



Alkermes Plc Reports Third Quarter 2019 Financial Results and Implementation of Restructuring

October 23, 2019

- Third Quarter Revenues of \$255.2 Million, Primarily Driven by Approximately 20% Year-Over-Year Growth of Proprietary Product Net Sales --
- Company Reports GAAP Net Loss per Share of \$0.34 and Non-GAAP Net Loss per Share of \$0.04 --
- Restructuring Significantly Decreases Operating Expense Base and is Expected to Deliver Cost Savings of Several Hundred Million Dollars Over the Next Few Years --
- Company Updates Financial Expectations for 2019 --

DUBLIN, Oct. 23, 2019 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today reported financial results for the third quarter of 2019 and the implementation of a restructuring plan following a review of the company's operations, cost structure and growth opportunities.

"As the profile of Alkermes changes, our executional priorities are clear: maximize the value of our commercial products and development candidates, streamline our cost structure and position the company for sustained future profitability. The restructuring is designed to further focus our R&D efforts on specific high-potential programs within CNS and oncology, improve financial efficiencies in our SG&A organization and drive growth," commented Richard Pops, Chief Executive Officer of Alkermes. "VIVITROL® and ARISTADA® provide a strong and growing foundation for our commercial business and the anticipated commercial launch of VUMERITY™ will provide a profitable new source of royalty revenues. We also continue to advance our pipeline programs, with the planned submission of the ALKS 3831 New Drug Application for both schizophrenia and bipolar I disorder this quarter, and the planned presentation of new data from ALKS 4230, our phase 1/2 immuno-oncology asset, at an upcoming medical meeting."

Quarter Ended Sept. 30, 2019 Financial Highlights

- Total revenues for the quarter were \$255.2 million, compared to \$248.7 million for the same period in the prior year, primarily driven by approximately 20% growth in net sales of our proprietary products, partially offset by a decrease in AMPYRA® revenues resulting from generic entry in 2018.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$52.9 million for the quarter, or a basic and diluted GAAP net loss per share of \$0.34. This compared to GAAP net loss of \$34.4 million, or a basic and diluted GAAP net loss per share of \$0.22, for the same period in the prior year.
- Non-GAAP net loss was \$7.0 million for the quarter, or a non-GAAP basic and diluted net loss per share of \$0.04. This compared to non-GAAP net income of \$11.6 million, or a non-GAAP basic and diluted net earnings per share of \$0.07, for the same period in the prior year.

Quarter Ended Sept. 30, 2019 Financial Results

Revenues

- Net sales of VIVITROL were \$85.2 million, compared to \$79.9 million for the same period in the prior year, representing an increase of approximately 7%.
- Net sales of ARISTADAⁱⁱ were \$53.6 million, compared to \$36.1 million for the same period in the prior year, representing an increase of approximately 48%.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$76.7 million, compared to \$77.2 million for the same period in the prior year, reflecting lower manufacturing revenues from RISPERDAL CONSTA.
- Manufacturing and royalty revenues from AMPYRA/FAMPYRA® were \$7.7 million, compared to \$20.3 million for the same period in the prior year, due to generic competition to AMPYRA entering the market in 2018 in the U.S.
- Research and development revenues were \$12.7 million, compared to \$16.3 million for the same period in the prior year. These revenues were primarily related to the collaboration with Biogen for VUMERITY.

Costs and Expenses

- Operating expenses were \$308.9 million, compared to \$285.9 million for the same period in the prior year, primarily reflecting increased investment in the commercialization of VIVITROL and ARISTADA and in the development of ALKS 4230.

"Our third quarter results reflect solid year-over-year growth of VIVITROL and ARISTADA. We are committed to further improving our financial efficiency and focusing the investments we are making to support our future growth," commented James Frates, Chief Financial Officer of Alkermes. "As we approach the end of the year, we are refining our financial expectations for 2019, including an increase in our expectations for non-GAAP net income, to reflect our results year-to-date, expectations for the fourth quarter and the impact of the restructuring announced today."

