

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 28, 2024

EMERGENT BIOSOLUTIONS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33137
(Commission File Number)

14-1902018
(IRS Employer
Identification No.)

**300 Professional Drive,
Gaithersburg, Maryland 20879**

(Address of principal executive offices, including zip code)

(240) 631-3200
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	EBS	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On June 28, 2024, Emergent BioSolutions Inc. (the “Company,” including its wholly-owned subsidiaries, “Emergent”), through its wholly-owned subsidiary, Emergent Product Development Gaithersburg Inc., received a contract modification from the Office of the Assistant Secretary for Preparedness and Response (“ASPR”), an agency of the U.S. Department of Health and Human Services (“HHS”) (“Modification No. 12”), exercising Option 5 for Emergent to supply ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) into the U.S. Strategic National Stockpile (the “SNS”) under Emergent’s existing 10-year contract with ASPR (the “ACAM2000 Contract”). Modification No. 12 is valued at \$99.9 million.

Modification No. 12 was made under a unilateral modification of the ACAM2000 Contract awarded by ASPR on August 30, 2019 and reflects Modification No. 11 to the ACAM Contract (“Modification No. 11”) that, among other changes, reduced the minimum purchase dose quantity for Option Years 5-9 (if such Options are exercised), increased the quantity of diluent replacement and amended the option period in which diluent replacement is provided and increased the quantity of syringe replacement in Option Year 5. The period of performance under Modification No. 12 requires Emergent to deliver doses of ACAM2000 into the SNS by September 30, 2024.

The preceding description of Modification No. 12, a copy of which is filed herewith as Exhibit 10.1 and is incorporated herein by reference. A copy of Modification No. 11 was filed as Exhibit 10.1 to Emergent’s Current Report on Form 8-K filed on May 1, 2024. The ACAM2000 Contract was filed as Exhibit 10.48 to Emergent’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

Item 7.01. Regulation FD Disclosure.

On July 2, 2024, the Company issued a press release announcing the contract modifications as discussed herein. A copy of the press release is furnished as Exhibit 99.1 to this current Report on Form 8-K and is incorporated by reference herein.

The information contained in this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On July 2, 2024, the Company announced that Emergent received a contract modification (“Modification No. 17”) of the BARDA AV7909 Contract (as defined below) from ASPR to procure additional doses of CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted) (previously known as “AV7909”) valued at \$30.0 million. This modification relates to Emergent’s AV7909 development and procurement contract with the Biomedical Advanced Research and Development Authority, which became effective on September 30, 2016 (the “BARDA AV7909 Contract”) and has been modified from time to time.

The preceding description of Modification No. 17 does not purport to be complete and is qualified in its entirety by reference to the full text of Modification No. 17, which is filed herewith as Exhibit 10.2 and is incorporated herein by reference. The BARDA AV7909 Contract is filed as a material agreement of Emergent as Exhibit 10.54 with Emergent’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit No.	Description
10.1†	Modification No. 12, effective June 28, 2024, to the ACAM2000 Contract.
10.2†	Modification No. 17, effective June 26, 2024, to the BARDA AV7909 Contract.
99.1	Press release issued by Emergent BioSolutions Inc. on July 2, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

† Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EMERGENT BIOSOLUTIONS INC.

Dated: July 2, 2024 By: _____ /s/ RICHARD S. LINDAHL
Name: Richard S. Lindahl
Title: Executive Vice President, Chief Financial
Officer and Treasurer

