



Cumberland Pharmaceuticals Reports 38% Revenue Growth In The First Quarter

May 14, 2019

NASHVILLE, Tenn., May 14, 2019 /PRNewswire/ -- **Cumberland Pharmaceuticals Inc. (NASDAQ: CPIX)**, a specialty pharmaceutical company focused on hospital acute care, gastroenterology, and oncology supportive care today announced first quarter 2019 financial results with net revenues of \$11.9 million, up 38% over the prior year quarter. At the end of the first quarter, Cumberland had \$115 million in total assets, including approximately \$34 million in cash and marketable securities.



QUARTER HIGHLIGHTS:

- Obtained FDA approval of our Next Generation **Caldolor®** product featuring a new patented formulation and improved packaging
- Received notification from the FDA that the Company's new drug application (NDA) for our line of **methotrexate** products is complete and acceptable for filing
- Added new university collaboration to the roster at **Cumberland Emerging Technologies (CET)**
- Completed a company-wide strategic review of products, partners, and organization

"During the first quarter, Cumberland successfully executed on our strategy to drive both revenue growth and profitability while advancing our clinical pipeline," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We will continue our strategy of building a diversified portfolio of brands to deliver long-term value in order to take Cumberland to the next level. Our dedicated staff remains focused every day on our mission of supporting patients through the delivery of high-quality pharmaceutical products."

KEY DEVELOPMENTS:

Methotrexate

On January 18, 2019, the Company received notification from the U.S. Food and Drug Administration (FDA) that the NDA for our new line of methotrexate products is complete and acceptable for filing. Furthermore, the FDA has set September 2019 as the Prescription Drug User Fee (PDUFA) action date for an approval decision. In November 2018, we submitted the NDA for approval from the FDA.

In conjunction with this submission, we remitted payment of \$1.3 million to the FDA for the PDUFA Application Fee associated with this methotrexate product line application. These products are designed to treat adult and pediatric patients with rheumatoid arthritis, as well as adults with psoriasis.

Caldolor

On January 28, 2019, the FDA approved the application of our next generation Caldolor (ibuprofen) injection product. In February 2018, Cumberland completed and filed with the FDA an application for approval. The product features a new, patented formulation in a more convenient to use package. In April 2018, the FDA determined that the application was complete and notified us of their acceptance for review. On August 2, 2018, we received a complete response from the FDA outlining additional quality and nonclinical data needed for the application's approval. On September 26, 2018, the Company submitted an amendment to our application containing additional quality and nonclinical data.

Cumberland Strategic Review

On March 29, 2019, we announced that we had initiated a strategic review of our brands, capabilities and international partners. This review followed our accelerated business development initiative, which delivered a series of transactions over the last thirty-six months. Because of that progress, we felt that it was prudent to take a fresh look at our portfolio, partners, and organization to ensure we have the proper focus and capabilities. As a result:

- In China, the largest market for pharmaceutical products outside the U.S., we have reached an agreement with Hong Kong WinHealth Pharmaceuticals (WinHealth) to assume responsibility for our Acetadote® and Caldolor brands in that market. WinHealth will provide \$2 million in milestone payments and up to an estimated \$290 million in revenue contribution over a ten-year period following the registration of both products in China.
- Meanwhile, we plan to return the U.S. rights to the EthyoI® and Totect® brands later this year in exchange for financial consideration provided over a two-year period. As a result, our hospital product efforts will become focused on our three key acute care products. We are expanding our hospital sales division as well as our field-based medical science team in order to ensure coverage and support for the majority of our acute care business in the U.S.
- We have also been meeting with our other key international partners and expect to announce additional improvements to that network over the remainder of the year.

New CET Collaboration Agreement

At CET, we are working with a select group of academic research institutions located in the mid-south region of the U.S. These relationships enable CET to identify therapeutic compounds addressing poorly met medical needs and partner with university-based researchers to advance their scientific discoveries through pre-clinical development. CET contributes product design and development support services to help our collaborators bridge the gap between discovery and clinical investigation.

In February 2019, CET and the technology transfer organization for the Medical University of South Carolina (MUSC) entered into an agreement, adding to CET's roster of academic collaborations which also includes Vanderbilt University, the University of Mississippi, Louisiana State University, and the University of Tennessee Research Foundation. Under the agreement, CET will evaluate MUSC discoveries, license intellectual property rights to promising technologies, and partner with MUSC research scientists to advance product development toward commercialization.

FINANCIAL RESULTS:

Net Revenue: For the three months ended March 31, 2019, net revenues were \$11.9 million, up 38% from \$8.6 million the prior year period.