Restructuring

In October 2019, Alkermes completed a review of the company's operations, cost structure and growth opportunities and implemented a restructuring plan. The restructuring included the elimination of approximately 160 current positions across the organization, a decrease in the company's expected near-term hiring plans and implementation of cost-saving measures related to external spend. These efforts are expected to result in cost savings of approximately \$150 million. The company expects to record a charge of approximately \$15 million in the fourth quarter of 2019 as a result of the restructuring, consisting of one-time termination benefits for employee severance, benefits and related costs.

Financial Expectations for 2019

The following outlines the company's updated financial expectations for 2019, which include the impact of the restructuring announced today:

- **Revenues:** The company continues to expect total revenues to range from \$1.14 billion to \$1.19 billion.
 - Included in this total revenue expectation is the \$150 million milestone payment that will be triggered by final approval of VUMERITY by the U.S. Food and Drug Administration (FDA).
 - The company now expects VIVITROL net sales to range from \$330 million to \$340 million, revised from the prior expectation of \$330 million to \$350 million.
 - The company now expects ARISTADA net sales to range from \$185 million to \$190 million, revised from the prior expectation of \$200 million to \$210 million.
- **Cost of Goods Manufactured and Sold:** The company continues to expect cost of goods manufactured and sold to range from \$180 million to \$190 million.
- **Research and Development (R&D) Expenses:** The company now expects R&D expenses to range from \$430 million to \$450 million, revised from the prior expectation of \$450 million to \$480 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company now expects SG&A expenses to range from \$590 million to \$610 million, revised from the prior expectation of \$590 million to \$620 million.
- **Amortization of Intangible Assets:** The company continues to expect amortization of intangible assets to be approximately \$40 million.
- **Restructuring:** The company expects a restructuring charge of approximately \$15 million.
- **Net Interest Expense:** The company now expects net interest expense to range from \$0 to \$5 million, revised from the prior expectation of \$5 million to \$10 million.
- **Other Income/Expense, Net:** The company expects a net other expense of approximately \$30 million related to the change in fair value of its contingent consideration.
- **Income Tax Expense:** The company now expects income tax expense to range from \$0 to \$5 million, revised from the prior expectation of \$10 million to \$15 million.
- **GAAP Net Loss:** The company continues to expect GAAP net loss to range from \$135 million to \$165 million, or a basic and diluted loss per share of \$0.86 to \$1.05, based on a weighted average basic and diluted share count of approximately 156 million shares outstanding.
- **Non-GAAP Net Income:** The company now expects non-GAAP net income to range from \$70 million to \$90 million, or a non-GAAP basic earnings per share of \$0.45 to \$0.57, based on a weighted average basic share count of approximately 157 million shares outstanding and a non-GAAP diluted earnings per share of \$0.44 to \$0.57, based on a weighted average diluted share count of approximately 159 million shares outstanding. This compares to the previous expectation of non-GAAP net income in the range of \$40 million to \$70 million, or a non-GAAP basic earnings per share of \$0.26 to \$0.45, based on a weighted average basic share count of approximately 156 million shares outstanding and a non-GAAP diluted earnings per share of \$0.25 to \$0.43, based on a weighted average diluted share count of approximately 161 million shares outstanding.
- **Share-Based Compensation:** The company now expects share-based compensation of approximately \$100 million, revised from the prior expectation of approximately \$120 million.
- **Capital Expenditures:** The company now expects capital expenditures to range from \$80 million to \$90 million, revised from the prior expectation of \$90 million to \$100 million.

Recent Events:

- Entered into clinical collaboration with Fred Hutchinson Cancer Research Center for a planned phase 2 multi-site trial to evaluate ALKS 4230 in combination with pembrolizumab in patients with advanced or recurrent head and neck squamous cell cancer.
- Received tentative approval from FDA for VUMERITY (dioximel fumarate), a novel oral fumarate with a distinct chemical structure, for the treatment of relapsing forms of MS.
- Presented new health economics and outcomes research at the 32nd Annual Psych Congress that highlighted the unmet needs of individuals living with schizophrenia and bipolar I disorder in real-world settings.
- Announced the appointment of Richard Gaynor, M.D. and Andy Wilson to the company's Board of Directors. Dr. Gaynor brings to the Board 18 years of experience in oncology-focused drug development, and Mr. Wilson brings to the Board 30 years of financial expertise and experience in strategic planning and business development. The company also announced the retirement of Floyd Bloom, M.D., a founder of Alkermes, Inc., from the Board.

