

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549  
FORM 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2023  
OR  
 **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 001-33637

**Cumberland Pharmaceuticals Inc.**

(Exact Name of Registrant as Specified In Its Charter)

Tennessee  
(State or Other Jurisdiction of  
Incorporation or Organization)  
  
1600 West End Avenue, Suite 1300,  
Nashville, Tennessee  
(Address of Principal Executive Offices)

62-1765329  
(I.R.S. Employer  
Identification No.)

37203  
(Zip Code)

(615) 255-0068  
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:		
Class	Trading Symbol	Name of exchange on which registered
Common stock, no par value	CPIX	Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files.) Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 14,255,700 shares of common stock as of November 7, 2023.

**CUMBERLAND PHARMACEUTICALS INC.**  
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**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements (Unaudited)**

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**  
**(Unaudited)**

	<b>September 30, 2023</b>	<b>December 31, 2022</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 18,507,965	\$ 19,757,970
Accounts receivable, net	12,620,120	13,163,681
Inventories, net	8,670,548	9,863,581
Prepaid and other current assets	1,971,164	3,084,978
Total current assets	41,769,797	45,870,210
Non-current inventories	8,301,845	7,527,167
Property and equipment, net	377,439	284,039
Intangible assets, net	27,121,070	30,590,678
Goodwill	914,000	914,000
Operating lease right-of-use assets	6,711,155	5,218,403
Other assets	2,555,638	2,520,661
Total assets	\$ 87,750,944	\$ 92,925,158
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 10,818,045	\$ 10,819,011
Operating lease current liabilities	334,288	172,910
Other current liabilities	16,175,937	17,587,911
Total current liabilities	27,328,270	28,579,832
Revolving line of credit	12,923,125	16,200,000
Operating lease non-current liabilities	5,388,900	4,586,301
Other long-term liabilities	6,455,091	7,585,019
Total liabilities	52,095,386	56,951,152
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 14,217,926 and 14,366,616 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	47,185,304	47,474,973
Accumulated deficit	(11,193,755)	(11,208,841)
Total shareholders' equity	35,991,549	36,266,132
Noncontrolling interests	(335,991)	(292,126)
Total equity	35,655,558	35,974,006
Total liabilities and equity	\$ 87,750,944	\$ 92,925,158

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Net revenues	\$ 10,085,926	\$ 11,413,072	\$ 30,199,441	\$ 32,887,269
Costs and expenses:				
Cost of products sold	1,765,590	2,224,443	4,536,628	6,468,212
Selling and marketing	4,743,142	4,110,397	13,692,535	13,281,511
Research and development	1,924,768	1,714,254	4,569,476	5,283,083
General and administrative	2,343,855	2,166,118	7,212,731	6,672,442
Amortization	1,175,174	1,486,448	3,563,493	4,609,146
Total costs and expenses	11,952,529	11,701,660	33,574,863	36,314,394
Operating loss	(1,866,603)	(288,588)	(3,375,422)	(3,427,125)
Interest income	98,603	21,602	205,854	52,709
Other income	—	—	2,828,871	—
Other income - settlement	475,000	—	475,000	—
Other income - insurance proceeds	346,800	—	346,800	611,330
Interest expense	(110,081)	(149,340)	(489,069)	(406,539)
Loss before income taxes	(1,056,281)	(416,326)	(7,966)	(3,169,625)
Income tax expense	(6,938)	(6,900)	(20,813)	(20,700)
Net loss	(1,063,219)	(423,226)	(28,779)	(3,190,325)
Net loss at subsidiary attributable to noncontrolling interests	13,921	14,587	43,865	60,813
Net income (loss) attributable to common shareholders	\$ (1,049,298)	\$ (408,639)	\$ 15,086	\$ (3,129,512)
Earnings (loss) per share attributable to common shareholders				
- basic	\$ (0.07)	\$ (0.03)	\$ —	\$ (0.21)
- diluted	\$ (0.07)	\$ (0.03)	\$ —	\$ (0.21)
Weighted-average shares outstanding				
- basic	14,277,229	14,477,478	14,343,560	14,618,975
- diluted	14,277,229	14,477,478	14,521,600	14,618,975

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**

	<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (28,779)	\$ (3,190,325)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization expense	3,702,687	4,816,630
Share-based compensation	271,146	320,598
Decrease in non-cash contingent consideration	(1,017,712)	(1,051,908)
Decrease in cash surrender value of life insurance policies over premiums paid	16,357	708,293
Increase in noncash interest expense	11,713	7,608
Life insurance proceeds	(346,800)	(611,330)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	890,361	(8,184,656)
Inventories	418,355	1,338,881
Other current assets and other assets	(439,320)	4,355,396
Accounts payable and other current liabilities	1,903,021	8,778,631
Other long-term liabilities	(327,329)	(2,472,453)
Net cash provided by operating activities	<u>5,053,700</u>	<u>4,815,365</u>
<b>Cash flows from investing activities:</b>		
Additions to property and equipment	(232,595)	(255,676)
Settlement of patent litigation	—	21,757
Life insurance policy proceeds received	—	877,597
Cash paid for acquisitions	—	(13,500,000)
Additions to intangible assets	(133,739)	(177,362)
Net cash used in investing activities	<u>(366,334)</u>	<u>(13,033,684)</u>
<b>Cash flows from financing activities:</b>		
Borrowings on line of credit	23,775,000	46,700,000
Repayments on line of credit	(27,051,875)	(44,000,000)
Cash payment of contingent consideration	(2,108,933)	(1,117,576)
Repurchase of common shares	(551,563)	(863,383)
Net cash provided by (used in) financing activities	<u>(5,937,371)</u>	<u>719,041</u>
Net decrease in cash and cash equivalents	(1,250,005)	(7,499,278)
Cash and cash equivalents at beginning of period	\$ 19,757,970	\$ 27,040,816
Cash and cash equivalents at end of period	<u>\$ 18,507,965</u>	<u>\$ 19,541,538</u>

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Equity**  
**(Unaudited)**

	Common stock		Accumulated deficit	Noncontrolling interests	Total equity
	Shares	Amount			
Balance, December 31, 2021	14,742,754	\$ 48,452,906	\$ (5,638,600)	\$ (212,328)	\$ 42,601,978
Share-based compensation	162,155	159,901	—	—	159,901
Repurchase of common shares	(174,149)	(566,043)	—	—	(566,043)
Net loss	—	—	(1,385,253)	(17,180)	(1,402,433)
Balance, March 31, 2022	14,730,760	\$ 48,046,764	\$ (7,023,853)	\$ (229,508)	\$ 40,793,403
Balance, March 31, 2022	14,730,760	\$ 48,046,764	\$ (7,023,853)	\$ (229,508)	\$ 40,793,403
Share-based compensation	2,250	(27,753)	—	—	(27,753)
Repurchase of common shares	(83,317)	(196,692)	—	—	(196,692)
Net loss	—	—	(1,335,620)	(29,046)	(1,364,666)
Balance, June 30, 2022	14,649,693	\$ 47,822,319	\$ (8,359,473)	\$ (258,554)	\$ 39,204,292
Balance, June 30, 2022	14,649,693	\$ 47,822,319	\$ (8,359,473)	\$ (258,554)	\$ 39,204,292
Share-based compensation	—	188,449	—	—	188,449
Repurchase of common shares	(33,110)	(78,793)	—	—	(78,793)
Net loss	—	—	(408,639)	(14,587)	(423,226)
Balance, September 30, 2022	14,616,583	\$ 47,931,975	\$ (8,768,112)	\$ (273,141)	\$ 38,890,722

	Common stock		Accumulated deficit	Noncontrolling interests	Total equity
	Shares	Amount			
Balance, December 31, 2022	14,366,616	\$ 47,474,973	\$ (11,208,841)	\$ (292,126)	\$ 35,974,006
Share-based compensation	150,260	90,156	—	—	90,156
Repurchase of common shares	(86,829)	(187,961)	—	—	(187,961)
Net income (loss)	—	—	192,184	(19,898)	172,286
Balance, March 31, 2023	14,430,047	\$ 47,377,168	\$ (11,016,657)	\$ (312,024)	\$ 36,048,487
Balance, March 31, 2023	14,430,047	\$ 47,377,168	\$ (11,016,657)	\$ (312,024)	\$ 36,048,487
Share-based compensation	—	97,877	—	—	97,877
Repurchase of common shares	(99,057)	(171,616)	—	—	(171,616)
Net income (loss)	—	—	872,200	(10,046)	862,154
Balance, June 30, 2023	14,330,990	\$ 47,303,429	\$ (10,144,457)	\$ (322,070)	\$ 36,836,902
Balance, June 30, 2023	14,330,990	\$ 47,303,429	\$ (10,144,457)	\$ (322,070)	\$ 36,836,902
Share-based compensation	3,500	83,112	—	—	83,112
Repurchase of common shares	(116,564)	(201,237)	—	—	(201,237)
Net loss	—	—	(1,049,298)	(13,921)	(1,063,219)
Balance, September 30, 2023	14,217,926	\$ 47,185,304	\$ (11,193,755)	\$ (335,991)	\$ 35,655,558

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

**CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**(1) ORGANIZATION AND BASIS OF PRESENTATION**

Cumberland Pharmaceuticals Inc. (“Cumberland,” the “Company,” or as used in the context of “we,” “us,” or “our”), is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription pharmaceutical products. We are dedicated to our mission of working together to provide unique products that improve the quality of patient care.

Our primary markets are hospital acute care, gastroenterology and oncology. These medical specialties are characterized by relatively concentrated prescriber bases that we believe can be served effectively by small, targeted sales forces. We promote our approved products through our hospital, oncology and field sales forces in the United States. We have also established international partnerships and are continuing to build a network of companies outside the U.S. to register and provide our medicines to patients in their countries.

Cumberland’s growth strategy involves maximizing the success of our existing brands, while continuing to add differentiated products. We have built our portfolio of FDA approved products through both development and acquisition. Additionally, we look for opportunities to expand our products into new patient populations through clinical trials, improved presentations and our support of select, investigator-initiated studies. We actively pursue opportunities to acquire additional marketed products, as well as late-stage development product candidates in our target medical specialties. Our clinical team is developing a pipeline of new product candidates to address poorly met medical needs.