Net revenue by product for the three months ended March 31, 2019, included \$3.3 million for Kristalose[®] and \$3.1 million for Ethyol[®]. Net revenue for the Company's other brands included \$2.1 million for Vibativ[®], \$1.3 million for Caldolor[®], \$0.8 million for Acetadote[®] (including the brand and Company's Authorized Generic), and \$0.6 million for our other brands.

Operating Expenses: Total operating expenses for the three months ended March 31, 2019 were \$12.1 million, compared to \$11.0 million during the prior year period. The primary drivers of this increase were the increase in sales, new cost of goods, and amortization expenses associated with the addition of Vibativ.

Earnings: Net income (loss) for the first quarter 2019 was \$(0.1) million or \$(0.00) per diluted share, compared to \$(2.4) million or \$(0.15) a share for the prior year period.

Adjusted Earnings (loss) for the first quarter were \$1.8 million or \$0.11 per diluted share, up from a loss of \$(1.4) million or \$(0.09) per diluted share for the prior year period. The definition and reconciliation of Adjusted Earnings to net income is provided in this release.

Balance Sheet: At March 31, 2019, Cumberland had \$34.3 million in cash and marketable securities, including approximately \$24.6 million in cash and equivalents. Total assets at March 31, 2019 were \$114.6 million. Total liabilities were \$59.4 million, including \$20.0 million outstanding on the Company's revolving line of credit, resulting in Total shareholder's equity of \$55.4 million.

Cumberland also has approximately \$44 million in tax net operating loss carryforwards, resulting from the prior exercise of stock options.

Conference Call and Webcast

A conference call and live Internet webcast will be held on Tuesday, May 14, 2019 at 4:30 p.m. Eastern Time to discuss the Company's first quarter 2019 financial results. To participate in the call, please dial 877-303-1298 (for U.S. callers) or 253-237-1032 (for international callers). A rebroadcast of the teleconference will be available for one week and can be accessed by dialing 855-859-2056 (for U.S. callers) or 404-537-3406 (for international callers). The Conference ID for the rebroadcast is 1692316. The live webcast and rebroadcast can be accessed via Cumberland's website at <http://investor.shareholder.com/cpix/events.cfm>.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the delivery of high-quality prescription brands to improve patient care. The Company develops, acquires and commercializes brands for the hospital acute care, gastroenterology and oncology market segments. These medical specialties are categorized by moderately concentrated prescriber bases that the Company believes can be penetrated effectively by small, targeted sales forces.

The Company's portfolio of FDA approved brands includes:

- **Acetadote[®]** (*acetylcysteine*) Injection, for the treatment of acetaminophen poisoning;
- **Caldolor[®]** (*ibuprofen*) Injection, for the treatment of pain and fever;
- **Kristalose[®]** (*lactulose*) for Oral Solution, a prescription laxative, for the treatment of chronic and acute constipation;
- **Omeclamox[®]-Pak**, (*omeprazole, clarithromycin, amoxicillin*) for the treatment of *Helicobacter pylori* (*H. pylori*) infection and related duodenal ulcer disease;
- **Vaprisol[®]** (*conivaptan*) Injection, to raise serum sodium levels in hospitalized patients with euvolemic and hypervolemic hyponatremia;
- **Ethyol[®]** (*amifostine*) Injection, for the reduction of xerostomia (dry mouth) in patients undergoing post-operative radiation treatment for head and neck cancer and the renal toxicity associated with the administration of cisplatin in patients with advanced ovarian cancer;
- **Totect[®]** (*dexrazoxane hydrochloride*) Injection, for emergency oncology intervention, to treat the toxic effects of anthracycline chemotherapy in case of extravasation (drug leakage from the bloodstream into the tissues); and
- **Vibativ[®]** (*telavancin*) Injection, for the treatment of certain serious bacterial infections including hospital-acquired and ventilator-associated bacterial pneumonia, as well as complicated skin and skin structure infections.

Cumberland's pipeline of product candidates includes:

- **Hepatoren[®]** (*ifetroban*) Injection, a Phase II candidate for the treatment of critically ill patients suffering from liver and

kidney failure associated with hepatorenal syndrome ("HRS");

- **Boxaban**[®] (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of asthma patients with aspirin-exacerbated respiratory disease ("AERD");
- **Vascular**[®] (*ifetroban*) Oral Capsules, a Phase II candidate for the treatment of patients with the systemic sclerosis (SSc) form of autoimmune disease;
- **Portaban**[®] (*ifetroban*) Injection and Oral Capsules, a Phase II candidate for the treatment of patients with portal hypertension associated with liver disease; and
- **RediTrex**[™] (*methotrexate*) Injection, an approval submission candidate for the treatment of active rheumatoid, juvenile idiopathic and severe psoriatic arthritis, as well as disabling psoriasis.

