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): December 06, 2022

EMERGENT BIOSOLUTIONS INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-33137**	**14-1902018**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

400 Professional Drive, Suite 400,
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:

☐ 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, Par Value $0.001 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 7.01 Regulation FD Disclosure.

On December 06, 2022, Emergent BioSolutions Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration accepted for Priority Review its supplemental New Drug Application for NARCAN® (naloxone HCl) Nasal Spray, 4mg as an over-the-counter emergency treatment for known or suspected opioid overdose. A copy of the Company's press release is attached hereto as Exhibit 99.1.

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 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit No.	Description
99.1	Press release issued by Emergent BioSolutions Inc. on December 06, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: December 06, 2022

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

EMERGENT

Emergent BioSolutions Announces U.S. FDA Acceptance and Priority Review of Supplemental New Drug Application for Over-the-Counter NARCAN® (naloxone HCl) Nasal Spray

December 6, 2022

- Emergent's supplemental new drug application is the first prescription-to-over-the-counter switch application in history to be granted Priority Review by the FDA.
- NARCAN® (naloxone HCl) Nasal Spray 4 mg, the first intranasal form of naloxone approved by the FDA in 2015, is designed for community use for the treatment of known or suspected opioid overdose.

GAITHERSBURG, Md., Dec. 06, 2022 (GLOBE NEWSWIRE) -- Today, Emergent BioSolutions Inc. (NYSE:EBS) announced that the U.S. Food and Drug Administration (FDA) has accepted for review its supplemental New Drug Application (sNDA) for NARCAN® (naloxone HCl) Nasal Spray, as an over-the-counter (OTC) emergency treatment for known or suspected opioid overdose. The application has been granted Priority Review by the FDA and, if approved, would be the first 4 mg naloxone nasal spray available OTC in the U.S. The Prescription Drug User Fee Act goal date is March 29, 2023.

The opioid epidemic is an ongoing national public health issue and has been exacerbated by the escalating use of synthetic opioids, namely fentanyl. According to the Centers for Disease Control and Prevention, deaths related to synthetic opioids increased nearly 60 percent from 2019 to 2020,[1] and in 2021 alone, more than 71,000 people died from opioids containing fentanyl.[2]

"As a leader in the fight to help combat the opioid epidemic, Emergent is committed to increasing access and awareness of naloxone, and we are taking this step to help address the rising and devastating number of opioid overdoses and fatalities happening across the country," said Robert G. Kramer, president and CEO of Emergent BioSolutions. "We look forward to working with the FDA to advance our application under Priority Review designation and believe in the scientific evidence that supports the efficacy and safety of NARCAN Nasal Spray as an over-the-counter option for opioid overdose reversal."

Emergent's submission to the FDA includes Human Factors studies conducted, as well as more than five years of post-marketing data to demonstrate the safe and effective use of NARCAN. Since its approval in 2015, Emergent has distributed millions of prescription NARCAN devices across the U.S. to national, state, and local government health departments and first responders closest to at-risk populations, including public health clinics, fire departments, and police departments. Accidental overdoses can happen to anyone, anywhere, at any time, and by shifting to OTC status, increased access to NARCAN will help address patient needs as the opioid epidemic continues to evolve.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is NARCAN Nasal Spray?

- NARCAN Nasal Spray is a prescription medicine used for the emergency treatment of a known or suspected opioid overdose emergency with signs of breathing problems and severe sleepiness or not being able to respond.
- NARCAN Nasal Spray is to be given right away and does not take the place of emergency medical care. Get emergency medical help right away after giving the first dose of NARCAN Nasal Spray, even if the person wakes up.

NARCAN Nasal Spray is safe and effective in children for known or suspected opioid overdose.

Who should not use NARCAN Nasal Spray?

Do not use NARCAN Nasal Spray if you are allergic to naloxone hydrochloride or any of the ingredients in NARCAN Nasal Spray.

