

IN THE FOREFRONT

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Emergent's Center for Innovation in Advanced Development and Manufacturing (CIADM) provides development and manufacturing of medical countermeasures.

CBNW meets Daniel J. Abdun-Nabi, CEO of Emergent BioSolutions Inc

CBNW: Could you provide a history of the company – and how it became involved in the market?

DJA: Our company history began in Lansing, Michigan, USA, in 1998 when we acquired the Michigan Biologic Products Institute, through a public auction, from the Michigan Department of Health. The assets included a 12.5-acre campus, approximately 180 employees, along with several products licensed by the US Food and Drug Administration (FDA).

Since then we have grown our global footprint, core competencies, and product portfolio – leading to a 20-year track record of providing US and allied governments with critically needed medical countermeasures to protect their military and civilian

populations from serious public health threats, including bioterror weapons like anthrax, smallpox, and botulism, known chemical warfare agents (CWAs), and emerging infectious diseases (EID) like Zika, Ebola, and pandemic influenza.

In addition to our products, Emergent also offers contract development and manufacturing services for both bulk drug substances and sterile injectable drug products for global customers through several facilities throughout North America, including those that have been inspected by multiple regulatory agencies worldwide.

Emergent has experienced organic growth accelerated through a successful M&A growth strategy. In recent years, we have expanded our portfolio of products addressing biological and

chemical threats, product candidates for EID, and platforms, including auto-injectors, hyperimmunes, broad-spectrum antibacterials, and broad-spectrum antivirals.

While the bulk of our customer base is in the US, we recognize the significance of the global market, particularly in Europe and Asia, and we are committed to expanding our international footprint. Emergent is partnering with key government agencies to ensure that they have access to critical countermeasures to address their preparedness and national security needs.

CBNW: What physical and personnel assets does Emergent BioSolutions bring to the market?

DJA: Across 13 sites, we have around

1,300 employees who embody our company's values. We have an experienced leadership team focused on diversifying the business, strengthening our leaders across the organization, engaging employees, and innovation. It is because of the expertise and commitment of our workforce that Emergent is recognized as a trusted government partner and service provider. Additionally, we receive important counsel and oversight from a diverse group of highly respected industry leaders who make up the company's Board of Directors.

Emergent's core competencies include government contracting, quality manufacturing, advanced product development, M&A and partnerships, and these position us for sustained growth and success.

We have manufacturing operations in seven facilities in the US and Canada.

Our international footprint includes R&D as well as manufacturing operations in Canada, along with sales and marketing offices in Singapore, the UK, and Germany. Recently we have announced a contract to supply one of our products out of Germany and to house another in a warehousing and distribution facility in the country.

Our field teams offer significant expertise in providing chemical and biological threat preparedness solutions to international organizations, including the European Commission, NATO and WHO, as well as to allied governments.

CBNW: Can you outline the different products that you offer to healthcare ➤

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providers, government and military colleagues?

DJA: Emergent has eight products, including vaccines, therapeutics, and devices that address biological and chemical threats and almost all our products are being delivered to our customers under active long-term government procurement contracts.

CBNW: What percentage of your business is in the safety and security sector and are your main customers in the civil sector?

DJA: A significant proportion of our business is in the safety and security sector. Emergent is focused on providing specialty products that address accidental, intentional, and naturally

occurring public health threats, including CBRN threats and EIDs. Our goal is to help ensure medical countermeasures are available for the protection of military and civilian populations.

With the increased risk of CBRN attacks, seen with recent white powder incidents and the Salisbury chemical attack in the UK, emergency responders are also at risk. As the threat assessment has evolved significantly over the past few years, we have expanded our reach to also prioritize offering protection to first-responder teams and intergovernmental and non-governmental organizations that operate in potentially high-risk areas such as NATO, WHO, Red Cross, and Doctors Without Borders. We continue to be agile so that we can respond to governments by offering our expertise in product manufacturing and supply to meet their changing needs.

CBNW: Can you give details about the advanced development of CBRN medical countermeasures at the CIADM facility?