For more information on Cumberland's approved products, including full prescribing and safety information, please visit the individual product websites, links to which can be found on the Company's website www.cumberlandpharma.com.

About Acetadote[®] (acetylcysteine) Injection

Acetadote, administered intravenously within 8 to 10 hours after ingestion of a potentially hepatotoxic quantity of acetaminophen, is indicated to prevent or lessen hepatic injury. Used in the emergency department, Acetadote is approved in the United States to treat overdose of acetaminophen, a common ingredient in many over-the-counter medications. Acetadote[®] is contraindicated in patients with hypersensitivity or previous anaphylactoid reactions to acetylcysteine or any components of the preparation. For full prescribing and safety information, visit www.acetadote.com.

About Caldolor[®] (ibuprofen) Injection

Caldolor is indicated in adults and pediatric patients for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, as well as the reduction of fever. It was the first FDA approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with a history of asthma or other allergic type reactions after taking aspirin or other NSAIDs.

Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. For full prescribing and safety information, including boxed warning, visit www.caldolor.com.

About Kristalose[®] (lactulose) Oral Solution

Kristalose is indicated for the treatment of acute and chronic constipation. It is a unique, proprietary, crystalline form of lactulose, with no restrictions on length of therapy or patient age. Kristalose is contraindicated in patients who require a low-galactose diet. Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically. For full prescribing and safety information, visit www.kristalose.com.

About Omeclamox[®]-Pak (omeprazole, clarithromycin, amoxicillin)

Omeprazole is an antisecretory drug, which works by decreasing the amount of acid the stomach produces. Clarithromycin and amoxicillin are antibacterial drugs, which inhibit the growth of bacteria allowing the stomach lining to heal. Omeclamox-Pak is contraindicated in patients with a history of hypersensitivity to omeprazole, any macrolide antibiotic or penicillin. For full prescribing and safety information, visit www.omeclamox.com.

About Vaprisol[®] (conivaptan hydrochloride) Injection

Vaprisol is an intravenous treatment for hyponatremia used in the critical care setting. Hyponatremia is an electrolyte disturbance in which sodium ion concentration in blood plasma is lower than normal. This can be associated with a variety of critical care conditions including congestive heart failure, liver failure, kidney failure and pneumonia.

The product is a vasopressin receptor antagonist that raises serum sodium levels and promotes free water secretion. Vaprisol is contraindicated in patients with hypovolemic hyponatremia. The coadministration of Vaprisol with potent CYP3A inhibitors, such as ketoconazole, itraconazole, clarithromycin, ritonavir, and indinavir, is contraindicated. For full prescribing and safety information, including boxed warning, visit www.vaprisol.com.

About Ethyol[®] (amifostine) Injection

Ethyol is indicated to reduce the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer. It is indicated to reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands. Ethyol is contraindicated in patients with known hypersensitivity to aminothiols compounds. For more information please visit www.ethyol.com.

About Totect[®] (dexrazoxane) Injection

Totect is an anthracycline extravasation agent approved by the FDA. Anthracyclines are used to treat many types of cancer and are among the most common cancer therapies.

Anthracycline extravasation occurs when there is accidental leaking of the intravenously-administered medication into the surrounding tissues. Anthracycline extravasation can result in serious complications for cancer patients including tissue necrosis with skin ulceration. In addition to tissue damage, an anthracycline extravasation may cause damage to the nerves, tendons, muscle, and joints. For more information please visit www.totect.com.

About Vibativ[®] (telavancin) for Injection

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. Intravenous unfractionated heparin sodium is contraindicated with VIBATIV administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after Vibativ administration. Vibativ is contraindicated in patients with a known hypersensitivity to telavancin. For more information please visit www.vibativ.com.

About Cumberland Emerging Technologies (CET)

Cumberland Emerging Technologies, Inc. (www.cet-fund.com) is a joint initiative between Cumberland Pharmaceuticals Inc., Vanderbilt University, LaunchTN, and WinHealth. The mission of CET is to advance biomedical technologies and products conceived at Vanderbilt University and other regional research centers towards the marketplace.

