# PHARMACEUTICALS

**Investor Presentation** 

### Safe Harbor Statement

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 forwardlooking 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 statements forward-looking 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.



# Company Overview

- Specialty pharmaceutical company
  - Portfolio of eight FDA approved products
  - Promoted by two national sales forces
- Several near-term catalysts for new growth opportunities
  - Vibativ post-acquisition integration and market expansion
  - Next Generation Caldolor product
  - RediTrex methotrexate product line
- 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<sup>®</sup> (Acetaminophen Toxicity)

Caldolor<sup>®</sup> (Pain and Fever)

Vaprisol<sup>®</sup> (Hyponatremia)

Vibativ<sup>®</sup> (HABP/VABP & cSSSI)

#### GASTROENTEROLOGY

Kristalose<sup>®</sup> (Acute/Chronic Constipation)

Omeclamox<sup>®</sup>-Pak (H. pylori)



#### ONCOLOGY

Ethyol<sup>®</sup> (Amifostine)

Totect<sup>®</sup> (Dexrazoxane)





- 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

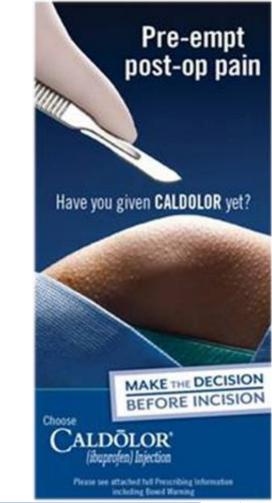
\*National Poison Data System, American Association of Poison Centers





CALDŌLOR®

- 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
- Submitted Next Generation product for approval





\*Symphony Source Health



- 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







- 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
- Growing interest for use in additional areas





# **Commercial Portfolio Expansion Strategy**

#### **IDENTIFY** Late Stage Candidates



**EXPAND** Existing Products



ACQUIRE Under-Promoted, Approved Brands



**DEVELOP** Early-Stage Candidates

### **PRODUCT PORTFOLIO**



# Acquisition Initiative



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





- Acquired Vibativ<sup>®</sup> from Theravance in November 2018
- Financial terms included:
  - \$20MM upfront payment
  - \$5MM milestone payment in 2019
  - Double-digit royalty on future net sales
- Transaction included the **global responsibility for** the product
- FDA-approved product with favorable margins







- Injectable antibiotic that treat serious, life-threatening infections
- Hospital product that aligns well with our current infrastructure
- Gross revenues of ~\$21MM in 2017
- Strong potential to continue brand growth
- Patent protection through 2027
- Established network of worldwide licensing partners







- RediTrex
- 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
- Provided submission to FDA for U.S. approval





# lfetroban Overview

- 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

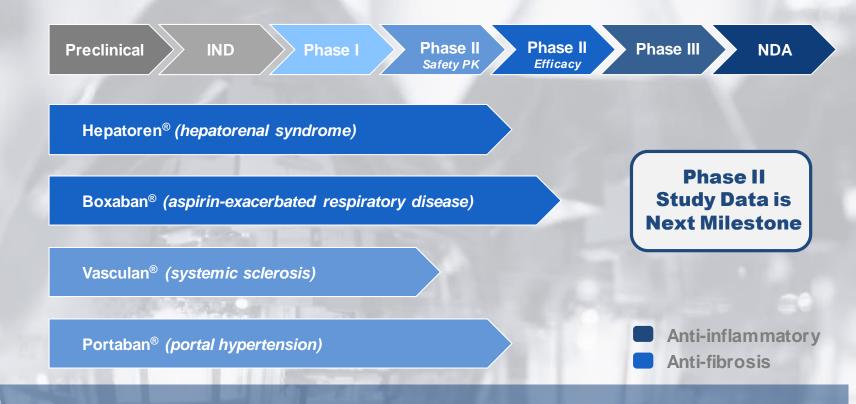
#### **Ifetroban Inhibits The Thromboxane Receptor (TPr):**