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES 1 2	
2. AMENDMENT/MODIFICATION NO. P00012	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. ASP329425	5. PROJECT NO. (If applicable)	
6. ISSUED BY ASPR/SNS ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	CODE ASPR/SNS	7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341	CODE ASPR/SNS	
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. Attn: STEVE RAMBO EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR GAITHERSBURG MD 208793419		(x)	9A. AMENDMENT OF SOLICITATION NO.	
CODE 1365869		FACILITY CODE	9B. DATED (SEE ITEM 11)	
		x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00071	
			10B. DATED (SEE ITEM 13) 08/30/2019	
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers <input type="checkbox"/> is extended. <input type="checkbox"/> is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required) 2024.Q99SN24.26088		Net Increase:		\$99,957,720.00
13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.			
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).			
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:			
X	D. OTHER (Specify type of modification and authority) FAR 52.217-9 Option to Extend the Term of the Contract			
E. IMPORTANT: Contractor <input checked="" type="checkbox"/> is not <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)				
Tax ID Number: [**]				
UEI: CNPVCR8DK7M8				
Points of Contact:				
COR: Bruce Lee, bruce.lee@hhs.gov, [**]				
CO: Kimberly Golden, kimberly.golden1@hhs.gov, [**]				
CS: Terri Reed, terri.reed@hhs.gov, [**]				
EMERGENT: Eric Balsley, Director Product Management, balsleye@ebsi.com; Jessica Eyler, Sr. Contracts Director, eylerj@ebsi.com; [**]				
Continued ...				
Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)		
		KIMBERLY L. GOLDEN		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED	
(Signature of person authorized to sign)			6-28-2024	
		(Signature of Contracting Officer)		

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CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50119C00071/P00012

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NAME OF OFFEROR OR CONTRACTOR
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. 1365869

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>This modification exercises Option Year 5 for the supply of [**] doses of ACAM2000; replacement of [**] diluent doses; and replacement of [**] transfer syringes. The work performed hereunder includes Wetvax Testing and ACAM Testing, as provided for in the Statement of Work, as amended, at no additional cost to the Government.</p> <p>OTA: N Appr. Yr.: 2024 CAN: Q99SN24 Object Class: 26088 Period of Performance: 10/01/2023 to 09/30/2024</p> <p>Add Item 10 as follows:</p> <p>OPTION 5001 - Task 1 Warm based manufacturing delivery for ACAM2000 Vaccine</p> <p>[**] doses @ [**] per dose = \$[**] Obligated Amount: \$[**]</p> <p>Add Item 11 as follows:</p> <p>OPTION 5002 - Task 2 Replace expiring ACAM2000 Diluent [**] @ [**] = \$[**] Obligated Amount: \$[**]</p> <p>Add Item 12 as follows:</p> <p>OPTION 5003 - Task 3 Replace expiring transfer syringes [**] @ [**] = \$[**] Obligated Amount: \$[**]</p>				[**]
10					[**]
11					[**]
12					[**]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES 1 3	
2. AMENDMENT/MODIFICATION NO. P00017	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. ASP330757	5. PROJECT NO. (If applicable)	
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	CODE ASPR-BARDA	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201	CODE	ASPR-BARDA
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR # 100 GAITHERSBURG MD 208793419		(x)	9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
		x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600030C	
			10B. DATED (SEE ITEM 13) 09/30/2016	
CODE 1365869	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required) 2024.Q990100.26088		Net Increase:	\$30,000,000.00	
13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
<u>CHECK ONE</u>	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.			
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).			
x	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR Part 43.103(a) - Bilateral Modifications			
	D. OTHER (Specify type of modification and authority)			
E. IMPORTANT: Contractor <input type="checkbox"/> is not <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Tax ID Number: [**] UEI: CNPVCR8DK7M8 The purpose of this modification is to exercise CLIN 0011C and update ARTICLE B.3. OPTION PRICES. Funds Obligated Prior to this Modification: \$[**] Funds Obligated with Mod #17: \$[**] Total Funds Obligated to Date: \$[**] All other terms and conditions remain unchanged. OTA: N Continued ... Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print) Paul Williams SVP, Products Business		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Yifan Yang - Digitally signed by Yifan Yang -S		
15B. CONTRACTOR/OFFEROR <i>Paul Williams</i> <small>Electronically signed by: Paul Williams Reason: I approve this document Date: Jun 26, 2024 20:51 EDT (Signature of person authorized to sign)</small>	15C. DATE SIGNED 26 JUN 2024	16B. UNITED STATES OF AMERICA S <small>(Signature of Contracting Officer)</small>	16C. DATE SIGNED Date: 2024.06.26 22:15:38 -04'00'	