The Company’s products are manufactured by third parties, which are overseen by our quality control and manufacturing professionals. We work closely with our warehousing and distribution partners to make our products available in the U.S.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements of the Company have been prepared on a basis consistent with the December 31, 2022, audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly present the information set forth herein. All significant intercompany accounts and transactions have been eliminated in consolidation. The unaudited condensed consolidated financial statements have been prepared in accordance with the regulations of the Securities and Exchange Commission (the “SEC”), and certain information and disclosures have been condensed or omitted as permitted by the SEC for interim period presentation. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes included in our Annual Report on Form 10-K for the year ended December 31, 2022 (the “2022 Annual Report on Form 10-K”). The results of operations for the three and nine months ended September 30, 2023, are not necessarily indicative of the results to be expected for the entire fiscal year or any future period.

***Recent Accounting Guidance***

***Recent Accounting Pronouncements***

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-13, “Financial Instruments-Credit Losses,” which changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans and other instruments, companies are required to use a new forward-looking “expected loss” model that generally results in an earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, companies measure credit losses in a manner similar with previous guidance, except that the losses are recognized as allowances rather than as reductions in the amortized cost of the securities. Companies have to disclose additional information, including information they use to track credit quality by year of origination for most financing receivables. Companies apply the ASU’s provisions as a cumulative-effect adjustment, if any, to the accumulated deficit as of the beginning of the first reporting period in which the guidance is adopted.

Related to ASU No. 2016-13 discussed above, in May 2019, the FASB issued ASU 2019-05, “Financial Instruments-Credit Losses (Topic 326): Targeted Transition Relief” which provides transition relief for ASU 2016-13 by providing entities with an alternative to irrevocably elect the fair value option for eligible financial assets measured at amortized cost upon adoption of the new credit losses standard. Certain eligibility requirements must be met and the election must be applied on an instrument-by-instrument basis. The election is not available for either available-for-sale or held-to-maturity debt securities. The Company adopted both ASU 2016-13 and ASU 2019-05 on January 1, 2023. Please refer to *Trade and Notes Receivables Policy* below.

## ***Accounting Policies:***

### ***Use of Estimates***

The preparation of the condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates under different assumptions and conditions. The Company's most significant estimates include: (1) its allowances for chargebacks and accruals for rebates and product returns, (2) the allowances for obsolescent or unmarketable inventory and (3) valuation of contingent consideration liabilities associated with business combinations.

### ***Operating Segments***

The Company has one operating segment which is specialty pharmaceutical products. Management has chosen to organize the Company based on the type of products sold. Operating segments are identified as components of an enterprise about which separate discrete financial information is evaluated by the chief operating decision maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. The Company, which uses consolidated financial information in determining how to allocate resources and assess performance, has concluded that our specialty pharmaceutical products compete in similar economic markets and similar circumstances. Substantially all of the Company's assets are located in the United States and total revenues are primarily attributable to U.S. customers.

### ***Trade and Note Receivables Policy***

Management performed a scoping exercise to ensure completeness over the application of Current Expected Credit Losses (CECL) across the various financial instruments including trade and note receivables. CECL is applicable to all financial assets measured at amortized cost. The authoritative guidance requires that all financial instruments should be evaluated, including cash equivalents such as 3-month T-Bills, even if the expected loss is determined to be zero, or materially zero. All bank balances are maintained in cash or money market funds. Therefore for the Company, this principally relates to trade receivables and two notes receivable. CECL also requires the measurement of expected credit losses on a collective (pool) basis when similar risk characteristics exist. This may include, either individually or in combination, some of the following characteristics of Accounting Standards Codification ("ASC") (326-20-55-5):

- a. Internal or external credit score/rating
- b. Risk ratings or classification
- c. Financial asset type
- d. Size
- e. Effective interest rate
- f. Term
- g. Geographical location
- h. Historical or expected credit loss patterns
- i. Reasonable and supportable forecast periods

The standard requires entities to pool financial assets but allows them to choose which risk characteristics to use. Under the requirements of the guidance, the Company would need to reassess at the end of each reporting period whether the pool of assets continue to display similar risk characteristics.

With twenty years of experience, Cumberland has experienced virtually no write downs of receivables as most of our receivables are due from large successful pharmaceutical, healthcare or government customers, consistently making payments on account. Although the payment behaviors of all of our customers are consistently reliable, for the sake of transparency, we have separated our customer base into seven separate pools. The Company performs a monthly analysis of aged accounts receivable to determine how much, if any, of the accounts receivable balance should be reserved as potential bad debt. The Company reviews all balances over 90 days past due for a possible reserve and considers any specific factors or information for balances aged under 90 days if there are indicators that the balance should be reserved, such as other aged balances with the customer or bankruptcy as well as any economic issues with a customer industry or region. The adoption of ASC 326 did not result in a material impact to the Company.



## (2) EARNINGS (LOSS) PER SHARE

The following table reconciles the numerator and denominator used to calculate basic and diluted earnings (loss) per share for the three and nine months ended September 30, 2023 and 2022:

	Three months ended September 30,	
	2023	2022
Numerator:		
Net loss attributable to common shareholders	\$ (1,049,298)	\$ (408,639)
Denominator:		
Weighted-average shares outstanding – basic	14,277,229	14,477,478
Dilutive effect of other securities	—	—
Weighted-average shares outstanding – diluted	14,277,229	14,477,478
	Nine months ended September 30,	
	2023	2022
Numerator:		
Net income (loss) attributable to common shareholders	\$ 15,086	\$ (3,129,512)
Denominator:		
Weighted-average shares outstanding – basic	14,343,560	14,618,975
Dilutive effect of other securities	178,040	—
Weighted-average shares outstanding – diluted	14,521,600	14,618,975

As of September 30, 2023 and 2022, restricted stock awards and options to purchase 440,389 and 233,750 shares of common stock, respectively, were outstanding but were not included in the computation of diluted earnings per share because the effect would be antidilutive.

### (3) REVENUES

#### Product Revenues

The Company accounts for revenues from contracts with customers under ASC 606.

The Company's net revenues consisted of the following for the three and nine months ended September 30, 2023 and 2022:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Products:				
Kristalose	\$ 3,887,476	\$ 3,903,305	\$ 12,313,321	\$ 11,418,673
Sancuso	1,933,222	3,960,652	5,736,981	10,756,411
Vibativ	2,789,579	1,909,750	6,785,592	6,008,005
Caldolor	1,155,509	921,811	3,316,866	3,075,355
Acetadote	120,052	99,792	440,071	337,685
Vaprisol	—	(436)	39,866	(252,059)
Omeclamox-Pak	23,288	35,600	28,832	31,925
RediTrex	(122,556)	85,809	(254,108)	238,712
Other revenue	299,356	496,789	1,792,020	1,272,562
Total net revenues	<u>\$ 10,085,926</u>	<u>\$ 11,413,072</u>	<u>\$ 30,199,441</u>	<u>\$ 32,887,269</u>

The Omeclamox-Pak net revenue for the third quarter of 2023 was impacted by our lack of commercial inventory of this product. The packager for our Omeclamox-Pak product encountered financial difficulties due to the impact of COVID-19. They are under new management and we are awaiting a potential resumption of supply. For the three and nine months ended September 30, 2023 and 2022, the amounts noted resulted from normal adjustments by channel partners.

With regard to Vaprisol, we are in the process of transitioning to a new manufacturer, who was issued a U.S. Food and Drug Administration ("FDA") Form 483 in the second quarter of 2022. Once these FDA Form 483 related issues are satisfactorily resolved by the manufacturer, we will then resubmit our application for their facility to the FDA for approval. For the nine months ended September 30, 2023 and the three and nine months ended September 30, 2022, net revenue was impacted by product return and accrual adjustments.

#### Other Revenues

The Company has agreements with international partners for commercialization of the Company's products with associated payments included in other revenues. Those agreements provide that each of the partners is responsible for seeking regulatory approvals for the product, and following approval, each partner will be responsible for the ongoing distribution and sales in the respective international territories. The Company provides a dossier for product registration and maintains responsibility for the relevant intellectual property. Cumberland is typically entitled to receive a non-refundable, up-front payment at the time each agreement is executed as consideration for the product dossier and for the rights to the distinct intellectual property rights in the respective international territory. These agreements also typically provide for additional payments upon a partner's achievement of a defined regulatory approval and sales milestones. The Company may also be entitled to receive royalties on future sales of the products and a transfer price on supplies. The contractual payments associated with the partner's achievement of regulatory approvals, sales milestones and royalties on future sales are recognized as revenue upon occurrence, or at such time that the Company has a high degree of confidence that the revenue would not be reversed in a subsequent period.

In the second quarter of 2023, the Company received \$1.0 million relating to a litigation settlement based on two \$500,000 milestone payments due to us for the license associated with our Vibativ product that is included in other revenue for the nine months ended September 30, 2023.

Other revenues include funding from federal grant programs including those secured from the FDA and from those secured by Cumberland Emerging Technologies Inc. ("CET") through the Small Business Administration. Grant revenue from these federal grant programs totaled approximately \$0.1 million and \$0.2 million for the three months ended September 30, 2023 and 2022, respectively, and approximately \$0.3 million for the nine months ended September 30, 2023 and 2022.

Other revenues also include lease income generated by CET's Life Sciences Center. It is a research facility that provides scientists with access to flexible lab space and other resources to develop biomedical products. This lease income, as noted in Footnote 5 - Leases, was approximately \$0.2 million and \$0.1 million for the three months ended September 30, 2023 and 2022, respectively, and \$0.4 million for the nine months ended September 30, 2023 and 2022.

#### (4) INVENTORIES

The Company works closely with third parties to manufacture and package finished goods for sale. Based on the arrangements with the manufacturer or packager, the Company will either take title to the finished goods at the time of shipment or at the time of arrival at the Company's warehouses. The Company then holds such goods in inventory until distribution and sale. These finished goods inventories are stated at the lower of cost or net realizable value with cost determined using the first-in, first-out method.

The Company continually evaluates inventory for potential losses due to excess, obsolete or slow-moving goods by comparing sales history and projections to the inventory on hand. When evidence indicates that the carrying value may not be recoverable, a charge is taken to reduce the inventory to its current net realizable value. At September 30, 2023, there were no cumulative obsolescence and discontinuance losses necessary. At December 31, 2022, the Company had recognized and maintained cumulative net realizable value charges for potential obsolescence and discontinuance losses of approximately \$0.5 million.

