equivalents, end of period</b>	<b>\$ 14,774</b>	<b>\$ 8,658</b>

*See accompanying notes.*



**Table of Contents**

**SANGAMO BIOSCIENCES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2009**

**(Unaudited)**

**NOTE 1 - BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of Sangamo Biosciences, Inc. ( Sangamo or the Company ) have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission ( SEC ). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. The condensed consolidated financial statements include the accounts of Sangamo and its wholly-owned subsidiary, Gendaq Limited, after elimination of all material intercompany balances and transactions. Operating results for the three and six months ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. These financial statements should be read in conjunction with the financial statements and footnotes thereto for the year ended December 31, 2008, included in Sangamo's Form 10-K as filed with the SEC. In accordance with SFAS No. 165, *Subsequent Events*, we have evaluated Company activities from July 1, 2009 through July 31, 2009 (date of filing of Form 10-Q with the SEC) noting no subsequent events which require disclosure.

**Use of Estimates and Classifications**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. On an ongoing basis, management evaluates its estimates, including critical accounting policies or estimates related to revenue recognition, clinical trial accruals, and stock-based compensation. We base our estimates on historical experience and on various other market specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates. Certain prior year balances have been reclassified to conform to the current presentation.

**Fair Value Measurement**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value and expands the disclosure requirements regarding fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 for financial assets and liabilities as well as for non-financial assets and liabilities that are recognized or disclosed at fair value on a recurring basis in the financial statements. In accordance with FSP No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), for all other non-financial assets and liabilities, SFAS 157 is effective for fiscal years beginning after November 15, 2008.

We adopted the measurement and disclosure requirements of SFAS 157 related to financial assets and liabilities as well as for non-financial assets and liabilities that are recognized or disclosed at fair value on a recurring basis in the financial statements effective January 1, 2008 on a prospective basis. We adopted the provisions of FSP 157-2 related to nonfinancial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis effective January 1, 2009 on a prospective basis.

The statement requires fair value measurement be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

**Table of Contents**

The following table summarizes our financial instruments as of June 30, 2009 (in thousands):

	June 30, 2009			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
Marketable securities:				
Commercial paper	\$ 12,988	\$	\$ 12,988	\$
Government agencies	24,499		24,499	
<b>Total</b>	<b>\$ 37,487</b>	<b>\$</b>	<b>\$ 37,487</b>	<b>\$</b>

**NOTE 2 - BASIC AND DILUTED NET LOSS PER SHARE**

Basic net loss per share is calculated based on the weighted average number of shares of common stock outstanding during the period. There are potential dilutive shares of common stock resulting from the assumed exercise of outstanding stock options and equivalents.

Because Sangamo is in a net loss position, diluted net loss per share excludes the effects of common stock equivalents consisting of options, which are all antidilutive. Had Sangamo been in a net income position, diluted earnings per share would have included the shares used in the computation of basic net loss per share as well as an additional 796,450 shares and 735,626 shares for the six months ended June 30, 2009 and 2008, respectively, related to outstanding options.

**NOTE 3 - AVAILABLE-FOR-SALE SECURITIES**

In April 2009, the FASB issued FSP No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* (FSP 115-2). FSP 115-2 provides new guidance on the recognition and presentation of other-than-temporary impairment, provides some new disclosure requirements as well as extends certain annual disclosure requirements to interim periods. FSP 115-2 is effective for interim periods and fiscal years ending after June 15, 2009. On April 1, 2009, we adopted the provisions of FSP 115-2 on a prospective basis for available-for-sale securities.

The following is a summary of available-for-sale securities recorded in cash equivalents or marketable securities in our Condensed Consolidated Balance Sheet as of June 30, 2009 and December 31, 2008. Estimated fair values of available-for-sale securities are based on quoted market prices (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized (Losses)	Estimated Fair Value
<b>June 30, 2009</b>				
Cash equivalents:				
U.S. government sponsored entity debt securities	\$ 10,572	\$	\$	\$ 10,572
Total	10,572			10,572
Marketable securities:				
U.S. government sponsored entity debt securities	24,450	49		24,499
Other debt securities	12,916	72		12,988
Total	37,366	121		37,487

Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

Total cash equivalents and marketable securities	\$ 47,948	\$ 121	\$	\$ 48,059
--	-----------	--------	----	-----------

**December 31, 2008**

Cash equivalents:

U.S. government sponsored entity debt securities	\$ 12,123	\$	\$	\$ 12,123
--	-----------	----	----	-----------

<b>Total</b>	<b>12,123</b>			<b>12,123</b>
--------------	---------------	--	--	---------------

Marketable securities:

U.S. government sponsored entity debt securities	24,471	153		24,624
--	--------	-----	--	--------

Corporate debt securities	20,675	123		20,798
---------------------------	--------	-----	--	--------

<b>Total</b>	<b>45,146</b>	<b>276</b>		<b>45,422</b>
--------------	---------------	------------	--	---------------

Total cash equivalents and marketable securities	\$ 57,269	\$ 276	\$	\$ 57,545
--	-----------	--------	----	-----------

**Table of Contents**

As of June 30, 2009 and December 31, 2008, other debt securities consisted of sovereign government-guaranteed foreign issuers.

As of June 30, 2009, all of our available-for-sale debt securities mature in less than one year and were in unrealized gain positions. Additionally, we had no gross realized gains or losses for the three and six months ended June 30, 2009 and June 30, 2008. Therefore, we had no other-than-temporary impairments of our available-for-sale securities as of June 30, 2009.

**NOTE 4 - COMPREHENSIVE LOSS**

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized gains and losses on available-for-sale securities that are excluded from net loss. Comprehensive loss and its components are as follows (in thousands):

	Three months ended		Six months ended	
	June 30,		June 30,	
	2009	2008	2009	2008
Net loss	\$ (4,511)	\$ (7,419)	\$ (11,343)	\$ (15,388)
Changes in unrealized gain on securities available-for-sale	(76)	(255)	(155)	(145)
Comprehensive loss	\$ (4,587)	\$ (7,674)	\$ (11,498)	\$ (15,533)

**NOTE 5 - MAJOR CUSTOMERS, PARTNERSHIPS AND STRATEGIC ALLIANCES****Agreement with Dow AgroSciences in Plant Agriculture**

We have an exclusive commercial license agreement with Dow AgroSciences LLC ( DAS ), a wholly owned indirect subsidiary of Dow Chemical Corporation. Under this agreement, we are providing DAS with access to our proprietary zinc finger DNA-binding protein (ZFP) technology and the exclusive right to use our ZFP technology to modify the genomes or alter the nucleic acid or protein expression of plant cells, plants, or plant cell cultures. We have retained rights to use plants or plant-derived products to deliver ZFP transcription factors (ZFP TFs) or zinc-finger nuclease (ZFN) into human or animals for diagnostic, therapeutic, or prophylactic purposes.

Pursuant to the Research License and Commercial Option Agreement which we entered into in October 2005, DAS made an initial cash payment to us of \$7.5 million. In November 2005, the Company sold approximately 1.0 million shares of common stock to DAS at a price of \$3.85 per share, resulting in proceeds of \$3.9 million. Our agreement with DAS provided for an initial three-year research term during which DAS agreed to pay Sangamo \$6.0 million in research funding over the three-year period and make additional payments of up to \$4.0 million in research milestone payments during this same period, depending on the success of the research program. We agreed to supply DAS and its sublicensees with ZFP TFs and/or ZFNs for both research and commercial use over the initial three year period of the agreement.

In June 2008, DAS exercised its option under the agreement to obtain a commercial license to sell products incorporating, or derived from, plant cells generated using our ZFP technology, including agricultural crops, industrial products and plant-derived biopharmaceuticals. The exercise of the option triggered a one-time commercial license fee of \$6.0 million, payment of the remaining \$2.3 million of the previously agreed \$4.0 million in research milestones, minimum sublicensing payments totaling up to \$25.3 million over 11 years, development and commercialization milestone payments for each product, and royalties on sales of products. Furthermore, DAS has the right to sublicense our ZFP technology to third parties for use in plant cells, plants, or plant cell cultures, and we will be entitled to 25% of any cash consideration received by DAS under such sublicenses. The research program has been extended beyond the initial three-year research term and DAS is providing additional research funding.

DAS may terminate the agreement at any time. In addition, each party may terminate the agreement upon an uncured material breach of the other party. In the event of any termination of the agreement, all rights to use our ZFP technology will revert to us, and DAS will no longer be permitted to practice our ZFP technology or to develop or, except in limited circumstances, commercialize any products derived from our ZFP technology.

The commercial license fee of \$6.0 million, the remaining research milestones of \$2.3 million, and the unrecognized portion of the initial cash payment are recognized ratably over the period from option exercise through December 31, 2009, which reflects the estimated timing over

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

which the ZFP manufacturing technology transfer will occur, as well as the period over which Sangamo will be performing additional research services for DAS.

---

## **Table of Contents**

Revenues under the DAS agreement were \$2.2 million and \$1.7 million during the three months ended June 30, 2009 and 2008, respectively, and \$4.4 million and \$3.0 million during the six months ended June 30, 2009 and 2008, respectively. Related costs and expenses incurred under the agreement were \$813,000 and \$500,000 during the three months ended June 30, 2009 and 2008, respectively, and \$1.6 million and \$1.0 million during the six months ended June 30, 2009 and 2008, respectively.

