CLEVELAND BIOLABS INC
Form 424B3
March 21, 2008

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-143755

Prospectus Supplement No. 3
(to Prospectus dated December 10, 2007)

CLEVELAND BIOLABS, INC.
5,514,999 Shares

This Prospectus Supplement No. 3 supplements and amends the prospectus dated December 10, 2007 (the "Prospectus") relating to the offer and sale of up to 5,514,999 shares of our common stock which may be offered from time to time by the selling stockholders identified in the Prospectus for their own accounts. This Prospectus Supplement is not complete without, and may not be delivered or used except in connection with the original Prospectus.

This Prospectus Supplement No. 3 includes the attached Form 10-K of Cleveland BioLabs, Inc. dated March 21, 2008, as filed by us with the Securities and Exchange Commission.

This Prospectus Supplement No. 3 modifies and supersedes, in part, the information in the Prospectus. Any information that is modified or superseded in the Prospectus shall not be deemed to constitute a part of the Prospectus, except as modified or superseded by this Prospectus Supplement No. 3. We may amend or supplement the Prospectus from time to time by filing amendments or supplements as required. You should read the entire Prospectus and any amendments or supplements carefully before you make an investment decision.

Investing in our common stock involves risk. See "Risk Factors" beginning on page 8 of the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if the Prospectus or this Prospectus Supplement No. 3 is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 3 is March 21, 2008.

United States Securities and Exchange Commission
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2007

or

¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____to _____

Commission file number 001-32954

CLEVELAND BIOLABS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**20-0077155**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
73 High Street, Buffalo, NY 14203	**(716) 849-6810**
(Address of principal executive offices)	Telephone No.

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange which registered**
Common Stock, par value $0.005 per share	NASDAQ Global Market

Securities Registered Pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter was $74,961,490. There were 13,158,477 shares of common stock outstanding as of March 1, 2008.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Stockholders, to be held on April 29, 2008, is incorporated by reference in Part III to the extent described therein.

CLEVELAND BIOLABS, INC.
FORM 10-K
03/21/08

Cleveland BioLabs, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2007

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. In particular, statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are contained or incorporated by reference in this report. We have based these forward-looking statements on our current expectations about future events. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond our control. The actual future results for Cleveland BioLabs, Inc. may differ materially from those discussed here for various reasons. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. We do not undertake and specifically decline any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments. When used in the report, unless otherwise indicated, "CBLI," "we," "our" and "us" refers to Cleveland BioLabs, Inc.

PART I

Item 1. Description of Business

GENERAL OVERVIEW

CBLI was incorporated in Delaware and commenced business operations in June 2003 as a development-stage, biotechnology company, with a very specific and targeted focus on radiation drug discovery. We have devoted substantially all of our resources to the identification, development and commercialization of new types of drugs for protection of normal tissues from exposure to radiation and other stresses, such as toxic chemicals and cancer treatments. CBLI's pipeline includes products from two primary families of compounds: protectans and curaxins. We are developing protectans as drug candidates that protect healthy tissues from acute stresses such as radiation, chemotherapy and ischemia (pathologies developed as a result of blocking blood flow to a part of the body). Curaxins are being developed as anticancer agents that could act as mono-therapy drugs or in combination with other existing anticancer agents.

On July 20, 2006, we sold 1,700,000 shares of common stock, par value $0.005 per share, in our initial public offering at a per share price of $6.00. After our initial public offering, our common stock was listed on the NASDAQ Capital Market under the symbol "CBLI" and on the Boston Stock Exchange under the symbol "CFB." Our trading symbol on the Boston Stock Exchange was later changed to "CBLI." On August 28, 2007, trading of our common stock transferred from the NASDAQ Capital Market to the NASDAQ Global Market. In September 2007, we ceased our listing on the Boston Stock Exchange.

TECHNOLOGY

Our development efforts are based on discoveries made in connection with the investigation of the cell-level process known as apoptosis. Apoptosis is a highly specific and tightly regulated form of cell death that can occur in response to external events such as exposure to radiation, toxic chemicals or internal stresses. Apoptosis is a major determinant of tissue damage caused by a variety of medical conditions including cerebral stroke, heart attack and acute renal failure. Conversely, apoptosis is also an important protective mechanism that allows the body to shed itself of defective cells, which otherwise can cause cancerous growth.

Research has demonstrated that apoptosis is sometimes suppressed naturally. For example, most cancer cells develop resistance to apoptotic death caused by drugs or natural defenses of the human body. Our research is geared towards identifying the means by which apoptosis can be affected and manipulated depending on the need.