The Company purchases the active pharmaceutical ingredient ("API") for Kristalose and maintains the inventory of that raw material. API for the Company's Vaprisol and Vibativ brands were included in the assets associated with the acquisition of those brands and are also included in the raw materials inventory. As part of the Vibativ acquisition, the Company acquired API and work in process inventories of \$15.6 million that were all initially classified as non-current inventories at the date of acquisition.

As these APIs are consumed in the manufacture of our products, the value of the API involved is transferred from raw materials to finished goods.

Consigned inventory represents Authorized Generic inventory stored with our partner until shipment to their customers.

At September 30, 2023 and December 31, 2022, total non-current inventory was \$8.3 million and \$7.5 million, respectively. It included Vibativ finished goods of \$1.3 million, Vibativ raw materials of \$4.3 million, Kristalose raw materials of \$1.5 million, Vaprisol raw materials of \$0.9 million and ifetroban raw materials of \$0.2 million. At December 31, 2022, the Company's non-current inventory included Vibativ raw materials of \$7.1 million and ifetroban raw materials of \$0.3 million and finished goods of \$0.1 million.

At September 30, 2023 and December 31, 2022, the Company's net inventories consisted of the following:

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
Raw materials and work in process	\$ 12,052,652	\$ 12,899,659
Consigned inventory	191,957	168,923
Finished goods	4,727,784	4,322,166
Total inventories	16,972,393	17,390,748
less non-current inventories	(8,301,845)	(7,527,167)
Total inventories classified as current	<u>\$ 8,670,548</u>	<u>\$ 9,863,581</u>

#### (5) LEASES

On November 15, 2021, Cumberland entered into a lease (the "Lease"), pursuant to which the Company leases approximately 16,903 rentable square feet of space (the "Leased Premise") at Broadwest located in Nashville, Tennessee with 1600 West End Avenue Partners, LLC (the "Landlord"). The Leased Premise serves as the Company's new corporate headquarters. The initial term of the Lease is one hundred fifty-seven (157) months, with two consecutive options to renew for a period of five years each, with the commencement date of October 25, 2022. This lease currently expires in November 2035.

The Company is responsible for paying rent to the Landlord under the Lease beginning three months after the commencement date. The Company pays a base rent of \$33.06 per square foot of rentable space with a gradual rental rate increase of 2.5% for each year thereafter of the prior year's base rental. In addition to the monthly base rent, the Company is responsible for its percentage share of the operating expenses of the building. The Lease also provided for a tenant improvement allowance which we used to build out the space.

In addition, the Company's operating leases also include the lease of approximately 14,200 square feet of wet laboratory and office space in Nashville, Tennessee by CET, our majority-owned subsidiary, where it operates the CET Life Sciences Center. This laboratory and office space at CET is leased through April 2028. The Company also subleases a portion of the space under this lease.

Operating lease liabilities were recorded as the present value of remaining lease payments not yet paid for the lease term discounted using the incremental borrowing rate associated with each lease. Operating lease right-of-use assets represent operating lease liabilities adjusted for lease incentives and initial direct costs. As the Company's leases do not contain implicit borrowing rates, the incremental borrowing rates were calculated based on information available at January 1, 2019 and October 25, 2022. Incremental borrowing rates reflect the Company's estimated interest rates for collateralized borrowings over similar lease terms. The weighted-average remaining lease term for the Broadwest and CET leases is 10.6 years at September 30, 2023. The weighted-average incremental borrowing rate used to discount the present value of the remaining lease payments is 9.28% for the Broadwest lease and 9.9% for the remaining CET lease. Also included as a right-of-use asset is an embedded lease of \$0.8 million related to our new manufacturer for Vaprisol.

#### Lease Position

At September 30, 2023 and December 31, 2022, the Company's lease assets and liabilities were as follows:

<b>Right-of-Use Assets</b>	<b>September 30, 2023</b>	<b>December 31, 2022</b>
Operating lease right-of-use assets	\$ 6,711,155	\$ 5,218,403
<b>Lease Liabilities</b>		
	<b>September 30, 2023</b>	<b>December 31, 2022</b>
Operating lease current liabilities	\$ 334,288	\$ 172,910
Operating lease noncurrent liabilities	5,388,900	4,586,301
Total	<u>\$ 5,723,188</u>	<u>\$ 4,759,211</u>

As of September 30, 2023, cumulative future minimum sublease income under non-cancelable operating subleases totals approximately \$1.7 million and will be paid through the leases ending in April 2028. Future minimum lease payments under non-cancelable operating leases (with initial or remaining lease terms in excess of one year) are as follows:

<b>Maturity of Lease Liabilities at September 30, 2023</b>	<b>Operating Leases</b>
2023	212,656
2024	863,320
2025	836,100
2026	909,911
2027	934,180
After 2027	5,588,192
Total lease payments	<u>9,344,359</u>
Less: Interest	3,621,171
Present value of lease liabilities	<u>\$ 5,723,188</u>

Rent expense is recognized over the expected term of the lease, including renewal option periods, if applicable, on a straight-line basis as a component of general and administrative expense. Rent expense and sublease income were as follows:

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
Rent expense	<u>\$ 244,305</u>	<u>\$ 239,647</u>	<u>\$ 765,455</u>	<u>\$ 861,398</u>
Sublease income	<u>\$ 155,025</u>	<u>\$ 128,395</u>	<u>\$ 400,524</u>	<u>\$ 424,632</u>

## **(6) SHAREHOLDERS' EQUITY AND DEBT**

### *Share repurchases*

Cumberland currently has a share repurchase program available to repurchase up to \$10 million of its common stock pursuant to Rule 10b-18 of the Securities Exchange Act of 1934. In January 2019, the Company's Board of Directors established the current \$10 million repurchase program to replace the prior authorizations. During the nine months ended September 30, 2023 and September 30, 2022, the Company repurchased 302,450 shares and 290,576 shares of common stock for approximately \$0.6 million and \$0.8 million, respectively. At September 30, 2023, approximately \$3.2 million was available for the repurchase of common shares under this program.

### *Share purchases and sales*

In the Company's May 2023 trading window, several members of Cumberland's Board of Directors entered into agreements for trading plans to purchase shares of the Company's stock pursuant to Rule 10b5-1 of the Securities Exchange Act of 1934. These purchases are designed to increase ownership in the Company by the members of the Board. These purchases began in August 2023 and as of September 30, 2023, a total of 14,731 shares have been purchased through these trading plans.

### *Share Sales*

In November 2017, Cumberland filed a Shelf Registration on Form S-3 with the SEC associated with the sale of up to \$100 million in corporate securities. The Shelf Registration was declared effective in January 2018. It also included an At the Market ("ATM") feature that allowed the Company to sell common shares at market prices, along with an agreement with B. Riley FBR Inc. to support such a placement of shares. The Company filed an updated Form S-3 with the SEC in December 2020, which was declared effective in January 2021. On December 27, 2021, the Company filed a related prospectus supplement in connection with the sale and issuance of shares having an aggregate gross sales price of up to \$19 million. The Company intends to continue an ATM feature through B. Riley FBR, Inc. that would allow the Company to issue shares of its common stock. The Company did not issue any shares under an ATM during the nine months ended September 30, 2023 or September 30, 2022.

### *Restricted Share Grants and Incentive Stock Options*

During the nine months ended September 30, 2023 and September 30, 2022, the Company issued 34,250 shares and 65,225 shares of restricted stock, respectively, to employees, advisors and directors. Restricted stock issued to employees and advisors generally cliff-vests on the fourth anniversary of the date of grant and for directors on the one-year anniversary of the date of grant. During the nine months ended September 30, 2023 and 2022, the Company also issued 192,550 and 172,300 incentive stock options, respectively, to employees that cliff-vest on the fourth anniversary of the date of grant, and are set to expire in 2033 and 2032, respectively.

Stock compensation expense is presented as a component of general and administrative expense in the condensed consolidated statements of operations as it relates to these restricted share grants and options. For the nine months ended September 30, 2023, we recorded a credit of \$0.05 million to stock compensation expense related to the forfeiture of unvested restricted stock awards.

### *New Debt Agreement*

On September 5, 2023, the Company entered into a new Revolving Credit Loan Agreement with Pinnacle Bank. This facility provides for an aggregate principal funding amount of up to \$25 million. The initial revolving line of credit is up to \$20 million, with the ability for Cumberland to increase the amount to \$25 million, under certain conditions. It has a three year term expiring on October 1, 2026. The interest rate is based on Benchmark (Term SOFR) plus a spread of 2.75%. Cumberland is subject to one financial covenant, the maintenance of a Funded Debt Ratio, determined on a quarterly basis. Borrowings under the line of credit are collateralized by substantially all of our assets.

As of September 30, 2023 and December 31, 2022, the Company had \$12.9 million and \$16.2 million, respectively, in borrowings outstanding under its revolving credit facility. The applicable interest rate under the Pinnacle Agreement was 8.25% at September 30, 2023.

### *Joint Venture Agreement*

In August 2020, Cumberland entered into an agreement with WinHealth Investment (Singapore) Ltd creating *WHC Biopharmaceuticals, Pte. Ltd.* The joint venture, as a limited liability company, will focus on acquiring, developing, registering, and commercializing development stage and commercial stage biopharmaceuticals for China, Hong Kong and other Asian markets. The agreement provides for initial investment from WinHealth in the form of a \$0.2 million equity contribution and an initial investment from Cumberland in the form of a \$0.2 million convertible note, which was funded during the first quarter of 2021. The joint venture will seek additional future capital from additional investors and has entered into exclusive option agreements to license product candidates from both Cumberland Pharmaceuticals Inc. and Cumberland Emerging Technologies Inc.

### **(7) INCOME TAXES**

As of September 30, 2023, the Company has approximately \$53.2 million in federal net operating loss carryforwards including approximately \$44.1 million of net operating loss carryforwards resulting from the exercise of nonqualified stock options. These have historically been used to significantly offset income tax obligations. The Company expects it will continue to pay minimal income taxes during 2023 and beyond, through the continued utilization of these net operating loss carryforwards, on any taxable income generated from our operations.

