

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): June 1, 2018 (June 1, 2018)

**CUMBERLAND PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

Tennessee

(State or other jurisdiction of incorporation)

001-33637

(Commission File Number)

62-1765329

(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:

- 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))

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.

The information contained in this Current Report on Form 8-K (including the exhibits hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

**Item 7.01. Regulation FD Disclosure**

Cumberland Pharmaceuticals Inc. (the "Company"), is a specialty pharmaceutical company focused on hospital acute care, gastroenterology, and oncology supportive care. Company representatives are presenting the Company to new investors utilizing the updated presentation which is furnished as [Exhibit 99.1](#) and is also on the Company's website, [www.cumberlandpharma.com](http://www.cumberlandpharma.com).

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Investor Presentation</a>





Investor Presentation

# Safe Harbor Statement

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This presentation contains forward-looking statements concerning our approved products and product development, our technology, our competitors, our intellectual property, our financial condition and our plans for research and development programs that involve risks, uncertainties and assumptions. These statements are based on the current estimates and assumptions of the management of Cumberland Pharmaceuticals as of the date of this presentation and are subject to uncertainty and changes in circumstances. Given these uncertainties, you should not place undue reliance upon these forward-looking statements. Such forward-looking statements are subject to risks, uncertainties, assumptions and other factors that may cause the actual results of Cumberland Pharmaceuticals to be materially different from those reflected in such forward-looking statements.

Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, those set forth under the headings "Risk factors" and "Management's discussion and analysis of financial condition and results of operations" in our Form 10-K and Form 10-Q Reports on file with the SEC. The Company does not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. All statements contained in this presentation are made only as of the date of this presentation. For more information on our brands, including full prescribing and safety information, please see the links to the product websites which can be found at [www.cumberlandpharma.com](http://www.cumberlandpharma.com).



# Company Overview

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- **Specialty pharmaceutical company**
  - Portfolio of **seven** FDA approved products
  - Promoted by **two** national sales forces
- Several **near-term catalysts** for new growth opportunities
- **Four Phase II products** in development with upcoming study milestones
- Proven record of **successful** product development and product acquisition
- **Strong financial position** and positive net cash flows from operations



# Marketed Brands



## HOSPITAL

**Acetadote®**  
(Acetaminophen Toxicity)

**Caldolor®**  
(Pain and Fever)

**Vaprisol®**  
(Hyponatremia)



## GASTROENTEROLOGY

**Kristalose®**  
(Acute/Chronic Constipation)

**Omeclamox®-Pak**  
(*H. pylori*)



## ONCOLOGY

**Ethyol®**  
(Amifostine)

**Totect®**  
(Dexrazoxane)



# IV ACETADOTE<sup>®</sup>

- IV treatment for **acetaminophen overdose**
- Developed and registered by **Cumberland**
- Acetaminophen is the **leading cause of poisoning in the U.S.\***
- Acetadote now **standard of care**
- Cumberland offers both Brand and Authorized Generic
- Favorable court rulings upholding patents
- Maintaining **significant market share**



\*National Poison Data System, American Association of Poison Centers

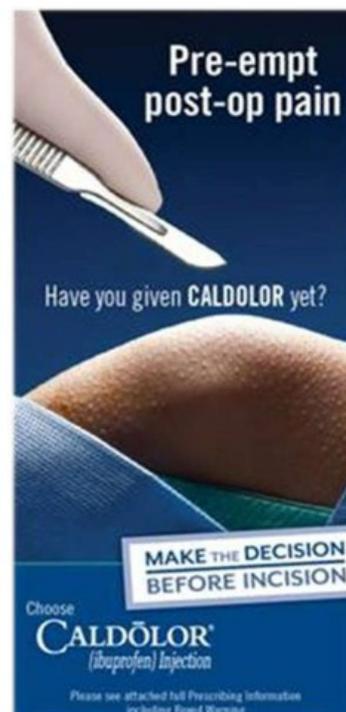


# CALDOLOR®

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- Patented, **injectable formulation of ibuprofen**
- Developed and registered by **Cumberland**
- **First injectable** approved in the US for pain & fever
- Unresolved pain remains **leading cause for hospital readmissions**, with a total **market potential of over 700M units\***
- Significant data supports pre-op management of inflammation
- **Pediatric labeling** approved by FDA and launched

