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Having Gotten Its Start With The Acquisition Of An Anthrax Vaccine In 1998, Emergent BioSolutions Inc. Is Both Focused On Its Biodefense Business, With Annual Revenues Of Approximately \$240 Million, And Its Expansion Into Other Vaccine Areas Including Tuberculosis, Typhoid, Influenza, And Chlamydia

**Healthcare
Biotechnology
(EBS-NYSE)**

Emergent BioSolutions Inc.

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R. Don Elsey
SVP, Finance and Administration
and CFO

BIO:

Mr. Elsey has served as chief financial officer since March 2006, senior vice president finance and administration since May 2007, and treasurer since June 2005. Mr. Elsey previously served as vice president finance June 2005 to May 2007. Prior to joining the company, Mr. Elsey served as the director of finance and administration at IGEN International, Inc., a biotechnology company, and its succes-

sor BioVeris Corporation, from April 2000 to June 2005. Prior to joining IGEN, Mr. Elsey served as director of finance at Applera, a genomics and sequencing company, and in several finance positions at International Business Machines, Inc. Mr. Elsey received an M.B.A. in finance and a B.A. in economics from Michigan State University. Mr. Elsey is a certified management accountant.

Company Profile:

Emergent BioSolutions Inc. is a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and therapeutics that assist the body's immune system to prevent or treat disease. Emergent's marketed product, BioThrax(R) (Anthrax Vaccine Adsorbed), is the only vaccine approved by the U.S. Food and Drug Administration for the prevention of anthrax infection. Emergent's product pipeline targets infectious diseases and includes programs focused on anthrax, tuberculosis, typhoid, flu and chlamydia.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Mr. Elsey, what is the focus of Emergent BioSolutions today?

Mr. Elsey: The company started in 1998 when the CEO, Fuad El-Hibri, together with a consortium of associates, put in the winning bid for the acquisition of the only licensed anthrax vaccine from the state of Michigan. His vision was to found a vaccine company that would become a major player in the vaccine space, as Fuad believed that vaccines had fallen

out of favor and had not received the focus that they deserved. Since the acquisition, the vision of the company was to expand its vaccine base in both the areas of biodefense and commercial vaccines, such as those that protected against tuberculosis, typhoid, chlamydia, or the flu. Our focus is to continue to capitalize on and expand our biodefense business, from which we have annual revenues of approximately \$240 million, while at the same time expanding a commercial portfolio to have greater involvement in all areas of the vaccine space.

CEOCFO: What does Emergent know about vaccines that other companies do not?

Mr. Elsey: A number of other companies have in the past few years jumped on the bandwagon that Fuad El-Hibri saw early on, which is vaccines have a key role in preventing disease and it is a lot more cost effective in the long run than curing disease. You are starting to see major pharmaceutical players such as Sanofi, Merck, and GlaxoSmithKline, have renewed interest in the vaccine space. Is it something that we definitely knew that these other companies did not know? I would not say that. I would say they have always known about vaccines, we just chose to jump in and focus on it a little bit earlier than they did in the resurgence in the vaccine space.

CEOCFO: Emergent is focusing on several diseases; how do you decide on what to target?

Mr. Elsey: First on the biodefense side, clearly, we have the only FDA-licensed anthrax vaccine and we are building on that. We work closely with the U.S. gov-

ernment and our product development activities in the biodefense arena are in response to what the government identifies as their key focus items. Without going into detail, the government has what they call Category-A pathogens that are the priorities to address from a bio-terror perspective. We respond to the government needs on those. With respect to the commercial side, we are looking at product candidates to address diseases with unmet and underserved medical needs and at the same time, we look for those areas where we are not necessarily going head to head with a company as big as a Glaxo or a Sanofi. We take a look at those areas where we believe there are good product candidates and where we believe we have a good market opportunity.

CEOFCFO: Emergent has an international presence; what are you doing where and why so many locations?

Mr. Elsey: We do have an international presence, but I would tell you it is more focused than it may appear from the outside. In 2005, Emergent acquired a vaccine development company in the UK, and we have continued to use that facility for product development activities. In addition, we have sales offices in Germany and Singapore, which are responsible for working with government entities in those locations to begin expanding the market

for our biodefense and commercial portfolio. Here in the U.S., we have several locations in Maryland – headquarters in Rockville, another product development facility in Gaithersburg, and a newly acquired manufacturing site in Baltimore. Our main manufacturing facility is in Lansing, Michigan. In all, we have over 600 employees.

