UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 11, 2004

SANGAMO BIOSCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction) **000-30171** (Commission File Number of incorporation) **68-0359556** (I.R.S. 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)

ITEM 5. OTHER EVENTS

On February 11, 2004, Sangamo BioSciences, Inc. and Edwards Lifesciences Corporation announced the filing of an investigational new drug application (IND) by Edwards Lifesciences with the U.S. Food and Drug Administration for EW-A-401, a novel therapeutic designed to stimulate the growth of normal blood vessels for the treatment of peripheral artery disease. A joint press release was issued by Sangamo and Edwards Lifesciences announcing the filing of the IND on February 11, 2004, a copy of which is attached hereto as Exhibit 99.1.

ITEM 7. EXHIBITS

- (c) Exhibits
 - 99.1 Joint Press Release of Sangamo BioSciences, Inc. and Edwards Lifesciences Corporation dated February 11, 2004 announcing the filing of an IND.
 - 99.2 Press Release of Sangamo BioSciences, Inc. dated February 11, 2004 reporting Sangamo BioSciences, Inc.'s financial results for the quarter and year ended December 31, 2003.

ITEM 12. RESULTS OF OPERATIONS AND FINANCIAL CONDITION

The information in this Item 12 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 12 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

On February 11, 2004, Sangamo BioSciences, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2003. A copy of the press release is attached as Exhibit 99.2.

SIGNATURES

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

DATE: February 11, 2004

SANGAMO BIOSCIENCES, INC.

By: /s/ EDWARD O. LANPHIER II Edward O. Lanphier II President, Chief Executive Officer 2

Exhibit Index

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SANGAMO BIOSCIENCES' PARTNER EDWARDS LIFESCIENCES FILES INVESTIGATIONAL NEW DRUG APPLICATION FOR PHASE I/II 'AVENGE' CLINICAL TRIAL

Trial to Explore Novel Therapeutic To Treat Peripheral Artery Disease

Richmond, Calif. and Irvine, Calif. – February 11, 2004 – Sangamo BioSciences, Inc. (Nasdaq: SGMO) and Edwards Lifesciences Corporation (NYSE: EW) announced today the filing of an investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for EW-A-401, a novel therapeutic designed to stimulate the growth of normal blood vessels for the treatment of peripheral artery disease (PAD).

The filing of the IND for the AVENGE trial (<u>A</u>ctivating <u>V</u>ascular <u>EN</u>dothelial <u>G</u>rowth Factor) and other associated milestones trigger \$1,000,000 in milestone payments from Edwards to Sangamo. This is the first IND filed for a therapeutic application of Sangamo's ZFP technology.

Pending FDA clearance of the IND, the Phase I/II AVENGE trial is scheduled to begin in the first half of 2004. The trial will be conducted at the Warren Grant Magnusen Clinical Center at the National Institutes of Health (NIH) in Bethesda, MD. Dr. Robert Lederman, a cardiologist and Investigator at the National Heart, Lung and Blood Institute who studies peripheral artery disease and the application of real-time MRI imaging in novel biological therapeutic cardiovascular interventions, will be the AVENGE trial's principal investigator. The trial is designed as a dose escalation study to measure the safety of EW-A-401 in patients with intermittent claudication, the most common form of PAD, which commonly manifests as leg muscle pain during exercise. In addition, the trial will explore the effectiveness of the therapeutic to improve blood flow, walking capacity, and quality of life.

In preclinical animal studies, EW-A-401 has proven effective in stimulating blood vessel growth and increasing blood flow in ischemic limbs. EW-A-401 is a polymer formulation of a plasmid DNA that encodes a zinc finger DNA-binding protein transcription factor (ZFP TF), designed to upregulate the vascular endothelial growth factor A (VEGF-A) gene. VEGF-A has been shown to be an important factor for stimulating blood vessel growth.

"This is a significant step for Edwards and for our ZFP Therapeutic angiogenesis program," said Michael A. Mussallem, Edwards' chairman and CEO. "Sangamo's ZFP TF platform has unique therapeutic advantages that have the potential to provide a significant alternative for many of the more than 8 million Americans suffering from peripheral artery disease, and possibly other forms of advanced cardiovascular disease in the future."

"As the first human clinical trial of any ZFP TF, the AVENGE trial is an important step for Sangamo BioSciences and for the patients this technology has been designed to help," said Edward Lanphier, Sangamo's president and CEO. "We believe that our approach has significant advantages as it more closely mimics the natural process of vascular development. Our VEGF ZFP TF is designed to activate a patient's own VEGF-A gene, stimulate the production of multiple VEGF-A protein isoforms and the growth of histologically and functionally normal blood vessels."