DJA: Since 2012, the US government and Emergent entered into a 25-year public-private partnership to establish one of our facilities as a Center for Innovation in Advanced Development and Manufacturing (CIADM), one of only three such facilities in the US designated by the US Department of Health and Human Services (HHS) to provide

BIOLOGICAL THREATS

- **BioThrax** – the only FDA-licensed anthrax vaccine in the world for the prevention of anthrax disease in a pre- or post-exposure setting
- **Raxibacumab** – anthrax monoclonal antibody for the treatment of inhalational anthrax
- **Anthrasil** – the only FDA-licensed anthrax immune globulin in the world for the treatment of inhalational anthrax
- **ACAM2000** – the only FDA-licensed smallpox vaccine for the prevention of smallpox disease
- **VIGIV** – the only FDA-licensed vaccinia immune globulin in the world for the treatment of complications from the smallpox vaccine
- **BAT** – the only FDA-licensed botulism antitoxin heptavalent in the world for the treatment of botulism

CHEMICAL THREATS

- **Trobigard** – atropine sulphate obidoxime chloride auto-injector for chemical threats. (This is not currently approved or cleared by the US Food and Drug Administration or any similar regulatory body, and is only distributed to authorized government buyers for use outside the US. This product is not distributed in the US)
- **RSDL** – reactive skin decontamination lotion kit, the only FDA-licensed device in the world for the removal and neutralization of known chemical warfare agents from the skin



Laboratory technicians in one of Emergent BioSolutions' 13 facilities.



Daniel J. Abdun-Nabi, Chief Executive Officer, Emergent BioSolutions Inc.

NCT Europe

A Vision of IB Consultancy

Simultaneous Training of 20 Teams on CBRNe Scenarios - Parallel Conference and Workshop Streams - Europe's Largest CBRNe Exhibition - Workshop on Novichoks and One Workshop with the Syrian Opposition.

The 7th edition of Europe's highly successful NCT event series, NCT Europe 2018, will take place from 3-5 July at the National Training Center (NTC) at the Bredero barrack in Vught, The Netherlands. The Dutch Ministry of Defense is a partner of the event and the most high-level CBRNe stakeholders from all over Europe will attend.

The three-day event will feature live CBRNe capability demonstrations on each day, one conference stream, multiple workshops, training sessions for civil and military responders, a large indoor and outdoor industry exhibition and the famous NCT BBQ Party.

Alongside the traditional NCT elements, NCT Europe will introduce a new feature at our NCT event series: NCT CBRNe multinational and multidisciplinary trainings.

As CBRNe events increasingly require an international response, the purpose of these trainings is to promote operational cooperation across Europe in CBRN and EOD/C-IED preparedness and response. Each team will be matched to a team from a different country. Join us now to experience the perfect balance between live exercises, demonstrations, interactive workshops and conferences. We look forward to welcoming the international CBRNe community to the Netherlands in 2018!

Upcoming events include

NCT Europe, 3-5 July 2018, NTC Vught, The Netherlands
www.nct-europe.com

NCT Asia, 16-18 October 2018, Hanoi, Vietnam
www.nct-asia.com

NCT South America, 5-7 February 2019, Rio de Janeiro, Brazil
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advanced development and manufacturing of medical countermeasures to support the US government's national security and public health emergency needs.

The facility, comprised of laboratory, manufacturing and office space offers flexible manufacturing of drug substance from microbial, cell culture or viral production platforms and is equipped with disposable manufacturing technology. The 112,000-ft (37,000-m) facility employs single-use manufacturing technology where applicable and has surge capacity readiness.

The CIADM facilitates advanced development of CBRN medical countermeasures and ensures domestic manufacturing surge capacity to address the US government's preparedness priorities and needs. The CIADM has been awarded four task orders by the US government to develop Ebola and Marburg therapeutics and a Zika vaccine.

One of the key goals for this facility is to establish the capability to produce 50 million doses of a pandemic influenza vaccine within four months following an outbreak.

CBNW: What is the core of the medical countermeasures for potential bioterror threats that you are developing?