### **Agreement with Sigma-Aldrich Corporation in Laboratory Research Reagents**

In July 2007, we entered into a license agreement with Sigma-Aldrich Corporation (Sigma). Under the license agreement, we are providing Sigma with access to our proprietary ZFP technology and the exclusive right to use the technology to develop and commercialize research reagents products and services in the research field, excluding certain agricultural research uses that Sangamo previously licensed to Dow AgroSciences LLC. Under the agreement, Sangamo and Sigma have agreed to conduct a three-year research program to develop laboratory research reagents using our ZFP technology. In addition, for three years we will assist Sigma in connection with Sigma's efforts to market and sell services employing our technology in the research field. We will transfer the ZFP manufacturing technology to Sigma or to a mutually agreed-upon contract manufacturer upon Sigma's request. Prior to the completion of this transfer, we will be responsible for supplying ZFPs for use by Sigma in performing services in the research field.

Under the terms of the agreement, Sigma made an initial payment comprising an upfront license fee and the purchase of one million (1,000,000) shares of Sangamo's common stock under a separate stock purchase agreement, resulting in a total upfront payment to Sangamo of \$13.5 million, which consists of an equity investment by Sigma in Sangamo common stock valued at \$8.55 million, a \$3.95 million license fee, and \$1.0 million of research funding. Under the license agreement, we may receive additional research funding of up to \$2.0 million, development milestone payments of up to \$5.0 million, and commercial milestone payments based on net sales of up to \$17.0 million, subject to the continuation of the agreement. During the term of the license agreement, Sigma is obligated to pay to Sangamo minimum annual payments, a share of certain revenues received by Sigma from sublicensees, and royalty payments on the sale of licensed products and services. Sigma also has the right to sublicense the ZFP technology for research applications and we will receive 50% of any sublicensing revenues in the first two years and 25% of any sublicensing revenues thereafter. We retain the sole right to use and license our ZFP technology for GMP production purposes, for the production of materials used in or administered to humans, and for any other industrial commercial use.

The agreement may be terminated by Sigma at any time with a 90-day notice or by either party upon an uncured material breach of the other party. In the event of any termination, all rights to use our ZFP technology will revert to us, and Sigma will no longer be permitted to practice our ZFP technology or to develop or, except in limited circumstances, commercialize any products derived from our ZFP technology.

Revenues related to the research license under the Sigma agreement are being recognized ratably over the three-year research term of the agreement and were \$329,000 during both three month periods ended June 30, 2009 and 2008, and \$658,000 during both six month periods ended June 30, 2009 and 2008. Revenues attributable to collaborative research and development performed under the Sigma agreement were \$1.3 million and \$250,000 for three months ended June 30, 2009 and 2008, respectively, and \$1.5 million and \$500,000 for the six months ended June 30, 2009 and 2008, respectively. Royalty revenues under the Sigma agreement were \$3,000 and \$16,000 during the three months ended June 30, 2009 and 2008, respectively, and \$66,000 and \$16,000 during the six months ended June 30, 2009 and 2008, respectively. Related costs and expenses incurred under the Sigma agreement were \$550,000 and \$322,000 during the three months ended June 30, 2009 and 2008, respectively, and \$1.2 million and \$639,000 during the six months ended June 30, 2009 and 2008, respectively.

### **Enabling Technology Collaborations**

#### ***Pharmaceutical Protein Production***

We have established several research collaborations in this area. Commencing in December 2004, we had a research collaboration agreement with Pfizer, Inc. (Pfizer) to use our ZFP technology to develop enhanced cell lines for protein pharmaceutical production. Under the terms of the agreement, Pfizer funded research at Sangamo and we provided our proprietary ZFP technology for Pfizer to assess its feasibility for use in mammalian cell-based protein production. We generated novel cell lines and vector systems for enhanced protein production as well as novel technology for rapid creation of new production cell lines. In December 2008, we entered into a license agreement with Pfizer to provide Pfizer with a worldwide, non-exclusive license for the use of certain ZFP Nuclease (ZFN) reagents to permanently eliminate the Glutamine Synthetase (GS) gene in Chinese Hamster Ovary (CHO) cell lines and for the use of these ZFN-modified cells for clinical and commercial production of therapeutic proteins. In December 2008, under the terms of this agreement, we received, and recognized as revenue, a one time payment of \$3.0 million from Pfizer for a fully paid commercial license.





## **Table of Contents**

In April 2007, we established a research and license agreement with Genentech, Inc. Under our agreement with Genentech, we are developing ZFNs capable of making targeted modifications to the genome of Genentech cell lines to generate cell lines with novel characteristics for protein pharmaceutical production purposes. Genentech paid an upfront fee, will pay an ongoing technology access fee, and certain payments upon achievement of specified milestones relating to the research of ZFNs and the development and commercialization of products manufactured using a modified cell line created by our ZFN technology. The agreement was expanded to include further ZFNs in February 2008. Under the expanded agreement, we may directly offer the ZFN-related services to Genentech and Sigma will in return receive a share of certain payments made to us by Genentech. Revenues recognized under the expanded agreement are included in royalty revenues from Sigma, as described above.

Revenues attributable to collaborative research and development performed under the Genentech agreement were \$429,000 and \$64,000 during the three months ended June 30, 2009 and 2008, respectively, and \$492,000 and \$264,000 for the six months ended June 30, 2009 and 2008, respectively. Related research and development costs and expenses performed under the Genentech agreement were \$94,000 and \$22,000 during the three months ended June 30, 2009 and 2008, respectively, and \$154,000 and \$54,000 during the six months ended June 30, 2009 and 2008, respectively.

### ***Transgenic Animals***

In April 2008, we entered into a license agreement with Open Monoclonal Technology, Inc. ( OMT ). Under the agreement we had the option to grant, at OMT s request, a royalty-bearing, non-exclusive, sublicensable worldwide license for the commercial use of a transgenic animal generated using our ZFP technology. In February 2009, we granted the commercial license to OMT and received a one-time license fee of \$250,000, which was recognized as revenue upon receipt. Additionally, we will receive payments upon the achievement of certain clinical development milestones, a share of payments received by OMT from sublicensees, and royalties on sales of any products developed using Sangamo s ZFP technology. For any given OMT product, OMT has the right to buy out its future royalty payment obligations under the agreement by paying a lump sum fee to Sangamo.

In July 2008, we entered into a research and license agreement with F. Hoffmann La Roche Ltd and Hoffmann-La Roche Inc. ( Roche ). During an initial research term, we will provide Roche with access to aspects of our proprietary ZFN technology for the targeted modification of a specified gene in a specified species in order to generate ZFN-modified cell lines and animals for research purposes. In addition, Roche has an option to receive an exclusive, worldwide license to use such animals in the production of therapeutic and diagnostic products.

In consideration for the rights and licenses granted to Roche, as well as our efforts in generating the specific ZFN materials provided to Roche, Roche has paid us an initial research event fee, a payment for the delivery of ZFN materials, and will pay ongoing research maintenance fees during the research term. In the event that Roche exercises its option to receive a commercial license, Roche will pay us an option exercise fee, payments upon the achievement of certain clinical development milestones relating to products produced under such commercial license, and royalties on sales of such products.

We have an existing agreement with Sigma to develop and commercialize research reagents and services and Sigma has the exclusive right to offer certain services involving our ZFN technology that are covered under the research agreements with Roche and OMT. Notwithstanding this exclusive right, Sigma has agreed that we may directly offer the ZFN-related services to Roche and OMT under the research agreements and Sigma will in return receive a share of certain payments made to us. Revenues recognized under the Roche and OMT agreements, net of payments made to Sigma, are included in royalty revenues attributable to the Sigma agreement, as described above.

### **Funding from Research Foundations**

#### ***The Juvenile Diabetes Research Foundation International***

In October 2006, we announced a partnership with the Juvenile Diabetes Research Foundation International (JDRF) to provide financial support to one of our Phase 2 human clinical studies (SB-509-601) of SB-509, a ZFP Therapeutic that is in development for the treatment of diabetic neuropathy. Under the agreement with JDRF and subject to its terms and conditions, including the Company s achievement of certain milestones associated with the Company s Phase 2 clinical trial of SB-509 for the treatment of mild to moderate diabetic neuropathy, JDRF will pay the Company an aggregate amount of up to \$3.0 million. Through June 30, 2009, the Company has received the entire \$3.0 million due from JDRF. After the first commercial launch of SB-509 in a major market, JDRF has the right to receive, subject to certain limitations, annual payments from Sangamo, until such time when the total amount paid to JDRF, including payments made on account of certain licensing arrangements, equals three times the amount received by us from JDRF.



**Table of Contents**

Under the JDRF agreement, we are obligated to use commercially reasonable efforts to carry out the Phase 2 trial and, thereafter, to develop and commercialize a product containing SB-509 for the treatment of diabetes and complications of diabetes. We are obligated to cover all costs of the Phase 2 trial that are not covered by JDRF's grant. If we fail to satisfy these obligations, JDRF may have the right, subject to certain limitations, to obtain an exclusive, sublicensable license, to the intellectual property generated by us in the course of the Phase 2 trial, to make and commercialize products containing SB-509 for the treatment of diabetes and complications of diabetes. If JDRF obtains such a license, it is obligated to pay us a percentage of its revenues from product sales and sublicensing arrangements. If JDRF fails to satisfy its obligations to develop and commercialize a product containing SB-509 under the Agreement, then their license rights will terminate and we will receive a non-exclusive, fully paid license, for any intellectual property developed during JDRF's use of the license, to research, develop and commercialize products containing SB-509 for the treatment of diabetes and complications of diabetes.

Revenues attributable to research and development activities performed under the JDRF partnership were \$500,000 and \$375,000 during the three months ended June 30, 2009 and 2008, respectively, and \$500,000 and \$750,000 during the six months ended June 30, 2009 and 2008, respectively. Related costs and expenses incurred were \$387,000 and \$1.1 million during the three months ended June 30, 2009 and 2008, respectively, and \$755,000 and \$2.6 million during the six months ended June 30, 2009 and 2008, respectively.