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If the need is to protect healthy tissues against an external event such as exposure to radiation, we focus our research efforts on attempting to temporarily and reversibly suppress apoptosis in those healthy tissues, thereby imitating the apoptotic-resistant tendencies displayed by cancer cells. A drug with this effect would also be useful in ameliorating the often severe side effects of anticancer drugs and radiation that cause collateral damage to healthy tissues during cancer treatment. Because the severe side effects of anticancer drugs and radiation often limit their dosage in cancer patients, an apoptosis suppressant drug may enable a more aggressive treatment regimen using anticancer drugs and radiation and thereby increase their effectiveness.

On the other hand, if the need is to destroy cancerous cells, we focus our research efforts on restoring apoptotic mechanisms that are suppressed in tumors, so that those cancerous cells will once again become vulnerable to apoptotic death. In this regard, we believe that our drug candidates could have significant potential for improving, and becoming vital to, the treatment of cancer patients.

Through our research and development, or R&D, and our strategic partnerships, we have established a technological foundation for the development of new pharmaceuticals and their rapid preclinical evaluation. We spent $17,429,652 and $6,989,804 on R&D in the fiscal years ended December 31, 2007 and December 31, 2006, respectively.

We have acquired rights to develop and commercialize the following prospective drugs:

- Protectans - modified factors of microbes and tumors that protect cells from apoptosis, and which therefore have a broad spectrum of potential applications. The potential applications include both non-medical applications such as protection from exposure to radiation, whether as a result of military or terrorist action or as a result of a nuclear accident, as well as medical applications such as reducing cancer treatment side effects.

- Curaxins - small molecules designed to kill tumor cells by simultaneously targeting two regulators of apoptosis. Initial test results indicate that curaxins can be effective against a number of malignancies, including renal cell carcinoma, or RCC (a highly fatal form of kidney cancer), soft-tissue sarcoma, and hormone-refractory prostate cancer.

In the area of radiation protection, we have achieved high levels of protection in animal models. With respect to cancer treatment, the biology of cancer is such that there is no single drug that can be successfully used to treat 100% or even 50% of all cancer patients. This means that there likely will be a need for additional anticancer drugs for each type of cancer.

These drug candidates demonstrate the value of our scientific foundation. Based on the expedited approval process currently available for non-medical applications such as protection from exposure to radiation, our most advanced drug candidate, Protectan CBLB502, may be approved for such applications within 24 to 36 months. Another drug candidate, Curaxin CBLC102, entered Phase IIa clinical trials earlier this year.

INDUSTRY

CBLI is a biotechnology, or biotech, company focused on developing cancer treatment, tissue protection and biodefense drugs. Historically, biotech was defined by newly discovered “genetic engineering” technology, which was first developed in universities and new startup biotech companies in the mid-1970s. Later, other technologies (based on a constant flow of discoveries in the field of biology) started playing a leading role in biotech development. Medicine, and specifically drug development, is a lucrative field for use of these technologies. Large pharmaceutical, or Pharma, companies joined the biotech arena through licensing, sponsored research, and corporate agreement relationships. Today biotech is a $300 billion industry (based on total market capitalization) and includes large companies such as Amgen, Inc. and Genentech, Inc.

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The traditional biotech business model is a derivative of the long drug development process. Typical biotech companies go through the following stages:

- During the first stage, biotech companies fund their development through equity or debt financings while conducting R&D, which culminates in phased drug trials.

- During the second stage, when their lead drug candidates enter the drug trials, biotech companies may start licensing their drug candidates to Pharma companies in order to (1) generate revenue, (2) gain access to additional expertise, and (3) establish relations with Pharma companies in the market who can eventually take a leading role in distributing successful drugs.

- At the most advanced stage, biotech companies generate revenues by selling drugs or other biotech products to consumers or through alliances of equals.

The Project BioShield Act, which was signed into law in July 2004, allocated $5.6 billion over ten years to fund the research, development and procurement of drugs, biological products or devices to treat or prevent injury from exposure to biological, chemical, radiological or nuclear agents as a result of a military, terrorist or nuclear attack. The legislation provides for a more expedited approval process by allowing for approval based on Phase I safety studies in humans and efficacy studies in two animal species (rodents and non-human primates) instead of Phase II and III human clinical trials. With the Project BioShield Act, biotech companies now have greater access to grants and contracts with the U.S. government. Several biotech companies have secured grants and contracts from the U.S. government to develop drugs and vaccines as medical countermeasures against potential terrorist attacks. For biotech companies focused on these types of drugs and vaccines, this type of funding, together with the scaled down Food and Drug Administration, or FDA, approval process, are major departures from the traditional biotech business model. The principal provisions of this law are to:

- Facilitate R&D efforts of biomedical countermeasures by the NIH;
- Provide for the procurement of needed countermeasures through a special reserve fund of $5.6 billion over ten years; and
- Authorize, under limited circumstances, the emergency use of medical products that have not been approved by the FDA.