Peripheral Arterial Disease Affects Between 8 Million and 10 Million Americans

According to the American Heart Association, PAD is estimated to affect between 8 million and 10 million people in the United States, although the condition is often under-diagnosed and undertreated. PAD is caused by blockages to the arteries that supply the legs with blood. The initial sign of PAD is leg muscle pain during exercise. As the disease progresses, patients can experience leg pain even when resting.

About Edwards Lifesciences

Edwards Lifesciences is a leader in advanced cardiovascular disease treatments and the number-one heart valve company in the world. Headquartered in Irvine, Calif., Edwards focuses on four main cardiovascular disease states: heart valve disease, coronary artery disease, peripheral vascular disease and congestive heart failure. The company's global brands, which are sold in approximately 100 countries, include Carpentier-Edwards, Cosgrove-Edwards, Swan-Ganz and Fogarty. Additional company information can be found at www.edwards.com.

About Sangamo BioSciences

Sangamo BioSciences, Inc is focused on the research and development of novel transcription factors for therapeutic gene regulation and repair. The company's most advanced therapeutic development program involves the use of transcription factors for the treatment of peripheral artery disease. Other therapeutic development programs are focused on ischemic heart disease, cancer, neuropathic pain, and monogenic diseases. Sangamo's core competencies enable the engineering of a class of transcription factors (ZFP TFs) that can control gene expression and consequently, cell function. Sangamo is also developing sequence-specific ZFP nucleases (ZFNs) for therapeutic gene correction as a treatment and possible cure for a variety of monogenic diseases such as severe combined immunodeficiency, sickle cell anemia and chronic granulatomous disease. For more information about Sangamo, visit the company's web site at www.sangamo.com or www.expressinglife.com.

This press release contains forward-looking statements regarding Sangamo's and Edwards' current expectations. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Factors that could cause actual results to differ include the early stage of EW-A-401 development, uncertainties related to the timing of initiation and completion of clinical trials, and whether clinical trial results will validate and support the safety and efficacy of EW-A-401. Further, there can be no assurance that the necessary regulatory approvals will be obtained or that Sangamo or Edwards will be able to develop commercially viable gene based therapeutics. Actual results may differ from those projected in forward-looking statements due to risks and uncertainties that exist in the companies' operations and business environments. These risks and uncertainties are described more fully in the companies' Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q as filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date and will not be updated.

Contact:

For Sangamo BioSciences Inc. Elizabeth Wolffe, Ph.D. 510-970-6000, x271 Manager, Corporate Communications ewolffe@sangamo.com For Edwards Lifesciences Corp. Barry Liden 949-250-5070 Director, Global Communications Burns McClellan, Inc. Tricia Morsch (media) 212-213-0006 Michelle Levine (investors) 415-352-6262

SANGAMO BIOSCIENCES REPORTS 2003 FOURTH QUARTER AND YEAR-END FINANCIAL RESULTS

Richmond, California – February 11, 2004 – Sangamo BioSciences, Inc. (Nasdaq: SGMO) today reported financial results for the fourth quarter ended December 31, 2003. The consolidated net loss, computed in accordance with generally accepted accounting principles (GAAP), which includes non-cash charges, was \$1.7 million, or \$0.07 per share as compared to a net loss of \$706,000, or \$0.03 per share in the same period in 2002. Excluding non-cash charges, the consolidated pro forma net loss was \$1.5 million, or \$0.06 per share. In the comparable quarter of 2002, Sangamo reported a consolidated pro forma net loss of \$532,000, or \$0.02 per share. At December 31, 2003, the company had cash, cash equivalents, and investments of \$44.3 million.

Revenues for the fourth quarter of 2003 were \$1.0 million as compared to fourth quarter 2002 revenues of \$2.5 million. The principal components of fourth quarter 2003 revenues were from Sangamo's partnerships in the areas of human therapeutics, enabling technologies and government research grants.

Total fourth quarter 2003 operating expenses were \$3.0 million as compared to \$3.5 million in the prior year period. Research and development expenses were \$2.3 million for the three months ended December 31, 2003 as compared to \$2.4 million for the fourth quarter of 2002. General and administrative expenses were \$545,000 for the fourth quarter of 2003 as compared to \$901,000 for the same period in 2002.

Net interest income for the fourth quarter of 2003 was \$162,000 as compared to \$261,000 in the comparable period of 2002.