### **(8) OTHER INCOME**

Cumberland recorded a total of \$3.7 million as other income in the first nine months of 2023. In March 2023, the Company was granted a barrier-to-innovation waiver from the FDA for certain fiscal year 2022 prescription drug fees resulting in a refund of \$1.8 million. In June 2023, the Company was granted another waiver from the FDA for the fiscal year 2023 fees in the amount of \$1.0 million. Both of these refunds were paid by the FDA in second quarter of 2023. In the third quarter of 2023, the Company recorded a \$0.5 million settlement relating to a manufacturing dispute as well as life insurance proceeds of \$0.3 million.

### **(9) COLLABORATIVE AGREEMENTS**

Cumberland is a party to several collaborative arrangements with research institutions to identify and pursue promising pharmaceutical product candidates. The funding for these programs is primarily provided through Federal Small Business Administration (SBIR/STTR) and other grant awards. The Company has determined that these collaborative agreements, with the exception of the collaborative payment received related to RediTrex, do not meet the criteria for accounting under ASC Topic 808, *Collaborative Agreements*. The agreements do not specifically designate each party's rights and obligations to each other under the collaborative arrangements. Except for patent defense costs, expenses incurred by one party are not required to be reimbursed by the other party. Expenses incurred under these collaborative agreements are included in research and development expenses and funding received from grants are recorded as net revenues in the condensed consolidated statements of operations.

### **(10) COMMITMENTS AND CONTINGENCIES**

The company is involved in litigation arising in the normal course of business. The Company does not believe that the disposition or ultimate resolution of existing claims or lawsuits will have a material adverse effect on the business or financial condition of the Company.

## (11) PRODUCT ACQUISITIONS AND RETURN OF PRODUCT RIGHTS

### *Vibativ*

During November 2018, the Company executed an agreement with Theravance Biopharma ("Theravance") to acquire the assets and global rights to Vibativ including responsibility for the marketing, distribution, manufacturing and regulatory activities associated with the brand. Vibativ is a patented, FDA approved injectable anti-infective for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia and complicated skin and skin structure infections. It addresses a range of Gram-positive bacterial pathogens, including those that are considered difficult-to-treat and multidrug-resistant.

Cumberland accounted for the transaction as a business combination in accordance with ASC 805 and the product sales are included in the results of operations subsequent to the acquisition date. The Company made an upfront payment of \$20 million at the closing of the transaction and a \$5 million milestone payment in early April 2019. In addition, Cumberland has agreed to pay royalties of up to 20% of on-going net sales of the product in the U.S. after a \$2.5 million threshold is met. The future royalty payments were recognized at their acquisition-date fair value as a contingent consideration liability, as part of the contingent consideration transferred in the business combination. Cumberland prepared the valuations of the contingent consideration liability utilizing significant unobservable inputs. As a result, the valuation is classified as Level 3 fair value measurement.

The following table presents the changes in the fair value of the contingent consideration liability that is remeasured on a recurring basis. The contingent consideration earned and accrued in operating expenses is paid to Theravance quarterly.

Balance at December 31, 2022	\$	4,154,823
Cash payment of royalty during the period		(537,623)
Change in fair value of contingent consideration included in operating expenses		(127,310)
Contingent consideration earned and accrued in operating expenses		762,405
Balance at September 30, 2023	\$	4,252,295

The contingent consideration liability of \$4.3 million was accounted for as \$1.8 million of other current liabilities and \$2.5 million of other long-term liabilities on the condensed consolidated balance sheet as of September 30, 2023.

### *Sancuso*

On January 3, 2022, Cumberland acquired the U.S. rights to the FDA-approved oncology-supportive care medicine Sancuso from Kyowa Kirin, Inc. ("Kyowa Kirin"), the U.S. affiliate of Japan-based Kyowa Kirin Co., Ltd.

Sancuso is the first and only FDA-approved prescription patch for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment. The active drug in Sancuso, granisetron, slowly dissolves in the thin layer of adhesive that sticks to the patient's skin and is released into their bloodstream over several days, working continuously to prevent chemotherapy-induced nausea and vomiting ("CINV"). It is applied 24 to 48 hours before receiving chemotherapy and can prevent CINV for up to five consecutive days. Alternative oral treatments must be taken several times (day and night) to deliver the same therapeutic doses.

Cumberland acquired U.S. rights to Sancuso and assumed full commercial responsibility for the product in the U.S. – including its marketing, promotion, distribution, manufacturing and medical support activities. The product's FDA registration was subsequently transferred from Kyowa Kirin to Cumberland in August 2023.

Cumberland has also accounted for this transaction as a business combination in accordance with ASC 805 and the product sales are included in the results of operations subsequent to the acquisition date. The Company made an upfront payment of \$13.5 million at the closing of the transaction. The agreement called for milestone payments of up to \$3.5 million based on the attainment of various approvals and sales performance. In March 2023, Cumberland made a \$1.0 million milestone payment to Kwoya Kirin based on the FDA approval of a manufacturing site for the product. In October 2023, Cumberland made a \$0.5 million milestone payment based on the successful transfer of the product's FDA registration from Kyowa Kirin to Cumberland.

The remaining \$2 million in milestones are tied to achievement of certain annual sales levels for the product.

In addition, Cumberland has agreed to pay a royalty of up to 10% of on-going net sales of Sancuso. The future royalty payments were required to be recognized at their acquisition-date fair value as a contingent consideration liability, as part of the contingent consideration transferred in the business combination. Cumberland has prepared a valuation of the contingent consideration liability utilizing significant unobservable inputs. As a result, the valuation is classified as Level 3 fair value measurement.

The acquisition was funded by cash and the Company's revolving credit facility. The fair value for the assets and liabilities assumed were as follows: prepaid expenses of \$1.8 million, inventory of \$2.6 million, goodwill of \$0.03 million, intangible assets of \$14.1 million, milestone payable of \$1.7 million and contingent liability of \$3.4 million.

The following table presents the changes in the fair value of the contingent consideration liability that is remeasured on a recurring basis.

Balance at December 31, 2022	\$	4,757,000
Cash payment of milestones and royalty during the period		(1,571,310)
Change in fair value of contingent consideration included in operating expenses		(890,402)
Contingent consideration earned and accrued in operating expenses		545,712
Balance at September 30, 2023	\$	<u>2,841,000</u>

The contingent consideration liability earned and accrued in operating expenses is paid to Kyowa Kirin quarterly. The contingent consideration liability of \$2.8 million was accounted for as \$1.8 million of current liabilities and \$1.1 million of other long-term liabilities on the condensed consolidated balance sheet as of September 30, 2023.

#### *RediTrex*

In November 2016, the Company announced an agreement with the Nordic Group B.V. ("Nordic") to acquire the exclusive U.S. rights to Nordic's injectable methotrexate product line designed for the treatment of active rheumatoid arthritis, juvenile idiopathic arthritis, severe psoriatic arthritis and severe disabling psoriasis.

As consideration for the license, Cumberland paid a deposit of \$100,000 at closing. The Company then provided \$0.9 million in consideration through a grant of 180,000 restricted shares of Cumberland common stock to be vested upon the FDA approval of the first Nordic product. Cumberland also agreed to provide Nordic a series of payments tied to the products' FDA approval, launch and achievement of certain sales milestones. Under the terms of the agreement, Cumberland was responsible for the product registration and commercialization in the U.S., while Nordic was responsible for product manufacturing and supply.

On November 27, 2019, Cumberland received FDA approval for the first Nordic injectable product line and authorization to market them under the RediTrex brand name. The 180,000 shares of restricted Cumberland common stock previously provided to Nordic vested upon approval and were valued at \$0.9 million on the vesting date. The FDA approval also resulted in a \$1.0 million milestone payment due to Nordic. During December 2020, Cumberland introduced RediTrex and the launch that took place in late 2021 resulting in a \$1.0 million milestone payment due to Nordic.

However, Cumberland encountered difficulties in introducing RediTrex to a new customer base and in achieving the needed managed care coverage due to market conditions during the pandemic. On July 12, 2022, the Company entered into an amendment to the agreement with Nordic returning all rights to them including the trademark and market authorization effective June 30, 2023. Cumberland then continued to distribute and support the product through June 30, 2023. In accordance with the terms of the amendment, Nordic has returned the 180,000 restricted Cumberland shares previously issued to Nordic, which were cancelled, refunded to Cumberland the milestone payment of \$1.0 million associated with the brand's U.S. approval and issued a credit note in favor of the Company in the amount of \$1.0 million for the unpaid milestone payment associated with the launch of the product line. The companies have cooperated on the transition and Cumberland will receive a long-term royalty on any Nordic sales of the product.



## **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations**

### *Disclosure regarding forward-looking statements*

The following discussion contains certain forward-looking statements which reflect management’s current views of future events and operations. These statements involve certain risks and uncertainties, and actual results may differ materially from them. Forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Actual results may differ significantly from the results discussed in these forward-looking statements. Some important factors which may cause results to differ from expectations include: availability of additional debt and equity capital; market conditions at the time additional capital is required; our ability to continue to acquire branded products; product sales; management of our growth and integration of our acquisitions and generally unpredictable conditions in national and international markets. While forward-looking statements reflect our beliefs and best judgment based upon current information, they are not guarantees of future performance. Other important factors that may cause actual results to differ materially from forward-looking statements are discussed in the sections entitled “Risk Factors” and “Special Note Regarding Forward-Looking Statements” of our Annual Report on Form 10-K for the year ended December 31, 2022, and our other filings with the SEC. We do not undertake to publicly update or revise any of our forward-looking statements, even in the event that experience or future changes indicate that the anticipated results will not be realized. The following presentation of management’s discussion and analysis of financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this report on Form 10-Q.

## OVERVIEW

### Our Business

Cumberland Pharmaceuticals Inc. (“Cumberland,” the “Company,” or as used in the context of “we,” “us,” or “our”), is a specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription pharmaceutical products. We are dedicated to our mission of working together to provide unique products that improve the quality of patient care.

Our primary markets are hospital acute care, gastroenterology and oncology. These medical specialties are characterized by relatively concentrated prescriber bases that we believe can be served effectively by small, targeted sales forces. We promote our approved products through our hospital, oncology and field sales forces in the United States. We have also established international partnerships and are continuing to build a network of companies outside the U.S. to register and provide our medicines to patients in their countries.

