## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

# FORM 8-K

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

Date of report (Date of earliest event reported): August 30, 2004

## SANGAMO BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

**000-30171** (Commission File Number) **68-0359556** (IRS Employer Identification No.)

**501 Canal Blvd, Suite A100** (Address of Principal Executive Offices) Richmond, California 94804 (Zip Code)

(510) 970-6000

(Registrant's Telephone Number, Including Area Code)

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

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

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01 Other Events

On August 30, 2004, Edwards Lifesciences Corporation issued a press release announcing that it had initiated its clinical trial of EW-A-401, a new therapeutic compound developed by Sangamo Biosciences, Inc. EW-A-401 is designed to stimulate the growth of normal blood vessels for the treatment of peripheral artery disease (PAD). This represents the first human clinical trial of a therapeutic application of Sangamo's ZFP technology.

A copy of the press release issued by Edwards Lifesciences Corporation relating to the clinical trial is filed as an exhibit to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits

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

## Exhibit No. 99.1 Press Release Issued August 30, 2004.

## 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: August 30, 2004

SANGAMO BIOSCIENCES, INC.

By:

/s/ EDWARD O. LANPHIER II

Edward O. Lanphier II President, Chief Executive Officer



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NEWS RELEASE

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#### EDWARDS LIFESCIENCES INITIATES CLINICAL TRIAL FOR THERAPY DESIGNED TO GROW NEW BLOOD VESSELS

**IRVINE, Calif., August 30, 2004** — Edwards Lifesciences Corporation (NYSE: EW), a global leader in medical technologies to treat advanced cardiovascular disease, announced today that the company has initiated the Phase I/II clinical trial of EW-A-401, a new therapeutic compound designed to stimulate the natural growth of normal blood vessels for the treatment of intermittent claudication, a symptom of peripheral artery disease (PAD). Intermittent claudication is caused by poor blood flow in the legs that results in leg muscle pain during exercise, and is the most common symptom of PAD. The compound was developed by Sangamo BioSciences, Inc. (Nasdaq: SGMO) and licensed to Edwards for use in the treatment and prevention of ischemic cardiovascular and vascular disease.

EW-A-401 encodes a zinc finger DNA-binding protein transcription factor (ZFP TF) designed to uniquely activate all isoforms of the Vascular Endothelial Growth Factor A (VEGF-A) gene to stimulate angiogenesis, or new blood vessel growth. In preclinical studies, EW-A-401 was shown to be effective in stimulating growth of functionally normal vessels and increasing blood flow in ischemic limbs.

"This unique therapy turns on the patient's own VEGF gene and induces the body to produce multiple VEGF-A proteins," said Dr. Frank Giordano, Director of Yale University School of Medicine's Cardiovascular Gene Therapy Program. "This approach has been used successfully to grow functionally normal blood vessels in pre-clinical

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models of PAD, and may have distinct advantages over previous approaches that have attempted to stimulate blood vessel growth by using a single VEGF gene isoform. Pre-clinical studies leading to this trial have suggested that the type of blood vessels produced when the natural VEGF gene is activated may be more normal and less 'leaky' than those formed in response to alternative approaches."

"While this therapy is still in the early stages of development, Edwards is excited to have entered the clinical phase, and we are motivated by the potential benefits that this compound could offer to patients worldwide," said Michael A. Mussallem, Edwards' chairman and CEO. "By combining our cardiovascular knowledge with Sangamo's proprietary gene regulation technology, we have the opportunity to develop novel new treatments for patients suffering from some of the most pervasive forms of cardiovascular disease. In the future, Edwards may pursue additional indications for the therapy, including critical limb ischemia and ischemic heart disease."

The U.S. Food and Drug Administration cleared an Investigational New Drug (IND) filing for the clinical trial in March, 2004 and the trial began earlier this month with the treatment of the first patient at the Warren Grant Magnuson Clinical Center of the National Institutes of Health in Bethesda Maryland, just outside of Washington, DC. Designed as a double blind, placebo-controlled, dose-escalation study involving 36 patients, the trial seeks primarily to measure EW-A-401's safety in treating intermittent claudication. In addition, investigators may gain some preliminary data on the therapy's effectiveness in improving patients' blood flow, walking capacity, and quality of life. If successful, the trial's design may allow Edwards to use the data to accelerate the evaluation of the compound's effectiveness in the second phase.

It is expected that the trial will take approximately 12 to 18 months to screen and enroll patients, with an additional six months of safety follow-up. Patients interested in participating in this trial can contact Annette Stine, the study's research coordinator, at

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301-402-5352 (e-mail stinea@nhlbi.nih.gov) or call the Patient Recruitment Center at 1-877-999-3099. Additional information can be found at: http://dir.nhlbi.nih.gov/labs/cb/cip/genetransfer.asp.

#### Peripheral Artery 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. Eventually, some PAD patients have such poor blood flow that they develop leg ulcers that do not heal.

### **About Edwards Lifesciences**

Edwards Lifesciences, a leader in advanced cardiovascular disease treatments, is the number-one heart valve company in the world and the global leader in acute hemodynamic monitoring. Headquartered in Irvine, Calif., Edwards focuses on specific cardiovascular opportunities including heart valve

disease, peripheral vascular disease and critical care technologies. The company's global brands, which are sold in approximately 100 countries, include Carpentier-Edwards, Cosgrove-Edwards, Fogarty, LifeStent, PERIMOUNT and Swan-Ganz. Additional company information can be found at http://www.Edwards.com.

#### About Sangamo BioSciences

Sangamo Biosciences, Inc. is focused on the research and development of novel DNA binding proteins for therapeutic gene regulation and correction. Sangamo's core competencies enable the engineering of a class of proteins known as zinc finger DNA binding proteins (ZFPs). By engineering ZFPs that recognize a specific DNA sequence

Sangamo has created ZFP transcription factors (ZFP TFs) that can control gene expression and consequently, cell function. Sangamo is also developing sequence-specific ZFP nucleases (ZFNs) for therapeutic gene correction as a treatment and possible cure for a variety of monogenic and infectious diseases. Other therapeutic development programs are focused on heart disease, cancer and neuropathic pain. For more information about Sangamo, visit the company's web site at www.sangamo.com or www.expressinglife.com.

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This news release includes forward-looking statements that involve risks and uncertainties, including those related to the development of, and clinical trials involving, EW-A-401; the pursuit of additional indications for ZFP therapy; the potential market for treating PAD; and more generally, timing or results of pending or future clinical trials, actions by the U.S. Food and Drug Administration and European Union, technological advances in the medical field, product demand and market acceptance, the effect of changing economic conditions, the impact of foreign exchange, and other risks detailed in the company's filings with the Securities and Exchange Commission. These forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though are inherently uncertain and difficult to predict. Actual results or experience could differ materially from the forward-looking statements.

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