***The Michael J. Fox Foundation***

In January 2007, Sangamo announced a partnership with the Michael J. Fox Foundation for Parkinson's Research ( MJFF ) to provide financial support of Sangamo's ZFP TFs to activate the expression of glial cell line-derived neurotrophic factor (GDNF) that has shown promise in preclinical testing to slow or stop the progression of Parkinson's disease. Under the agreement with MJFF and subject to its terms and conditions, MJFF has paid the Company \$950,000 over a period of two years and we have received the total funds due from MJFF.

Revenues attributable to research and development performed under the MJFF partnership were \$0 and \$30,000 during the three months ended June 30, 2009 and 2008, respectively, and \$0 and \$282,000 during the six months ended June 30, 2009 and 2008, respectively. Related costs and expenses incurred under the MJFF partnership were \$178,000 and \$124,000 during the three months ended June 30, 2009 and 2008, respectively, and \$377,000 and \$377,000 during the six months ended June 30, 2009 and 2008, respectively.

***The Bill and Melinda Gates Foundation***

In May 2009, Sangamo announced that it had been awarded a Grand Challenges Explorations Grant of \$100,000 by the Bill and Melinda Gates Foundation ( Gates Foundation ) to support research into the use of Sangamo's ZFNs to develop an *in vivo* treatment of HIV/AIDS. Under the agreement, the Gates Foundation will pay Sangamo the award to support research over the period of a year from May 1, 2009 to April 30, 2010.

Revenues attributable to research and development performed under the grant were \$13,000 for the three month and six month periods ended June 30, 2009. Related costs and expenses incurred under the grant were \$13,000 for the three and six month periods ended June 30, 2009.

**NOTE 6 - INCOME TAXES**

We maintain deferred tax assets that reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. These deferred tax assets include net operating loss carryforwards, research credits and capitalized research and development. The net deferred tax asset has been fully offset by a valuation allowance because of the Company's history of losses. Utilization of operating losses and credits may be subject to substantial annual limitation due to ownership change provisions of the Internal Revenue Code of 1986, as amended and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

**Table of Contents****NOTE 7 - STOCK-BASED COMPENSATION**

The following table shows total stock-based compensation expenses included in the condensed consolidated statement of operations for the three month and six month periods ended June 30, 2009 and 2008 (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Costs and expenses:				
Research and development	\$ 707	\$ 678	\$ 1,423	\$ 1,534
General and administrative	806	594	1,579	1,456
Total stock-based compensation expense	\$ 1,513	\$ 1,272	\$ 3,002	\$ 2,990

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations contains trend analysis, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, without limitation, statements containing the words believes, anticipates, expects, continue, and other words of similar import or the negative of those terms or expressions. Such forward-looking statements are subject to known and unknown risks, uncertainties, estimates and other factors that may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Actual results could differ materially from those set forth in such forward-looking statements as a result of, but not limited to, the Risk Factors described below. You should read the following discussion and analysis along with the financial statements and notes attached to those statements included elsewhere in this report and in our annual report on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission on March 3, 2009.

**Overview**

We were incorporated in June 1995. From our inception through June 30, 2009, our activities related primarily to establishing and operating a biotechnology research and development organization and developing relationships with our corporate collaborators. Our scientific and business development endeavors currently focus on the engineering of novel zinc finger DNA-binding proteins (ZFPs) for the regulation and modification of genes. We have incurred net losses since inception and expect to incur losses in the future as we continue our research and development activities. To date, we have funded our operations primarily through the issuance of equity securities, borrowings, payments from research grants and from corporate collaborators and strategic partners. As of June 30, 2009, we had an accumulated deficit of \$185.4 million.

Our revenues have consisted primarily of revenues from our corporate partners for ZFP transcription factors (ZFP TFs) and ZFP nucleases (ZFNs), contractual payments from strategic partners for research programs and research milestones, and research grant funding. We expect revenues will continue to fluctuate from period to period and there can be no assurance that new collaborations or partner fundings will continue beyond their initial terms.

In the development of our ZFP technology platform we have continued to place more emphasis internally on higher-value therapeutic product development and less on our enabling technology applications. We believe this shift in emphasis has the potential to increase the return on investment to our stockholders by allocating capital resources to higher value, therapeutic product development activities. At the same time, it may reduce our revenues over the next several years and subject us to higher financial risk by increasing expenses associated with product development. We have filed Investigational New Drug (IND) applications with the U.S. Food and Drug Administration (FDA) and have initiated three Phase 2 clinical trials of a ZFP Therapeutic in subjects with diabetic neuropathy and one Phase 2 clinical trial in subjects with amyotrophic lateral sclerosis (ALS). We are also conducting a Phase 1 clinical trial to evaluate a ZFP Therapeutic for the treatment of HIV/AIDS. Development of novel therapeutic products is costly and is subject to a lengthy and uncertain regulatory process by the FDA. Our future products are gene-based therapeutics. Adverse events in both our own clinical program and other programs may have a negative impact on regulatory approval, the willingness of potential commercial partners to enter into agreements and the perception of the public.



**Table of Contents**

Research and development expenses consist primarily of salaries and personnel expenses, stock-based compensation expenses, laboratory supplies, pre-clinical and clinical studies, manufacturing expenses, allocated facilities expenses, subcontracted research expenses and expenses for trademark registration and technology licenses. Research and development costs incurred in connection with collaborator-funded activities are expensed as incurred. Costs to acquire technologies that are utilized in research and development and that have no alternative future use are expensed as incurred. We believe that continued investment in research and development is critical to attaining our strategic objectives. We expect these expenses will increase as we focus on development of ZFP Therapeutics. Additionally, in order to develop ZFP TFs and ZFNs as commercially relevant therapeutics, we expect to expend additional resources for expertise in the manufacturing, regulatory affairs and clinical research aspects of biotherapeutic development.

General and administrative expenses consist primarily of salaries and personnel expenses for executive, finance and administrative personnel, stock-based compensation expenses, professional fees, allocated facilities expenses, patent prosecution expenses and other general corporate expenses. As we pursue commercial development of our therapeutic leads we expect the business aspects of the Company to become more complex. We may be required in the future to add personnel and incur additional costs related to the maturity of our business.

**Critical Accounting Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Such estimates are described in Note 1, Basis of Presentation and Summary of Significant Accounting Policies to the Unaudited Notes to Condensed Consolidated Financial Statements. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources, and evaluate our estimates on an ongoing basis. Actual results could differ from those estimates under different assumptions or conditions. There have been no material changes in our critical accounting estimates during the quarter ended June 30, 2009 compared to the disclosures in Part II, Item 7 of our annual report on Form 10-K for the year ended December 31, 2008.

**RESULTS OF OPERATIONS**

*Three months and six months ended June 30, 2009 and 2008*

**Revenues**

	Three months ended June 30, (in thousands, except percentage values)				Six months ended June 30, (in thousands, except percentage values)			
	2009	2008	Change	%	2009	2008	Change	%
Revenues:								
Collaboration agreements	\$ 4,213	\$ 2,378	\$ 1,835	77%	\$ 7,370	\$ 4,462	\$ 2,908	65%
Research grants	513	464	49	11%	513	1,145	(632)	(55)%
Total revenues	\$ 4,726	\$ 2,842	\$ 1,884	66%	\$ 7,883	\$ 5,607	\$ 2,276	41%

Total revenues consist of revenues from collaboration agreements, strategic partnerships and research grants.

Revenues from our corporate collaboration and strategic partnering agreements were \$4.2 million for the three months ended June 30, 2009, compared to \$2.4 million in the corresponding period in 2008. The increase in collaboration agreement revenues was primarily attributable to increased revenues of \$1.0 million in connection with our laboratory research reagents license agreement with Sigma-Aldrich Corporation (Sigma), increased revenues of \$483,000 in connection with our research license and commercial option agreement with Dow AgroSciences LLC (DAS), and increased revenues of \$366,000 in connection with our research and license agreement with Genentech. Research grant revenues were \$513,000 for the three months ended June 30, 2009, compared to \$464,000 in the corresponding period in 2008. The increase in research grant revenues was primarily due to increased revenues of \$125,000 related to our grant from the Juvenile Diabetes Research Foundation (JDRF), partially offset by decreased revenues of \$59,000 in connection with our grant from the Defense Advanced Research Projects Agency (DARPA).

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

Revenues from our corporate collaboration and strategic partnering agreements were \$7.4 million for the six months ended June 30, 2009, compared to \$4.5 million in the corresponding period in 2008. The increase in collaboration agreement revenues was primarily attributable to increased revenues of \$1.4 million in connection with our research license and commercial option agreement with DAS, increased revenues of \$1.0 million in connection with our laboratory research reagents license agreement with Sigma,

**Table of Contents**

increased revenues of \$250,000 in connection with our agreement with Open Monoclonal Technology, and increased revenues of \$228,000 in connection with our research and license agreement with Genentech. Research grant revenues were \$513,000 for the six months ended June 30, 2009, compared to \$1.1 million in the corresponding period in 2008. The decrease in research grant revenues was primarily due to decreased revenues of \$282,000 related to our grant from the Michael J. Fox Foundation, decreased revenues of \$250,000 related to our grant from JDRF, and decreased revenues of \$113,000 in connection with our grant from DARPA.

**Operating Expenses**

	Three months ended June 30, (in thousands, except percentage values)				Six months ended June 30, (in thousands, except percentage values)			
	2009	2008	Change	%	2009	2008	Change	%
Operating expenses:								
Research and development	\$ 6,877	\$ 8,286	\$ (1,409)	(17)%	\$ 14,133	\$ 16,929	\$ (2,796)	(17)%
General and administrative	3,007	2,545	462	18%	5,933	5,472	461	8%
Total expenses	\$ 9,884	\$ 10,831	\$ (947)	(9)%	\$ 20,066	\$ 22,401	\$ (2,335)	(10)%

**Research and Development**

Research and development expenses consist primarily of salaries and personnel expenses, stock-based compensation expense, laboratory supplies, pre-clinical and clinical studies, manufacturing expenses, allocated facilities expenses, subcontracted research expenses and expenses for trademark registration and technology licenses. We expect to continue to devote substantial resources to research and development in the future and expect research and development expenses to increase in the next several years if we are successful in advancing our ZFP Therapeutic product candidates into clinical trials. To the extent we collaborate with others with respect to clinical trials, increases in research and development expenses may be reduced or avoided.