Our portfolio of FDA approved brands includes:

- **Acetadote**<sup>®</sup> (*acetylcysteine*) injection, for the treatment of acetaminophen poisoning;
- **Caldolor**<sup>®</sup> (*ibuprofen*) injection, for the treatment of pain and fever;
- **Kristalose**<sup>®</sup> (*lactulose*) for oral solution, a prescription laxative, for the treatment of constipation;
- **Omeclamox**<sup>®</sup>-**Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of *Helicobacter pylori* (*H. pylori*) infection and related duodenal ulcer disease;
- **Sancuso**<sup>®</sup> (*granisetron*) transdermal system, for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment;
- **Vaprisol**<sup>®</sup> (*conivaptan*) injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia; and
- **Vibativ**<sup>®</sup> (*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.

In addition to these commercial brands, we have Phase II clinical programs underway evaluating our ifetroban product candidates for patients with cardiomyopathy associated with 1) Duchenne Muscular Dystrophy (“DMD”), a fatal, genetic neuromuscular disease and 2) Systemic Sclerosis (“SSc”) or scleroderma, a debilitating autoimmune disorder characterized by fibrosis of the skin and internal organs. In June 2023, we received FDA clearance to proceed directly to a Phase II study for patients with Idiopathic Pulmonary Fibrosis, the most common form of progressive fibrosing interstitial lung disease. We are now entering into agreements with medical centers around the country and look forward to initiating the trial.

Cumberland has built core competencies in the acquisition, development and commercialization of pharmaceutical products in the U.S. – and we believe we can leverage this existing infrastructure to support our continued growth both domestically and internationally. Our management team consists of pharmaceutical industry veterans with experience in business development, product development, regulatory, manufacturing, sales, marketing and finance.

Our business development team identifies, evaluates, and negotiates product acquisition, licensing and co-promotion agreements. Our product development team creates proprietary formulations, manages our clinical studies, prepares our FDA submissions and staffs our medical call center. Our quality and manufacturing professionals oversee the manufacturing, release and shipment of our products. Our marketing and sales organization is responsible for our commercial activities, and we work closely with our distribution partners to ensure the availability and delivery of our products.

## GROWTH STRATEGY

Cumberland's growth strategy involves maximizing the success of our existing brands while continuing to add differentiated products. We have built our portfolio of FDA approved products through both development and acquisition. We are also continuing to establish international partnerships to bring our medicines to patients in other countries. Additionally, we look for opportunities to expand our products into new patient populations through clinical trials, improved presentations and our support of select, investigator-initiated studies. We actively pursue opportunities to acquire additional marketed products, as well as late-stage development product candidates in our target medical specialties. Our clinical team is developing a pipeline of new product candidates to address poorly met medical needs.

We are supplementing these activities with the earlier-stage drug development at Cumberland Emerging Technologies ("CET"), our majority-owned subsidiary. CET partners with academic research institutions to identify and support the progress of promising new product candidates, which Cumberland could further develop and commercialize.

Specifically, we are seeking long-term sustainable growth by:

- **Supporting and expanding the use of our marketed products.** We continue to evaluate our products following their FDA approval to determine if additional clinical data could expand their market and use. For example, we have secured pediatric approval of Acetadote and Caldolor and expanded the labeling for both brands accordingly. We also added pre-surgery dosing for Caldolor, and recently included newborns to the patients who can benefit from the product. We will continue to explore such opportunities to bring our products to new patient populations.
- **Selectively adding complementary brands.** In addition to our product development activities, we are also seeking to acquire products or late-stage development product candidates to continue to build a portfolio of complementary brands. We focus on under-promoted, FDA-approved drugs as well as late-stage development products that can improve patient care. We will continue to target product acquisition candidates that are competitively differentiated, have valuable intellectual property or other protective features, and allow us to leverage our existing infrastructure. Our acquisitions of Vibativ and Sancuso are examples of the implementation of this strategy.
- **Progressing our clinical pipeline and incubating future product opportunities at CET.** We believe it is important to build a pipeline of innovative new product opportunities, as we are doing through our ifetroban Phase II development programs. We are also supplementing our acquisitions and late-stage development activities with early-stage drug development activities with CET.
- **Leveraging our infrastructure through co-promotion partnerships.** We believe that our commercial infrastructure can help drive prescription volume and product sales. We look for strategic partners that can complement our capabilities and enhance opportunities for our brands. For example, our co-promotion partnerships have allowed us to expand the support for Kristalose across the U.S.
- **Building an international contribution to our business.** We have established our own commercial capabilities, including three sales divisions, to cover the U.S. market for our products. We are also building a network of select international partners to register our products and make them available to patients in their countries. We will continue to develop and expand our network of international partners while supporting our partners' registration and commercialization efforts in their respective territories. The acquisition of Vibativ resulted in several new international partners and market opportunities.
- **Managing our operations with financial discipline.** We continually work to manage our expenses in line with our revenues to deliver positive cash flow from operations. We remain in a strong financial position, with favorable gross margins and a strong balance sheet.

## RECENT DEVELOPMENTS

### New Vibativ Pediatric Study Publication

In October 2023, we announced a new publication in *Antimicrobial Agents and Chemotherapy* detailing the results of the first clinical study investigating the safety and pharmacokinetics of our Vibativ injection in children 2 to 17 years of age. Vibativ is an intravenous antibiotic approved by the FDA for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia as well as complicated skin and skin structure infections caused by certain gram-positive bacteria in adults. This is the first reported study evaluating Vibativ in pediatric patients.

Antimicrobial resistance poses a significant challenge in the treatment of bacterial infections, necessitating the development of new antibiotic therapies. The results of this study suggest that a single dose of Vibativ is safe in children and they experience reduced exposure to Vibativ, compared with the same body weight-based dosing in adults.

### New Bank Credit Facility

On September 5, 2023, Cumberland entered into a new Revolving Credit Loan Agreement with Pinnacle Bank for a three-year term. The agreement provides for an aggregate principal funding amount of up to \$25 million. It provides an initial revolving credit line with \$20 million of availability, and the ability of Cumberland to increase the amount to \$25 million under certain conditions. The interest rate is based on Benchmark (Term SOFR), plus a spread of 2.75%, and is subject to one financial covenant, the maintenance of a Funded Debt Ratio, determined on a quarterly basis.

### Federal NOPAIN Act

We announced in April 2023 that we expect that our Caldolor injection product will be eligible for special Medicare reimbursement under the *Non-Opioids Prevent Addiction in the Nation Act* (the “NOPAIN Act”), which was enacted as part of the Consolidated Appropriations Act of 2023.

The NOPAIN Act requires Medicare to provide separate reimbursement for non-opioid products that are used to manage pain during surgeries conducted in hospital outpatient departments or in ambulatory surgical centers. The NOPAIN Act applies, in part, to products that are indicated to provide analgesia without acting upon the body’s opioid receptors. As a result, we expect that the NOPAIN Act will affect Medicare reimbursement for Caldolor, our non-opioid analgesic injection product.

The reimbursement for non-opioid pain alternatives under the NOPAIN Act will apply to those products that are furnished between January 1, 2025 and January 1, 2028. It is anticipated that in 2024, the Centers for Medicare & Medicaid Services (CMS) will issue regulations implementing the NOPAIN Act and detailing the conditions for, and amount of, the separate reimbursement.

In the *Medicare Hospital Outpatient Prospective Payment System Proposed Rule*, the CMS requested that manufacturers with potentially applicable non-opioid products submit comments and supporting clinical evidence regarding products that should be eligible for separate payment. We submitted a comment letter along with the requisite clinical information to the CMS in September 2023 explaining why Caldolor should be included and separately reimbursed.

Caldolor is approved by the FDA for use in adults and pediatric patients 3 months and older for the management of mild to moderate pain as a sole therapy, and for the management of moderate to severe pain as an adjunct to an opioid. A series of published clinical studies have demonstrated that Caldolor significantly reduces patient pain, while also significantly reducing patients’ need for opioids.

## **Ifetroban Clinical Studies**

We have been evaluating our ifetroban product candidate, a selective thromboxane-prostanoid receptor antagonist, in a series of clinical studies. It has been dosed in nearly 1,400 subjects and has been found to be safe and well tolerated in healthy volunteers and various patient populations. Patient enrollment is well underway in two company sponsored Phase II clinical programs to evaluate ifetroban in Systemic Sclerosis or scleroderma, a debilitating autoimmune disorder characterized by diffuse fibrosis of the skin and internal organs; and the Cardiomyopathy associated with Duchenne Muscular Dystrophy (“DMD”), a rare and fatal genetic neuromuscular disease that results in deterioration of the skeletal, heart and lung muscles.

Cumberland is sponsoring the FIGHT DMD™ trial, a multicenter, randomized, placebo-controlled Phase II study evaluating the safety, pharmacokinetics and efficacy of two doses of oral ifetroban for the treatment of the cardiomyopathy associated DMD. The trial is evaluating 12 months of oral ifetroban in 24 subjects with early-stage cardiomyopathy and 24 subjects with advanced-stage heart disease across 10 U.S. centers that specialize in DMD cardiomyopathy. The safety and efficacy endpoints include left ventricular ejection fraction using cardiac MRI, pulmonary function, quantitative muscle strength, daily activity and quality of life measures.

The FDA Orphan Product Division awarded Cumberland \$1 million in funding under its Orphan Products Grants Program to support this trial. This was the first DMD trial awarded such funding.

In June 2023, we presented results from an interim analysis for the FIGHT DMD™ trial at the 29th annual *Parent Project Muscular Dystrophy Conference* in Dallas, Texas. The interim analysis was conducted on data from 25 patients with DMD who completed six of the 12 total months of treatment and assessments. Both doses of ifetroban were reported well tolerated in DMD participants ages 7 years of age or older. There was also a positive trend in leg muscle strength, but no statistically significant differences have been identified at this point.

In May 2023, we announced that the FDA has cleared the Investigational New Drug Application for a Phase II study in patients with Idiopathic Pulmonary Fibrosis (“IPF”), the most common form of progressive fibrosing interstitial lung disease. As a result, we are initiating our FIGHTING FIBROSIS trial designed to enroll 128 patients in over 20 medical centers of excellence across the U.S. This Phase II clinical trial will study the safety, tolerability and efficacy of oral ifetroban in patients with IPF. Recent studies have shown ifetroban can both prevent and enhance resolution of lung fibrosis in multiple preclinical models.

