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HHS Ends VaxGen's \$877.5M Contract On Anthrax Vaccine.
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VaxGen Inc. is out of the Project BioShield game.

To probably no one's surprise, the Department of Health and Human Services (HHS) canceled its \$877.5 million anthrax vaccine contract, an arrangement beset by development setbacks and miscommunication since it was unveiled two years ago. The Brisbane, Calif.-based company's inability to begin a second Phase II trial of its recombinant protective antigen (rPA) vaccine by Monday finally sank its ship.

HHS blamed the failure "to successfully cure the condition-endangering performance" for causing VaxGen to miss the deadline, hence the termination, according to a letter sent to the firm. "The clinical hold was our first signal that they weren't going to be able to meet this milestone," HHS spokesman Marc Wolfson told BioWorld Today.

The FDA told the company last month that the study couldn't begin, so HHS provided an extension into this week to resolve that hold. (See BioWorld Today, Nov. 6, 2006.)

That didn't happen, and on Wednesday, VaxGen's shares (Pink Sheets:VXGN) closed at \$1.47. The company's value has been on a downward slide for some time now, owing to multiple problems associated with the anthrax vaccine program. To date, VaxGen has spent more than \$175 million on its anthrax vaccine, and Lance Ignon, its vice president of corporate affairs, charged that HHS' failure to carry out "a productive partnership" hampered progress.

"We're most disappointed about never having the ability to engage in a constructive dialogue with the government to address areas of mutual concern," he told BioWorld Today. "Had there been a willingness to really roll up the sleeves and help us solve these issues that we encountered, there would have been a much greater likelihood of success in this program."

Not everyone shared that opinion, including John Clerici, a lawyer with McKenna

Long & Aldridge LLP in Washington, and a consultant to vaccine makers.

"The failure of VaxGen falls squarely with VaxGen," he told BioWorld Today. "They failed to deliver what they were contractually bound to deliver and what they promised the government they could deliver."

The continuing hold on the investigational product, rPA102, is due to stability concerns. Though VaxGen supplied analytical methods and additional stability data to the FDA, Wolfson said the agency nonetheless "had some real problems" with what was submitted. The held study was to test a slightly different adjuvant preparation than the original one, a change necessitated by an unexpected interaction between rPA and the vaccine's adjuvant, aluminum hydroxide.

After the product's reformulation needs came to light earlier this year, HHS extended the delivery date by six months to November 2008, but also "unilaterally modified" the agreement to require more studies, clinical and preclinical, Ignon said, before allowing the vaccine to be delivered to the Strategic National Stockpile. (See BioWorld Today, May 11, 2006.)

VaxGen A Warning To Others?

HHS last month imposed the Monday deadline, and VaxGen officials fumed about the changes over the course of the contract. The firm predicted that such tweaks could chill the entire federal government program for buying civilian biodefense products. The wider effort, Ignon cautioned, "is not going to work if contractors are prohibited from having an open, constructive dialogue with the customer."

Further, he questioned the viability of fixing drug development efforts to deadlines. "But this is a very different paradigm here," Ignon conceded, one VaxGen admittedly bought into upon entering the contract, though he said the timeline was added "at the 11th hour," shortly before the contract was originally awarded. "We objected strenuously, but frankly, a company of our size is not in a strong position to argue. It was basically, 'Take it or leave it.'"

The contract remains the largest ever under Project BioShield. VaxGen was selected from multiple applicants, Wolfson said, to a request for proposal. (See BioWorld Today, Nov. 8, 2004.)

HHS could hold VaxGen liable for any excess costs if an alternative anthrax vaccine is bought for more from another contractor, per the Federal Acquisition Regulation's default trigger. While this contract is a failure for all parties, Clerici said, including the American public, it's a good example of why BioShield doesn't pay for products until they're ready for delivery.

The department already has contracted with Emergent Biosolutions Inc., of Gaithersburg, Md., for 10 million doses of a first-generation anthrax vaccine, and 8 million have been delivered and paid for to date. Already approved by the FDA, it's also bought by the Department of Defense for military use. Shares in Emergent (NYSE:EBS) were up nearly 10 percent Wednesday to \$11.40. Privately held Avecia Bio-

technology Inc. has another rPA anthrax vaccine, and that company, of Milford, Mass., has received NIH support for its development.

Wolfson, who said HHS remains committed to procuring an rPA vaccine, noted that the department would publicly discuss further anthrax plans next month on a revised timeline for procuring vaccines of one sort or another. The 75 million-dose goal remains.

"It will be interesting to see how the government addresses the void," Clerici said. "How the remaining 65 million is addressed is to be determined."

Lessons learned from putting all those eggs in one basket could help HHS reach that goal more efficiently in the future, assuming multiple contracts are made with multiple contractors, and the newly established Biomedical Advanced Research and Development Authority (BARDA) should help companies better fund advanced research on antidotes and vaccines against biological weapons and infectious diseases, "taking some of the pressure off BioShield," Clerici said.

The anthrax vaccines are envisioned as a supplement to antibiotics for post-exposure treatment, to shorten the course of antibiotic use as a first line of response. To date, HHS has stockpiled enough antibiotics for 40 million Americans. The department also is looking to procure anthrax therapeutics, for which BioShield contracts have been meted out to Human Genome Sciences Inc., of Rockville, Md., and Cangene Corp., of Winnipeg, Manitoba.

Ignon said the jury is still out on rPA102's future, and also suggested that VaxGen's outlook is unclear. "We have an attenuated smallpox vaccine and a state-of-the-art manufacturing facility," he said, "and we are going to do everything we can to make sure at this point that we maximize shareholder value."

VaxGen has the right to appeal the termination and any government claim for excess costs associated with alternative anthrax vaccines.

----- INDEX REFERENCES -----

COMPANY: EMERGENT BIOSOLUTIONS [INC](#); [HUMAN GENOME SCIENCES INC](#); CANGENE CORP; [VAXGEN INC](#); UK DEPARTMENT OF HEALTH

NEWS SUBJECT: (Business Management (1BU42); Government (1G080); Contracts & Orders (1CO29); Sales & Marketing (1MA51))

INDUSTRY: (Infectious Diseases (1IN99); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Marketing & Sales (1PH83); Bacterial (1BA64); Science (1SC89); Science & Engineering (1SC33); Healthcare (1HE06); Drugs (1DR89); Anthrax (1AN07); Infection Control & Epidemiology (1IN02); Antibiotics (1AN81); Vaccines (1VA57))

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OTHER INDEXING: (AVECIA BIOTECHNOLOGY INC; BARDA; BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY; BIOSHIELD; BYLINE: AARON LORENZO; CANGENE CORP; DEPARTMENT OF DEFENSE; DEPARTMENT OF HEALTH; EMERGENT BIOSOLUTIONS INC; FDA; FEDERAL ACQUISITION REGULATION; HHS; HHS ENDS VAXGEN; HUMAN GENOME SCIENCES INC; HUMAN SERVICES; NIH; NYSE:EBS; PINK SHEETS:VXGN; PROJECT BIOSHIELD; STRATEGIC NATIONAL STOCKPILE; VAXGEN; VAXGEN INC) (BioWorld Today; Clerici; Ignon; John Clerici; Lance Ignon; Lessons; Marc Wolfson; Privately; Wolfson) (Biological products industry (Contracts)) (Vaccines; Clinical trials) (Trade) (Biotechnology industry (BIO); Business (BUSN)) (Contracts & orders let (490); Contracts & orders received (610))

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