\*Symphony Source Health



 **KRISTALOSE**<sup>®</sup>  
(lactulose) For Oral Solution

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- **Unique** crystalline formulation of lactulose
- Prescription strength laxative
- **Clinically proven** increases in patient satisfaction
- Acquired from Mylan Laboratories
- Repositioned to reflect **branded status**
- New pricing allowed co-pay support
- Expanding **Managed Care coverage**





# Ethyol<sup>®</sup> (amifostine) for Injection

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- Re-launch of an FDA-approved **oncology hospital brand**
- **Protects against** the harmful effects of cancer treatments
- **Protects the patient's healthy tissue, not the tumor**
- Indicated for use with **head & neck and ovarian cancers**
- Potential to become Cumberland's **largest selling brand**



# Portfolio Expansion Strategy



## IDENTIFY

*Late Stage Candidates*



## ACQUIRE

*Under-Promoted,  
Approved Brands*



## EXPAND

*Existing Products*



## DEVELOP

*Early-Stage Candidates*

**PRODUCT  
PORTFOLIO**



# Acquisition Initiative



## GOAL TO ADD ONE NEW PRODUCT PER YEAR

through business development initiative or internal product development



Active, ongoing initiative to identify, evaluate and acquire/license **new products** into the portfolio



Source opportunities through direct efforts and intermediaries



Seek commercial and late stage development assets that fit our **strategy and focus**

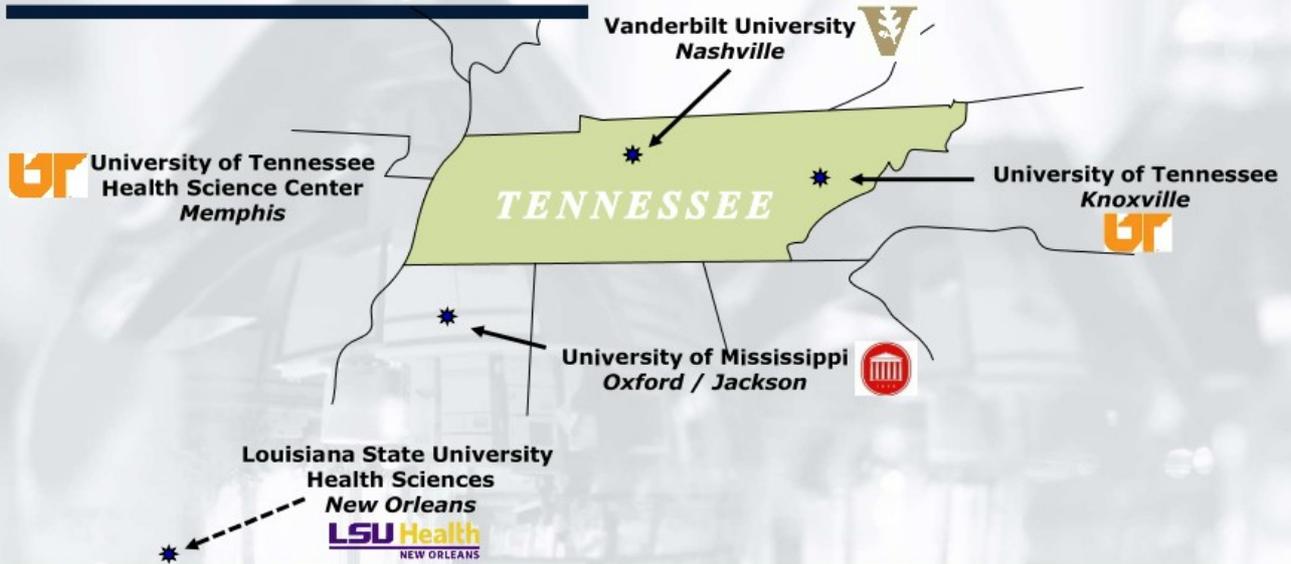
- Branded, Rx products in hospital acute care or gastroenterology
- Sales of **\$5-25 million or larger** with attractive margins



- **New delivery of methotrexate** designed for the treatment of various forms of **arthritis**
- **Exclusive U.S. rights** through a long-term partnership with the **Nordic Group** (based in Europe)
- **Widely used** throughout Europe with a **strong brand presence**
- The U.S. methotrexate market is seeing **significant growth**
- **Preparing FDA submission** for approval in the U.S.