We have also completed Phase II clinical programs with ifetroban in patients with Hepatorenal Syndrome, Portal Hypertension and Aspirin Exasperated Respiratory Disease. Additional preclinical and pilot clinical studies of ifetroban are underway, including several investigator-initiated trials.

Our plan going forward is to complete each of our Company-sponsored studies, analyze their final data, announce top-line results and decide on the best development path for the registration of ifetroban, which we continue to believe has the potential to benefit many patients with orphan diseases that represent unmet medical needs.

## **Sancuso Acquisition and Approval of New Manufacturing Plant**

In early 2022, Cumberland acquired the U.S. rights to the FDA-approved oncology-supportive care medicine Sancuso from Kyowa Kirin, Inc., the U.S. affiliate of Japan-based Kyowa Kirin Co., Ltd. Sancuso is the first and only FDA-approved prescription patch for the prevention of nausea and vomiting in patients receiving certain types of chemotherapy treatment. We assumed commercial responsibility for the product in the U.S. – including its marketing, promotion, distribution, manufacturing and medical support activities – early last year and, as of September 2023, have fully completed the transition of Sancuso to Cumberland. In late 2022, the FDA approved moving the product’s manufacturer to a new facility, and the production of supplies for Cumberland at that plant is planned for the fourth quarter of 2023.

In June 2023, we launched an expanded oncology sales division comprised of both field-based and inside sales personnel to feature the product.

## **International Agreements**

During the third quarter of 2022, we signed a new agreement with PiSA Pharmaceutical (“PiSA”) for the exclusive supply and distribution of our ibuprofen injection product in Mexico. Cumberland will be responsible for sharing the U.S. dossier and providing product supply, while PiSA will be responsible for obtaining the regulatory approval and then commercializing the product in Mexico. PiSA expects to provide the product in both 400- and 800-milligram vials.

Meanwhile, we continue to support our international partners in their efforts to register our Vibativ brand in their countries.

In late 2022, we announced a new partnership with Saudi Arabia-based Tabuk Pharmaceutical to introduce Vibativ into the Middle East. The arrangement provides Tabuk exclusive rights to distribute Vibativ in Saudi Arabia and Jordan, with the option to expand into other countries in the region. Tabuk is in the process of updating the Vibativ registration in Saudi Arabia with new manufacturing information as they also prepare for the launch in that country.

Also in 2022, we entered into an agreement with D.B. Pharm to register and commercialize our Vibativ product in South Korea. D.B. Pharm also distributes our Caldolor product in South Korea. They filed for the approval of Vibativ in November 2022 and we have been supporting their efforts through the review process of their application there.

Meanwhile, our Vibativ partner for the Chinese market, SciClone Pharmaceuticals, had their approval application in China accepted for review in September 2021. We have since been supporting SciClone and their requests associated with the review of that submission. They are working toward the approval and believe that there is significant potential for Vibativ in their country.

## **Vaprisol Supply Update**

Demand for our Vaprisol product increased in 2020 during the pandemic, and we worked to support the expanded use of the product in hospitals and clinics during the health care crisis. During 2021, we shipped all remaining inventory of the product and notified the FDA that supplies of the product are not currently available. We have since transferred the manufacturing of the product to a new facility. Our new manufacturing partner, Nephron Pharmaceuticals (“Nephron”), is working with the FDA to address several Form 483 and warning letter issues in a timely manner.

Meanwhile, we are working with Nephron to provide interim supplies of a special compounded conivaptan product to the market in support of critically ill patients. The companies will share in the sales of this compounded product, which is expected to be manufactured and released in the fourth quarter of 2023. We then expect to file for the approval to manufacture branded Vaprisol once all FDA issues at the Nephron site are resolved.

## **SEC Settlement**

On September 27, 2023, the U.S. Securities and Exchange Commission (the “SEC”) finalized the settlement of an administrative proceeding involving certain instances where some directors and officers of the Company were late in filing public reports regarding changes in their stock ownership pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and that the Company did not make the needed disclosure concerning these late filings in its Annual Report on Form 10-K as outlined in Item 405 of Regulation S-K. Without admitting or denying the allegations, the Company agreed to pay a \$200,000 civil penalty to the SEC and to commit to the timely filing of such needed disclosures in the future. The Company does not expect this matter to materially impact its business or operations.

## **Omeclamox-Pak Supply Update**

The packager for Omeclamox-Pak encountered financial difficulties in 2020 due to the impact of the COVID-19 pandemic, and their operations were suspended. As a result, we depleted our inventory of the product and notified the FDA that it is currently unavailable. We are awaiting availability of those operations, while also exploring other alternatives to restart the product’s packaging.

## **Summary**

We remain committed to our mission of working together to provide unique products that improve the quality of patient care.

To fulfill this mission we are building a portfolio of innovative and differentiated products through a multifaceted strategy that includes the development of new candidates as well as the acquisition of established brands. Our resulting, diversified product line has enabled us to weather external challenges while our team remains responsive to the evolving market. We are prepared for and look forward to future opportunities to carry out our mission throughout the remainder of the year.

## **CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES**

Please see a discussion of our critical accounting policies and significant judgments and estimates in Note 1 to the Company's Condensed Consolidated Financial Statements accompanying this report and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2022 Annual Report on Form 10-K.

### **Accounting Estimates and Judgments**

The preparation of condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. We base our estimates on past experience and on other factors we deem reasonable given the circumstances. Past results help form the basis of our judgments about the carrying value of assets and liabilities that cannot be determined from other sources. Actual results could differ from these estimates. The Company's most significant estimates include: (1) its allowances for chargebacks and accruals for rebates and product returns, (2) the allowances for obsolescent or unmarketable inventory and (3) valuation of contingent consideration liabilities associated with business combinations.

## RESULTS OF OPERATIONS

### Three months ended September 30, 2023 compared to the three months ended September 30, 2022

The following table presents the unaudited interim statements of operations for continuing operations for the three months ended September 30, 2023 and 2022:

	Three months ended September 30,		
	2023	2022	Change
Net revenues	\$ 10,085,926	\$ 11,413,072	\$ (1,327,146)
Costs and expenses:			
Cost of products sold	1,765,590	2,224,443	(458,853)
Selling and marketing	4,743,142	4,110,397	632,745
Research and development	1,924,768	1,714,254	210,514
General and administrative	2,343,855	2,166,118	177,737
Amortization	1,175,174	1,486,448	(311,274)
Total costs and expenses	11,952,529	11,701,660	250,869
Operating loss	(1,866,603)	(288,588)	(1,578,015)
Interest income	98,603	21,602	77,001
Other income - settlement	475,000	—	475,000
Other income - insurance proceeds	346,800	—	346,800
Interest expense	(110,081)	(149,340)	39,259
Loss before income taxes	(1,056,281)	(416,326)	(639,955)
Income tax expense	(6,938)	(6,900)	(38)
Net loss	\$ (1,063,219)	\$ (423,226)	\$ (639,993)

The following table summarizes net revenues by product for the periods presented:

Products:	Three months ended September 30,		
	2023	2022	Change
Kristalose	\$ 3,887,476	\$ 3,903,305	\$ (15,829)
Sancuso	1,933,222	3,960,652	(2,027,430)
Vibativ	2,789,579	1,909,750	879,829
Caldolor	1,155,509	921,811	233,698
Acetadote	120,052	99,792	20,260
Vaprisol	—	(436)	436
Omeclamox-Pak	23,288	35,600	(12,312)
RediTrex	(122,556)	85,809	(208,365)
Other revenue	299,356	496,789	(197,433)
Total net revenues	\$ 10,085,926	\$ 11,413,072	\$ (1,327,146)

*Net revenues.* Net revenues for the three months ended September 30, 2023, were \$10.1 million compared to \$11.4 million for the three months ended September 30, 2022. As noted in the table above, net revenue increased during the quarter for three of our marketed products: Vibativ, Caldolor and Acetadote.

Kristalose revenue of \$3.9 million for the third quarter of 2023, ended the quarter at the same level as the prior year period.

Acetadote revenue includes net sales of our Acetadote brand and our share of net sales from our Authorized Generic. During the third quarter of 2023, there was an increase of \$0.02 million in the product's revenue when compared to the prior year period due to an increase in shipments.

There was no Vaprisol revenue for the third quarter of 2023 as Cumberland is currently out of inventory of the product. We await FDA approval on a new manufacturer.



Caldolor revenue was \$1.2 million for the third quarter of 2023, which was \$0.2 million higher than the third quarter of 2022 primarily due to increased international shipments.

Vibativ revenue was \$2.8 million for the three months ended September 30, 2023, an increase of \$0.9 million from the same prior year period. The increase in net revenue of the product was the result of successful implementation of a series of new initiatives in support of the brand as well as a decline in product returns.

Sancuso revenue was \$1.9 million for the third quarter of 2023, compared to \$4.0 million for the third quarter of 2022. The decline resulted primarily from deductions from sales including managed care rebates.

Omeclamox-Pak had no sales for the third quarter of 2023, as Cumberland is currently out of commercial inventory of this product. The packager for our Omeclamox-Pak product encountered financial difficulties in 2020. Net revenue for the three months ended September 30, 2023, reflects sales deduction adjustments.

There were no RediTrex sales in the third quarter of 2023, as Cumberland concluded our distribution of the product effective June 30, 2023. Net revenue for the three months ended September 30, 2023, reflects sales deduction adjustments.

Other revenue was \$0.3 million for the three months ended September 30, 2023, compared to \$0.5 million for the three months ended September 30, 2022.

*Cost of products sold.* Cost of products sold for the third quarter of 2023 and 2022 were \$1.8 million and \$2.2 million, respectively. Cost of products sold, as a percentage of net revenues, were 17.5% during the three months ended September 30, 2023, compared to 19.5% during the three months ended September 30, 2022. The improvement in cost of products sold is primarily due to the availability of new lower cost inventory and less inventory write-downs.

*Selling and marketing.* Selling and marketing expense for the third quarter of 2023 increased \$0.6 million compared to the same period last year. This increase is primarily attributable to the timing of the expenditures.

