

CASE STUDY

Public Relations: Therapeutics Company with a Biodefense Product

This therapeutics company has been successful on two fronts. With a lead monoclonal antibody product available for purchase by the U.S. government for anthrax infection and the rest of the company's pipeline focused in bacterial, viral and fungal infections, the company needed to address two distinct constituencies—government and industry. With two pharmaceutical partnerships covering certain infectious disease targets, the company validated Heteropolymer (HP) Antibody products are moving into clinical development.

Investor/Public Relations

- Develop corporate calendar of events to include press release dissemination of milestones on HP Antibody products
- Work with corporate partners on announcement of partnerships
- Collaborate with PR departments at partnership companies to agree on messaging and release dissemination
- Track progress of U.S. government status on RFP for stock pile purchase
- Develop and maintain relationships with Washington-based media covering bioterrorism as well as industry media to ensure appropriate coverage of the company in the media
- Review corporate materials including fact sheet and corporate presentation for up to date messaging
- Conference alerts for the company's participation at key investor, business development and medical meetings

Return on Investment

- Key national and industry coverage of the company's HP technology in *Associated Press (National Syndication)*, *UPI*, *Reuters*, *Washington Post*, *Washington Business Journal*, *DowJones VentureWire*, *Lifescience*, *Scrip*, *GEN*, *BioCentury*, *Nature Biotechnology*, *BioWorld*, and broadcast coverage
- Inclusion of Anthim™ for anthrax in *R&D Directions Top 100 Great Investigational Drugs*
- Prominently featured at key investor, scientific and business development conferences

AP Associated Press

Government Signs Anthrax Drug Deal

By STEPHEN MANNING
AP Business Writer

COLLEGE PARK, Md. (AP) - The Department of Health and Human Services has signed a deal that could include an order for 100,000 doses of a drug to treat anthrax once it has entered the body, part of the federal government's push to stockpile drugs to counter the lethal germ.

The biotech company Human Genome Sciences said Monday that it has signed a contract with HHS to provide a 10 gram sample of its drug ABthrax for \$1.8 million for the agency to study. The agreement also gives the agency the option of later buying 100,000 doses, which could be worth \$200 million or more.

Under the \$5.6 billion Project BioShield initiative, the federal government is stockpiling drugs and vaccines to use in the case of a widespread release of biological or chemical weapons.

That includes treatments for anthrax, a spore that can be lethal if inhaled and left untreated. Last year, a \$877.5 million contract was awarded to VaxGen Inc. of Upland, Calif., to produce 75 million doses of an anthrax vaccine.

For the week of September 26, 2005

BioCentury  Week ended 09/23/05
PRICES 1583.18 VOLUME \$72.3M
down 3% down 6.4%

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Emerging Company Profile

Elusys: Double-barreled antibodies

By Michael Flanagan
Staff Writer

Elusys Therapeutics Inc. is building its hopes on a revenue stream from its Anthim monoclonal antibody against anthrax, which should be ready for government procurement by the middle of next year. The company plans to use the money to fund development of its preclinical pipeline of heteropolymer antibody candidates in two years. Elusys plans to start clinical testing with the first of these anti-infective agents, which has shown potential both for treatment and prophylactic use in *Staphylococcus aureus* infections.

Anthim, a *PSA8* against the *Bacillus anthracis* protective antigen, is designed to prevent the anthrax toxin from entering susceptible cells. Anthim was developed under a CRADA with the U.S. Army Medical Research Institute of Chemical Diseases.

In animal studies, 80% of rabbits given a single intramuscular dose of Anthim

Elusys Therapeutics Inc.
Pine Brook, N.J.
Technology: Heteropolymer antibodies
Disease focus: Infectious disease
Clinical status: Phase I
Founded: 1998 by Jeff Hinman and Jeff Wolf
University collaborators: University of Pennsylvania, University of Texas
Number of employees: 28
Funds raised: \$42 million
Investors: Essex Woodlands Health Ventures, Invesco Private Capital, Crescendo Ventures, Eagle Advisors
CEO: Elizabeth Pesticco
Patents: 6 issued covering anthrax antibody therapeutic and Heteropolymer antibody technology

the liver, where the pathogen is destroyed by the Kupfer cells and the RBGs are released back into circulation.

One HP candidate to treat systemic lupus erythematosus (SLE) has completed a Phase I trial in healthy volunteers (see *BioCentury*, June 10, 2002). However, Pesticco said that Elusys (Pine Brook, N.J.) has decided to rock the boat and focus on its infectious disease pipeline.

First among these is ET-211, an HP candidate that consists of an anti-C2b antibody cross-linked with an antibody against *Staphylococcus aureus* protein A (SpA), which is located on the bacterial cell surface. Mice given ET-211 were protected against lethal doses of multiple strains of the bacteria, including methicillin-resistant *S. aureus* (MRSA).

Pesticco said a key feature of ET-211 is that "in addition to clearing the bloodstream of a pathogen, it is capable of

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R&D DIRECTIONS

100greatinvestigationaldrugs

Gap is slowly filled

PRIZER LEADS THE WAY WITH FOUR OF THE GREAT INVESTIGATIONALS, BUT LESSER-SIZED COMPANIES ALSO MAKE AN IMPACT.

BY LYLE D. FITZSIMMONS

As product development at small and mid-size pharmaceutical companies, as well as biotech startups, continues to slow, more is filling the productivity gap that large pharmaceutical companies have been experiencing, according to a study done by the Tufts Center for the Study of Drug Development (TuftsCSD). Although large pharmaceutical companies were responsible for more than three-fourths of the new molecular entity approvals in the United States in 2001, that rate slipped to lower than anticipated by 2004 and remained low through 2005.

According to Tufts experts, the advanced use of gene technology to reduce late-stage development failures and contain rising costs have begun to prompt companies toward approval despite starting challenges that include increased regulatory drug safety requirements, health care reform, and rising R&D costs.

"While drug developers have understood that their long-term viability depends on improving R&D productivity—and have taken steps to address that issue, they're also able to see their efforts pay off in terms of productivity gains and greater numbers of new molecular products reaching the marketplace," says Kenneth Kohn, Director, Tufts.

Prizer continues to continue to lead the effects of the drug pipeline of biotechnology — which has been an \$800 million development investment — but the company is attempting to fight the industry's long and slow slide with several other potentially promising pipeline candidates, which include methicillin-resistant *S. aureus* (MRSA).

Many of the compounds on the list address unmet medical needs and were selected for inclusion from the thousands being developed at large and small companies throughout the world.

It is important that the list include the drugs that are still in development.

Seven of the 100 drugs on the 2005 R&D Directions list have since received regulatory approval from FDA, Pfizer's first drug, *antibiotic* for lung and genitourinary cancer and *thyroid neoplasm* CP-472064 for metastatic and primary breast cancer, *antibiotic* for metastatic breast cancer, *antibiotic* for metastatic breast cancer, *antibiotic* for metastatic breast cancer, *antibiotic* for metastatic breast cancer, *antibiotic* for metastatic breast cancer.

Some teams analyze data from Novartis CP-472064 for annual sales of \$400 million in 2007 and another for annual sales of \$200 million in the same year.

These companies are expanding their management of R&D, especially by actively learning late-stage development costs through greater use of information technology and other development practices," Dr. Kohn says.