# Collaboration Partners



# Ifetroban Overview

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- A **potent, selective** antagonist of thromboxane receptor (TPr)
- **Initially developed by Bristol-Myers Squibb** as an anti-platelet agent
- **Safety is well-established** in 26 clinical studies with **over 1,300 subjects**
- Cumberland is collaborating with Vanderbilt, Harvard, Scripps and other academic centers
- Cumberland successfully manufactures **both IV and oral formulations**



# Rationale for Ifetroban

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## Ifetroban Inhibits The Thromboxane Receptor (TPr):

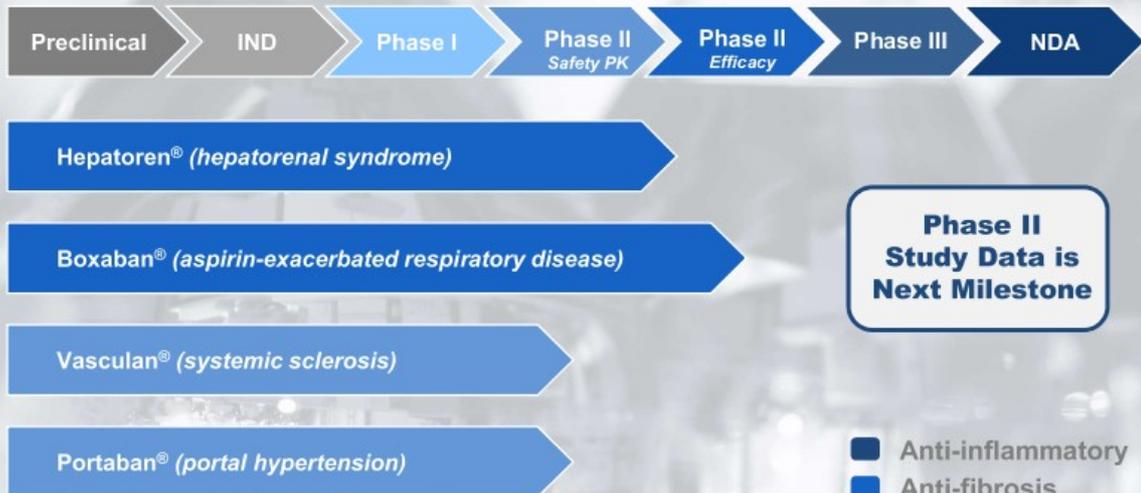
- Antagonist of smooth muscle contraction, platelet aggregation, and inflammation
- New data also demonstrates impact on fibrosis

- **Hepatorenal Syndrome:** Renal Vasoconstriction, Liver Inflammation, & Fibrosis
- **Aspirin Exacerbated Respiratory Disease (AERD):** Airway Constriction, Vasoconstriction, & Cellular Infiltration/Inflammation
- **Systemic Sclerosis:** Vasoconstriction, Autoimmune Inflammatory Process, & Fibrosis
- **Portal Hypertension:** Endothelial Dysfunction, Liver Fibrosis, & Inflammation



# Ifetroban Development Pipeline

Existing Safety Profile of >1,300 Patients



# Financial Overview

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	FY 2017
<i>(\$ in millions)</i>	
Net Revenues	\$41.2
Cost of Products Sold	<u>7.4</u>
Gross Profit	<b>\$33.8</b>
Selling & Marketing	\$21.5
Research & Development	3.9
General Administrative	10.0
Amortization	<u>2.4</u>
Operating Income (Loss)	(\$4.0)
Adjusted Earnings*	<b>\$0.1</b>

\*Represents a non-GAAP financial measure. For a reconciliation, see the Appendix.



# Summary Balance Sheet

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(\$ IN MILLIONS)

FY as of Dec 31, 2017

CASH & SECURITIES	\$50.1
<b>TOTAL ASSETS</b>	<b>93.2</b>
TOTAL LIABILITIES	9.8
<b>RETAINED EARNINGS</b>	<b>11.7</b>
<b>TOTAL EQUITY</b>	<b>63.9</b>

*\*Continued Share Repurchase Program*

*\*Tax carry forward credits of \$44 million available*



# Building Our Product Portfolio

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**Deploying a Multifaceted Strategy to Drive Value Creation**

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# Cumberland Moving Forward

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Diverse product portfolio **with 7 FDA approved brands**