Recent Highlights

- Sangamo BioSciences' partner Edwards Lifesciences files first ZFP Therapeutic investigational new drug application (IND): During its 2003 Investor Conference, Edwards Lifesciences Corp. updated investors on its program with Sangamo to develop zinc finger DNA-binding protein transcription factors (ZFP TFs) for the treatment of peripheral artery disease. Edwards gave guidance that they expected to file an IND application for its ZFP VEGF Therapeutic with the Food and Drug Administration (FDA) in the first quarter of 2004. The IND was subsequently filed on February 10, 2004. The AVENGE trial (Activating Vascular ENdothelial Growth Factor A), pending FDA clearance of the IND, is scheduled to begin in the first half of 2004 and will be the first human clinical trial of a ZFP TF.
- Licensing of Onyx Pharmaceuticals' proprietary oncolytic vector technology to develop an Armed Therapeutic Virus to treat metastatic cancer: Sangamo exclusively licensed rights to Onyx's oncolytic adenovirus vector technology to develop an Armed Therapeutic Virus™ (ATV™) that encodes a zinc finger DNA binding protein. In its initial application, Sangamo will engineer the ATV™ to express ZFP TFs designed to upregulate the expression of granulocyte macrophage colony stimulating factor, a powerful activator of the immune system shown to augment anti-tumor immune responses. The license agreement provides Sangamo with exclusive worldwide rights for all therapeutic uses of the ATV™ encoding ZFP TFs that regulate the expression of any endogenous human gene. Under the terms of the agreement, Sangamo will have full rights and responsibility for research and commercial development of the ZFP TF ATV™. Onyx will receive milestone payments as products advance into clinical testing and will receive royalties on product sales
- Publication of scientific paper in the journal <u>Cancer Research</u> describing ZFP TF repression of VEGF A: Sangamo scientists authored an article entitled "Repression of Vascular Endothelial Growth Factor A in Glioblastoma Cells Using Engineered Zinc Finger Transcription Factors " that was published in the scientific journal <u>Cancer Research</u>. The paper is the most recent of several peer-reviewed publications that highlight the potential therapeutic applications and specificity of Sangamo's proprietary gene regulation technology. The <u>Cancer Research</u> article describes the use of

Sangamo's ZFP TFs to repress the expression of the VEGF A gene in a highly tumorigenic glioblastoma cell line, U87MG. VEGF-A is a potent stimulator of new blood vessel growth, or angiogenesis, a process of critical importance to the progression of certain tumors. Constitutive high-level expression of VEGF A has been seen in a variety of solid tumors including brain cancers such as glioblastomas. For this reason, inhibition of angiogenesis, and specifically VEGF, has been an attractive therapeutic target for the treatment of cancer.

Twelve Month Results

For the year ended December 31, 2003 the net loss attributable to common stockholders was \$10.4 million, or \$0.42 per share, compared to \$29.8 million, or \$1.22 per share for the year ended December 31, 2002. Net loss in 2002 was significantly higher than in 2003 due to expenses relating to the closing of Sangamo's wholly owned U.K. subsidiary, Gendaq Limited and the consolidation of research operations at Sangamo's Richmond, California site. Included in the net loss for the year ended December 31, 2002 were \$18.0 million of impairment charges for patents and goodwill, stock-based compensation expenses of \$1.5 million and a one-time restructuring charge of \$371,000. Excluding non-cash charges, the pro forma net loss was \$9.9 million, or \$0.40 per share for 2003 and \$9.5 million or \$0.39 per share for 2002. Revenues for the year ended December 31, 2003 were \$2.6 million as compared to \$4.3 million in 2002. Excluding restructuring and non-cash charges, total pro forma expenses for the years ended December 31, 2003 and 2002 were \$13.8 million and \$15.7 million, respectively.

At December 31, 2003, the company had cash, cash equivalents, and investments of \$44.3 million, compared with \$52.6 million at December 31, 2002. Total shares outstanding at December 31, 2003 were 25.0 million as compared to 24.7 million at December 31, 2002.

Conference Call

Sangamo will host a conference call today at 2:00 p.m. PST, which will be open to the public. During the conference call, the company will review these results, discuss other business matters, and provide forward-looking guidance with respect to 2004.

The conference call dial-in numbers are 800-498-2152 for domestic callers and 706-634-5122 for international callers. For those unable to listen in at the designated time, a conference call replay will be available for one week following the conference call, from approximately 3:00 p.m. PST on February 11, 2004 to 9:00 p.m. PST on February 18, 2004. The conference call replay numbers for domestic and international callers are 800-642-1687 and 706-645-9291, respectively. The conference ID number for the replay is 5441287.