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CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
HHSO100201600030C/P00017

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NAME OF OFFEROR OR CONTRACTOR
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. 1365869

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
13	Appr. Yr.: 2024 CAN: Q990100 Object Class: 26088 Period of Performance: 09/30/2016 to 08/31/2025 Add Item 13 as follows: CLIN 0011C Additional Surge Capacity (Licensure)				[**]

The purpose of this modification is to modify ARTICLE B.3 OPTION PRICES,

ARTICLE B.3. OPTION PRICES – CLIN 0011 is modified to add CLIN 0011C as follows:

CLIN	Period of Performance	Supplies/ Services	Doses	Price per Dose	Total Not to Exceed Cost
0011C (Option Quantity)	6/27/2024-9/30/2024	Additional Surge Capacity (Licensure)	[**]	\$[**] (≤ [**] months from date of manufacture)	\$[**] (Funded)
			[**]	\$ [**] (≤ [**] months from date of manufacture)	

End of Modification #17

Emergent BioSolutions Awarded \$250+ Million in Contract Modifications to Supply U.S. Government with Four Critical Medical Countermeasure Products

GAITHERSBURG, Md., July 2, 2024 (GLOBE NEWSWIRE) – Emergent BioSolutions Inc. (NYSE: EBS) today announced it has received more than \$250 million in contract modifications from the Administration for Strategic Preparedness and Response (ASPR) at the United States Department of Health and Human Services (HHS), to deliver millions of doses of four medical countermeasures (MCMs). These contract modifications will help ensure continued supply/stockpiling of critical MCMs to address biological threats and emergencies against anthrax, smallpox and botulism.

The four awards include:

- A contract modification valued at \$30.0 million to supply CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted) this year. Previously known as AV7909, CYFENDUS® is a two-dose anthrax vaccine for post-exposure prophylaxis use in individuals 18 years of age and older. This new procurement funding is from Emergent's existing 10-year contract with the Biomedical Advanced Research and Development Authority (BARDA) under contract (HHSO100201600030C).
- A contract modification valued at \$99.9 million to supply ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) this year. ACAM2000® is licensed for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. This is under Emergent's existing 10-year contract with ASPR (75A50119C00071).
- Two new contract options totaling \$122.9 million have been awarded to supply the Strategic National Stockpile with VIGIV® [Vaccinia Immune Globulin Intravenous (Human)] drug product, and BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)] drug substance and delivery of drug production this year and into early 2025. VIGIV® is used for treatment of complications to smallpox vaccination, while BAT® is indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients. Both are under Emergent's existing 10-year contracts with ASPR (75A50119C00037 and 75A50119C00075, respectively).

"Securing multiple contract modifications with the U.S. government for our medical countermeasure products affirms that Emergent is a trusted biodefense partner, and also demonstrates the strength and sustainment of our product portfolio," said Paul Williams, senior vice president, products head at Emergent. "As part of our longstanding public-private partnership, we stand ready to continue fulfilling preparedness priorities and stockpiling efforts in the U.S. and abroad."

Emergent specializes in developing, manufacturing, and supplying MCMs for military and civilian populations. The types and quantities of products that should be maintained in a stockpile will depend on the population requiring protection, the products available for meeting the threat, as well as government resources and priorities.

About CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted)**Indication**

CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted) is a vaccine indicated for post-exposure prophylaxis of anthrax disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when given with recommended antibacterial drugs.

The efficacy of CYFENDUS® vaccine for post-exposure prophylaxis (PEP) is based solely on studies in animal models of inhalational anthrax.

Important Safety Information

Contraindication: Do not take CYFENDUS® vaccine if you are allergic to CYFENDUS® vaccine, BioThrax® (Anthrax Vaccine Adsorbed) or any ingredient of the vaccine.

