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): January 10, 2020 (January 7, 2020)

CUMBERLAND PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

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

2525 West End Avenue, Suite 950, Nashville, Tennessee 37203
(Address of principal executive offices) (Zip Code)

(615) 255-0068
(Registrant's telephone number, including area code)

Not Applicable
(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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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:

Class	Trading Symbol	Name of exchanged 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 o

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. o

Item 8.01 Other Events

On January 7, 2020, Cumberland announced the launch of Caldolor® (*ibuprofen*) Injection in a ***ready-to-use bag*** that may be administered without dilution for pain relief. This launch follows FDA approval in 2019 of the product's new delivery method.

A non-steroidal anti-inflammatory drug (NSAID), Caldolor may be used as the sole method of treatment for mild-moderate pain or as part of a multi-modal treatment for severe pain. Thus it is positioned to play an important role in combatting the nation's opioid crisis, which claims the lives of over 130 Americans a day, according to *The Centers for Disease Control and Prevention*.

The new formulation of Caldolor comes in a pre-mixed bag containing 800 mg of ibuprofen in a 200 mL patented low sodium formulation for injection that is ready to use. It is the first and only FDA-approved pre-mixed bag of ibuprofen. Caldolor is still available as an 800 mg/8mL single-dose vial (100mg/mL) for dilution in addition to the ready-to-use bag (4 mg/mL). The new, premixed presentation provides healthcare professionals a formulation that is easy to administer, helping manage the treatment of patient pain and fever, while reducing opioid consumption.

A copy of the press release is furnished as Exhibit 99.1.

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: January 10, 2020

By: */s/ Michael Bonner*
Michael Bonner
Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press release dated January 7, 2020

CUMBERLAND PHARMACEUTICALS ANNOUNCES

THE NATIONAL LAUNCH OF A NEW CALDOLOR

READY-TO-USE PRODUCT

Caldolor® now available in a pre-mixed, ready-to-use bag.

Product designed to help address national opioid crisis.

NASHVILLE, Tenn. (Tuesday, January 7, 2020) – Cumberland Pharmaceuticals Inc. **(NASDAQ: CPIX),** a specialty pharmaceutical company with a focus on hospital acute care, today announced the launch of Caldolor® (*ibuprofen*) Injection in a ***ready-to-use bag*** that may be administered without dilution for pain relief. This launch follows FDA approval in 2019 of the product's new delivery method.

A non-steroidal anti-inflammatory drug (NSAID), Caldolor may be used as the sole method of treatment for mild-moderate pain or as part of a multi-modal treatment for severe pain. Thus it is positioned to play an important role in combatting the nation's opioid crisis, which claims the lives of over 130 Americans a day, according to *The Centers for Disease Control and Prevention*.

Even short-term opioid use after surgery can lead to long-term addiction. Prompt and appropriate pain management is vital to mitigating opioid use. Published data for Caldolor supports administration just prior to surgery and throughout the postoperative period. As a result patients experience significantly less pain upon awakening, then remain in significantly less pain, while also reducing their opioid consumption.

"We have been encouraged by the significant number of physicians who have incorporated Caldolor into their pain management regimens as a way to combat the negative effects of opioid use," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "The new ready-to-use presentation of Caldolor offers hospitals and other medical facilities a proven product that is now easier to administer and, thus, has the potential to further reduce opioid use."

Caldolor possesses three key therapeutic properties: anti-inflammatory, analgesic and antipyretic action. Uncontrolled inflammation may contribute to hypersensitivity to pain and lead to chronic post-operative pain. Pre-empting this response with Caldolor may reduce the need for continued post-operative opioids and improve recovery through reduction in opioid-related side effects, such as nausea, vomiting and constipation.

The new formulation of Caldolor comes in a pre-mixed bag containing 800 mg of ibuprofen in a 200 mL patented low sodium formulation for injection that is ready to use. It is the first and only FDA-approved pre-mixed bag of ibuprofen. Caldolor is still available as an 800 mg/8mL single–dose vial (100mg/mL) for dilution in addition to the ready-to-use bag (4 mg/mL). The new, premixed presentation provides healthcare professionals a formulation that is easy to administer, helping manage the treatment of patient pain and fever, while reducing opioid consumption.