While there are a number of biotech and Pharma companies that are attempting to develop new anti-radiation and anti-cancer drugs to treat these medical conditions, these areas are nevertheless considered unmet medical needs, which means that there are currently no existing methods to satisfactorily treat these medical conditions.

STRATEGIES AND OBJECTIVES

Our primary objective is to become a leading developer of drugs for the protection of human tissues against radiation and other stresses and for cancer treatment. Key elements of our strategy include:

- *Aggressively working towards the commercialization of Protectan CBLB502*. Our most advanced drug candidate, Protectan CBLB502, offers the potential to protect normal tissues against exposure to radiation. Because of the potential military and defense implications of such a drug, the normally lengthy FDA approval process for these non-medical applications is substantially abbreviated resulting in a large cost savings to us. We anticipate having a developed drug available for these non-medical applications within 18-30 months. The FDA approval process is estimated to take an additional six months.

- *Leveraging our relationship with leading research and clinical development institutions.* The Cleveland Clinic Foundation, one of the top research medical facilities in the world, is one of our co-founders. In addition to providing us with drug leads and technologies, the Cleveland Clinic will share valuable expertise with us as clinical trials are performed on our drug candidates. In January 2007, we entered into a strategic research partnership with Roswell Park Cancer Institute, or RPCI, in Buffalo, New York. This partnership will enhance the speed and efficiency of our clinical research and provide us with access to the state-of-the-art clinical development facilities of a globally recognized cancer research center.

- *Utilizing governmental initiatives to target our markets.* Our focus on drug candidates such as Protectan CBLB502, which has applications that have been deemed useful for military and defense purposes, provides us with a built-in market for our drug candidates. This enables us to invest less in costly retail and marketing resources. In an effort to improve our responsiveness to military and defense needs, we have established a collaborative relationship with the Armed Forces Radiobiology Research Institute.

- *Utilizing other strategic relationships.* We have collaborative relationships with other leading organizations that enhance our drug development and marketing efforts. For example, one of our founders, with whom we maintain a strategic partnership, is ChemBridge Corporation. Known for its medicinal chemistry expertise and synthetic capabilities, ChemBridge provides valuable resources to our drug development research.

PRODUCTS IN DEVELOPMENT

Protectans

We are exploring a new natural source of factors that suppress the programmed cell death (apoptosis) response in human cells, which can be rapidly developed into therapeutic products. These inhibitors are anti-apoptotic factors developed by microorganisms of human microflora throughout millions of years of co-evolution with mammalian host. We are using the same strategy that was applied for the discovery of antibiotics, one of the biggest medical achievements of the 20th century. We have established a technological pipeline for screening of such factors, named protectans, and their rapid preclinical evaluation. Such inhibitors can be used as protection from cancer treatment side effects and antidotes against injuries induced by radiation and other stresses associated with severe pathologies (i.e., heart attack or stroke).

Protectan CBLB502

Protectan CBLB502 is our leading radioprotectant molecule in the protectans series. Protectan CBLB502 represents a rationally-designed derivative of the microbial protein, flagellin. Flagellin is secreted by *Salmonella typhimurium* and many other Gram-negative bacteria, and in nature, arranges itself in a hollow cylinder to form the filament in bacterial flagellum and acts as a natural activator of NF-kB (nuclear factor-kappa B), a protein complex widely used by cells as a regulator of genes that control cell proliferation and cell survival. Thus, Protectan CBLB502 reduces injury from acute stresses by mobilizing several natural cell protecting mechanisms, including inhibition of apoptosis, reduction of oxidative damage and induction of factors (cytokines) that induce protection and regeneration of stem cells in bone marrow and intestine. Potential applications for Protectan CBLB502 include reduction of radiation therapy or chemotherapy side effects in cancer patients, protection from Acute Radiation Syndrome (ARS) in defense scenarios, and protection from acute organ failure. Protectan CBLB502 is administered through intramuscular injection.

