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

October 21, 2025 (October 21, 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 October 20, 2025, Cumberland Pharmaceuticals Inc. ("Cumberland") announced strategic arrangements with RedHill Biopharma Ltd. (Nasdaq: RDHL), a specialty biopharmaceutical company, to jointly commercialize Talicia®. The FDA-approved oral capsule is indicated for the treatment of Helicobacter pylori infection in adults, a bacterial infection and leading risk factor for gastric cancer.

A copy of the release is furnished as Exhibit 99.1.

Exhibit No.	Description
99.1	Press release dated October 21, 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: October 21, 2025

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

CUMBERLAND PHARMACEUTICALS ANNOUNCES THE ADDITION OF AN ESTABLISHED FDA APPROVED PRODUCT TO ITS COMMERCIAL PORTFOLIO

Cumberland to expand its gastroenterology offerings

with the market-leading Helicobacter pylori therapy

NASHVILLE, Tenn., (Oct. 20, 2025) – Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), a specialty pharmaceutical company focused on delivering high-quality products to improve patient care, announced strategic arrangements with **RedHill Biopharma Ltd.** (Nasdaq: RDHL), a specialty biopharmaceutical company, to jointly commercialize **Talicia®.** The FDA-approved oral capsule is indicated for the treatment of *Helicobacter pylori* infection in adults, a bacterial infection and leading risk factor for gastric cancer.

Under the terms of the agreement, Cumberland and RedHill will form a new, jointly owned company. RedHill will contribute all its Talicia assets to the new company, including the product's growing international licenses with associated revenues. Cumberland will provide $4 million in investment capital. Cumberland will assume responsibility for the product's distribution and record the product sales. Talicia net revenues were $8 million in 2024. The two companies will equally share in those net revenues and collaborate on all operational aspects, including sales, marketing, manufacturing, regulatory and supply chain functions. Through this co-commercialization agreement, Cumberland will leverage its established national field sales force to lead promotional efforts for Talicia and expand its reach among office-based healthcare providers.

"Talicia features an outstanding clinical profile and represents an excellent strategic match for our organization," said A.J. Kazimi, CEO of Cumberland Pharmaceuticals. "It provides us with an immediate growth opportunity, as we will build on the excellent foundation RedHill has created and bring this critical therapy to many more patients."

Talicia is the only all-in-one treatment containing omeprazole, amoxicillin and rifabutin. It was FDA approved based on two large Phase 3 studies demonstrating excellent safety and efficacy results. The product features include three key advantages: 1) high eradication rates at >90%, 2) simplicity of an all-in-one capsule and 3) low resistance.

As a result of these attributes, Talicia is now listed as a first line option in the newly updated *American College of Gastroenterology* guidelines for the treatment of *H. pylori* infections.

"These arrangements represent an excellent opportunity for Cumberland, a highly capable and driven partner with a strong gastroenterology market presence, to add a market-leading approved product to its portfolio," said Rick Scruggs, Chief Commercial Officer of RedHill Inc. We believe Cumberland can help drive prescriptions and deliver revenue growth, further strengthening Talicia's U.S. market leadership."

The product is patent protected through 2042 and received eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation.

There is broad U.S. insurance coverage established for the product with includes 70% of American lives covered by commercial plans and 60% coverage by government plans.

Talicia is dispensed by retail pharmacies across the country. An agreement with CVS provides for stocking of the product at 1,700 of their pharmacies.

For full prescribing information, visit https://www.talicia.com/.

About Talicia®

Approved by the FDA for the treatment of *H. pylori* infection in adults in November 2019, Talicia is a novel, fixed-dose, all-in-one oral capsule combination of two antibiotics (amoxicillin and rifabutin) and a proton pump inhibitor (omeprazole). Talicia received eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation and is also covered by U.S. patents extending patent protection through 2042 with additional patents and applications pending and granted in various territories worldwide.

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on U.S. development and commercialization of drugs for gastrointestinal diseases, infectious diseases and oncology. RedHill promotes the FDA approved gastrointestinal drug **Talicia®,** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[i]. RedHill's key clinical late-stage development programs include: (i) **opaganib (ABC294640)**, a first-in-class, orally administered sphingosine kinase-2 (SPHK2) selective inhibitor with anti-inflammatory, antiviral, and anticancer activity, targeting multiple indications with U.S. government and academic collaborations for development for radiation and chemical exposure indications such as GI-Acute Radiation Syndrome (GI-ARS), a Phase 2/3 program for hospitalized COVID-19, and a Phase 2 study in prostate cancer in combination with darolutamide; (ii) **RHB-204**, a next-generation optimized formulation of RHB-104, with a planned Phase 2 study for Crohn's disease (based on RHB-104's positive Phase 3 Crohn's disease study results) and Phase 3-stage for pulmonary nontuberculous mycobacteria (NTM) disease; (iii) **RHB-107** (**upamostat**), an oral broad-acting, host-directed, serine protease inhibitor with potential for pandemic preparedness, is in late-stage development as a treatment for non-hospitalized symptomatic COVID-19 and is also targeting multiple other cancer and inflammatory gastrointestinal diseases; and (iv) **RHB-102**, with potential UK submission for chemotherapy and radiotherapy induced nausea and vomiting, positive results from a U.S. Phase 3 study for acute gastroenteritis and gastritis and positive results from a U.S. Phase 2 study for IBS-D. RHB-102 is partnered with Hyloris Pharma (EBR: HYL) for worldwide development and commercialization outside North America.

More information about the Company is available at www.redhillbio.com / X.com/RedHillBio.

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 Phase II clinical studies evaluating its ifetroban product candidate in patients 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.

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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