Proven **development and commercialization capabilities**



Various initiatives in place to support **near-term growth**



**Four Phase II** products in development with upcoming study milestones



**Strong financial position** with positive net cash flows from operations



**Valuation gap** given assets, cash, sales, and pipeline





**CUMBERLAND**<sup>®</sup>  
PHARMACEUTICALS

Investor Presentation



# Appendix



**TOTECT**<sup>®</sup>  
(dexrazoxane) for injection

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- FDA-approved **oncology hospital brand**
- Indicated to treat toxic effects of **extravasation** (leakage) associated with anthracycline chemotherapy
- Can **limit damage** from extravasation and enable patients to continue treatment
- Anthracyclines are **widely used** in the treatment of breast cancer, soft tissue sarcomas, and lymphomas



# Vaprisol<sup>®</sup>

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- IV treatment for **hyponatremia**
- Patented, branded hospital product
- Delivered in a pre-mixed bag
- Promotes free water secretion in hospitalized patients suffering from an imbalance of sodium and water levels
- Condition results from a variety of critical care conditions including **ICU, neurology, nephrology, & oncology**
- Acquired from Astellas



# Omeclamox-Pak

H. pylori Treatment  
for patients with duodenal ulcer disease

	Omeclamox-Pak	PrevPac*	Pylera*
Number of Prescriptions/Co-Pays	1/1	1/1	2/2
Days of Therapy	10	10-14	10
Doses Per Day	2	2	4
Pills Per Day	8	8	14
Total Pill Burden	80	112	140

- **Newest treatment** for Helicobacter pylori (H. pylori) a frequent cause of stomach ulcers
- **A triple therapy brand**
  - Omeprazole (Prilosec)
  - Clarithromycin
  - Amoxicillin
- **Requires fewer pills** than other products that treat H. pylori
- **Shorter course of therapy** enhances compliance



# Partnership Strategy Slide

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## Streamline Operational Effectiveness and Expanding Market Penetration via Partnerships



U.S. distribution  
partnership with  
**Cardinal Health**



Co-Promotional partnership  
to **expand our hospital  
coverage across the U.S.**



Strategic alliance for  
**brand representation  
with the U.S.**



Co-Promotional partnership  
to **expand medical  
specialties covered** in  
support of Kristalose



# International Distribution

Bringing our medicines to patients throughout the world through a growing network of distinguished international partners

## North America



## South America

**GRIFOLS**  
Laboratorios  
**VALMOR, C.A.**  
Industria Farmaceutica Nacional

## Europe

**GRIFOLS**



## Middle East



## Asia



## Oceania



# Hepatoren<sup>®</sup> in HRS

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- Patients with HRS have **severe multi-organ dysfunction**
  - **No FDA approved treatment** for this unmet medical need
  - **Orphan Drug candidate**, with an estimated patient population of 175,000
- 
- Cumberland has **completed initial Phase IIA study**
    - Ifetroban was **well-tolerated** across all doses with **no safety concerns**
    - Showed **signals of improved kidney function**



## Boxaban<sup>®</sup> in AERD

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- **Chronic condition** characterized by asthma, sinus infections, and nasal polyps
  - **No FDA approved treatment** for this unmet medical need
  - Potential **Orphan Drug candidate**
- 
- Cumberland has **completed initial Phase IIA study**
    - Ifetroban was **well-tolerated** with **no safety concerns**
    - Showed **signals of efficacy** and improved respiratory function



## Vasculan<sup>®</sup> in SSc

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- **Chronic, life-threatening** multi-system autoimmune
- **Highest death rate** of any autoimmune disease
- **No FDA approved treatment** for this unmet medical need
- **Orphan Drug candidate**, with an estimated patient population of 165,000
- Cumberland is currently **conducting an initial Phase IIA study**



## Portaban<sup>®</sup> in PH

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- The **most serious** complications of **liver cirrhosis**
- **Median survival is 6 years** from diagnosis
- **No FDA approved treatment** for this unmet medical need
- **Orphan Drug candidate**, with an estimated patient population of 100,000
- Cumberland is currently **conducting an initial Phase IIA study**



## Reconciliation of Net Income to Adjusted Earnings

*(\$ in thousands except per share data)*

**FY 2017**

Net Income (Loss) Attributed to the Common Shareholders	(7,979)
Net Loss at Subsidiary Attributable to Noncontrolling Interests	<u>71</u>
Net Income (Loss)	<b>(8,050)</b>
Income Tax Expense (Benefit)	\$4,175
Depreciation and Amortization	2,648
Share-Based Compensation	1,115
Other Adjustments to Net Income	372
Interest Income	(299)
Interest Expense	<u>93</u>
Adjusted Earnings	\$54



