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POINT OF VIEW

Finding Dollars for Biodefense

Opportunities and Challenges for Biotech Firms

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Driven by heightened threats of bioterrorism, federal funding for biological defense has skyrocketed. At the same time, responsibility for fighting bioterrorism remains split among a number of federal agencies, leaving some confusion about who will fund what efforts. Even with the passage of the Homeland Security Act, identifying federal opportunities for biotechnology companies continues to be a challenge.

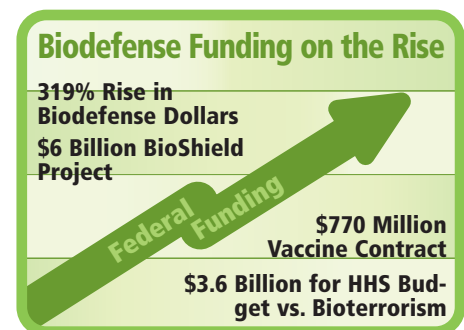
Nonetheless, companies willing to do business with the federal government have a number of resources for locating suitable opportunities for contracts and grants. This report addresses the growth in federal funding for defending against bioterrorism, the resources available for finding such opportunities, and recent

initiatives to make business with the federal government more attractive for biotech companies.

Funding Bioterrorism Defense

With an escalating risk of bioterrorism, an unprecedented federal commitment exists to fund an array of defenses to biological attacks. For 2003, the President's budget targeted an additional \$4.5 billion—a 319% increase over 2002 funding levels for defending against bioterrorism. The National Institutes of Health's share of the 2003 funds included \$1.7 billion for biodefense research.

For 2004, the President announced Project BioShield, an estimated \$6 billion over the next 10 years to “pay for ‘next-generation’ medical countermeasures.” For the Department of Homeland Security alone, the 2004 budget includes \$400 million for the Strategic National Stockpile of drugs and vaccines, \$890 million for biodefense vaccines and medications, and \$365 million for biological countermeasures.



This surge in federal funding has produced some super-sized contracts, such as the \$770-million award to **Acambis** (Cambridge, U.K., and Cambridge, MA) by the Centers for Disease Control and Prevention (CDC) and Health and Human Services for production of small-pox vaccine. **Anacor Pharmaceuticals** (Palo Alto, CA) received a \$21.6-million contract from the Defense Advanced Research Projects Agency for developing technology to target enzymes in anthrax, tularemia, and other infectious diseases.

A growing stream of other federal contracts, subcontracts, and grants for biodefense research, drugs, and vaccines have flowed to a host of other biotech-

nology and pharmaceutical companies within the last year.

The accelerating emphasis upon biodefense is also underscored by a number of other federal initiatives within the last year. In June 2002, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act (Pub. L. 107-188) “to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.”

Recently, the FDA hired 100 additional reviewers to handle new drug applications related to bioterrorism and to offer guidance to companies developing such products. Within the Department of Defense, the heightened priority of fighting bioterrorism is illustrated by the “23rd Army Science Conference” held in December 2002 (www.asc2002.com/agenda.htm), which devoted substantial portions of the agenda to biodefense research initiatives, such as:

- Automated generation of nucleic acid biosensors for biothreat agents
- Application of real-time fluorogenic polymerase chain reaction to nucleic acid-based detection of simulants and biothreat agents
- Inhalation as an alternative route of delivery for medical countermeasures against biological terror agents.

The rising funding commitments, the expanding number of contractors and contracts, and the increasing emphasis on biodefense all confirm that the federal government will depend more heavily on the bioindustry to develop and produce new technology to counter bioterrorism threats.

Finding Biodefense Opportunities

While biodefense is ascending to the top of the federal priority list, finding the

opportunities still requires some perseverance. A number of factors complicate the search for federal opportunities, including multiple agencies involved in the procurement of biotechnology research, products, and services; scattered databases and resources reporting opportunities; and brief notice periods and abbreviated response times for such opportunities.

Nonetheless, many companies have successfully navigated the federal labyrinth. Some of the primary resources for finding biodefense opportunities are listed below.

Government-Wide Database

Except for certain classes of solicitations, such as classified procurements or urgent requirements, proposed federal acquisitions generally must be publicly announced.

For example, the Federal Acquisition Regulation (FAR § 5.201[a]) requires agencies to post notice of proposed contract actions on a government Internet site (www.fedbizopps.gov). As with any bulky database, it takes practice and patience (and sometimes luck) to find relevant opportunities; however, this site has the advantage not only of reporting nearly all federal solicitations at any given time, but also of including subcontracting opportunities, links to webpages of specific agencies, and information for small businesses.

Homeland Security Dept.