*Research and development.* Research and development costs for the third quarter of 2023 and 2022 were \$1.9 million and \$1.7 million, respectively. A portion of our research and development costs is variable as we continue to fund the ongoing clinical initiatives associated with our pipeline product candidates. These variable costs depend on the number of active trials, study sites and patients as well as the cost per patient in each of our clinical programs. The larger research and development costs for the third quarter of 2023 resulted from an increase in these study costs.

*General and administrative.* General and administrative expense for the third quarter of 2023 was \$2.3 million compared to \$2.2 million for the same period in 2022. The increase was primarily due to the settlement of an administrative proceeding with the U.S. SEC.

The components of the statements of operations discussed above reflect the following impacts from Vibativ:

<b>Financial Impact of Vibativ</b>	<b>Three months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Net revenue	\$ 2,789,579	\$ 1,909,750
Cost of products sold <sup>(1)</sup>	563,688	1,103,581
Royalty and operating expenses	621,941	(179,303)
Vibativ contribution	\$ 1,603,950	\$ 985,472

<sup>(1)</sup> The Vibativ inventory included in the costs of product sold during the period was acquired and paid for by Cumberland as part of the acquisition of the brand during 2018.

The components of the statements of operations discussed above reflect the following impacts from Sancuso:

<b>Financial Impact of Sancuso</b>	<b>Three months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Net revenue	\$ 1,933,222	\$ 4,060,652
Cost of products sold <sup>(1)</sup>	314,735	388,535
Royalty and operating expenses	792,654	1,024,014
Sancuso contribution	\$ 825,833	\$ 2,648,103

<sup>(1)</sup> The Sancuso inventory included in the costs of product sold during the period was acquired and paid for by Cumberland as part of the acquisition of the brand during 2022.

*Amortization.* Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization for the three months ended September 30, 2023 and 2022, totaled approximately \$1.2 million and \$1.5 million, respectively. The decline in amortization expense resulted from adjustments to the useful life of Sancuso as determined by the valuation of the product in December 2022.

*Income taxes.* Income tax expense for the three months ended September 30, 2023, was comparable to the income tax expense for the three months ended September 30, 2022.

As of September 30, 2023, we had approximately \$53.2 million in federal net operating loss carryforwards including approximately \$44 million of net operating loss carryforwards resulting from the exercise of nonqualified stock options that have historically been used to significantly offset income tax obligations. We expect to continue to pay minimal income taxes during 2023 and beyond, through the continued utilization of these net operating loss carryforwards, on any taxable income generated from our operations.

*Other income.* In the third quarter of 2023, we recognized a gain of \$0.5 million to settle a manufacturing dispute and a \$0.3 million for a payout earned on a company owned insurance policy.

## RESULTS OF OPERATIONS

### Nine months ended September 30, 2023 compared to the nine months ended September 30, 2022

The following table presents the unaudited interim statements of operations for continuing operations for the nine months ended September 30, 2023 and 2022:

	Nine months ended September 30,		
	2023	2022	Change
Net revenues	\$ 30,199,441	\$ 32,887,269	\$ (2,687,828)
Costs and expenses:			
Cost of products sold	4,536,628	6,468,212	(1,931,584)
Selling and marketing	13,692,535	13,281,511	411,024
Research and development	4,569,476	5,283,083	(713,607)
General and administrative	7,212,731	6,672,442	540,289
Amortization	3,563,493	4,609,146	(1,045,653)
Total costs and expenses	33,574,863	36,314,394	(2,739,531)
Operating loss	(3,375,422)	(3,427,125)	51,703
Interest income	205,854	52,709	153,145
Other income	2,828,871	—	2,828,871
Other income - settlement	475,000	—	475,000
Other income - insurance proceeds	346,800	611,330	(264,530)
Interest expense	(489,069)	(406,539)	(82,530)
Loss before income taxes	(7,966)	(3,169,625)	3,161,659
Income tax expense	(20,813)	(20,700)	(113)
Net loss	\$ (28,779)	\$ (3,190,325)	\$ 3,161,546

The following table summarizes net revenues by product for the periods presented:

Products:	Nine months ended September 30,		
	2023	2022	Change
Kristalose	\$ 12,313,321	\$ 11,418,673	\$ 894,648
Sancuso	5,736,981	10,756,411	(5,019,430)
Vibativ	6,785,592	6,008,005	777,587
Caldolor	3,316,866	3,075,355	241,511
Vaprisol	39,866	(252,059)	291,925
Acetadote	440,071	337,685	102,386
Omeclamox-Pak	28,832	31,925	(3,093)
RediTrex	(254,108)	238,712	(492,820)
Other revenue	1,792,020	1,272,562	519,458
Total net revenues	\$ 30,199,441	\$ 32,887,269	\$ (2,687,828)

*Net revenues.* Net revenues for the nine months ended September 30, 2023, were \$30.2 million compared to \$32.9 million for the nine months ended September 30, 2022, a decrease of \$2.7 million.

Kristalose revenue was \$12.3 million during the first nine months of 2023, compared to \$11.4 million for the prior year period. Revenue increased due to an overall increase in units shipped during 2023.

Sancuso revenue was \$5.7 million for the nine months ended September 30, 2023, compared to \$10.8 million for the same period last year. The decline resulted primarily from deductions from sales including product returns and managed care rebates.

Vibativ revenue was \$6.8 million for the nine months ended September 30, 2023, compared to \$6.0 million for the same period last year. The increase in net revenue of the product was the result of successful implementation of a series of new initiatives in support of the brand as well as a decline in product returns.

There was no Vaprisol revenue for the first nine months of 2023 as Cumberland is currently out of commercial inventory of the product. Net revenue was positively impacted by various sales adjustments.

Omeclamox-Pak had no sales for the nine months ended September 30, 2023, as Cumberland is currently out of commercial inventory of this product. The packager for our Omeclamox-Pak product encountered financial difficulties and currently is under new management and a reorganization.

Acetadote revenue includes net sales of our Acetadote brand and our share of net sales from our Authorized Generic. There was a \$0.1 million increase in the product's revenue for the nine months ended September 30, 2023, when compared to the prior year period as a result of a decrease in product returns in 2023.

Caldolor revenue was \$3.3 million for the first three quarters of 2023, a \$0.2 million increase over 2022. Higher international revenue is driving the increase.

Other revenue was \$1.8 million for the nine months ended September 30, 2023, representing a \$0.5 million increase from the same period in 2022, as a result of two milestone payments recognized in 2023.

*Cost of products sold.* Cost of products sold for the first nine months of 2023 were \$4.5 million, a decrease of \$1.9 million compared to the same period last year due to the availability of new lower cost inventory and fewer inventory write downs.

*Selling and marketing.* Selling and marketing expense for the nine months ended September 30, 2023, increased \$0.4 million compared to the prior year period. This increase is primarily attributable to the timing of the expenditures.

*Research and development.* Research and development costs were \$4.6 million for the first nine months of 2023 compared to \$5.3 million for the same period last year. The primary reason for this decline is \$0.7 million in reduced FDA fees. A portion of our research and development costs is variable as we continue to fund the ongoing clinical initiatives associated with our pipeline product candidates. These variable costs depend on the number of active trials, study sites and patients as well as the cost per patient in each of our clinical programs.

*General and administrative.* General and administrative expense for the nine months ended September 30, 2023, increased to \$7.2 million compared to \$6.7 million during the nine months ended September 30, 2022. In 2023, we experienced an increase in deferred compensation, hiring expenses and the settlement of an administrative proceeding with the U.S. SEC.

The components of the statements of operations discussed above reflect the following impacts from Vibativ:

**Financial Impact of Vibativ**

	<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Net revenue <sup>(1)</sup>	\$ 7,785,592	\$ 6,158,005
Cost of products sold <sup>(2)</sup>	1,081,001	2,433,061
Royalty and operating expenses	1,738,568	484,057
Vibativ contribution	<u>\$ 4,966,023</u>	<u>\$ 3,240,887</u>

<sup>(1)</sup> 2023 net revenue includes a \$1,000,000 payment to Cumberland related to a settlement agreement of milestone payments.

<sup>(2)</sup> The Vibativ inventory included in the costs of product sold during the period was acquired and paid for by Cumberland as part of the acquisition of the brand during 2018.

**Financial Impact of Vibativ**

	<b>Since Acquisition</b>
Net revenue <sup>(1)</sup>	\$ 51,544,077
Cost of products sold <sup>(2)</sup>	16,806,108
Royalty and operating expenses	8,275,758
Vibativ contribution	<u>\$ 26,462,211</u>

<sup>(1)</sup> Net revenue includes a \$1,000,000 payment to Cumberland related to a settlement agreement of milestone payments.

<sup>(2)</sup> The Vibativ inventory included in the costs of product sold during the period was acquired and paid for by Cumberland as part of the acquisition of the brand during 2018.

The components of the statements of operations discussed above reflect the following impacts from Sancuso:

**Financial Impact of Sancuso**

	<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
Net revenue	\$ 5,736,981	\$ 11,106,411
Cost of products sold <sup>(1)</sup>	886,041	1,134,670
Royalty and operating expenses	2,183,209	3,135,140
Sancuso contribution	\$ 2,667,731	\$ 6,836,601

<sup>(1)</sup> The Sancuso inventory included in the costs of product sold during the period was acquired and paid for by Cumberland as part of the acquisition of the brand during 2022.

**Financial Impact of Sancuso**

	<b>Since Acquisition</b>
Net revenue	\$ 19,292,584
Cost of products sold <sup>(1)</sup>	2,429,641
Royalty and operating expenses	6,385,235
Sancuso contribution	\$ 10,477,708

<sup>(1)</sup> The Sancuso inventory included in the costs of product sold during the period was acquired and paid for by Cumberland as part of the acquisition of the brand during 2022.

**Amortization.** Amortization expense is the ratable use of our capitalized intangible assets including product and license rights, patents, trademarks and patent defense costs. Amortization for the nine months ended September 30, 2023, and nine months ended September 30, 2022, totaled approximately \$3.6 million and \$4.6 million, respectively. The decrease was attributable to the valuation of the Sancuso acquisition completed in December 2022.

**Income taxes.** Income tax expense for the nine months ended September 30, 2023, was \$0.02 million, similar to the income tax expense recognized for the nine months ended September 30, 2022.