Research and development expenses were \$6.9 million for the three months ended June 30, 2009, compared to \$8.3 million in the corresponding period in 2008. The decrease in research and development expenses was primarily attributable to decreased pre-clinical and manufacturing expenses of \$1.5 million, primarily associated with our HIV / AIDS and glioblastoma multiforme programs, and decreased expenses related to consulting of \$262,000 and lab supplies of \$184,000. This decrease was partially offset by increased clinical trials expenses of \$454,000, primarily associated with our Phase 2 ALS study.

Research and development expenses were \$14.1 million for the six months ended June 30, 2009, compared to \$16.9 million in the corresponding period in 2008. The decrease in research and development expenses was primarily attributable to decreased pre-clinical and manufacturing expenses of \$1.9 million, primarily associated with our HIV / AIDS and glioblastoma multiforme programs, and decreased expenses related to consulting of \$507,000, lab supplies of \$368,000 and stock-based compensation of \$111,000. This decrease was partially offset by increased clinical trials expenses of \$377,000, primarily associated with our Phase 2 ALS study.

**General and Administrative**

General and administrative expenses consist primarily of salaries and personnel expenses for executive, finance and administrative personnel, stock-based compensation expenses, professional services expenses, allocated facilities expenses, patent prosecution expenses and other general corporate expenses. As we pursue commercial development of our therapeutic leads, we expect the business aspects of the Company to become more complex. We may be required in the future to add personnel and incur additional costs related to the maturity of our business.

General and administrative expenses were \$3.0 million for the three months ended June 30, 2009, compared to \$2.5 million in the corresponding period in 2008. The increase was primarily attributable to increased stock-based compensation expenses of \$212,000 and professional services expenses of \$191,000.

General and administrative expenses were \$5.9 million for the six months ended June 30, 2009, compared to \$5.5 million in the corresponding period in 2008. The increase was primarily attributable to increased professional services expenses of \$195,000 and stock-based compensation expenses of \$123,000.





**Table of Contents****Interest and Other Income, net**

	Three months ended June 30, (in thousands, except percentage values)				Six months ended June 30, (in thousands, except percentage values)			
	2009	2008	Change	%	2009	2008	Change	%
Interest and other income, net	\$ 647	\$ 570	\$ 77	14%	\$ 840	\$ 1,406	\$ (566)	(40)%

Interest and other income, net, was \$647,000 for the three months ended June 30, 2009, compared to \$570,000 in the corresponding period in 2008. The increase was primarily due to increased foreign currency remeasurement gains of \$492,000 related to the cash balance held at our wholly-owned UK subsidiary, Gendaq Limited, partially offset by lower interest income earned of \$414,000 due to lower average investment balances and lower interest rates.

Interest and other income, net, was \$840,000 for the six months ended June 30, 2009, compared to \$1.4 million in the corresponding period in 2008. The decrease was primarily due to lower interest income earned of \$1.0 million due to lower average investment balances and lower interest rates. The decrease was partially offset by foreign currency remeasurement gains of \$436,000 for the six months ending June 30, 2009, compared to foreign currency remeasurement losses of \$3,000 in the corresponding period of 2008. Remeasurement gains/losses related to the cash balance held at our wholly-owned UK subsidiary, Gendaq Limited.

**Liquidity and Capital Resources**

Since inception, we have funded our operations primarily through the issuance of equity securities, borrowings, payments from research grants and from corporate collaborators and strategic partners. As of June 30, 2009, we had cash, cash equivalents, marketable securities and interest receivable totaling \$52.6 million.

During the six months ended June 30, 2009, the net cash used in operating activities was \$13.2 million. Net cash used in operating activities related to our net loss of \$11.3 million and changes in operating assets and liabilities of \$4.5 million. The changes in operating assets and liabilities were primarily comprised of decreases in deferred revenues of \$4.0 million and decreases in accounts payable and accrued liabilities of \$1.3 million, partially offset by increases in accrued compensation and employee benefits of \$595,000 and decreases in accounts receivable of \$487,000. This was partially offset by net non-cash charges of \$2.7 million. Non-cash charges were primarily comprised of \$3.0 million related to stock-based compensation and \$291,000 in depreciation and amortization, partially offset by foreign currency remeasurement gains of \$493,000. During the six months ended June 30, 2008, net cash used in operating activities of \$18.2 million related to our net loss of \$15.4 million and changes in operating assets and liabilities of \$5.2 million. The changes in operating assets and liabilities were primarily comprised of increases in accounts receivable of \$8.8 million, decreases in accounts payable and accrued liabilities of \$927,000, decreases in accrued compensation and employee benefits of \$358,000, partially offset by increases in deferred revenues of \$4.8 million. This was partially offset by net non-cash charges of \$2.5 million. Non-cash charges were primarily comprised of \$3.0 million related to stock-based compensation and depreciation and amortization of \$244,000, partially offset by amortization of premium / discount on marketable securities of \$776,000.

During the six months ended June 30, 2009, net cash provided by investing activities was \$7.8 million and was primarily comprised of maturities of marketable securities of \$36.5 million, partially offset by purchases of marketable securities of \$28.7 million. During the six months ended June 30, 2008, net cash provided by investing activities was \$13.5 million and was primarily comprised of maturities of marketable securities of \$51.1 million and proceeds from sales of investments of \$4.0 million, partially offset by purchases of marketable securities of \$41.0 million.

Net cash provided by financing activities for the six months ended June 30, 2009 was \$276,000 and primarily related to proceeds from the issuance of common stock. Net cash provided by financing activities for the six months ended June 30, 2008 was \$1.0 million and related to proceeds from the issuance of common stock.

While we expect our rate of cash usage to increase in the future, in particular, to support our product development endeavors, we believe that the available cash resources, funds received from corporate collaborators, strategic partners and research grants will be sufficient to finance our operations through 2010. We may need to raise additional capital to fund our ZFP Therapeutic development activities. Additional capital may not be available in terms acceptable to us, or at all. If adequate funds are not available, our business and our ability to develop our technology and our ZFP Therapeutic products would be harmed.



## **Table of Contents**

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk for changes in interest rates relates primarily to our cash equivalents and investments. The investments are available-for-sale. We do not use derivative financial instruments in our investment portfolio. We attempt to ensure the safety and preservation of our invested funds by limiting default and market risks. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible within these guidelines. We satisfy liquidity requirements by investing excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers. We mitigate default risk by investing in only investment-grade securities. The portfolio includes marketable securities with active secondary or resale markets to ensure portfolio liquidity. All investments have a fixed interest rate and are carried at market value, which approximates cost.

Our market risks at June 30, 2009 have not changed materially from those discussed in Item 7A of our Form 10-K for the year ended December 31, 2008 on file with the Securities and Exchange Commission.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **(a) Evaluation of Disclosure Controls and Procedures**

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures as of the end of the period covered by this report were functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

#### **(b) Change in Internal Control over Financial Reporting**

No change in the Company's internal control over financial reporting occurred during the Company's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We are not party to any material pending legal proceedings, other than routine litigation incidental to our business.

### **ITEM 1A. RISK FACTORS**

This Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of Sangamo, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our revenues, expenses, net loss and loss per share.

#### **Risks Relating to Development, Commercialization and Regulatory Approval of our Products and Technology**

*ZFP Therapeutics have undergone limited testing in humans and our ZFP Therapeutics may fail safety studies in clinical trials.*

We have initiated and completed a Phase 1 study and a Phase 2 clinical trial in our lead ZFP Therapeutic program, SB-509. In addition, we have completed enrollment and treatment of the patients in several of our Phase 2 trials of SB-509 for diabetic neuropathy and ALS and the drug has been well tolerated. However, if our lead ZFP Therapeutic fails one of its safety studies, it could reduce our ability to attract new investors and corporate partners. In January 2005, we filed an IND application with the FDA for SB-509, a ZFP TF activator of VEGF-A, for the treatment of mild to moderate diabetic neuropathy. We have completed enrollment and treatment of a Phase 1, single blind, single dose, dose-escalation trial

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

to measure the laboratory and clinical safety of SB-509. We have completed enrollment and treatment of a repeat-dosing Phase 2 clinical trial (SB-509-601) and have 2 other related Phase 2 trials ongoing for this indication (SB-509-701 and SB-509-703). We also have initiated a Phase 2 clinical trial (SB 509-801)

---

**Table of Contents**

to evaluate SB-509 for the treatment of ALS. A significant number of the trial subjects have received more than one dose of SB-509 during the course of these Phase 2 studies. In addition, Phase 1 clinical trials of an identical ZFP TF have been carried out in subjects with peripheral artery disease. In December 2008, in collaboration with scientists at the University of Pennsylvania, we filed an IND application for a Phase 1 trial of our CCR5 ZFN-based therapeutic, SB-728-T, for treatment of HIV/AIDS. This trial began enrolling subjects in February 2009 at the University of Pennsylvania. These early studies of a ZFP Therapeutic are a highly visible test of our ZFP Therapeutic approach. Since we have increased our focus on ZFP Therapeutic research and development, investors will increasingly assess the value of our technology based on the continued progress of ZFP Therapeutic products into and through clinical trials. If clinical trials of our lead therapeutic were halted due to safety concerns, this would negatively affect our operations and the value of our stock.