Biodefense Applications

Our scientists have demonstrated that injecting Protectan CBLB502 into mice, rats and non-human primates protects them from lethal doses of total body gamma radiation. An important advantage of Protectan CBLB502, above any other radioprotectant known to us, is the ability to effectively protect not only the hematopoietic system, but also the gastrointestinal, or GI, tract, which are among the most sensitive areas of the human body to radiation. High levels of radiation, among other effects, induce moderate to severe bone marrow damage. The immune and blood stem cells are also depleted and death is caused by anemia, infection, bleeding and poor wound healing. Protectan CBLB502's ability to effectively protect the hematopoietic system and GI tract may make Protectan CBLB502 uniquely useful as a radioprotective antidote. Protectan CBLB502 was shown to be safe at its therapeutic doses in rodents and non-human primates. In addition, Protectan CBLB502 has proved to be a stable compound for storage purposes. It can be stored at temperatures close to freezing, room temperature or extreme heat. Manufacture of Protectan CBLB502 is relatively inexpensive, due to its high yield bacterial producing strain and simple purification process.

Our research has also demonstrated that a single injection of less than 1% of the maximum tolerable dose of Protectan CBLB502 protected greater than 80% of National Institutes of Health, or NIH, Swiss mice from exposure to as high as 13 Gy of total body irradiation. No other known compounds in development show this degree of protective effect from this level of radiation exposure.

Protectan CBLB502 also showed strong radioprotective efficacy as a single therapy in non-human primates, enabling the survival of 70% of the CBLB502-treated animals that received whole-body radiation versus the non-treated control group, in which 75% of the animals died. Of the non-human primates in the control group that survived, none were without significant abnormalities. In contrast, the surviving non-human primates treated with CBLB502 possessed no significant structural abnormalities in their bone marrow, immune system organs, or small intestines after 40 days. This is consistent with data previously obtained from trials on mice. Irradiated mice treated with CBLB502 survived to their normal life span without developing any significant abnormalities and while preserving the normal formation of blood cells (hematopoiesis). This data suggests that CBLB502 may offer true protection from gamma-irradiation induced ARS, including the lethal effects on both the GI and hematopoietic systems.

A study completed in late 2007 demonstrated the efficacy of Protectan CBLB502 as a mitigator of hematopoietic (bone marrow/blood production) damage up to 48 hours after radiation exposure. This was the first primate study pointing towards CBLB502's high utility in protection of civil populations, where countermeasures would be stockpiled and then distributed.

In the study, five groups of ten rhesus primates received 5 Gy (approximately 20% of lethal dose) of gamma radiation. The control group received a placebo, while the four experimental groups received a single intramuscular injection of Protectan CBLB502 at one of the following times: 1, 16, 24 or 48 hours after irradiation. No mortality was observed in CBLB502-treated groups after 30 days, while 20% mortality was observed in the control group. Thrombocytopenia has been shown to be the best predictor of primate post-irradiation mortality in recent studies.

The duration and occurrence of severe thrombocytopenia (a decrease of platelet*s*, the blood cells that prevent bleeding) was strongly reduced by CBLB502. The average number of severe thrombocytopenia (< 50,000 platelets/ul) days per primate was drastically reduced from 4.3 in the control group to 0.6-1.5 in all four CBLB502-treated groups.

In addition, duration and occurrence of severe neutropenia (a decrease in white blood cells, which serve as the primary defense against infections) was also reduced by CBLB502. For example, an average number of days of extremely severe neutropenia (< 100 neutrophils/ul) per primate was reduced from 2.7 in the control group to 0.3-1.5 in the experimental groups.

We submitted Protectan CBLB502 in response to a Request for Information, or RFI, from the Department of Health and Human Services, or HHS, in July 2007, which noted the agency's intention to pursue an initial acquisition of 100,000 treatment courses of a medical countermeasure for neutropenia arising as a consequence of ARS. The RFI further stated that there would be options for up to an additional 100,000 treatment courses to meet HHS’s requirement of at least 200,000 treatment courses.

We intend to initiate a human safety study in the first half of 2008 for Protectan CBLB502 in ARS, which is the only stage of human testing required for approval in this indication.

Regulatory Status

Extraordinary radioprotective properties, an excellent toxicity profile, outstanding stability and inexpensive production of Protectan CBLB502 make it a primary candidate for entering formal preclinical and clinical studies. Initially, Protectan CBLB502 will be developed for non-medical purposes — as a radioprotectant antidote for the protection of people from severe doses of ionizing radiation. Our drug development strategy complies with the recently adopted FDA rules for investigational drugs that address situations such as radiation injury, where it would be unethical to conduct efficacy studies in humans. While Phase II and Phase III human clinical trials are normally required for the approval of marketing an investigational drug, under the FDA rules, Protectan CBLB502 would be considered for approval for this indication based on Phase I safety studies in humans and efficacy studies in two animal species (rodents and non-human primates). Based upon this expedited approval process, Protectan CBLB502 could be approved for non-medical applications within 24 to 36 months. Because Phase II and Phase III testing involves applying a drug candidate to a large numbers of participants who suffer from the targeted disease and condition and can last for a total of anywhere from three to six or additional years, bypassing these phases represents a significant time and cost savings in receiving FDA approval.

