

Edgar Filing: SIGA TECHNOLOGIES INC - Form 8-K

SIGA TECHNOLOGIES INC
Form 8-K
March 22, 2004

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): March 22, 2004

SIGA Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or other Jurisdiction
of Incorporation or Organization)

0-23047

(Commission File Number)

13-3864870

(I.R.S. Employer
Identification Number)

420 Lexington Avenue, Suite 601
New York, New York

(Address of Principal Executive Offices)

10170

(Zip Code)

(212) 672-9100

(Registrant's telephone number, including area code)

ITEM 9. Regulation FD Disclosure.

On March 22, 2004, SIGA Technologies, Inc., a Delaware corporation ("SIGA"), issued a press release pursuant to which SIGA announced a successful small pox vaccine trial and a possible sale of certain non-core vaccine assets. The text of the press release is set forth below:

"SIGA ANNOUNCES SUCCESSFUL SMALLPOX VACCINE TRIAL AND POSSIBLE
SALE OF CERTAIN NON-CORE VACCINE ASSETS

New York, March 22, 2004 -- SIGA Technologies, Inc. (NASDAQ: SIGA) and

Edgar Filing: SIGA TECHNOLOGIES INC - Form 8-K

(FRANKFURT: SGW 919 473) today announced a successful smallpox vaccine trial using SIGA's proprietary live vector vaccine delivery system. In the study, mice immunized intranasally/orally with SIGA's smallpox vaccine prototype showed 100% immunity to vaccinia virus challenge. "Our team has been developing these innovations since 1998. The technology is real, it is practical." said Dr. Dennis E. Hruby, Chief Scientific Officer of SIGA.

Pursuant to the Press Release, SIGA announced a successful smallpox vaccine trial using SIGA's proprietary live vector vaccine delivery system. In the study, mice immunized intranasally/orally with SIGA's smallpox vaccine prototype showed 100% immunity to vaccinia virus challenge. "Our team has been developing these innovations since 1998. The technology is real, it is practical." said Dr. Dennis E. Hruby, Chief Scientific Officer of SIGA.

Smallpox virus is considered one of the most significant threats for use as a biowarfare agent due to the fact that people are no longer vaccinated against it, because it is very easily transmitted, and its high mortality rates. Mass immunizations of the general population using the current live vaccine are not recommended, as there are known complications in certain individuals from vaccination (including encephalitis, myocarditis, and death), At present there is no vaccine for smallpox that can be safely administered to the general population without significant risk of adverse reactions.

SIGA's vaccine delivery technology is designed to activate the immune system at the body's mucosal surfaces--the mouth, the nose, the lungs, the gastrointestinal, and the urogenital tracts--in order to prevent infection at the earliest possible stage. SIGA's live vector system utilizes *Streptococcus gordonii*, a normal bacterial inhabitant of the human oral cavity, as a vehicle to deliver proteins from pathogens in order to induce immunity to infections in test animals without exposing them to the dangers of live, infectious agents. Unlike the traditional smallpox vaccine, which relies on live virus to develop immunity, SIGA's novel vaccine delivery system may allow a person to develop immunity without having to risk exposure to dangerous infection. "The results of this trial provide important support for our efforts to develop a safe and effective vaccine for smallpox," said Dr. Hruby. SIGA is exploring the opportunity to possibly divest certain vaccine assets, including selected vaccine assets acquired from Plexus Vaccine Inc., which are not part of SIGA's core vaccine programs. No assurance can be given whether or on what terms such a divestiture may be made.

2

About SIGA Technologies, Inc.

SIGA Technologies is applying bacterial genomics in the design and development of novel products for the prevention and treatment of serious infectious diseases, with an emphasis on products for biological warfare defense. SIGA has the potential of becoming a significant force in the discovery of vaccine and pharmaceutical agents to fight emerging pathogens. SIGA's product development programs emphasize the increasingly serious problem of drug resistant bacteria and emerging pathogens. SIGA's vaccine and drug platforms are based on its pioneering research into the structure, function and processing of bacterial surface proteins. SIGA is leveraging these platforms through multiple strategic partners, including Wyeth-Ayerst Laboratories (the

Edgar Filing: SIGA TECHNOLOGIES INC - Form 8-K

pharmaceutical division of American Home Products) and the National Institutes of Health. For more information about SIGA, please visit SIGA's Web site at www.siga.com.

This news release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements, including statements regarding the efficacy and intended utilization of SIGA's technologies under development, are not guarantees of future performance. Actual results may differ materially from the expectations contained in the forward-looking statements. Factors that may cause such differences include the risk that potential products that appeared promising in early research or clinical trials to SIGA or its collaborators do not demonstrate efficacy or safety in subsequent pre-clinical or clinical trials, and the risk that SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market products tested in such trials. More detailed information about SIGA and the factors discussed above is set forth in SIGA's filings with the Securities and Exchange Commission, including SIGA's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, and in other documents that SIGA has filed with the U.S. Securities and Exchange Commission. Investors and security holders are urged to read those documents free of charge at the Commission's web site at www.sec.com. Those documents may also be obtained free of charge from SIGA. SIGA does not undertake to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise."

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K 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 Current Report on Form 8-K shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

3

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.

SIGA TECHNOLOGIES, INC.

By: /s/ Thomas N. Konatich

Thomas N. Konatich
Acting Chief Executive Officer and
Chief Financial Officer

Date: March 22, 2004

4