About Sangamo BioSciences, Inc.

Sangamo BioSciences, Inc is focused on the research and development of novel transcription factors for therapeutic gene regulation and repair. The company's most advanced therapeutic development program involves the use of transcription factors for the treatment of peripheral artery disease. Other therapeutic development programs are focused on ischemic heart disease, cancer, neuropathic pain, and monogenic diseases. Sangamo's core competencies enable the engineering of a class of transcription factors (ZFP TFs) that can control gene expression and consequently, cell function. Sangamo is also developing sequence-specific ZFP nucleases (ZFNs) for therapeutic gene correction as a treatment and possible cure for a variety of monogenic diseases such as severe combined immunodeficiency and sickle cell anemia. For more information about Sangamo, visit the company's web site at www.sangamo.com or www.expressinglife.com.

This press release may contain forward-looking statements based on Sangamo's current expectations. These forward-looking statements include, without limitation, references to the research and development of novel ZFP TFs, ZFNs and therapeutic applications of Sangamo's ZFP technology platform. Actual

results may differ materially from these forward-looking statements due to a number of factors, including uncertainties related to the timing of initiation of clinical trials, technological challenges, Sangamo's ability to develop commercially viable products and technological developments by our competitors. See the company's SEC filings, and in particular, the risk factors described in the company's Annual Report on Form 10-K and its most recent 10-Q. Sangamo assumes no obligation to update the forward-looking information contained in this press release.

Contact:

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Burns McClellan, Inc. Tricia Morsch (media) 212-213-0006 Michelle Levine (investors) 415-352-6262

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Financials Attached

SELECTED FINANCIAL DATA

(in thousands, except per share data) (unaudited)

	Three Months Ended December 31,			Twelve Months Ended December 31,				
		2003		2002	_	2003		2002
Consolidated Statement of Operations Data:								
Revenues	\$	1,003	\$	2,464	\$	2,579	\$	4,343
Operating expenses:								
Research and development		2,287		2,424		10,187		12,213
General and administrative		545		901		3,594		3,815
Restructuring charge		_		_				371
Impairment of patents and goodwill				—		—		18,010
Stock-based compensation		200		174		567		1,499
Total operating expenses		3,032		3,499		14,348		35,908
Loss from operations		(2,029)		(1,035)		(11,769)	_	(31,565)
Interest income, net		162		261		752		1,366
Other income		187		68		584		435
Net loss	\$	(1,680)	\$	(706)	\$	(10,433)	\$	(29,764)
Basic and diluted net loss per common share	\$	(0.07)	\$	(0.03)	\$	(0.42)	\$	(1.22)
Shares used in computing basic and diluted net loss per common share		24,907		24,669		24,811		24,493
Pro-Forma Operations Data (1):								
Total revenues	\$	1,003	\$	2,464	\$	2,579	\$	4,343
Research and development		2,287		2,424		10,187		11,853
General and administrative		545		901		3,594		3,815
Operating expenses		2,832		3,325		13,781		15,668
Interest and other income, net		349		329		1,336		1,801
Net loss		(1,480)	\$	(532)	\$	(9,866)	\$	(9,524)
Basic and diluted net loss per common share	\$	(0.06)	\$	(0.02)	\$	(0.40)	\$	(0.39)

Reconciliation Between Net Loss on a GAAP Basis and

Pro Forma Net Loss:				
GAAP net loss attributable to common stockholders	\$ (1,680) \$	(706) \$	(10,433) \$	(29,764)
Stock based compensation	200	174	567	1,499
Patent amortization	—	—	—	360
Impairment of patents and goodwill	—		—	18,010
Restructuring charge	—		—	371
Pro forma net loss	\$ (1,480) \$	(532) \$	(9,866) \$	(9,524)

CONDENSED BALANCE SHEET DATA

	Dec. 31, 2003			Dec. 31, 2002		
Cash, cash equivalents, and investments	\$	44,343	\$	52,575		
Total assets		46,232		56,227		
Total stockholders' equity		44,661		54,246		

(1) The above pro forma non-GAAP information is based upon our unaudited consolidated statements of operation for the periods shown with certain adjustments. This presentation is not in acordance with, or an alternative for, generally accepted accounting principles (GAAP). However, management believes pro forma non-GAAP reporting provides useful insight into the Company's on-going operations and trends that affect the core business and uses such reporting internally to evaluate and manage the Company's operations. Sangamo has chosen to provide this information to investors to enable them to compare and evaluate operating results and as a means to emphasize the results of on-going operations.