***The results of early Phase 1 and Phase 2 trials are based on a small number of patients over a short period of time, and our progress may not be indicative of results in a large number of patients or of long-term efficacy in late stage clinical trials.***

The results in early phases of clinical testing are based upon limited numbers of patients and a limited follow-up period. Typically, our Phase 1 clinical trials for indications of safety enroll less than 50 patients. The initial results from the Phase 1 clinical trial of our ZFP Therapeutic, SB-509 product, became available in the first half of 2006 and the complete data set was presented in June 2008. The primary end point of the trial was clinical and laboratory safety; however, we collected some preliminary efficacy data that showed trends of clinical improvement in some subjects. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in earlier stage clinical trials. If a larger population of patients does not experience positive results, or if these results are not reproducible, our products may not receive approval from the FDA. Failure to confirm favorable results from earlier trials by demonstrating the safety and effectiveness of our ZFP Therapeutic products in late stage clinical trials with larger patient populations could have a material adverse effect on our business that would cause our stock price to decline significantly.

Our first Phase 2 clinical trial (SB-509-601) for safety and efficacy in subject with diabetic neuropathy enrolled 110 patients, and top-line data from this study were presented in November 2008. While these results demonstrated that the drug was well-tolerated in a repeat-dose setting, no differences were observed in neurologic end-points between the SB-509 and placebo-treated subjects. Subsequently we have performed subgroup analyses of these data which suggest that positive and clinically relevant effects of the drug are more clearly demonstrated in subjects with a certain severity of disease. However, there is no assurance that clinical efficacy of SB-509 can be demonstrated at later stages of testing.

***We have limited experience in conducting clinical trials.***

Our ZFP Therapeutics may fail to show the desired safety and efficacy in initial clinical trials. We have completed a Phase 1 trial and have several ongoing Phase 2 clinical trials of our ZFP Therapeutic for diabetic neuropathy, completing enrollment on one of these studies. We have an additional Phase 2 trial of this drug for ALS and have an ongoing Phase 1 trial of a ZFP Therapeutic for HIV/AIDS. However, the FDA will require additional clinical testing which involves significantly greater resources, commitments and expertise that may require us to enter into a collaborative relationship with a pharmaceutical company that could assume responsibility for late-stage development and commercialization. We have limited experience in conducting clinical trials and may not possess the necessary resources and expertise to complete such trials, and there is no guarantee that we will be able to enter into collaborative relationships with third parties that can provide us with the funding and expertise for such trials.

***We may not be able to find acceptable patients or may experience delays in enrolling patients for our clinical trials.***

We may be competing for suitable patients with other clinical trials. We or the FDA may suspend our clinical trials at any time if either believes that we are exposing the subjects participating in these trials to unacceptable health risks. The FDA or institutional review boards and/or institutional biosafety committees at the medical institutions and healthcare facilities where we sponsor clinical trials may suspend any trial indefinitely if they find deficiencies in the conduct of these trials. The FDA and institutional review boards may also require large numbers of patients, and the FDA may require that we repeat a clinical trial.

***Our potential therapeutic products are subject to a lengthy and uncertain regulatory process, and we may encounter unanticipated toxicity or adverse events or fail to demonstrate efficacy, causing us to delay, suspend or terminate the development of a ZFP Therapeutic. If these potential products are not approved, we will not be able to commercialize those products.***

The FDA must approve any human therapeutic product before it can be marketed in the United States. The process for receiving regulatory approval is long and uncertain, and a potential product may not withstand the rigors of testing under the regulatory approval processes.

Before commencing clinical trials in humans, we must submit an Investigational New Drug (IND) application to the FDA. The FDA has 30 days to comment on the application and if the agency has no comments, we or our commercial partner may begin clinical trials.



## **Table of Contents**

Clinical trials are subject to oversight by institutional review boards and the FDA. In addition, our proposed clinical studies require review from the Recombinant DNA Advisory Committee ( RAC ), which is the advisory board to the National Institutes of Health ( NIH ), focusing on clinical trials involving gene transfer. We will typically submit a proposed clinical protocol and other product-related information to the RAC three to six months prior to the expected IND application filing date.

Clinical trials:

must be conducted in conformance with the FDA's good clinical practices, within the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and other applicable regulations;

must meet requirements for Institutional Review Board ( IRB ) oversight;

must follow Institutional Biosafety Committee ( IBC ) and NIH RAC guidelines where applicable;

must meet requirements for informed consent;

are subject to continuing FDA oversight;

may require oversight by a Data Safety Monitoring Board ( DSMB );

may require large numbers of test subjects; and

may be suspended by a commercial partner, the FDA, or us at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the IND application or the conduct of these trials. While we have stated our intention to file additional IND applications during the next several years, this is only a statement of intent, and we may not be able to do so because the associated product candidates may not meet the necessary preclinical requirements. In addition, there can be no assurance that, once filed, an IND application will result in the actual initiation of clinical trials.

***As we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates.***

We cannot commercialize any of our ZFP Therapeutics to generate revenue until the appropriate regulatory authorities have reviewed and approved the applications for the product candidates. We cannot assure that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate that we or our collaborators develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Regulatory approval processes outside the United States include all of the risks associated with the FDA approval process. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

***Regulatory approval, if granted, may be limited to specific uses or geographic areas, which could limit our ability to generate revenues.***

Regulatory approval will be limited to the indicated use for which we can market a product. Further, once regulatory approval for a product is obtained, the product and its manufacturer are subject to continual review. Discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer, and manufacturing facility, including withdrawal of the product from the



## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

market. In Japan and Europe, regulatory agencies also set or approve prices.

Even if regulatory clearance of a product is granted, this clearance is limited to those specific states and conditions for which the product is useful, as demonstrated through clinical trials. We cannot ensure that any ZFP Therapeutic product developed by us, alone or with others, will prove to be safe and effective in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing clearance in a given country.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities, so we cannot predict whether or when we would be permitted to commercialize our product. These foreign regulatory approval processes include all of the risks associated with FDA clearance described above.

## **Table of Contents**

***Commercialization of our technologies will depend, in part, on strategic partnering with other companies. If we are not able to find strategic partners in the future or our strategic partners do not diligently pursue product development efforts, we may not be able to develop our technologies or products, which could slow our growth and decrease the value of our stock.***

We expect to rely, to some extent, on our strategic partners to provide funding in support of our research and to perform independent research and preclinical and clinical testing. Our technology is broad based, and we do not currently possess the resources necessary to fully develop and commercialize potential products that may result from our technologies or the resources or capabilities to complete the lengthy marketing approval processes that may be required for the products. Therefore, we plan to rely on strategic partnerships to help us develop and commercialize ZFP Therapeutic products. If we are unable to find strategic partners or if the partners we find are unable or unwilling to advance our programs, or if they do not diligently pursue product approval, this may slow our progress and defer our revenues. Our partners may sublicense or abandon development programs or we may have disagreements with our partners, which would cause associated product development to slow or cease. There can be no assurance that we will be able to establish strategic collaborations for ZFP Therapeutic product development. We may require significant time to secure collaborations or strategic partners because we need to effectively market the benefits of our technology to these future collaborators and strategic partners, which use the time and efforts of research and development personnel and our management. Further, each collaboration or strategic partnering arrangement will involve the negotiation of terms that may be unique to each collaborator or strategic partner. These business development efforts may not result in a collaboration or strategic partnership.

The loss of any future strategic partnering agreements would not only delay or terminate the potential development or commercialization of products we may derive from our technologies, but it may also delay or terminate our ability to test ZFP Therapeutic candidates for specific genes. If any strategic partner fails to conduct the collaborative activities successfully and in a timely manner, the preclinical or clinical development or commercialization of the affected product candidates or research programs could be delayed or terminated.

Under typical strategic partnering agreements we would expect to receive revenue for the research and development of a ZFP Therapeutic product and based on achievement of specific milestones. Achieving these milestones will depend, in part, on the efforts of our strategic partner as well as our own. If we, or any strategic partner, fail to meet specific milestones, then the strategic partnership may be terminated, which could decrease our revenues. For more information on risks relating to our third party collaborative agreements, see Risks Relating to our Collaborative Relationships.

***We have increased the focus of our research and development programs on human therapeutics, which will increase operating expenditures and the uncertainty of our business.***

We have significantly increased the emphasis and focus of our research and development activities on ZFP Therapeutics. This change may increase operating expenditures due to larger financial outlays to fund preclinical studies, manufacturing, and clinical research. The focus on ZFP Therapeutics will also increase the visibility of our lead therapeutic programs and the potential impact on the stock price of news releases relating to these programs.

***We are conducting proprietary research to discover ZFP Therapeutic product candidates. These programs increase our financial risk of product failure, may significantly increase our research expenditures, and may involve conflicts with future collaborators and strategic partners.***

Our proprietary research programs consist of research which is funded solely by the Company and in which the Company retains exclusive rights to therapeutic products generated by such research. This is in contrast to certain of our research programs that may be funded by corporate partners and in which we may share rights to any resulting products. We have conducted proprietary research since inception. However, in the past several years, our strategy has shifted toward placing greater emphasis on proprietary research and therapeutic development and we expect this trend will continue in 2009 as we continue to prosecute our Phase 2 clinical trials and bring new ZFP Therapeutics into clinical trials. Conducting proprietary research programs may not generate corresponding revenue and may create conflicts with our collaborators or strategic partners over rights to our intellectual property with respect to our proprietary research activities. Any conflict with our collaborators or strategic partners could reduce our ability to enter into future collaborations or strategic partnering agreements and negatively impact our relationship with existing collaborators and strategic partners which could reduce our revenue and delay or terminate our product development. The implementation of this strategy will involve substantially greater business risks, the expenditure of significantly greater funds than our historic research activities and will require substantial commitments of time from our management and staff.