Allergic reactions: Appropriate medical treatment and supervision must be available after receiving CYFENDUS® vaccine to manage possible serious allergic reactions. Get medical help right away if you have any symptoms of a serious allergic reaction.

Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to CYFENDUS® vaccine.

Pregnancy: CYFENDUS® vaccine can cause fetal harm when administered to a pregnant individual. Before getting CYFENDUS® vaccine, tell your healthcare provider if you may be pregnant, plan to get pregnant soon, or are nursing a baby.

Adverse reactions: The most common adverse reactions reported were tenderness, pain, warmth, itching, swelling, redness, bruising, arm motion limitations, muscle aches, tiredness, headache, and fever.

U.S. Prescribing Information

The full Prescribing Information for CYFENDUS® vaccine can be found [here](#).

About ACAM2000® (Smallpox (Vaccinia) Vaccine, Live)

ACAM2000® is the primary smallpox vaccine designated for use in a bioterrorism emergency, with doses having been supplied to the U.S. Strategic National Stockpile. ACAM2000® is also licensed in Australia and Singapore and is currently stockpiled both in the U.S. and internationally.

ACAM2000® is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.

The labeling for ACAM2000® contains a contraindication for individuals with severe immunodeficiency. Severe localized or systemic infection with vaccinia (progressive vaccinia) may occur in persons with weakened immune systems. Individuals with severe immunodeficiency who are not expected to benefit from the vaccine should not receive ACAM2000®. The risk for experiencing severe vaccination complications must be weighed against the risk for experiencing a potentially fatal smallpox infection.

Additionally, there are warnings and precautions for myocarditis, pericarditis, encephalitis, encephalomyelitis, encephalopathy, generalized vaccinia, severe vaccinia skin infections, erythema multiforme major (including Stevens-Johnson Syndrome), eczema vaccinatum resulting in permanent sequelae or death, ocular complications; blindness and fetal death have occurred following either primary vaccination or revaccination with live vaccinia virus smallpox vaccines. These risks are increased in certain individuals and may result in severe disability, permanent neurological sequelae and/or death.

Please see full [Prescribing Information](#) for full Boxed Warning and additional safety information.

About VIGIV® [Vaccinia Immune Globulin Intravenous (Human)]

(See full prescribing information for complete boxed warning)

WARNING: INTERACTIONS WITH GLUCOSE MONITORING SYSTEMS

Blood glucose measurement in patients receiving Vaccinia Immune Globulin Intravenous (Human) (VIGIV) must be done with a glucose-specific method (monitor and test strips) to avoid interference by maltose contained in VIGIV. Maltose in IGIV products may give falsely high blood glucose levels in certain types of blood glucose testing systems (for example those based on the GDH-PQQ or glucose-dye-oxidoreductase methods) resulting in inappropriate administration of

insulin and life-threatening hypoglycemia. Cases of true hypoglycemia may go untreated if the hypoglycemic state is masked by falsely elevated glucose readings.

Carefully review the product information of the blood glucose testing system, including that of the test strips, to determine if the system is appropriate for use with maltose-containing parenteral products.

VIGIV (vaccinia immune globulin intravenous, human) is an Immune Globulin (Human), 5% Liquid, indicated for the treatment and/or modification of the following conditions: eczema vaccinatum; progressive vaccinia; severe generalized vaccinia; vaccinia infections in individuals who have skin conditions such as burns, impetigo, varicella-zoster, or poison ivy; or in individuals who have eczematous skin lesions because of either the activity or extensiveness of such lesions; and aberrant infections induced by vaccinia virus that include its accidental implantation in eyes (except in cases of isolated keratitis), mouth, or other areas where vaccinia infection would constitute a special hazard. VIGIV is not considered to be effective in the treatment of postvaccinal encephalitis.

