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

December 9, 2024 (December 9, 2024)
Date of Report (date of earliest event reported)

CUMBERLAND PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Tennessee	**001-33637**	**62-1765329**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

1600 West End Avenue, Suite 1300 Nashville, Tennessee 37203
(Address of Principal Executive Offices)
(615) 255-0068
Registrant's telephone number, including area code

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, no par value	CPIX	NASDAQ Global Select Market

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 8.01 Other Events

On December 9, 2024, Cumberland Pharmaceuticals Inc. (“Cumberland” or the “Company”) announced the U. S. Food and Drug Administration ("FDA") has approved a supplemental New Drug Application (sNDA) for its Acetadote® (N-acetylcysteine for injection) product. Acetadote is an intravenous (IV) formulation of N-acetylcysteine (NAC) indicated to prevent or lessen liver injury after ingestion of potentially toxic quantities of acetaminophen[1]. The newly approved dosing regimen simplifies the administration of Acetadote by combining the first two bags of the standard regimen into a single, slower infusion.

A copy of the release is furnished as Exhibit 99.1.

Exhibit No.	Description
99.1	Press release dated December 9, 2024

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.

Cumberland Pharmaceuticals Inc.

Dated: December 9, 2024

By: */s/ John Hamm*
John Hamm
Chief Financial Officer

FDA APPROVES ACETADOTE® sNDA

- New Dosing Regimen Simplifies Administration -

NASHVILLE, Tenn. (December 9, 2024) - Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), a specialty pharmaceutical company focused on delivering high-quality products to improve patient care, announced today the FDA has approved a supplemental New Drug Application (sNDA) for its Acetadote® (N-acetylcysteine for injection) product. Acetadote is an intravenous (IV) formulation of N-acetylcysteine (NAC) indicated to prevent or lessen liver injury after ingestion of potentially toxic quantities of acetaminophen[1].

Acetaminophen, a common over-the-counter pain reliever and fever reducer, is the leading cause of acute liver failure in the United States. Each year, thousands of individuals experience accidental or intentional acetaminophen poisoning, leading to serious liver damage.

The newly approved dosing regimen simplifies the administration of Acetadote by combining the first two bags of the standard regimen into a single, slower infusion. This streamlined approach has been implemented in hospitals across multiple countries and demonstrated to reduce the frequency of medication errors and potentially serious non-allergic anaphylactoid reactions (NAARs) without compromising the effectiveness of Acetadote[2-6]. By simplifying the dosing regimen, health care providers can administer the life-saving treatment more efficiently, potentially improving patient outcomes.

“This FDA approval is a significant step forward in the treatment of acetaminophen overdose,” said Rick Dart, MD, PhD, Director at the Rocky Mountain Poison and Drug Center. “By streamlining the administration of NAC, we can improve patient outcomes and reduce the risk of adverse events. This simplified dosing regimen is a valuable tool for health care providers in managing this potentially life-threatening condition.”

“We are thrilled to announce the FDA approval of this simplified dosing regimen for Acetadote,” said A.J. Kazimi, Cumberland's Chief Executive Officer. “This important milestone underscores our commitment to improving patient care and providing innovative solutions for urgent medical needs. By streamlining the administration process, we aim to enhance patient outcomes and reduce the burden on health care providers.”

Key Highlights:

- FDA-approved sNDA adds a simplified, IV NAC dosing regimen to the product prescribing information.
- New IV NAC dosing regimen is both safe and effective.
- New dosing regimen aims to minimize interruptions in care, medication errors and incidence of dose-related reactions.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is the largest biopharmaceutical company founded and headquartered in Tennessee and is focused on providing unique products that improve the quality of patient care. The company develops, acquires, and commercializes products for the hospital acute care, gastroenterology and oncology market segments.

The company's portfolio of FDA-approved brands includes:

- **Acetadote®** (*acetylcysteine*) injection, for the treatment of acetaminophen poisoning;
- **Caldolor®** (*ibuprofen*) injection, for the treatment of pain and fever;
- **Kristalose®** (*lactulose*) oral, a prescription laxative, for the treatment of constipation;
- **Sancuso®** (*granisetron*) transdermal, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment;
- **Vaprisol®** (*conivaptan*) injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia; and
- **Vibativ®** (*telavancin*) injection, for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, as well as complicated skin and skin structure infections.

The company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidate in patients with cardiomyopathy associated with Duchenne Muscular Dystrophy, Systemic Sclerosis and Idiopathic Pulmonary Fibrosis.

For more information on Cumberland's approved products, including full prescribing information, please visit the individual product websites, which can be found on the company's website www.cumberlandpharma.com.

References:

1. Acetadote [Package Insert]. Nashville, TN: Cumberland Pharmaceuticals, Inc.; 2024.
2. O'Callaghan C, Graudins A, Wong A. A two-bag acetylcysteine regimen is associated with shorter delays and interruptions in the treatment of paracetamol overdose. Clin Toxicol (Phila). 2022 Mar;60(3):319-323.
3. Sudanagunta S, Camarena-Michel A, Pennington S, et al. Comparison of Two-Bag Versus Three-Bag N-Acetylcysteine Regimens for Pediatric Acetaminophen Toxicity. Ann Pharmacother. 2023 Jan;57(1):36-43.
4. Syafira N, Graudins A, Yarema M, et al. Comparing development of liver injury using the two versus three bag acetylcysteine regimen despite early treatment in paracetamol overdose. Clin Toxicol (Phila). 2022 Apr;60(4):478-485.
5. Wong A, Isbister G, McNulty R, Isoardi K, Harris K, Chiew A, Greene S, Gunja N, Buckley N, Page C, Graudins A. Efficacy of a two bag acetylcysteine regimen to treat paracetamol overdose (2NAC study). EClinicalMedicine. 2020 Mar 19;20:100288
6. Cole JB, Oakland CL, Lee SC, et al. Is two better than three? A systematic review of two-bag intravenous NAC regimens for acetaminophen poisoning. West J Emerg Med. 2023 Sep;24(6)

Forward-Looking Statements

This press release contains forward-looking statements, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. Forward-looking statements include, among other things, statements regarding the company's intent, belief or expectations, and can be identified by the use of terminology such as "may," "will," "expect," "believe," "intend," "plan," "estimate," "should," "seek," "anticipate," "look forward" and other comparable terms or the negative thereof. As with any business, all phases of Cumberland's operations are subject to factors outside of its control, and any one or combination of these factors could materially affect Cumberland's operation results. These factors include macroeconomic conditions, including rising interest rates and inflation, competition, an inability of manufacturers to produce Cumberland's products on a timely basis, failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, natural disasters, public health epidemics, maintaining an effective sales and marketing infrastructure, and other events beyond the company's control as more fully discussed in its most recent annual report on Form 10-K as filed with the U.S. Securities and Exchange Commission ("SEC"), as well as the company's other filings with the SEC from time to time. There can be no assurance that results anticipated by the company will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

SOURCE: Cumberland Pharmaceuticals Inc.

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