CET helps manage the development and commercialization process for select projects, and provides expertise on intellectual property, regulatory, manufacturing and marketing issues that are critical to successful new biomedical products. CET's Life Sciences Center provides laboratory space, equipment and infrastructure for CET's activities and other early-stage life sciences ventures.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the federal securities laws, which are subject to certain risks and reflect Cumberland's current views on future events based on what it believes are reasonable assumptions. These forward-looking statements involve certain risks and uncertainties, and actual results may differ materially from them. Some important factors which may cause results to differ from expectations include: market conditions, competition, an inability of manufacturers to supply Cumberland's products on a timely basis or failure of manufacturers to comply with regulations applicable to pharmaceutical manufacturers including quality control obligation, maintaining an effective sales and marketing infrastructure, availability of additional debt and equity capital required to finance the business, market conditions at the time additional capital is required, our ability to continue to acquire brands, product sales, management of our growth and integration of our acquisitions, as well as other risks discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K, and other filings with the SEC. There can be no assurance that results anticipated by the Company will be realized or that they will have the expected effects. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to publicly revise these statements to reflect events after the date hereof.

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

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 24,609,415	\$ 27,938,960
Marketable securities	9,667,073	8,290,679
Accounts receivable, net	9,973,995	7,844,249
Inventories, net	11,259,233	12,078,343
Prepaid and other current assets	2,456,453	2,963,806
Total current assets	57,966,169	59,116,037
Non-current inventories	15,862,092	15,749,000
Property and equipment, net	744,085	771,213
Intangible assets, net	32,910,261	33,655,099
Goodwill	882,000	784,000
Deferred tax assets, net	43,605	87,210
Other assets	6,209,417	2,531,309
Total assets	\$ 114,617,629	\$ 112,693,868
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 9,292,014	\$ 11,093,297
Other current liabilities	18,706,631	16,710,927
Total current liabilities	27,998,645	27,804,224
Revolving line of credit	20,000,000	20,000,000
Other long-term liabilities	11,428,257	9,319,143
Total liabilities	59,426,902	57,123,367
Commitments and contingencies		
Equity:		
Shareholders' equity:		
Common stock—no par value; 100,000,000 shares authorized; 15,547,517 and 15,481,497 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	50,759,257	51,098,613
Retained earnings	4,672,276	4,746,154
Total shareholders' equity	55,431,533	55,844,767
Noncontrolling interests	(240,806)	(274,266)
Total equity	55,190,727	55,570,501
Total liabilities and equity	\$ 114,617,629	\$ 112,693,868

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Income (loss)
(Unaudited)

	Three months ended March 31,	
	2019	2018
Net revenues	\$ 11,902,747	\$ 8,587,605
Costs and expenses:		
Cost of products sold	1,999,736	1,527,961
Selling and marketing	5,120,505	4,670,511
Research and development	1,267,601	1,874,939
General and administrative	2,670,056	2,330,281
Amortization	1,021,645	636,135
Total costs and expenses	<u>12,079,543</u>	<u>11,039,827</u>
Operating income (loss)	(176,796)	(2,452,222)
Interest income	115,861	82,494
Interest expense	(60,911)	(18,302)
Income (loss) before income taxes	(121,846)	(2,388,030)
Income tax (expense) benefit	81,428	(4,159)
Net income (loss)	(40,418)	(2,392,189)
Net (income) loss at subsidiary attributable to noncontrolling interests	(33,460)	12,950
Net income (loss) attributable to common shareholders	<u>\$ (73,878)</u>	<u>\$ (2,379,239)</u>
Earnings (loss) per share attributable to common shareholders		
- basic	\$ —	\$ (0.15)
- diluted	\$ —	\$ (0.15)
Weighted-average shares outstanding		
- basic	15,472,952	15,689,240
- diluted	15,472,952	15,689,240
Comprehensive income (loss) attributable to common shareholders	(73,878)	(2,379,239)
Net (income) loss at subsidiary attributable to noncontrolling interests	(33,460)	12,950
Total Comprehensive income (loss)	<u>\$ (40,418)</u>	<u>\$ (2,392,189)</u>

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

	Three months ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net income (loss)	\$ (40,418)	\$ (2,392,189)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	1,076,246	692,991
Deferred tax expense	43,605	—
Share-based compensation	364,434	339,209
(Decrease) increase in non-cash contingent consideration	(269,422)	—
Noncash interest expense	10,497	18,303
Noncash investment gains	(44,191)	(43,338)
Net changes in assets and liabilities affecting operating activities:		
Accounts receivable	(2,129,746)	2,093,950
Inventories	819,110	76,323
Other current assets and other assets	134,578	600,884
Accounts payable and other current liabilities	3,499	(1,254,535)
Other long-term liabilities	(353,925)	103,991
Net cash provided by (used in) operating activities	<u>(385,733)</u>	<u>235,589</u>
Cash flows from investing activities:		
Additions to property and equipment	(27,474)	(94,881)
Purchases of marketable securities	(7,816,191)	(15,151,948)
Proceeds from sale of marketable securities	6,483,988	4,257,657
Additions to intangibles	(363,711)	(532,954)
Net cash used in investing activities	<u>(1,723,388)</u>	<u>(11,522,126)</u>
Cash flows from financing activities:		
Borrowings on line of credit	19,000,000	12,000,000
Repayments on line of credit	(19,000,000)	(9,800,000)