DJA: We have a robust pipeline of products in development both for biological and chemical threats as well as EIDs, with a number of them potentially for dual-market use. This means products could be used by governments for stockpiling as well as in the traditional commercial settings of hospitals and specialty clinics.

We are currently developing a next-generation

A selection of Emergent BioSolutions' products.



anthrax vaccine with an enhanced product profile that includes requiring fewer doses and eliciting a faster immune response. We are also developing autoinjectors that can deliver nerve agent antidotes specified by our various government customers and an intranasal spray treatment for cyanide exposure potentially for first responders.

In our EID portfolio, we have a Zika vaccine in a phase 1 trial, a therapeutic for serious complicated influenza A disease in a phase 2 trial, and a Zika therapeutic that we expect will be in a phase 1 study this year.

An important component of our strategy is to grow through acquisition, so we are constantly evaluating what products for CBRN threats might be out there that could complement our portfolio.

CBNW: What percentage of your business is in the military sector?

DJA: A significant proportion of Emergent's business comes from contracts with the US government. In 2017, Emergent reported annual revenues of \$560.9 million, 78% of which is revenue from US government customers. We have 89% of our revenue coming from the US market, and 11% from international markets. We also look forward to

expanding our partner relationships with allied governments across the globe to fully address the growing CBRN and EID threats that are of importance to them.

CBNW: What are the advantages of your products and services over your competitors in the market?

DJA: Emergent is in a unique space with specialty products for specialty markets. We leverage our core competencies to meet our government customers' needs to protect their respective military and civilian populations. We have six only-in-class products that are the only products licensed by the FDA for their stated indications. These are our anthrax and smallpox vaccines, CWA decontaminant lotion, botulism anti-toxin, anthrax polyclonal immune globulin, and vaccinia immune globulin.

CBNW: Where do you see the greatest potential growth sector for your products?

DJA: Our biggest opportunity is to serve our US customers while simultaneously expanding further into international markets, with a focus on the preparedness needs of government ministries of health and defence. There is a heightened awareness of public health threats and there are concerted efforts to address them.

For example, the European Commission has a Joint Procurement Agreement that aims to secure equitable access to medical countermeasures and an improved security of supply, coupled with more balanced pricing for participating EU countries. Our role is to meet the needs of these customers and supply the vaccines, therapeutics, and devices that align with their preparedness plans. Preparedness against CBRN threats and emerging infectious diseases is an important component of global security and Emergent is proud to be in the forefront. ■

Emergent is developing next-generation anthrax and Zika vaccines.



WORLD CBRN &

MEDICAL CONGRESS

17 - 19 October 2018, Prague, Czech Republic

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Wide active involvement and participation of NATO, EU and national experts in the area of CBRN and MEDICAL field.

KEYNOTE SPEAKERS:

- **Mr. William Alberque** – Director, Arms Control, Disarmament & WMD Non Proliferation Centre, NATO
- **BG Zoltán Bubenik, MD** – Director, Military Medical Agency, CZE
- **COL Michael Cohen** – Medical Advisor/Command Surgeon, NATO Special Operations Headquarters, NATO
- **COL László Fazekas, MD** – Director, NATO MILMED COE, NATO
- **Mr. Olivier Luyckx** – Security and Nuclear Safety Unit of the European Commission, Directorate General for International Cooperation and Development (DG DEVCO), EU
- **Prof. Simo Nikkari** – Director of the Centre for Biothreat Preparedness, FIN
- **COL (GS) Vratislav Osvald** – Director, NATO JCBRN Defence Centre of Excellence, NATO
- and others

The Congress consists of:

- Congress Plenary / Discussion forum at strategic level
- CBRN Conference
- Medical Conference
- NATO MED CD&E (Concept Development & Experimentation) Workshop

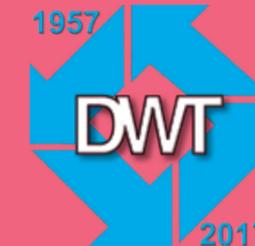


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