For companies wanting to do business with the federal government, the Homeland Security Act (Pub. L. 107-296, § 313) includes an innovative program for a “Technology Clearinghouse” within the Homeland Security Department. This program includes:

- A centralized federal clearinghouse

of information regarding technology to enhance homeland security

- Announcements seeking “unique and innovative technologies” relating to homeland security

- Technical assistance teams to screen proposals submitted to the homeland security department

- Distribution of information “to persons seeking guidance on how to pursue proposals to develop or deploy technologies that would enhance homeland security.”

In addition, the department has established an Office of Private Sector Liaison, provided a list of individuals to assist companies with submission of technology information to the department, and included other useful information, for doing business with the department and with other federal agencies (www.dhs.gov/dhspublic/display?theme=37).

The Technology Clearinghouse appears to be a work in progress but should eventually become a useful means for technology companies to reach an enormous audience of federal, state, and local government agencies.

Department of Defense

The Department of Defense (DOD) currently maintains a separate website (www.dodbusopps.com) for posting notices of upcoming solicitations, although this site will soon be consolidated with the government-wide website described above.

As an alternative to waiting for a specific request for proposals, companies with innovative technology or ideas may consider submission of unsolicited proposals in response to broad agency announcements. For example, the Army Medical Research and Materiel Command (mrmc-www.army.mil) includes a proce-

ture for "Submitting a Research Proposal" for "Chem/Bio Defense" initiatives.

Similarly, the DOD Technical Support Working Group (www.bids.tswg.gov) includes the Combatting Terrorism Technology Support Office that recently sought proposals for such biological defense efforts as "easy to use" biological decontamination kits, a handheld confirmatory biological dosimetry tool, anthrax-spore destruction, and facility biological-toxin aerosol warning monitor.

The recent contract and grant awards for biodefense research, vaccines, and services by various DOD entities (e.g., DARPA, Army Medical Research Institute of Infectious Diseases, and Naval Medical Center) are strong indicators of more to come.

Health & Human Services Dept.

The Department of Health and Human Services (HHS) controls a substantial portion of the budget for biodefense. Indeed, the role of HHS and the CDC in the award of the \$770-million smallpox vaccine contract makes this agency a key source of funding opportunities. The CDC has its own website (www.cdc.gov/funding.htm) identifying funding opportunities.

With a \$1.75-billion budget for biodefense research, the National Institute of Allergy and Infectious Diseases (NIAID) will represent a major source of federal opportunities for biofirms. NIAID announces numerous opportunities for biodefense research funding on its website and identifies agency personnel as points of contact (www.niaid.nih.gov/biodefense/research/funding.htm).

In addition, the government-wide website (www.fedbizopps.gov) includes

a number of proposed NIAID contracts catalogued under the "biodefense" search term.

Encouraging Biotech Participation

Hardly anything about contracting with the federal government is easy. Recognizing some of the disincentives to doing business with the government, Congress has taken some steps to encourage technology companies to bring their products and services to the federal market place.

For biotechnology companies, DOD has the authority (Pub. L. 107-107, § 836[a][2]) to buy products and services as commercial items. In federal contracting, designation of anything as a "commercial item" greatly lessens the hassle of being a government contractor.

For example, companies selling commercial items receive simpler contracts with fewer clauses (FAR § 12.301), enjoy greater protection of technical data (FAR § 12.211), and do not have to submit reams of certified cost or pricing data with proposals (FAR § 15.403-1[b]).

While this statutory provision for biotechnology products and services is set to expire at the end of Fiscal Year 2003, Deidre Lee, the director of defense procurement and acquisition policy, is currently reviewing this authority to determine whether it needs to be extended.

In addition, the Homeland Security Act included provisions known as the Safety Act (Public Law 107-296, §§ 861-65) to limit liability and lawsuits against companies selling "qualified antiterrorism technology."

In the most general terms, the Safety Act seeks to reduce or eliminate certain types of damages, offer immunity from

liability, and otherwise limit lawsuits against companies whose "qualified" antiterrorism technology purportedly failed to work during a terrorist attack.

Congress enacted this legislation to encourage companies to develop new anti-terrorism technology without the fear of crippling liability lawsuits. To qualify such technology, the seller must submit hazard and safety information to the Homeland Security Department, which must then review and approve the technology as being "qualified" antiterrorism technology.

Conclusion

For biotechnology companies, the federal demand for biodefense research, products, and services is escalating rapidly. Although the biodefense opportunities for federal contracts and grants remain fragmented among a number of agencies, several trends show promise of making the hunt for federal funding easier—the Homeland Security Technology Clearinghouse, the emergence of websites specifically identifying biodefense initiatives, and the consolidation of proposed contract actions into a government-wide database.

Becoming a government contractor is still a risky proposition, but an increasing number of biocompanies have entered the federal marketplace within the last two years, and more will follow as Congress and the Executive Branch take steps to encourage more companies to step forward with biodefense products and services. **GEN**

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