- Announced positive topline results from EVOLVE-MS-2, a phase 3 study designed to evaluate the gastrointestinal (GI) tolerability of VUMERITY compared to TECFIDERA® in patients with relapsing-remitting multiple sclerosis.
- Entered into a settlement and license agreement with Amneal Pharmaceuticals LLC (Amneal) to resolve Amneal's *inter partes* review petition challenging U.S. Patent Number 7,919,499, an Orange Book-listed patent for VIVITROL.

Conference Call

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:00 a.m. ET (1:00 p.m. BST) on Wednesday, Oct. 23, 2019, to discuss these financial results and provide an update on the company. The webcast may be accessed on the Investors section of Alkermes' website at www.alkermes.com. The conference call may be accessed by dialing +1 877 407 2988 for U.S. callers and +1 201 389 0923 for international callers. In addition, a replay of the conference call will be available from 11:00 a.m. ET (4:00 p.m. BST) on Wednesday, Oct. 23, 2019, through Wednesday, Oct. 30, 2019, and may be accessed by visiting Alkermes' website or by dialing +1 877 660 6853 for U.S. callers and +1 201 612 7415 for international callers. The replay access code is 13694597.

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases and oncology. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for diseases that include schizophrenia, depression, addiction, multiple sclerosis, and cancer. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Non-GAAP Financial Measures

This press release includes information about certain financial measures that are not prepared in accordance with GAAP, including non-GAAP net income (loss) and non-GAAP basic and diluted net earnings (loss) per share. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Non-GAAP net income (loss) adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; certain other one-time or non-cash items; changes in the fair value of contingent consideration; changes in the fair value of warrants and equity method investments; restructuring charges; and the income tax effect of these reconciling items.

The company's management and board of directors utilize these non-GAAP financial measures to evaluate the company's performance. The company provides these non-GAAP measures of the company's performance to investors because management believes that these non-GAAP financial measures, when viewed with the company's results under GAAP and the accompanying reconciliations, are useful in identifying underlying trends in ongoing operations. However, non-GAAP net income (loss) and non-GAAP basic and diluted net earnings (loss) per share are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance. Further, non-GAAP net income (loss) and non-GAAP basic and diluted net earnings (loss) per share should not be considered measures of our liquidity.

A reconciliation of certain GAAP to non-GAAP financial measures has been provided in the tables included in this press release.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the company's business plans or prospects; the company's expectations concerning future financial and operating performance, including the potential cost savings that may be achieved in connection with the company's implementation of a restructuring, and the company's potential future profitability and continued growth, including expectations of continued revenue growth from the company's commercial products and royalty streams and the potential addition of VUMERITY as a new source of royalty revenue; expectations concerning the company's continued investment in its development pipeline and commercial products and capabilities, and the value that can be derived therefrom; the potential therapeutic and commercial value of the company's marketed and development products; expectations concerning the timing, details and results of the company's clinical development activities, including plans for the presentation of new data for ALKS 4230 at an upcoming medical meeting; the company's expectations and timelines for regulatory activities and interactions with the FDA, including the company's planned submission of an NDA for ALKS 3831 for the treatment of schizophrenia and the treatment of bipolar I disorder; and the company's expectations relating to the anticipated launch of VUMERITY and the financial benefits that may be achieved under the company's license and collaboration agreement with Biogen. The company cautions that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: that the expected cost savings related to the company's implementation of a restructuring plan may not be achieved or may be lower than anticipated; the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to any of our products or products using our proprietary technologies, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the FDA in different ways than we interpret it; the FDA may not agree with our regulatory approval strategies or components of our filings for our products, including our clinical trial designs, conduct and methodologies and adequacy of the data included to support the proposed indications; clinical development activities may not be completed on time or at all; the results of our clinical development activities may not be positive, or predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted or approved in a timely manner; the company and its licensees may not be able to continue to successfully commercialize their products; there may be a reduction in payment rate or reimbursement for the company's products or an increase in the company's financial obligations to governmental payers; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products; the company's products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and those risks and uncertainties described under the heading "Risk Factors" in the company's most recent Annual Report on Form 10-K and in subsequent filings made by the company with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