Sales of shares of common stock, net of offering costs	—	200,909
Payments of deferred offering costs	—	(248,108)
Cash payment of contingent consideration	(507,505)	—
Repurchase of common shares	(712,919)	(1,016,156)
Net cash provided by (used in) financing activities	(1,220,424)	1,136,645
Net decrease in cash and cash equivalents	(3,329,545)	(10,149,892)
Cash and cash equivalents at beginning of period	27,938,960	45,412,868
Cash and cash equivalents at end of period	\$ 24,609,415	\$ 35,262,976

CUMBERLAND PHARMACEUTICALS INC. AND SUBSIDIARIES

Reconciliation of Net Income (loss) Attributable to Common Shareholders to Adjusted Earnings (loss) and Adjusted Diluted Earnings (loss) Per Share
(Unaudited)

	Three months ended March 31, 2019		Three months ended March 31, 2018	
	Earnings impact	Earnings per share impact	Earnings impact	Earnings per share impact
Net income (loss) attributable to common shareholders	\$ (73,878)	\$ —	\$ (2,379,239)	\$ (0.15)
Less: Net (income) loss at subsidiary attributable to noncontrolling interests	(33,460)	—	12,950	—
Net income (loss)	(40,418)	—	(2,392,189)	(0.15)
Adjustments to net income (loss)				
Income tax expense (benefit)	(81,428)	(0.01)	4,159	—
Depreciation and amortization	1,076,246	0.07	692,991	0.04
Share-based compensation (a)	364,434	0.02	339,209	0.02
Impact of Vibativ cost of product sold (b)	551,494	0.03	—	—
Interest income	(115,861)	(0.01)	(82,494)	(0.01)
Interest expense	60,911	—	18,302	—
Adjusted Earnings (loss) and Adjusted Diluted Earnings (loss) Per Share	\$ 1,815,378	\$ 0.11	\$ (1,420,022)	\$ (0.09)
Diluted weighted-average common shares outstanding:		<u>15,891,570</u>		<u>15,689,240</u>

The Company provided the above adjusted supplemental financial performance measures, which are considered "non-GAAP" financial measures under applicable SEC rules and regulations. These financial measures should be considered supplemental to, and not as a substitute for, financial information prepared in accordance with Generally Accepted Accounting Principles ("GAAP"). The definition of these supplemental measures may differ from similarly titled measures used by others.

Because these supplemental financial measures exclude the effect of items that will increase or decrease the Company's reported results of operations, management encourages investors to review the Company's consolidated financial statements and publicly filed reports in their entirety. A reconciliation of the supplemental financial measures to the most directly comparable GAAP financial measures is included in the tables accompanying this release.

Cumberland's management believes these supplemental financial performance measures are important as they are used by management, along with financial measures in accordance with GAAP, to evaluate the Company's operating performance. In addition, Cumberland believes that they will be used by certain investors to measure the Company's operating results. Management believes that presenting these supplemental measures provides useful information about the Company's underlying performance across reporting periods on a consistent basis by excluding items that Cumberland does not believe are indicative of its core business performance or reflect long-term strategic activities. Certain of these items are not settled through cash payments and include: depreciation, amortization, share-based compensation expense and income taxes. Cumberland utilizes its net operating loss carryforwards to pay minimal income taxes. In addition, the use of these financial measures provides greater transparency to investors of supplemental information used by management in its financial and operational decision-making, including the evaluation of the Company's operating performance.

The Company defines these supplemental financial measures as follows:

- **Adjusted Earnings (loss):** net income (loss) adjusted for the impact of income taxes, depreciation and amortization expense, share-based compensation, Vibativ cost of product sold and interest income and interest expense.

(a) Represents the share-based compensation of Cumberland.

(b) Represents the non-cash impact of the Vibativ cost of products sold. Cumberland has elected to add these costs back in the calculation of adjusted earnings as all the Vibativ inventory was transferred to Cumberland as part of the transaction with Theravance at no additional cost to the consideration agreed for the product acquisition.

- **Adjusted Diluted Earnings (loss) Per Share:** Adjusted Earnings (loss) divided by diluted weighted-average common shares outstanding.

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SOURCE Cumberland Pharmaceuticals Inc.

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