As part of this expedited approval process, the FDA has indicated that it intends to engage in a highly interactive review of Investigational New Drug, or IND, applications and New Drug Applications, or NDAs, and to provide for accelerated review or approval of certain medical products for counterterrorism applications, including granting eligible applications “Fast Track” approval status. The Fast Track designation ordinarily allows a product to be considered for accelerated approval through the use of surrogate endpoints to demonstrate effectiveness. As a result of these provisions, the FDA has broader authority to consider evidence of partial tumor shrinkage or other surrogate endpoints of clinical benefit in deciding on approval. This new policy is intended to facilitate the study of cancer therapies and shorten the total time required for marketing approvals. In cases where priority review is given to Fast Track applications, the applicant is permitted to submit applications on a rolling basis.

As part of the process to receive final FDA approval for Protectan CBLB502 for non-medical applications, we have completed Good Manufacturing Practices compliant (cGMP) manufacturing of Protectan CBLB502. The yields from the process and the purity of the final product exceeded our expectations. We were able to develop a complicated, high-yield manufacturing process for CBLB502 because of the excellent work of our in-house team and consultants, and our subcontractor, SynCo Bio Partners B.V, which was able to prototype the process and resolve multiple challenges during the industrial development. We currently have drug substance corresponding to over 100,000 projected human doses, or potentially many more, depending on the final therapeutic dose to be used, which will be determined in the coming months through our Phase I safety trial. The process we developed gives us the ability to manufacture up to five million estimated doses within a year without any additional scale-up; and if necessary, scale-up could be implemented relatively easily.

In order for us to receive final FDA approval for Protectan CBLB502 for non-medical applications, we need to:

- Submit an IND application and receive approval from the FDA;
- Perform a Phase I dose-escalation human study on a small number of volunteers;
- Conduct pivotal animal efficacy studies with the GMP manufactured drug candidate;
- Perform a human safety study in a larger number of volunteers using the dose of CBLB502 previously shown to be safe in humans and efficacious in animals; and
- File a Biologic License Application, or BLA.

In our most optimistic business scenario, all of these steps could be accomplished in 18 months. In a more conservative business scenario, it may take up to 30 months or more to complete the development and file the BLA for the approval of Protectan CBLB502 for non-medical applications.

The Project BioShield Act of 2004, which further expedites the approval of drug candidates for certain uses, is intended to bolster our nation's ability to provide protections and countermeasures against biological, chemical, radiological or nuclear agents that may be used in a military, terrorist or nuclear attack.

This law also allows for the use of expedited peer review when assessing the merit of grants and contracts of up to $1,500,000 for countermeasure research. We have been awarded a $1,500,000 research grant pursuant to this law.

The Defense Threat Reduction Agency of the U.S. Department of Defense, or DoD, awarded us a $1.3 million grant in March 2007, to fund "development leading to the acquisition" of Protectan CBLB502 as a radiation countermeasure, in collaboration with the Armed Forces Radiobiology Research Institute, which has also received significant independent funding for work on Protectan CBLB502.

The DoD also recently awarded a $1 million grant to our founding partner, the Cleveland Clinic, to conduct pre-clinical studies on Protectan CBLB502 for use in tourniquet and other ligation-reperfusion battlefield injuries where blood flow is stopped and then restored after a prolonged period of time.

Market Opportunities

Protectan CBLB502 is a candidate for procurement by the DoD. In general, the procurement process is conducted on the basis of full and open competition that cannot be limited, unless the DoD determines that the public requesting policy would otherwise seriously jeopardize national security.

Prior to determining the best treatment, the DoD issues a Request for Information, or RFI, for treatments available or in development for a specific condition resulting from an identified threat. The RFI provides an incentive for companies to research and develop countermeasures that are superior to those selected for stockpiling. Through the RFI, companies may compete for future contracts that will revise and update stockpile content for emerging threats and to discover advanced technologies and new countermeasures.

Following its review of the responses it receives, the DoD issues a Request for Proposal, or RFP. The RFP solicits proposals for the manufacturing of specified treatments for a defined number of doses to be delivered within a specified time frame (a maximum of eight years). A contract may be awarded once the review of the RFP responses has been completed, though payments by the government are made only upon product delivery.

If the product or the use indicated in the RFP of an approved product is not approved, licensed, or cleared for commercial distribution at completion of the review, the DoD has the authority to procure the required amount if it has:

- Determined that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years after the date of a determination, and
- Determined that the product is authorized for emergency use.

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