VIVITROL® is a registered trademark of Alkermes, Inc.; ARISTADA® and ARISTADA INITIO® are registered trademarks of Alkermes Pharma Ireland Limited and VUMERITY™ is a trademark of Alkermes Pharma Ireland Limited used by Biogen under an exclusive license; RISPERDAL CONSTA®, INVEGA SUSTENNA®, XEPLION®, INVEGA TRINZA® and TREVICTA® are registered trademarks of Johnson & Johnson; and AMPYRA® and FAMPYRA® are registered trademarks of Acorda Therapeutics, Inc.

(tables follow)

ⁱ AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg is developed and marketed in the U.S. by Acorda. Biogen Inc. markets this product as FAMPYRA® (prolonged-release fampridine tablets) outside the U.S. under a licensing agreement with Acorda.

ⁱⁱ The term "ARISTADA" as used in this press release refers to ARISTADA and ARISTADA INITIO®, unless the context indicates otherwise.

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018
Revenues:		
Product sales, net	\$ 138,774	\$ 116,035
Manufacturing and royalty revenues	103,783	116,411
Research and development revenue	12,686	16,274
Total Revenues	<u>255,243</u>	<u>248,720</u>
Expenses:		
Cost of goods manufactured and sold	42,319	39,410
Research and development	107,671	101,265
Selling, general and administrative	148,701	128,777
Amortization of acquired intangible assets	10,173	16,426
Total Expenses	<u>308,864</u>	<u>285,878</u>
Operating Loss	<u>(53,621)</u>	<u>(37,158)</u>
Other (Expense) Income, net:		
Interest income	3,509	2,561
Interest expense	(3,385)	(3,346)
Change in the fair value of contingent consideration	1,300	4,200
Other expense, net	(1,664)	(90)
Total Other (Expense) Income, net	<u>(240)</u>	<u>3,325</u>
Loss Before Income Taxes	<u>(53,861)</u>	<u>(33,833)</u>
(Benefit) Provision for Income Taxes	<u>(983)</u>	<u>611</u>
Net Loss — GAAP	<u>\$ (52,878)</u>	<u>\$ (34,444)</u>
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.22)</u>
Non-GAAP (loss) earnings per share — basic and diluted	<u>\$ (0.04)</u>	<u>\$ 0.07</u>
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP and Non-GAAP	<u>157,199</u>	<u>155,328</u>
Basic — Non-GAAP	<u>157,199</u>	<u>155,328</u>
Diluted — Non-GAAP	<u>157,199</u>	<u>159,763</u>

An itemized reconciliation between net loss on a GAAP basis and non-GAAP net (loss) income is as follows:

Net Loss — GAAP	\$ (52,878)	\$ (34,444)
Adjustments:		
Share-based compensation expense	26,729	25,068
Amortization expense	10,173	16,426
Depreciation expense	10,173	9,842
Change in the fair value of contingent consideration	(1,300)	(4,200)
Income tax effect related to reconciling items	155	(869)
Non-cash net interest expense	168	170
Change in the fair value of warrants and equity method investments	(206)	(367)
Non-GAAP Net (Loss) Income	<u>\$ (6,986)</u>	<u>\$ 11,626</u>

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Revenues:		