CEOFCFO: Where are you in the process with your various vaccines?

Mr. Elsey: We have BioThrax, our FDA-licensed vaccine that generates current revenues. Our product candidates in late-stage Phase II development include an anthrax therapeutic, a recombinant an-

thrax vaccine, the most-clinically advanced recombinant tuberculosis vaccine in development, which is underway in a Phase IIb efficacy study in South Africa, and Typhella™, a single-dose oral typhoid vaccine that will be studied in more advanced clinical trials in the near future. We also have a preclinical development program for a chlamydia vaccine and a universal flu vaccine.

CEOFCFO: What is the financial picture like at the company?

Mr. Elsey: The financial picture is one where we have grown revenues 13% per year since 2005. Ever since 2005 and

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since we have gone public we have been a profitable company. The results that we just released for 2009 on a preliminary unaudited basis are \$234 million in revenue and approximately \$25 to \$28 million in net income. The outlook for 2010, which we announced recently at the JP Morgan Healthcare Conference, is \$235 to \$255 million in revenue and \$20 to \$30 million in net income after tax.

CEOFCFO: Who is buying BioThrax®, and how is it used?

Mr. Elsey: We primarily have two customers for BioThrax® (Anthrax Vaccine Adsorbed) but procurement occurs through one organization. Procurement is under the responsibility of the Depart-

ment of Health and Human Services (HHS), which purchases doses both for stockpiling purposes as well as for supplying the Department of Defense (DoD) for active immunization of troops deployed in high-threat areas. The DoD consumes about 1.5 to 2 million doses a year and the rest go into the Strategic National Stockpile (SNS) for use in a possible civilian attack. The SNS as it stands today has approximately 350 million doses of a broad-spectrum antibiotic for initial therapy for anthrax exposure, and they have about 325 or 350 million doses of a smallpox vaccine. Their stated demand for BioThrax is 75 million doses in the stockpile and our estimate is that they are at about 20 million doses currently. We ship and can produce today between seven and eight million doses a year and HHS buys every dose that we make.

CEOFCFO: Would you tell us about your manufacturing facilities and can you ramp up easily if needed?

Mr. Elsey: In 2008, we completed construction and installation of equipment in a new manufacturing facility at our Michigan campus. It is capable, on a single manufacturing train, of producing approximately 35 million doses per year. The facility can accommodate two trains, so we could make potentially 60 to 70 million doses a year. Construction of that building is complete

and we have begun steps to qualify and validate that facility. The FDA has various rigorous protocols with regard to licensing of biological products and requires the product to be licensed with the building. Our BioThrax product, which is already licensed, but which will now be manufactured in a new building, will have to go through a new licensing process. We estimate that will take twenty four to thirty months with our current course and speed in a standard environment. If in fact there was an emergency and that building had to be turned on, it could probably produce product in approximately eight weeks.

CEOCFO: Do you consider selling into other governments in the near future?

Mr. Elsey: We have been working through our German and Singapore sales offices cautiously because the U.S. government purchases our full capacity. If we had a modest order of ten thousand to fifty thousand doses, I believe that the government would permit us to make those sales. But until we have the new manufacturing capacity up and operational and licensed, we will be unable to accept an order that was let's say a million doses for a particular country. We have sold to other countries in very modest amounts and we have been working with a variety of foreign governments and their respective Ministries of Health and Ministries of Defense to help educate them and help them plan. Hopefully, we get this new building approved in the not too distant future and that coincides with an ability and a demand from ex-U.S. governments that we will be able to meet at that time.

CEOCFO: Recently you joined the board of the MdBio Foundation; would you tell us about that?

Mr. Elsey: As you may know, the state of Maryland really put a keen emphasis on biotechnology way back in the 1980's and formed technology corridors and technology hubs in both Montgomery County, Maryland and the Baltimore area. In conjunction with that, and working with such organizations as the National Institutes of Health, Johns Hopkins University, and the University of Maryland, the State formed the Tech Council of Maryland, of which one piece is MdBio. The MdBio Foundation, which is under the overall wing of the Tech Council, was established in the early 1990's. One of its goals is to promote science education at the high school level across the state, so that students have access to resources in the biotechnology field that schools in general do not have access to or cannot afford. An example of a program is the availability of a mobile lab outfitted with state-of-the-art equipment that visits schools with a staff of expert instructors, who will take high school students through specific experiments and seminars. To promote biotechnology education in the state of Maryland – that, in a nutshell, is the mission of the foundation.

