

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

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 October 26, 2026, Cumberland Pharmaceuticals Inc. (the “Company” or “Cumberland”), an innovation-focused biopharmaceutical company developing new products for rare diseases, issued a press release providing an update on its ifetroban product candidate, which is in development as a potential treatment for the cardiomyopathy associated with Duchenne muscular dystrophy (“DMD”). A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933 (the “Securities Act”), as amended, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On October 26, 2026, the Company provided an update on its ifetroban product candidate in development as a potential treatment for the cardiomyopathy associated with DMD.

The Company announced plans to submit a New Drug Application (“NDA”) to the U.S. Food and Drug Administration (the “FDA”) for ifetroban as a treatment for the cardiomyopathy associated with DMD. The decision to file the NDA for a Traditional Approval follows a pre-NDA meeting held this fall with the FDA. The planned submission will include data from the Company’s FIGHT DMD™ clinical study and its ongoing open-label extension, data from two natural history databases of DMD patients, preclinical data published in the Journal of the American Heart Association, manufacturing information and a safety database that includes more than 1,400 subjects across approximately 30 clinical studies of ifetroban.

The 12-month Phase 2 FIGHT DMD™ trial ([NCT03340675](#)) demonstrated that high-dose ifetroban treatment resulted in a statistically significant 5.4% absolute improvement in left ventricular ejection fraction (LVEF) ($p=0.002$) compared to a control group composed of placebo-treated patients combined with propensity score-matched natural history patients. The study findings also included reductions in cardiac damage markers (NT-proBNP and cardiac troponin I) in the high-dose group. All patients who completed the 12-month study opted to continue in the open-label extension. Long-term cardiac MRI data from Months 24 and 36 of the open-label extension are being analyzed and will be included in the NDA.

The Company’s decision to submit the NDA followed an End-of-Phase 2 meeting with the FDA in September 2025 and a follow-up Type C meeting in January 2026. The FDA suggested a Phase 3, randomized, placebo-controlled trial and raised several questions regarding the Phase 2 study results including the suitability of the LVEF endpoint, comparator related issues and the development of the statistical analysis plan. In response, Cumberland provided additional data supporting its efficacy findings, natural history data from a second DMD registry, and documentation of how the statistical analysis plan was developed.

The Company then requested a pre-NDA meeting with the FDA, which was held this fall. During the pre-NDA meeting, the format and content of the planned submission were discussed including the needed reports and requested analysis. Cumberland is proposing the FIGHT DMD™ trial as the pivotal study to be combined with comparison data from two natural history databases to support product approval. FDA expressed concerns about whether the proposed data package would be sufficient to address the requirement for substantial evidence of efficacy needed for approval and requested additional analysis and other supporting information. Following the meeting the FDA granted the Company's request for rolling review of the NDA, which allows completed sections of the application to be provided to the FDA for review, before the full application is submitted.

Cumberland’s Board of Directors recently approved proceeding with the NDA submission given the urgency of addressing the unmet medical need in this patient population. There can be no assurance that the FDA will accept the NDA for filing or approve ifetroban on the basis of the data submitted, even with the inclusion of the additional analysis and information that FDA requested in the pre-NDA meeting.

Ifetroban is a once-daily oral medication that works by blocking the thromboxane-prostanoid receptor, which plays a key role in inflammation and fibrosis. The drug has received Orphan Drug Designation, Rare Pediatric Disease Designation and Fast Track Designation from the FDA for the indication of cardiomyopathy associated with DMD.

Long-term safety data from the ongoing open-label extension support the tolerability of ifetroban in DMD. Through up to 36 months of treatment across the Phase 2 trial and the open-label extension, ifetroban was generally well tolerated in DMD patients with no treatment-related serious adverse events and no new safety concerns identified. Exploratory analyses of novel blood biomarkers identified a 30% reduction in MYL3 and a 50% reduction in MYOD1 (circulating markers of heart muscle and cell damage), alongside a 2.4-fold increase in FGF16 and a 2.1-fold increase in TSPAN7 (proteins associated with cardioprotection and tissue repair) with 12 months of high-dose ifetroban treatment compared with the combined placebo and natural history control group. These exploratory findings are consistent with the proposed mechanism of action of ifetroban in DMD cardiomyopathy.

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. Cardiac complications are universal in this patient population and represent the leading cause of death. 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.

Cumberland has secured a growing portfolio of patents protecting ifetroban for this DMD heart disease indication. The FDA has also conditionally accepted DYSORBAN[®] as the proprietary name for the product.

More information regarding the FIGHT DMD[™] trial is available at www.fightdmdtrial.com

Cumberland Pharmaceuticals Inc. is an innovation-focused biopharmaceutical company developing new therapies to address significant unmet medical needs and improve the patient outcomes. The Company is advancing a clinical pipeline of late-stage product candidates across multiple therapeutic areas with significant unmet medical needs.

Cumberland has completed a Phase 2 study of ifetroban in patients with systemic sclerosis and is conducting a Phase 2 study in idiopathic pulmonary fibrosis. In addition, researchers at Vanderbilt Health completed a Phase 2a clinical trial of ifetroban to prevent metastasis in high-risk solid tumors. The study's primary safety endpoint was achieved, along with favorable trends in decreased metastasis recurrence and metastasis-free survival.

For more information, please see www.cumberlandpharma.com.

This Current Report on Form 8-K and the press release filed as Exhibit 99.1 contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words such as "may," "will," "expect," "plan," "anticipate," "intend," "believe," "estimate," "potential," "continue," "could," "should," "would" and similar expressions, although not all forward-looking statements contain these words. These statements include, among others, statements regarding the timing, content and completion of the NDA submission, including the rolling review; Cumberland's plan to seek approval based on the FIGHT DMD[™] trial and natural history data without conducting a Phase 3 trial; the results of the ongoing open-label extension and the 24- and 36-month MRI analyses; regulatory review, approval and labeling; the potential benefits of Orphan Drug, Rare Pediatric Disease, including eligibility for a priority review voucher, and Fast Track designations, which may not be realized; the proprietary name; patent protection and exclusivity; manufacturing; commercialization and market acceptance; the need for additional capital; competition; reliance on third parties; and other ifetroban programs. These statements are based on current assumptions and plans of Cumberland's management and are subject to risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from those expressed or implied by the forward-looking statements. Important factors that could cause such differences include, among others, the risk that the FDA will refuse to file the NDA or will not approve ifetroban, including because of concerns about the LVEF endpoint, the natural-history comparator or the statistical analysis plan; the risk that the FDA will not agree with Cumberland's interpretation of the minutes or outcomes of its meetings with the FDA; the risk that the FDA will require a Phase 3 trial or other additional studies or data, which could significantly delay or prevent approval and require substantial additional capital; the risk that data from the open-label extension, including the 24- and 36-month MRI analyses, will not be favorable; Cumberland's ability to meet the FDA's other approval requirements, including chemistry, manufacturing and controls requirements; the risk that rolling review will not shorten the review timeline; restrictions that may be placed on the label, if approved; changes in FDA requirements, policies or regulatory pathways; and the risks described under the heading "Risk Factors" in Cumberland's most recent Form 10-K and subsequent Form 10-Q filings, as well as other reports filed with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this Current Report on Form 8-K or, with respect to statements in the press release, the date of the press release. Cumberland undertakes no obligation to update any forward-looking statement except as required by law.

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: October 26, 2026

By:

/s/ John Hamm

John Hamm

Chief Financial Officer