## **Table of Contents**

*We may be unable to license gene transfer technologies that we may need to commercialize our ZFP TF technology.*

In order to regulate or modify a gene in a cell, the ZFP TF or ZFN must be efficiently delivered to the cell. We have licensed certain gene transfer technologies for use with our Enabling Technologies, which are ZFP TFs and ZFNs used in pharmaceutical discovery research and protein production. We are evaluating these systems and other technologies that may need to be used in the delivery of ZFP TFs or ZFNs into cells for in vitro and in vivo applications, including ZFP Therapeutics. However, we may not be able to license the gene transfer technologies required to develop and commercialize our ZFP Therapeutics. We have not developed our own gene transfer technologies, and we rely on our ability to enter into license agreements to provide us with rights to the necessary gene transfer technology. The inability to obtain a license to use gene transfer technologies with entities which own such technology on reasonable commercial terms, if at all, could delay or prevent the preclinical evaluation, clinical testing, and/or commercialization of our therapeutic product candidates.

*We do not currently have the infrastructure or capability to manufacture therapeutic products on a commercial scale.*

In order for us to commercialize these therapeutic products directly, we would need to develop, or obtain through outsourcing arrangements, the capability to execute all of these functions. If we are unable to develop or otherwise obtain the requisite preclinical, clinical, regulatory, manufacturing, marketing, and sales capabilities, we would be unable to directly commercialize our therapeutics products which would limit our future growth.

*Even if our technology proves to be effective, it still may not lead to commercially viable products.*

Even if our collaborators or strategic partners are successful in using our ZFP technology in drug discovery, protein production, therapeutic development, or plant agriculture, they may not be able to commercialize the resulting products or may decide to use other methods competitive with our technology. To date, no company has received marketing approval or has developed or commercialized any therapeutic or agricultural products based on our technology. Should our technology fail to provide safe, effective, useful, or commercially viable approaches to the discovery and development of these products, this would significantly limit our business and future growth and would adversely affect our value.

*Even if our product development efforts are successful and even if the requisite regulatory approvals are obtained, our ZFP Therapeutics may not gain market acceptance among physicians, patients, healthcare payers and the medical community.*

A number of additional factors may limit the market acceptance of products including the following:

rate of adoption by healthcare practitioners;

rate of a product's acceptance by the target population;

timing of market entry relative to competitive products;

availability of alternative therapies;

price of our product relative to alternative therapies;

availability of third-party reimbursement;

extent of marketing efforts by us and third-party distributors or agents retained by us; and

side effects or unfavorable publicity concerning our products or similar products.

**Risks Relating to our Industry**

*If our competitors develop, acquire, or market technologies or products that are more effective than ours, this would reduce or eliminate our commercial opportunity.*

Any products that we or our collaborators or strategic partners develop by using our ZFP technology platform will enter into highly competitive markets. Even if we are able to generate ZFP Therapeutics that are safe and effective for their intended use, competing technologies may prove to be more effective or less expensive, which, to the extent these competing technologies achieve market acceptance, will limit our revenue opportunities. In some cases, competing technologies have proven to be satisfactorily effective and less expensive, as has been the case with technologies competitive with our Enabling Technology applications. Competing technologies may include other methods of regulating gene expression or modifying genes. ZFP TFs and ZFNs have broad application in the life sciences industry and compete with a broad array of new technologies and approaches being applied to genetic research by many companies. Competing proprietary technologies with our product development focus include:

For ZFP Therapeutics:

small molecule drugs;

**Table of Contents**

monoclonal antibodies;

recombinant proteins;

gene therapy/cDNAs;

antisense; and

siRNA and microRNA approaches

For our Enabling Technology Applications:

*For protein production:* gene amplification, meganucleases, insulator technology, mini-chromosomes;

*For target validation:* antisense, siRNA; and

*For plant agriculture:* recombination approaches, mutagenesis approaches, meganucleases, mini-chromosomes;

In addition to possessing competing technologies, our competitors include pharmaceutical and biotechnology companies with:

substantially greater capital resources than ours;

larger research and development staffs and facilities than ours; and

greater experience in product development and in obtaining regulatory approvals and patent protection;

These organizations also compete with us to:

attract qualified personnel;

attract parties for acquisitions, joint ventures or other collaborations; and

license the proprietary technologies of academic and research institutions that are competitive with our technology, which may preclude us from pursuing similar opportunities.

Accordingly, our competitors may succeed in obtaining patent protection or commercializing products before us. In addition, any products that we develop may compete with existing products or services that are well established in the marketplace.

***Our gene regulation and gene modification technology is relatively new, and if we are unable to use this technology in all our intended applications, it would limit our revenue opportunities.***

Our technology involves a relatively new approach to gene regulation and gene modification. Although we have generated ZFPs for thousands of gene sequences, we have not created ZFPs for all gene sequences and may not be able to do so, which could limit the usefulness of our technology. In addition, while we have demonstrated the function of engineered ZFP TFs in mammalian cell culture, yeast, insects, plants, and animals, we have not yet definitively done so in humans, and the failure to do so could restrict our ability to develop commercially viable products. If we, and our collaborators or strategic partners, are unable to extend our results to new commercially important genes, experimental animal models, and human clinical studies, we may be unable to use our technology in all its intended applications. Also, delivery of ZFP TFs and ZFNs into cells and organisms, including humans, in these and other environments is limited by a number of technical hurdles, which we may be unable to surmount. This is a particular challenge for therapeutic applications of our technology that will require the use of gene transfer systems that may not be effective for the delivery of our ZFP TFs or ZFNs in a particular therapeutic application.

The expected value and utility of our ZFP TFs and ZFNs is in part based on our belief that the targeted or specific regulation of gene expression and targeted gene modification may enable us to develop a new therapeutic approach as well as to help scientists better understand the role of genes in disease, to aid their efforts in drug discovery and development. We also believe that the regulation of gene expression and targeted gene addition will have utility in agricultural applications. There is only a limited understanding of the role of specific genes in all these fields. Life sciences companies have developed or commercialized only a few products in any of these fields based on results from genomic research or the ability to regulate gene expression. We, our collaborators, or our strategic partners, may not be able to use our technology to identify and validate drug targets or to develop commercial products in the intended markets.

---

## **Table of Contents**

### ***Adverse events in the field of gene therapy may negatively impact regulatory approval or public perception of our potential products.***

Our potential therapeutic products are delivered to patients as gene-based drugs, or gene therapy. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy is unsafe, and, consequently, our products may not gain the acceptance of the public or the medical community. Negative public reaction to gene therapy in general could result in greater government regulation and stricter labeling requirements of gene therapy products, including any of our products, and could cause a decrease in the demand for any products we may develop.

### ***Laws or public sentiment may limit the production of genetically modified agricultural products in the future, and these laws could reduce our partner's ability to sell these products.***

Genetically modified products are currently subject to public debate and heightened regulatory scrutiny, either of which could prevent or delay production of agricultural products. In October 2005, we entered into a Research License and Commercial Option Agreement with DAS. In June 2008, DAS exercised its option for a commercial license to our technology. Under this agreement, we will provide DAS with access to our proprietary ZFP technology and the exclusive right to use our ZFP technology to modify the genomes or alter the nucleic acid or protein expression of plant cells, plants, or plant cell cultures. The field-testing, production, and marketing of genetically modified plants and plant products are subject to federal, state, local, and foreign governmental regulation. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of our genetically modified products in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our product development programs or the commercialization of resulting products.

The FDA currently applies the same regulatory standards to foods developed through genetic engineering as those applied to foods developed through traditional plant breeding. Genetically engineered food products, however, will be subject to pre-market review if these products raise safety questions or are deemed to be food additives. Governmental authorities could also, for social or other purposes, limit the use of genetically modified products created with our gene regulation technology.

Even if we are able to obtain regulatory approval for genetically modified products, our success will also depend on public acceptance of the use of genetically modified products including drugs, plants, and plant products. Claims that genetically modified products are unsafe for consumption or pose a danger to the environment may influence public attitudes. Our genetically modified products may not gain public acceptance. The subject of genetically modified organisms has received negative publicity in the United States and particularly in Europe, and such publicity has aroused public debate. The adverse publicity in Europe could lead to greater regulation and trade restrictions on imports of genetically altered products. Similar adverse public reaction or sentiment in the United States to genetic research and its resulting products could result in greater domestic regulation and could decrease the demand for our technology and products.

### **Risks Relating to our Finances**

#### ***We anticipate continuing to incur operating losses for the next several years. If material losses continue for a significant period, we may be unable to continue our operations.***

We have generated operating losses since we began operations in 1995. The extent of our future losses and the timing of profitability are uncertain, and we expect to incur losses for the foreseeable future. We have been engaged in developing our ZFP TF technology since inception, which has and will continue to require significant research and development expenditures. In July 2007, we completed a registered direct offering to institutional investors for a total of 3,278,689 shares of common stock, at a price of \$9.15 per share, resulting in net proceeds to us of \$28.0 million. Also in July 2007, we entered into a license agreement and a related stock purchase agreement with Sigma-Aldrich Corporation (Sigma) under which we sold to Sigma 1.0 million shares of Sangamo's common stock valued at \$8.55 million. In June 2006, in an underwritten public offering and pursuant to an effective registration statement, we sold 3,100,000 shares of common stock at a public offering price of \$6.75 per share, resulting in net proceeds of approximately \$20.2 million. In November 2005, we completed a registered direct offering to institutional and strategic investors for a total of 5,080,000 shares of common stock at a price of \$3.85 per share to the investors, resulting in net proceeds to Sangamo of approximately \$18.2 million. To date, we have generated all other funding from revenues derived from strategic partnering agreements, Enabling Technology collaborations, federal government research grants and grants awarded by research foundations. As of June 30, 2009, we had an accumulated deficit of \$185.4 million. Losses will increase as we expand and extend our research and development activities into human therapeutic product development. If the time required us to generate significant product revenues and achieve profitability is longer than we currently anticipate or if we are unable to generate liquidity through equity financing or other sources of funding, we may not be able to sustain our operations.