- 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

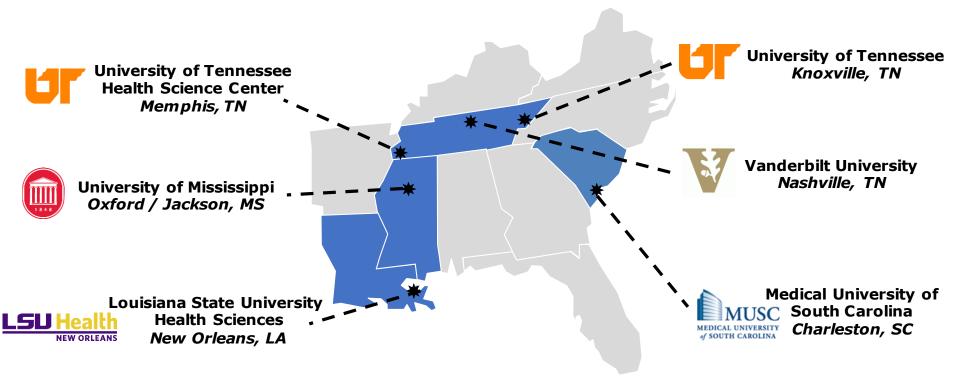


### Ifetroban Development Pipeline

#### Existing Safety Profile of >1,300 Patients

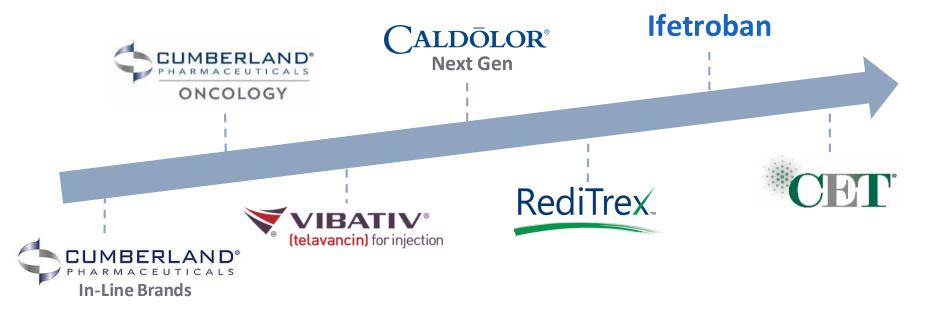








## **Expanding Our Product Portfolio**



#### **Deploying a Multifaceted Strategy to Create Value**

### **Financial Overview**

(\$ in I	millions)	Q3 2018
Ne	t Revenues	\$8.5
Со	st of Products Sold	1.5
Gro	oss Profit	\$7.0
Sel	lling & Marketing	\$4.8
Re	search & Development	1.3
Ge	neral Administrative	2.1
Am	ortization	0.6
Ор	erating Income (Loss)	(\$1.8)
Adj	justed Earnings*	(\$0.5)

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

### **Summary Balance Sheet**

(\$ IN MILLIONS)	Q3 as of Sep 30, 2018
CASH & SECURITIES	\$47.8
TOTAL ASSETS	87.4
TOTAL LIABILITIES	29.5
RETAINED EARNINGS	6.9
TOTAL EQUITY	58.2

\*Continued Share Repurchase Program \*Tax carry forward credits of \$44 million available



# Cumberland Moving Forward



Diverse product portfolio with 8 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



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# Appendix





- 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





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 Helicobactor 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





- 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





# Partnership Strategy Slide

#### Streamline Operational Effectiveness and Expanding Market Penetration via Partnerships







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 Bring a Distribution Partners

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



# Hepatoren<sup>®</sup> in HRS

- 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

- 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

- 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

- 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
- Patient enrollment completed in Phase IIA study



# **Reconciliation of Net Income** to Adjusted Earnings

(\$ in thousands except per share data)	Q3 2018
Net Income (Loss) Attributed to the Common Shareholders	(\$1,643,044)
Net Loss at Subsidiary Attributable to Noncontrolling Interests	20,977
Net Income (Loss)	(\$1,664,021)
Income Tax Expense (Benefit)	\$4,159
Depreciation and Amortization	713,323
Share-Based Compensation	339,930
Interest Income	(166,220)
Interest Expense	<u>    19,199</u>
Adjusted Earnings	(\$753,630)