Prudent and careful management of pain is among the most important responsibilities of every healthcare provider. New strategies are emerging to control acute and chronic pain in the hospital setting, and Cumberland has provided grants in support of educational webinars in partnership with two of the nation's leading physician services companies. Through these initiatives, three webinars have been developed that introduce healthcare providers to new therapies and pain modalities for more effective pain

management. These accredited webinars recognize that many patients are first introduced to opioids in a hospital or surgery center setting and, in some cases, may become dependent upon or even abuse their opioid treatments. This cycle can be avoided through the introduction of non-opioid medications like Caldolor which can serve as the basis for multimodal strategies to improve pain management.

There is a growing body of published evidence showing that Caldolor can significantly decrease both surgical pain and opioid use. One clinical study, conducted at The Ohio State Wexner Medical Center, assessed the efficacy of Caldolor compared to ketorolac for the treatment of postoperative pain in patients undergoing arthroscopic knee surgery, and it revealed more effective pain control and opioid-sparing activity with Caldolor when compared to ketorolac. The results of this study demonstrated that the use of IV ibuprofen, compared to IV ketorolac, significantly lowered postoperative pain scores and opioid consumption in patients undergoing arthroscopic knee surgeries.

Another study, conducted at Tufts University School of Dental Medicine in Boston, compared the preemptive analgesic effects of Caldolor to IV acetaminophen in controlling post-surgical pain and reliance on opioids for rescue pain control. The study investigators concluded that preemptive anesthesia with Caldolor IV ibuprofen is superior when compared to IV acetaminophen in reducing post-surgical pain and opioid use.

Cumberland has recently completed a clinical study for the use of Caldolor in patients from birth to 6 months of age. This comes after the Company conducted clinical trials and received FDA approval which extended the approved adult use to use in children aged 6 months to 17 years old. Topline results from the newborn study are forthcoming and will add to the growing body of literature that supports the safety and efficacy of the product.

About Caldolor

Caldolor can be a key component in cost effective Enhanced Recovery After Surgery (ERAS) multimodal treatment protocols. Clinical studies of Caldolor demonstrate:

- Up to a 58% reduction in opioid use compared to placebo group[1]
- Up to a 43% reduction in VAS scores at rest compared to opioids alone[2]
- Patients reporting significantly less pain shortly after waking[3]
- Patients remain in significantly less pain during recovery[3]
- Potential to improve quality of recovery and reduce postsurgical fatigue[4]
- Significant pain and fever reduction in children ages six months and older[5]

Caldolor is indicated in adults and pediatric patients six months and older for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It should be noted that 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 treatment with Caldolor. For full prescribing information, including boxed warning, visit www.caldolor.com.

References:

1.) Shephard DM, Jahnke H, White WL, et al. Randomized, double-blinded, placebo-controlled trial comparing two multimodal opioid-minimizing pain management regimens following transsphenoidal surgery. *J Neurosurg* 2018; 128(2): 444-451.
2.) Moss. JR, Watcha MF, Bendel LP, et al. A multicentre, randomized, double-blind placebo-controlled, single dose trial of the safety and efficacy of intravenous ibuprofen for treatment of pain in pediatric patients undergoing tonsillectomy. *Pediatric Anesthesia* 2014; 24(5): 483-498.
3.) Singla N, Rock A, and Pavliv L. A multi-center, randomized, double-blind placebo-controlled trial of intravenous-ibuprofen (IV-ibuprofen) for treatment of pain in post-operative orthopaedic adult patients. *Pain Med* 2010; 11(8): 1284-1293.
4.) Le V, Kurnutala L, Schianodicola J, et al. Premedication with intravenous ibuprofen improves recovery characteristics and stress response in adults undergoing laparoscopic cholecystectomy: a randomized controlled trial. *Pain Med* 2016; 17(6): 1163-1173.
5.) CALDOLOR [Package Insert] Nashville, TN: Cumberland Pharmaceuticals Inc. 2019.

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 and gastroenterology market segments. These medical specialties are categorized by moderately concentrated prescriber bases that we believe can be penetrated effectively by targeted sales forces. 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*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox®-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of Helicobacter pylori (*H. pylori*) infection and related duodenal ulcer disease;
- **RediTrex™** (*methotrexate*) Injection, for the treatment of adult and pediatric patients with rheumatoid arthritis and adults with psoriasis;
- **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.

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 has 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"), Hepatorenal Syndrome ("HRS") and Portal Hypertension ("PH").

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 our intent, belief or expectations. 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 results of operations. These factors include market conditions, competition, an inability of manufacturers to produce Cumberland's products on a timely basis or failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers, maintaining an effective sales and marketing infrastructure and other factors discussed in the Company's most recent Form 10-K and subsequent 10-Q's as filed with the SEC. 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.

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SOURCE: Cumberland Pharmaceuticals Inc.