VIGIV is contraindicated in: isolated vaccinia keratitis; Individuals with a history of anaphylaxis or prior severe systemic reaction associated with the parenteral administration of this or other human immune globulin preparations; IgA-deficient patients with antibodies against IgA and a history of IgA hypersensitivity, as it contains trace amounts of IgA (40 mcg/mL).

Warnings and Precautions for VIGIV include:

- Hypersensitivity to human immune globulin (acute anaphylaxis)
- Acute renal dysfunction/failure. Use VIGIV with caution in patients with pre-existing renal insufficiency and in patients at increased risk of developing renal insufficiency.
- Thrombosis may occur with immune globulin products, including VIGIV. For patients at risk of thrombosis, administer VIGIV at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.
- Hemolysis or hemolytic anemia
- Aseptic meningitis syndrome (AMS)
- Noncardiogenic pulmonary edema [Transfusion-Related Acute Lung Injury (TRALI)]
- Transmission of infectious agents from human plasma
- Monitor renal function and urine output in patients at risk of renal failure; check baseline blood viscosity in patients at risk of hyperviscosity; and conduct confirmatory tests if hemolysis or TRALI is suspected.
- Blood glucose monitoring

There is no human or animal data for use of VIGIV during pregnancy. VIGIV should only be given to pregnant and nursing women if the potential benefits outweigh the potential risks. It is not known whether VIGIV is excreted in human milk. The safety and efficacy of VIGIV has not been established in pediatric and geriatric populations.

The most frequently reported adverse reactions to VIGIV treatment in clinical trials (>10%) include: headache, nausea, rigors, and dizziness.

Please see full [Prescribing Information](#) for VIGIV for additional safety information.

About BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)]

BAT® is a mixture of immune globulin fragments indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in

adults and pediatric patients. The effectiveness of BAT is based solely on efficacy studies conducted in animal models of botulism.

The Warnings and Precautions for BAT include:

- Severe hypersensitivity reactions, including anaphylaxis, as well as delayed allergic reactions, including serum sickness may occur following BAT administration. Prepare for monitoring and management of allergic reactions.
- Infusion reactions. These reactions may be related to the infusion rate of BAT.
- Interference with blood glucose testing. Because BAT contains maltose, interference with non-glucose specific blood sugar testing systems can occur. Use glucose-specific testing systems.
- Transmissible infections agents. BAT is made from equine plasma and may contain infectious agents, e.g. viruses.

There is no human or animal data for use of BAT during pregnancy. BAT should only be given to pregnant and nursing women if the potential benefits outweigh the potential risks. It is not known whether BAT is excreted in human milk. The safety and efficacy of BAT has not been established in pediatric and geriatric populations. Only limited safety data exists for pediatric populations.

The most common adverse reactions observed in ≥5% of healthy volunteers in clinical trials were headache, nausea, pruritus, and urticaria. The most common adverse reactions reported in ≥1% of patients in a clinical study were pyrexia, rash, chills, nausea, and edema. One serious adverse reaction of hemodynamic instability was observed in one patient in the clinical study.

Please see full [Prescribing Information](#) for BAT for additional safety information.

About Emergent BioSolutions

At Emergent, our mission is to protect and enhance life. For 25 years, we've been at work defending people from things we hope will never happen—so we are prepared just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our [website](#) and follow us on [LinkedIn](#), [X](#), [Instagram](#), [Apple Podcasts](#) and [Spotify](#).

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding the development, availability, and government procurement of ACAM2000® vaccine, CYFENDUS® vaccine, BAT® and VIGIV® are forward-looking statements. We generally identify forward-looking statements by using words like “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “should,” “will,” “would,” and similar expressions or variations thereof, or the negative thereof, but these terms are not the exclusive means of identifying such statements. Forward-looking statements are based on our current intentions, beliefs, and expectations regarding future events based on information that is currently available. We cannot guarantee that any forward-looking statement will be accurate. Readers should realize that if underlying assumptions prove inaccurate or if known or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Readers are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events, or circumstances. Readers should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

Investor Contact:
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