---

## **Table of Contents**

*We may be unable to raise additional capital, which would harm our ability to develop our technology and products.*

We have incurred significant operating losses and negative operating cash flows since inception and have not achieved profitability. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure and research and ZFP Therapeutic product development activities. While we believe our financial resources will be adequate to sustain our current operations at least through 2010, we may seek additional sources of capital through equity or debt financing. In 2008 and 2009, we have been in the midst of a global recession, and the credit markets have experienced significant upheaval, while the equity market has demonstrated a high degree of volatility. As a result, we believe that the difficulty of an emerging biotechnology company raising capital through equity or debt financing has increased significantly. We do not know when, or if, the prospects for an emerging biotechnology company to raise capital will improve. In addition, as we focus our efforts on proprietary human therapeutics, we will need to seek FDA approval of potential products, a process that could cost in excess of \$100 million per product. We cannot be certain that we will be able to obtain financing on terms acceptable to us, or at all. If adequate funds are not available, our business and our ability to develop our technology and ZFP Therapeutic products would be harmed.

*We are at the development phase of operations and may not succeed or become profitable.*

We began operations in 1995 and are in the early phases of ZFP Therapeutic product development. We have incurred significant losses and our net losses for the past three years ended 2008, 2007 and 2006 were \$24.3 million, \$21.5 million, and \$17.9 million, respectively. To date, our revenues have been generated from strategic partners, Enabling Technology collaborations, and federal government and research foundation grants. Since 2005, we have placed significant emphasis on higher-value therapeutic product development and related strategic partnerships. This shift in emphasis has the potential to increase the return on investment to our stockholders by allocating capital resources to higher value, therapeutic product development activities. At the same time, it increases our financial risk by increasing expenses associated with product development. In addition, the preclinical or clinical failure of any single product, such as our Phase 2 clinical trials of SB-509, may have a significant effect on the actual or perceived value of our shares. Our business is subject to all of the risks inherent in the development of a new technology, which included the need to:

attract and retain qualified scientific and technical staff and management, particularly scientific staff with expertise to develop our early-stage technology into therapeutic products;

obtain sufficient capital to support the expense of developing our technology platform and developing, testing, and commercializing products;

develop a market for our products;

successfully transition from a company with a research focus to a company capable of supporting commercial activities; and

attract and enter into research collaborations with research and academic institutions and scientists.

### **Risks Relating to our Collaborative Relationships**

*If conflicts arise between us and our collaborators, strategic partners, scientific advisors, or directors, these parties may act in their self-interest, which may limit our ability to implement our strategies.*

If conflicts arise between our corporate or academic collaborators, strategic partners, or scientific advisors or directors and us, the other party may act in its self-interest, which may limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates.

## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

Some of our collaborators or strategic partners could also become competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

***If we establish drug development collaborations, our collaborators may control aspects of our clinical trials, which could result in delays and other obstacles in the commercialization of our proposed products.***

For some programs we may be dependent on third party collaborators to design and conduct our clinical trials. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations. In addition, if any of these collaborative partners withdraw support for our programs or proposed products or otherwise impair their development, our business could be negatively affected.

**Table of Contents**

***Our collaborators or strategic partners may decide to adopt alternative technologies or may be unable to develop commercially viable products with our technology, which would negatively impact our revenues and our strategy to develop these products.***

Our collaborators or strategic partners may adopt alternative technologies, which could decrease the marketability of ZFP technology. Additionally, because many of our collaborators or strategic partners are likely to be working on more than one development project, they could choose to shift their resources to projects other than those they are working on with us. If they do so, this would delay our ability to test our technology and would delay or terminate the development of potential products based on our ZFP technology. Further, our collaborators and strategic partners may elect not to develop products arising out of our collaborative and strategic partnering arrangements or to devote sufficient resources to the development, manufacturing, marketing, or sale of these products. If any of these events occur, we may not be able to develop our technologies or commercialize our products.

***If we do not successfully commercialize ZFP-based research reagents under our license agreement with Sigma-Aldrich Corporation or ZFP-based agricultural products with Dow AgroSciences, or if Sigma or Dow AgroSciences terminates our agreements, our ability to generate revenue under these license agreements may be limited.***

In July 2007, we entered into a license agreement with Sigma to collaborate in the application and development of ZFP-based products for use in the laboratory research reagents markets, and in June 2008, following a research period, Dow AgroSciences (DAS) exercised its commercial license option under a license agreement with Sangamo relating to plant agriculture. These agreements provide Sigma with access to Sangamo's ZFP technology and the exclusive right to use Sangamo's ZFP technology to develop and commercialize products for use as research reagents and to offer services in related research fields, and provide DAS with the exclusive right to develop agricultural products using our ZFP technology in plant cells, plants, or plant cell cultures. Both companies also have the right to sublicense our technology in their respective areas. In addition to upfront payments, Sangamo may also receive additional license fees, shared sublicensing revenues, royalty payments and milestone payments depending on the success of the development and commercialization of the licensed products and services covered under both agreements. The commercial milestones and royalties are based upon net sales of licensed products.

We cannot be certain that Sigma, DAS and Sangamo will succeed in the development of commercially viable products in these fields of use, and there is no guarantee that Sigma, DAS and Sangamo will achieve the milestones set forth in the respective license agreements. To the extent Sigma, DAS and Sangamo do not succeed in developing and commercializing products or if Sigma, DAS and Sangamo fail to achieve such milestones, our revenues and benefits under the license agreements will be limited. In addition, the respective license agreements may be terminated by Sigma and DAS at any time by providing us with a 90-day notice. In the event Sigma or DAS decides to terminate the license agreements, our ability to generate revenue under such license agreements will cease.

***If we do not successfully commercialize certain ZFP Therapeutic programs relating to diabetic neuropathy under our agreement with JDRF, JDRF may have the right to continue to advance the program and we may lose control of the intellectual property generated in the collaboration and development of the product and may only receive a portion of the revenue generated if commercialization by JDRF is successful.***

In October 2006, we entered into a Research, Development and Commercialization Agreement with JDRF. Under the agreement and subject to its terms and conditions, including our achievement of certain milestones associated with our Phase 2 clinical trial of SB-509 (SB-509-601) for the treatment of diabetic neuropathy, JDRF has paid us a total of \$3.0 million through June 30, 2009. We are obligated to cover the costs of the Phase 2 trial that are not covered by JDRF's grant.

Under the agreement, we are obligated to use commercially reasonable efforts to carry out the Phase 2 trial and, thereafter, to develop and commercialize, a product containing SB-509 for the treatment of diabetes and complications of diabetes. If we fail to satisfy these obligations, JDRF may have the right, subject to certain limitations, to obtain an exclusive, sublicensable license, to the intellectual property generated by us in the course of the Phase 2 trial, to make and commercialize products containing SB-509 for the treatment of diabetes and complications of diabetes. If JDRF obtains such a license, it is obligated to pay us a percentage of its revenues from product sales and sublicensing arrangements. If JDRF fails to satisfy its obligations to develop and commercialize a product containing SB-509 under the Agreement, then their license rights will terminate and we will receive a non-exclusive, fully paid license, for any intellectual property developed during JDRF's use of the license, to research, develop and commercialize products containing SB-509 for the treatment of diabetes and complications of diabetes. There is no guarantee that we will be successful in commercializing a product containing SB-509 in the future. If we fail to do so under the agreement with JDRF, we may lose control of the intellectual property generated in the development of the product and may only receive a portion of the revenue generated if commercialization by JDRF is successful.

## **Table of Contents**

*Our collaborations with outside scientists may be subject to change, which could limit our access to their expertise.*

We work with scientific advisors and collaborators at academic research institutions. These scientists are not our employees and may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. Although our scientific advisors and academic collaborators sign agreements not to disclose our confidential information, it is possible that some of our valuable proprietary knowledge may become publicly known through them, which may cause competitive harm to our business.

### **Risks Relating to our Intellectual Property and Business Operation**

*Because it is difficult and costly to protect our proprietary rights, and third parties have filed patent applications that are similar to ours, we cannot ensure the proprietary protection of our technologies and products.*

Our commercial success will depend in part on obtaining patent protection of our technology and successfully defending any of our patents that may be challenged. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and can involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, we cannot predict the breadth of claims allowed in patents we own or license.

We are a party to various license agreements that give us rights under specified patents and patent applications. Our current licenses, as our future licenses frequently will, contain performance obligations. If we fail to meet those obligations, the licenses could be terminated. If we are unable to continue to license these technologies on commercially reasonable terms, or at all, we may be forced to delay or terminate our product development and research activities.

With respect to our present and any future sublicenses, since our rights derive from those granted to our sublicensor, we are subject to the risk that our sublicensor may fail to perform its obligations under the master license or fail to inform us of useful improvements in, or additions to, the underlying intellectual property owned by the original licensor.

We are unable to exercise the same degree of control over intellectual property that we license from third parties as we exercise over our internally developed intellectual property. We do not control the prosecution of certain of the patent applications that we license from third parties; therefore, the patent applications may not be prosecuted as we desire or in a timely manner.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

we or our licensors were the first to make the inventions covered by each of our pending patent applications;

we or our licensors were the first to file patent applications for these inventions;

the patents of others will not have an adverse effect on our ability to do business;

others will not independently develop similar or alternative technologies or reverse engineer any of our products, processes or technologies;

any of our pending patent applications will result in issued patents;

any patents issued or licensed to us or our collaborators or strategic partners will provide a basis for commercially viable products or will provide us with any competitive advantages;

any patents issued or licensed to us will not be challenged and invalidated by third parties; or

we will develop additional products, processes or technologies that are patentable.