**Other income.** In 2023, we recognized a \$2.8 million refund of FDA fees for the periods of 2022 and 2023 to further the development of our new product candidates. We recognized a gain of \$0.5 million in the third quarter of 2023 associated with a manufacturing dispute settlement as well as expected proceeds of \$0.3 million for a payout associated with a company owned insurance policy.

## LIQUIDITY AND CAPITAL RESOURCES

### Working Capital

Our primary sources of liquidity are cash equivalents, cash flows from operations and the amounts borrowed under our line of credit. We believe that our internally generated cash flows, existing working capital and our line of credit will be adequate to finance internal growth, finance business development initiatives, and fund capital expenditures for the foreseeable future.

The following table summarizes our liquidity and working capital as of September 30, 2023 and December 31, 2022:

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
Cash and cash equivalents	\$ 18,507,965	\$ 19,757,970
Working capital (current assets less current liabilities)	\$ 14,441,527	\$ 17,290,378
Current ratio (multiple of current assets to current liabilities)	1.5	1.6
Revolving line of credit availability	<u>\$ 7,076,875</u>	<u>\$ 3,800,000</u>

The following table summarizes our net changes in cash and cash equivalents for the nine months ended September 30, 2023 and September 30, 2022:

	<u>Nine months ended September 30,</u>	
	<u>2023</u>	<u>2022</u>
Net cash provided by (used in):		
Operating activities	\$ 5,053,700	\$ 4,815,365
Investing activities	(366,334)	(13,033,684)
Financing activities	(5,937,371)	719,041
Net increase (decrease) in cash and cash equivalents	<u>\$ (1,250,005)</u>	<u>\$ (7,499,278)</u>

The net \$1.3 million decrease in cash and cash equivalents for the nine months ended September 30, 2023, was primarily attributable to cash used in investing and financing activities partially offset by cash provided by operating activities.

Cash provided by operating activities totaled \$5.1 million for the nine months ended September 30, 2023, primarily the result of the add backs of non-cash expenses including depreciation, amortization and share-based compensation expense totaling \$4.0 million. It also resulted from a decrease of accounts receivable of \$0.9 million, a decrease in inventory of \$0.4 million and an increase of net accounts payable and other current liabilities of \$1.9 million. It was partially offset by a decrease in non-cash contingent consideration of \$1.0 million, an increase in other assets of \$0.4 million and a decrease of \$0.3 million in other long-term liabilities.

Cash used in investing activities of \$0.4 million for the nine months ended September 30, 2023, was the result of additions to property and equipment and intangibles.

Financing activities use of cash totaled \$5.9 million for the nine months ended September 30, 2023, and included the repayments on our line of credit of \$3.3 million, the \$0.6 million in cash used to repurchase shares of our common stock and the \$2.1 million used for the payment of a Sancuso milestone, plus royalties on sales of Vibativ and Sancuso.

The \$7.5 million decrease in cash and cash equivalents for the nine months ending September 30, 2022, was primarily attributable to cash used in investing and partially offset by cash provided by operating and financing activities.

Cash provided by operating activities totaled \$4.8 million for the nine months ending September 30, 2022, primarily the result of the add back of non-cash expenses of depreciation, amortization and share-based compensation expense totaling \$5.1 million. It also resulted from decreases in inventory of \$1.3 million, decrease in other assets of \$4.4 million and increases in accounts payable and other liabilities of \$8.8 million. This was partially offset by accounts receivable increasing by \$8.2 million, mainly from the addition of Sancuso sales, and the decrease in long-term liabilities of \$2.5 million.

Cash used in investing activities for the nine months ending September 30, 2022, was the result of the acquisition of Sancuso.

Our financing activities for the nine months ending September 30, 2022, included the increase in our line of credit of \$2.7 million partially offset by the \$0.9 million in cash used to repurchase shares of our common stock as well as the \$1.1 million used for the payment of royalties for sales of Vibativ and Sancuso.

## **Debt Agreement**

On September 5, 2023, the Company entered into a new Revolving Credit Loan Agreement with Pinnacle Bank. This facility provides for an aggregate principal funding amount of up to \$25 million. The initial revolving line of credit is up to \$20 million, with the ability for Cumberland to increase the amount to \$25 million, under certain conditions. It has a three year term expiring on October 1, 2026. The interest rate is based on Benchmark (Term SOFR) plus a spread of 2.75%. Cumberland is subject to one financial covenant, the maintenance of a Funded Debt Ratio, determined on a quarterly basis. Borrowings under the line of credit are collateralized by substantially all of our assets.

## **OFF-BALANCE SHEET ARRANGEMENTS**

During the nine months ended September 30, 2023 and 2022, we did not engage in any off-balance sheet arrangements.

## **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

### **Interest Rate Risk**

We are exposed to market risk related to changes in interest rates on our cash on deposit in highly-liquid money market accounts and our revolving credit facility. We do not utilize derivative financial instruments or other market risk-sensitive instruments to manage exposure to interest rate changes. The main objective of our cash investment activities is to preserve principal while maximizing interest income through low-risk investments.

We believe that our interest rate risk related to our cash and cash equivalents is not material. The risk related to interest rates for these accounts would produce less income than expected if market interest rates fall. Based on current interest rates, we do not believe we are exposed to significant downside risk related to a change in interest on our money market accounts at September 30, 2023.

The interest rate risk related to borrowings under our line of credit was based on Term SOFR plus an interest rate spread. The pricing under the Pinnacle Agreement provides for an interest rate spread of 1.75% to 2.75% above Term SOFR with a minimum Term SOFR of 0.90%. The applicable interest rate under the Pinnacle Agreement was 8.25% at September 30, 2023. As of September 30, 2023, we had \$12.9 million in borrowings outstanding under our revolving credit facility.

### **Exchange Rate Risk**

While we operate primarily in the United States, we are exposed to foreign currency risk. Currently, we do not utilize financial instruments to hedge exposure to foreign currency fluctuations. We believe our exposure to foreign currency fluctuation is minimal as our purchases in foreign currency have a maximum exposure of 90 days based on invoice terms with a portion of the exposure being limited to 30 days based on the due date of the invoice. Foreign currency exchange gains and losses were immaterial for the nine months ended September 30, 2023 and 2022. Neither a five percent increase nor decrease from current exchange rates would have a material effect on our operating results or financial condition.

## **Item 4. Controls and Procedures**

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

During the three months ended September 30, 2023, there has not been any change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings

Please see discussion of *SEC Settlement* in Part I, Item. 2. Management's Discussion and Analysis of Financial Condition and Results of Operations, which is incorporated herein by reference.

In addition, the information required by this item is incorporated by reference from Part I, Item 1. Financial Statements, Notes to Unaudited Condensed Consolidated Financial Statements, Note 10.

### Item 1A. Risk Factors

In addition to the other information set forth in this quarterly report, an investor should consider the risk factors included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

#### *Our operations are subject to the effects of a rising rate of inflation.*

Inflation rates have increased recently to levels not seen in decades. If our costs, in particular costs related to clinical trial expenses and/or employee-related expenses, were to become subject to significant inflationary pressures, it may adversely impact our business, operating results and financial condition. In addition, the United States Federal Reserve has raised, and is expected to continue to raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience increases in the near future (especially if inflation rates continue to rise) on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with COVID-19, the ongoing conflicts in Eastern Europe and the Middle East, and employee availability and wage increases.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

#### Purchases of Equity Securities

We currently have a share repurchase program to purchase up to \$10 million of our common stock pursuant to Rule 10b-18 of the Exchange Act. In January 2019, our Board of Directors established the current \$10 million repurchase program to replace the prior authorizations for repurchases of our outstanding common stock.

The following table summarizes the activity, by month, during the three months ended September 30, 2023:

Period	Total Number of Shares or Units Purchased, which were also Part of the Publicly Announced Plans or Programs	Average Price Paid per Share (or Unit)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
July	29,132	\$ 1.56	\$ 3,348,711
August	53,518	1.68	3,258,885
September	33,914	1.94	3,192,982
Total	116,564		



## Item 6. Exhibits

No.	Description
10.1	<a href="#"><u>Revolving Credit Loan Agreement, dated as of September 5, 2023, by and between Cumberland Pharmaceuticals Inc. and Pinnacle Bank, incorporated herein by reference to Exhibit 10.1 of the Company's Form 8-K (File No.: 001-33637) as filed with the SEC on September 6, 2023.</u></a>
31.1*	<a href="#"><u>Certification of Chief Executive Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
31.2*	<a href="#"><u>Certification of Chief Financial Officer Pursuant to Rule 13-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
32.1**	<a href="#"><u>Certification of Chief Executive and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
101.INS*	INLINE XBRL INSTANCE DOCUMENT - THE INSTANCE DOCUMENT DOES NOT APPEAR IN THE INTERACTIVE DATA FILE BECAUSE ITS XBRL TAGS ARE EMBEDDED WITHIN THE INLINE XBRL DOCUMENT.
101.SCH*	INLINE XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT
101.CAL*	INLINE XBRL TAXONOMY EXTENSION CALCULATION LINKBASE DOCUMENT
101.DEF*	INLINE XBRL TAXONOMY EXTENSION DEFINITION LINKBASE DOCUMENT
101.LAB*	INLINE XBRL TAXONOMY EXTENSION LABEL LINKBASE DOCUMENT
101.PRE*	INLINE XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE DOCUMENT
104	COVER PAGE INTERACTIVE DATA FILE (FORMATTED AS INLINE XBRL AND CONTAINED IN EXHIBIT 101)

\* Filed herewith.

\*\* Furnished herewith.



**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, A.J. Kazimi, certify that:

1. I have reviewed this Form 10-Q of Cumberland Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 13, 2023 By:

/s/ A.J. Kazimi

A.J. Kazimi

Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, John Hamm, certify that:

1. I have reviewed this Form 10-Q of Cumberland Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 13, 2023 By:

/s/ John Hamm

John Hamm

Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE AND  
CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2023 of Cumberland Pharmaceuticals Inc. (the “Company”), as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, A.J. Kazimi, Chief Executive Officer and John Hamm, Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. section 1350), that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ A. J. Kazimi

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A.J. Kazimi  
Chief Executive Officer

November 13, 2023

/s/ John Hamm

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John Hamm  
Chief Financial Officer

November 13, 2023