CEOCFO: Is the investment community paying attention to Emergent?

Mr. Elsey: Yes, it is. We went public in late 2006 and it has been a lot of work to educate the investment community. Bio-defense is an area that they did not understand clearly, particularly with regard to the U.S. government's commitment to it. When we went public, we had three investment banks cover us, JP Morgan, Cowen & Company and HSBC. HSBC has since decided to focus strictly on commercial banking and has dropped investment banking. Since then, we have picked up coverage from Caris and Company and Wedbush Securities and, more recently, Sidoti and Company and Madison Williams and Company. We believe there will be additional coverage later this year. When we first presented at JP Morgan back in January of 2007, we had rather sparse attendance. In the recent conference, we had a room with over seventy people attending. We have increased coverage and attention steadily and considerably over the past years. When we went public, we went out with five million shares, which was not a very large public float. Now, we have 31 million shares outstanding and over eighteen million shares are now in public hands. That has definitely allowed more people today to purchase stock and pay attention.

CEOCFO: Address potential investors; lay out what you see ahead for the next couple of years. Why should people be interested and what might they miss that should be understood?

Mr. Elsey: We are focused on growth. There are a number of key milestones across the portfolio this year - from a financial perspective and a commercial portfolio perspective on both the biodefense and the commercial vaccine businesses. We have made it a goal to pursue additional M&A to bring additional products into the pipeline. We are self-funding, so we do not go out to the market every year and dilute the current stockholders. From a value proposition with where we see the expansion of the biodefense demand and our ability to fill that demand with the standard manufacturing capacity, you are looking at a revenue stream that quite likely will go from \$240 million to north of \$400 or \$500 million just in the biodefense side.

If we are successful at bringing on board late-stage commercial candidates that can be driving a \$2 to \$4 hundred million per product per year by 2013-2014, and put that financial model together, do enough present value on it, then you find that the share price would have significant potential to it. Clearly, it depends on your view of the glass, is it half full or half empty? What we deal with the most in talking to people is the skepticism about the U.S. government on biodefense. We feel that the commitment is solid and we feel it is long-term. There has been a recent interview with one of the military advisors to the 9/11 commission, and he is calling for prophylactic proactive immunization of every man, woman, and child in the U.S. His thesis is that first, if you proactively immunize everybody, then you take the terror agent off the table. Second, if you wait until after the fact, the impact will not only be in human lives lost, but also a cleanup cost in the trillions of dollars. One of the scenarios is the release of anthrax spores into the air intake of, for example, a major mall or a high-rise building. If that happens you can either bulldoze the building or immunize everyone that would ever set foot in that building from that day forward, because spores will last for decades. Cleaning up those buildings or reacting to it after the fact, will entail a huge economic cost. We believe this is an insurance policy, just like buying smallpox vaccines, just like trying to corner the market on H1N1 vaccine prior to what we thought was going to be a horrible pandemic. But if you take a look at the cost of the insurance policy versus the cost of reacting to after the fact, the economic equation is such that we believe the government has no option but to focus very clearly on bioterrorism and to be even more robust in their protection measures.

CEOCFO: Final thoughts, what should people reading about Emergent BioSolutions take away most?

Mr. Elsey: The most important take away that I would like people to have about Emergent is an appreciation of our unique position in the biotech industry as a whole. We sit in between the start up biotechs and the big-time biotechs like the Amgens and Genentechs, for whom I have great respect. What differentiates us

is that we sell a licensed product today, we have large-scale manufacturing capacity, we have experience in dealing with FDA on regulatory matters, we are experienced in navigating the government contracting process, we deliver on our milestones, and we have a track record of success, while at the same time we continue to aggressively pursue development work on a number of vaccines and therapeutic candidates. So, when one tries to

evaluate the investment potential of biotech, you either have this cash-burn model that is for the very early stage biotech or you have an Amgen, where you've been around for 35 years and have \$15 billion in annual revenue. We fit in-between and that makes it hard for some people to evaluate. But I think you have to take a very objective look and ask, "Does it make sense that the government is going to continue to maintain their

response to bioterrorism?" And if the answer is yes, then you almost see the potential revenue of our biodefense business. We are able to sign multi-year contracts, which consume our full capacity at known revenue levels, another unique strength of our company. In addition, if you look at the potential of the commercial products and what they can bring, you will find a very compelling investment story.



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