Others have filed and in the future are likely to file patent applications that are similar to ours. We are aware that there are academic groups and other companies that are attempting to develop technology that is based on the use of zinc finger and other DNA-binding proteins, and that these groups and companies have filed patent applications. Several patents have been issued, although we have no current plans to use the associated inventions. If these or other patents issue, it is possible that the holder of any patent or patents granted on these applications may bring an infringement action against our collaborators, strategic partners, or us claiming damages and seeking to enjoin commercial activities relating to the affected products and processes. The costs of litigating the claim could be substantial. Moreover, we cannot predict whether we, our collaborators, or strategic partners would prevail in any actions. In addition, if the relevant patent claims were upheld as valid and enforceable and our products or processes were found to infringe the patent or patents, we could be prevented from making, using, or selling the relevant product or process unless we could obtain a license or were able to design around the patent claims. We can give no assurance that such a license would be available on commercially reasonable terms, or at all, or that we would be able to successfully design around the relevant patent claims. There may be significant litigation in the genomics industry regarding patent and other intellectual property rights, which could subject us to litigation. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources.

---

## **Table of Contents**

We cannot guarantee that third parties will not challenge our intellectual property. One of our in-licensed foreign patents, licensed to Sangamo from Johns Hopkins University which forms the basis for five European Regional Phase patents, has been revoked as a result of an opposition by a third party. Our licensor, Johns Hopkins University, appealed the revocation but in April 2007, the European Technical Board of Appeal released its decision dismissing the appeal. This outcome may limit our ability to exclude potential competitors in the field of targeted recombination and gene correction in Europe but does not affect our ability to practice our targeted recombination and gene correction programs in Europe. Moreover, we also hold licenses to six US patents to the technology covered by the opposed European patent, and hold licenses to related applications pending in Canada and Japan. As of August 1, 2009, US patent number US6,265,196, licensed to Sangamo from Johns Hopkins University, was undergoing re-examination. In addition in 2008, US5,792,640, also licensed from Johns Hopkins University, completed a first re-examination process and a re-exam certificate was issued on September 9, 2008. However, a second re-exam proceeding was ordered on November 4, 2008. We cannot predict the outcome of the reexamination, which may be unfavorable to us.

We rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets, however, are difficult to protect. While we require employees, academic collaborators, and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information or enforce these confidentiality agreements.

Our collaborators, strategic partners, and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations and strategic partnerships, then we may not be able to receive patent protection or protect our proprietary information.

*If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.*

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals, and various radioactive compounds typically employed in molecular and cellular biology. We routinely use cells in culture and gene delivery vectors, and we employ small amounts of radioisotopes in trace experiments. Although we maintain up-to-date licensing and training programs, we cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling, or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our resources. We currently carry insurance covering certain claims arising from our use of these materials. However, if we are unable to maintain our insurance coverage at a reasonable cost and with adequate coverage, our insurance may not cover any liability that may arise. We are subject to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. To date, we have not experienced significant costs in complying with regulations regarding the use of these materials.

*Failure to attract, retain, and motivate skilled personnel and cultivate key academic collaborations will delay our product development programs and our research and development efforts.*

We are a small company with 76 full-time employees as of July 31, 2009, and our success depends on our continued ability to attract, retain, and motivate highly qualified management and scientific personnel and our ability to develop and maintain important relationships with leading research and academic institutions and scientists. Competition for personnel and academic and other research collaborations is intense. The success of our technology development programs depends on our ability to attract and retain highly trained personnel. We have experienced a rate of employee turnover that we believe is typical of emerging biotechnology companies. If we lose the services of personnel with the necessary skills, it could significantly impede the achievement of our research and development objectives. We are not presently aware of any plans of specific employees to retire or otherwise leave the company. If we fail to negotiate additional acceptable collaborations with academic and other research institutions and scientists, or if our existing collaborations are unsuccessful, our ZFP Therapeutic development programs may be delayed or may not succeed.

### **Risks Relating to our Common Stock and Corporate Organization**

*Our stock price has been volatile and may continue to be volatile, which could result in substantial losses for investors.*

During the quarter ended June 30, 2009, our common stock price ranged from a low of \$3.51 to high of \$4.98. During the past two years, our common stock price has fluctuated significantly, ranging from a low of \$1.95 to a high of \$13.65 during the year ended December 31, 2008, and a low of \$6.22 to a high of \$19.08 during the year ended December 31, 2007. The recent market instability caused by the turmoil in the financial industry has further contributed to the volatility of our stock price. Volatility in our common stock could cause stockholders to incur substantial losses. An active public market for our common stock may not be sustained, and the market price of our common stock may continue to be highly volatile. The market price of our common stock has fluctuated significantly in response to various factors, some of which are beyond our control, including but not limited to the following:

announcements by us or future partners providing updates on the progress or development status of ZFP Therapeutics;

**Table of Contents**

data from clinical trials;

changes in market valuations of similar companies;

overall market conditions;

deviations in our results of operations from the guidance given by us or estimates of securities analysts;

announcements by us or our competitors of new or enhanced products, technologies or services or significant contracts, acquisitions, strategic relationships, joint ventures or capital commitments;

regulatory developments;

additions or departures of key personnel;

future sales of our common stock or other securities by the Company, management or directors, liquidation of institutional funds that comprised large holdings of Sangamo stock; and

decreases in our cash balances.

***Our common stock is relatively thinly traded, which means large transactions in our common stock may be difficult to conduct in a short time frame.***

We have a relatively low volume of daily trades in our common stock on the Nasdaq Global Market. For example, the average daily trading volume in our common stock on the Nasdaq Global Market over the ten-day trading period prior to July 30, 2009 was 211,860 shares per day. Any large transactions in our common stock may be difficult to conduct and may cause significant fluctuations in the price of our common stock.

***Our stock price is also influenced by public perception of gene therapy and government regulation of potential products.***

Reports of serious adverse events in a retroviral gene transfer trial for infants with X-linked severe combined immunodeficiency (X-linked SCID) in France and subsequent FDA actions putting related trials on hold in the United States had a significant negative impact on the public perception and stock price of certain companies involved in gene therapy. Stock prices of these companies declined whether or not the specific company was involved with retroviral gene transfer for the treatment of infants with X-linked SCID, or whether the specific company's clinical trials were placed on hold in connection with these events. Other potential adverse events in the field of gene therapy may occur in the future that could result in greater governmental regulation of our potential products and potential regulatory delays relating to the testing or approval of our potential products. These external events may have a negative impact on public perception of our business, which could cause our stock price to decline.

***Anti-takeover provisions in our certificate of incorporation and Delaware law could make an acquisition of the Company more difficult and could prevent attempts by our stockholders to remove or replace current management.***

Anti-takeover provisions of Delaware law and in our certificate of incorporation and our bylaws may discourage, delay or prevent a change in control of our company, even if a change in control would be beneficial to our stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. In particular, under our certificate of incorporation our board of directors may issue up to 5,000,000 shares of preferred stock with rights and privileges that might be senior to our common stock, without the consent of the holders of the common stock.



## Edgar Filing: SANGAMO BIOSCIENCES INC - Form 10-Q

Moreover, without any further vote or action on the part of the stockholders, the board of directors would have the authority to determine the price, rights, preferences, privileges, and restrictions of the preferred stock. This preferred stock, if it is ever issued, may have preference over, and harm the rights of, the holders of common stock. Although the issuance of this preferred stock would provide us with flexibility in connection with possible acquisitions and other corporate purposes, this issuance may make it more difficult for a third party to acquire a majority of our outstanding voting stock.

Similarly, our authorized but unissued common stock is available for future issuance without stockholder approval.

In addition, our bylaws:

state that stockholders may not act by written consent but only at a stockholders meeting;

establish advance notice requirements for nominations for election to the board of directors or proposing matters that can be acted upon at stockholders meetings; and

prohibit stockholders from calling a special meeting of stockholders.

**Table of Contents**

We are also subject to Section 203 of the Delaware General Corporation Law, which provides, subject to certain exceptions, that if a person acquires 15% of our voting stock, the person is an interested stockholder and may not engage in business combinations with us for a period of three years from the time the person acquired 15% or more of our voting stock.

***Insiders have influence over Sangamo and could delay or prevent a change in corporate control.***

The interest of management could conflict with the interest of our other stockholders. Our executive officers and directors beneficially own, in the aggregate, approximately 10% of our outstanding common stock as of June 30, 2009. As a result, these stockholders, if they choose to act together, may have a material impact on all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of Sangamo, which in turn could reduce the market price of our stock.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

The annual meeting of shareholders was held on June 4, 2009. Two matters were voted on and each was approved. The results were as follows:

**PROPOSAL I**

To elect six director nominees to hold office until the 2010 Annual Meeting of Stockholders or until their successors are duly elected and qualified:

NOMINEE	VOTES FOR	VOTES WITHHELD
Edward O. Lanphier, II	32,559,825	580,492
Paul B. Cleveland	32,692,089	448,228
William G. Gerber	31,933,667	1,206,605
John W. Larson	30,018,410	3,121,907
Steven J. Mento	32,694,406	445,911
Thomas G. Wiggans	31,044,552	2,095,765

**PROPOSAL II**

The proposal to ratify the selection of Ernst & Young LLP as the Company's independent registered public accounting firm for the year ending December 31, 2009 was approved.

FOR	AGAINST	ABSTAINED	NON VOTES
32,245,412	145,714	749,191	0

**ITEM 6. EXHIBITS**

(a) Exhibits:

- 31.1 Rule 13a - 14(a) Certification by Principal Executive Officer
- 31.2 Rule 13a - 14(a) Certification by Principal Financial and Accounting Officer
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350.

**Table of Contents**

**SIGNATURES**

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

SANGAMO BIOSCIENCES, INC. Dated: July 31, 2009

/s/ H. Ward Wolff  
H. Ward Wolff  
Executive Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)