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

March 19, 2025 (March 19, 2025)
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 March 19, 2025, Cumberland Pharmaceuticals Inc. ("Cumberland") announced that results from its Phase 2 FIGHT DMD clinical trial were selected for a late-breaking presentation at the Muscular Dystrophy Association (MDA) Clinical & Scientific Conference in Dallas. The trial demonstrated significant cardiac benefits for patients with Duchenne muscular dystrophy (DMD), potentially addressing the leading cause of death in this devastating disease.

A copy of the release is furnished as Exhibit 99.1.

Exhibit No.	Description
99.1	Press release dated March 19, 2025

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: March 19, 2025

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

FIGHT DMD Trial Results
Selected for Late-Breaking Presentation
at MDA Clinical & Scientific Conference

Ifetroban demonstrated significant 5.4% improvement in cardiac function

NASHVILLE, Tenn. (March 19, 2025) – Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), a specialty pharmaceutical company with development efforts focused on rare diseases, today announced that results from its Phase 2 FIGHT DMD clinical trial were selected for a late-breaking presentation at the Muscular Dystrophy Association (MDA) Clinical & Scientific Conference in Dallas. The trial demonstrated significant cardiac benefits for patients with Duchenne muscular dystrophy (DMD), potentially addressing the leading cause of death in this devastating disease.

The presentation, delivered today by Dr. John Jerry Parent, highlighted the breakthrough findings from Cumberland's study of ifetroban in DMD heart disease. For the abstract presented at the meeting, please see the MDA website.

The Phase 2 FIGHT DMD trial demonstrated that high-dose ifetroban treatment resulted in a 3.3% improvement in left ventricular ejection fraction (LVEF) compared to placebo. When compared with propensity-matched natural history controls, the difference was even more pronounced, with high-dose treatment providing a significant 5.4% overall improvement in LVEF, as control patients experienced a 3.6% decline in LVEF. This improvement in cardiac function could translate to meaningful benefits in quality of life and survival for DMD patients. The complete presentation slides are now available on Cumberland's website.

"The enthusiastic response from MDA conference attendees reinforces the importance of our work in targeting DMD-related heart disease," said John Jerry Parent, MD, Associate Professor of Clinical Pediatrics and Medical Director of the Pediatric Heart Transplant at Indiana University School of Medicine and Site Investigator at Riley Children's Hospital for the FIGHT DMD trial. "These findings represent a potential paradigm shift in how we approach cardiac complications in DMD patients."

"We are honored that the MDA recognized the significance of our FIGHT DMD trial by selecting it for a late-breaking presentation," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "This platform allowed us to share our promising results with the global DMD community, including leading researchers, clinicians and patient advocates who are working tirelessly to improve outcomes for those affected by this devastating disease."

"These results offer hope to thousands of families affected by DMD," said Sharon Hesterlee, PhD, Chief Research Officer, MDA. "While current therapies focus on preserving muscle function, addressing the cardiac complications of DMD remains an urgent unmet need. Cumberland's work with ifetroban represents a critical step forward in potentially extending and improving the lives of DMD patients."

Ifetroban, an oral thromboxane receptor antagonist, has received both *Orphan Drug Designation* and *Rare Pediatric Disease Designation* from the FDA for DMD-related heart disease.

Cumberland has secured a growing portfolio of patents with claims associated with the product for this DMD indication. Next steps include further data analysis and completion of a full study report in preparation for an end-of-Phase-2 meeting with the FDA to determine next steps associated with the product's development and commercialization.

For more information about the FIGHT DMD trial, please visit www.fightdmdtrial.com.

About Duchenne muscular dystrophy (DMD)

DMD is a rare and incurable pediatric disease caused by mutations in the gene encoding dystrophin, a protein critical for muscle function, including the heart. Patients with DMD slowly lose muscle function, resulting in the inability to walk, difficulty breathing and heart failure. While current treatments can help manage some DMD symptoms, there are no approved therapies specifically targeting DMD-related heart disease, highlighting a critical unmet medical need.

About ifetroban

Ifetroban is a once-daily oral medication that works by blocking the thromboxane receptor, which plays a key role in inflammation and fibrosis. The drug has received both *Orphan Drug Designation* and *Rare Pediatric Disease Designation* from the FDA, highlighting its potential significance in treating this devastating condition. If approved, ifetroban would be the first therapy specifically indicated for DMD-related heart disease.

A previous study conducted at Vanderbilt University Medical Center demonstrated that ifetroban is protective against cardiomyopathy in several preclinical models of muscular dystrophy. The results of that study were published in the *Journal of the American Heart Association* (West 2019). Based on those promising results, Cumberland Pharmaceuticals became the first recipient of an FDA Office of Orphan Products Development clinical trial grant for DMD, funding the development of this Phase 2 clinical trial.

References:

Soslow JH, Xu M, Slaughter JC, et al. Cardiovascular Measures of All-Cause Mortality in Duchenne Muscular Dystrophy. Circ Heart Fail. 2023 Aug;16(8):e010040. doi: 10.1161/CIRCHEARTFAILURE.122.010040. Epub 2023 Jun 8. PMID: 37288563; PMCID: PMC10524475.

West JD, Galindo CL, Kim K, et al. Antagonism of the thromboxane-prostanoid receptor as a potential therapy for cardiomyopathy of muscular dystrophy. J Am Heart Assoc. 2019;8(21):e011902. doi: 10.1161/JAHA.118.011902.

About Cumberland Pharmaceuticals

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

Cumberland'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.

In addition to this Duchenne muscular dystrophy program, the company also has Phase 2 clinical studies underway evaluating its ifetroban product candidate in patients with 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.

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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