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

November 30, 2021 (November 29, 2021)
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.)

2525 West End Avenue, Suite 950 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 November 29, 2021, Cumberland announced the U.S. Food and Drug Administration (FDA) has approved expanded labeling for Caldolor®, an intravenously delivered formulation of ibuprofen to now include use in pre-operative administration. The non-narcotic pain reliever may now be administered just prior to surgery to enable patients to wake up from their procedure in significantly less pain.

The newly FDA-approved label includes information regarding the product's indications and usage, appropriate patient populations, clinical study results, potential side effects, patient safety details, and instructions for use in pregnant women, children and other populations.

A copy of the release is furnished as Exhibit 99.1.

Exhibit No.	Description
99.1	Press release dated November 29, 2021

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: November 30, 2021

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

CALDOLOR® NOW FDA APPROVED
FOR PRE-OPERATIVE ADMINISTRATION

Dosed prior to surgery, Caldolor® demonstrated significant reduction in pain intensity

NASHVILLE, Tennessee (Monday, November 29, 2021) – Cumberland Pharmaceuticals Inc. **(NASDAQ: CPIX),** a specialty pharmaceutical company today announced the U.S. Food and Drug Administration (FDA) has approved expanded labeling for Caldolor®, an intravenously delivered formulation of ibuprofen to now include use in pre-operative administration. The non-narcotic pain reliever may now be administered just prior to surgery to enable patients to wake up from their procedure in significantly less pain.

The newly FDA-approved label includes information regarding the product's indications and usage, appropriate patient populations, clinical study results, potential side effects, patient safety details, and instructions for use in pregnant women, children and other populations.

Supporting this expanded use of Caldolor, a study of orthopedic surgical pain confirmed the significant pain reduction when the product was administered every six hours (started pre-operatively) with supplemental morphine available on an as needed basis. A total of 185 patients were randomized and treated with either Caldolor® 800 mg or placebo administered every six hours (started pre-operatively) and morphine provided on an as needed basis. Efficacy was demonstrated as a statistically significant greater reduction in pain intensity over 24 hours post-operatively for patients treated with Caldolor® as compared to those receiving placebo.

Dr. Stephen Southworth, an orthopedic surgeon at the Orthopedic Institute of North Mississippi concluded that "Caldolor® administered pre-operatively should be considered in *Enhanced Recovery After Surgery* (ERAS) protocols for the management of postoperative pain including that of traumatic origin. When administered immediately prior to surgery, patients given Caldolor experience less postoperative pain and a decrease in their opioid use."

"Before the pandemic began, healthcare systems across the country were in the midst of a public health mission to control surgical pain while decreasing opioid consumption," said A.J. Kazimi, chief executive officer of Cumberland Pharmaceuticals Inc. "We are proud to see the continued support for Caldolor's use in surgical care, with the product's approved labeling now including the expanded use of the product prior to surgery. We feel confident that this important development provides additional insights into how intravenous ibuprofen can help healthcare professionals and patients as elective surgeries resume."

About Caldolor®

Caldolor is indicated in adults and pediatric patients for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as for the reduction of fever. It was the first FDA-approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with a history of asthma or other allergic-type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during product treatment.

For full prescribing information, including boxed warning, visit www.caldolor.com.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality prescription brands to improve patient care. The Company develops, acquires, and commercializes brands for the hospital acute care, gastroenterology and rheumatology 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;
- **Vaprisol®** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **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;
- **Kristalose®** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **RediTrex®** *(methotrexate)* Injection, for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis; and
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease.

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

The Company also has a series of Phase II clinical programs underway evaluating its ifetroban product candidates in patients with cardiomyopathy associated with Duchenne Muscular Dystrophy ("DMD"), Systemic Sclerosis ("SSc"), and Aspirin-Exacerbated Respiratory Disease ("AERD").