Product sales, net	\$	374,890	\$	317,684
Manufacturing and royalty revenues		340,595		359,253
Research and development revenues		41,732		53,325
License revenues		1,000		48,250
Total Revenues		758,217		778,512
Expenses:				
Cost of goods manufactured and sold		133,903		127,303
Research and development		314,676		316,434
Selling, general and administrative		444,996		385,181
Amortization of acquired intangible assets		30,187		48,742
Total Expenses		923,762		877,660
Operating Loss		(165,545)		(99,148)
Other Expense, net:				
Interest income		10,785		5,946
Interest expense		(10,405)		(11,959)
Change in the fair value of contingent consideration		(27,800)		(17,300)
Other expense, net		(1,534)		(2,815)
Total Other Expense, net		(28,954)		(26,128)
Loss Before Income Taxes		(194,499)		(125,276)
(Benefit) Provision for Income Taxes		(3,233)		4,322
Net Loss — GAAP	\$	(191,266)	\$	(129,598)

Net (Loss) Earnings Per Share:

GAAP net loss per share — basic and diluted	\$	(1.22)	\$	(0.84)
Non-GAAP net (loss) earnings per share — basic	\$	(0.12)	\$	0.28
Non-GAAP net (loss) earnings per share — diluted	\$	(0.12)	\$	0.27

Weighted Average Number of Ordinary Shares Outstanding:

Basic and diluted — GAAP		156,845		154,979
Basic — Non-GAAP		156,845		154,979
Diluted — Non-GAAP		156,845		160,224

An itemized reconciliation between net loss on a GAAP basis and non-GAAP net (loss) income is as follows:

Net Loss — GAAP	\$	(191,266)	\$	(129,598)
Adjustments:				
Share-based compensation expense		79,590		76,043
Amortization expense		30,187		48,742
Depreciation expense		29,715		29,016
Change in the fair value of contingent consideration		27,800		17,300
Income tax effect related to reconciling items		5,170		(5,535)
Non-cash net interest expense		505		531
Change in the fair value of warrants and equity method investments		(907)		600
Restructuring expense		—		3,598
Debt refinancing charge		—		2,298
Non-GAAP Net (Loss) Income	\$	(19,206)	\$	42,995

**Condensed Consolidated Balance Sheets
(In thousands)**

	September 30,		December 31,	
	2019		2018	
Cash, cash equivalents and total investments	\$	608,533	\$	620,039
Receivables		250,234		292,223
Contract assets		5,022		8,230
Inventory		100,987		90,196
Prepaid expenses and other current assets		54,493		53,308
Property, plant and equipment, net		341,406		309,987
Intangible assets, net and goodwill		253,687		283,874
Other assets		143,633		167,150
Total Assets	\$	1,757,995	\$	1,825,007
Long-term debt — current portion	\$	2,843	\$	2,843
Other current liabilities		367,551		336,931
Long-term debt		274,838		276,465
Contract liabilities — long-term		11,188		9,525
Other long-term liabilities		33,391		27,958
Total shareholders' equity		1,068,184		1,171,285
Total Liabilities and Shareholders' Equity	\$	1,757,995	\$	1,825,007
Ordinary shares outstanding (in thousands)		157,476		155,757

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2019, which the company intends to file in October 2019.

Alkermes plc and Subsidiaries
2019 Guidance — GAAP to Non-GAAP Adjustments

An itemized reconciliation between projected loss per share on a GAAP basis and projected earnings per share on a non-GAAP basis is as follows:

(In millions, except per share data)	Amount	Shares	(Loss) Earnings Per Share
Projected Net Loss — GAAP	\$ (150.0)	157	\$ (0.96)
Adjustments:			
Share-based compensation expense	100.0		
Amortization expense	40.0		
Depreciation expense	40.0		
Change in the fair value of contingent consideration	30.0		
Restructuring	15.0		
Income tax effect related to reconciling items	4.0		
Non-cash net interest expense	1.0		
Projected Net Income — Non-GAAP	\$ 80.0	159	\$ 0.50

Projected GAAP and non-GAAP measures reflect mid-points within ranges of estimated guidance.

Alkermes Contacts:

For Investors: Sandy Coombs +1 781 609 6377

For Media: Eva Stroynowski +1 781 609 6823



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