What is the most important information I should know about NARCAN Nasal Spray? NARCAN Nasal Spray is used to temporarily reverse the effects of opioid medicines. The medicine in NARCAN Nasal Spray has no effect in people who are not taking opioid medicines. Always carry NARCAN Nasal Spray with you in case of an opioid overdose.

1. Use NARCAN Nasal Spray right away if you or your caregiver think signs or symptoms of an opioid overdose are present, even if you are not sure, because an opioid overdose can cause severe injury or death. Signs and symptoms of an opioid overdose may include:
    - unusual sleepiness and you are not able to awaken the person with a loud voice or by rubbing firmly on the middle of their chest (sternum)
    - breathing problems including slow or shallow breathing in someone difficult to awaken or who looks like they are not breathing
    - the black circle in the center of the colored part of the eye (pupil) is very small, sometimes called "pinpoint pupils," in someone difficult to awaken
2. Family members, caregivers, or other people who may have to use NARCAN Nasal Spray in an opioid overdose should

know where NARCAN Nasal Spray is stored and how to give NARCAN Nasal Spray before an opioid overdose happens.

3. Get emergency medical help right away after giving the first dose of NARCAN Nasal Spray. Rescue breathing or CPR (cardiopulmonary resuscitation) may be given while waiting for emergency medical help.
4. The signs and symptoms of an opioid overdose can return after NARCAN Nasal Spray is given. If this happens, give another dose after 2 to 3 minutes using a new NARCAN Nasal Spray device and watch the person closely until emergency help is received.

What should I tell my healthcare provider before using NARCAN Nasal Spray?

Before using NARCAN Nasal Spray, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- are pregnant or plan to become pregnant. Use of NARCAN Nasal Spray may cause withdrawal symptoms in your unborn baby. Your unborn baby should be examined by a healthcare provider right away after you use NARCAN Nasal Spray.
- are breastfeeding or plan to breastfeed. It is not known if NARCAN Nasal Spray passes into your breast milk.

Tell your healthcare provider about the medicines you take, including prescription and over-the-counter medicines, drugs, vitamins, and herbal supplements.

What are the possible side effects of NARCAN Nasal Spray?

NARCAN Nasal Spray may cause serious side effects, including:

Sudden opioid withdrawal symptoms which can be severe. In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving NARCAN Nasal Spray and may include:

- body aches
- diarrhea
- increased heart rate
- fever
- runny nose
- sneezing
- goose bumps
- sweating
- yawning
- nausea or vomiting
- nervousness
- restlessness or irritability
- shivering or trembling
- stomach cramping
- weakness
- increased blood pressure

Some patients may show aggressive behavior upon abrupt reversal of an opioid overdose.

In infants under 4 weeks old who have been receiving opioids regularly, sudden opioid withdrawal may be life-threatening if not treated the right way. Signs and symptoms include: seizures, crying more than usual, and increased reflexes.

These are not all of the possible side effects of NARCAN Nasal Spray. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

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Please see full Prescribing Information.

For additional information on NARCAN® Nasal Spray, please visit www.NARCAN.com.

About Emergent BioSolutions

At Emergent, our mission is to protect and enhance life. For over 20 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, Twitter, and Instagram.

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 of Over-the-Counter NARCAN (naloxone HCl) Nasal Spray, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "estimate," "expect," "forecast," "intend," "may," "plan," "should," "will," 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. We cannot guarantee that any forward-looking statement will be accurate. Readers should realize that if underlying assumptions prove inaccurate 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.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by any forward-looking statements. Readers should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the Securities and Exchange Commission, when evaluating our forward-looking statements.

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[1] Centers for Disease Control and Prevention. (2022, February 23). Fentanyl facts. Centers for Disease Control and Prevention. Retrieved November 21, 2022, from https://www.cdc.gov/stopoverdose/fentanyl/index.html

[2] Centers for Disease Control and Prevention. (2022, May 11). U.S. overdose deaths in 2021 increased half as much as in 2020 - but are still up 15%. Centers for Disease Control and Prevention. Retrieved November 21, 2022, from https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm

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Source: Emergent BioSolutions