



Alkermes plc Reports First Quarter 2017 Financial Results

April 27, 2017

—First Quarter Revenues Increased 22% Year-Over-Year to \$191.8 Million, GAAP Loss per Share of \$0.45 and Non-GAAP Loss per Share of \$0.18 —

—VIVITROL® Net Sales Grew by 33% Year-Over-Year to \$58.5 Million —

—ARISTADA® Gaining Traction in Growing Long-Acting Antipsychotic Market; Preparing for Launch of Two-Month Dose Following June 5, 2017 PDUFA Date —

DUBLIN--(BUSINESS WIRE)--Apr. 27, 2017-- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for the first quarter of 2017.

"Our results this quarter reflect solid year-over-year growth of our commercial portfolio, driven by our proprietary products, VIVITROL® and ARISTADA®. Looking ahead to the remainder of the year, we remain focused on making these important medicines available to patients and driving growth," commented James Frates, Chief Financial Officer of Alkermes. "With our strong financial position and growing commercial portfolio, we are well positioned to invest in our advancing late-stage pipeline and our commercial organization to support Alkermes' expanding portfolio of proprietary products. Today, we are reiterating our financial expectations for 2017 that we provided in February."

"The strength of the Alkermes business is grounded in our diversified portfolio of proprietary commercial products and late-stage development candidates, each of which represent a potential blockbuster opportunity in major CNS disease categories," said Richard Pops, Chief Executive Officer of Alkermes. "Our late-stage pipeline continues to advance rapidly in 2017 with the planned New Drug Application submission for ALKS 5461 for the adjunctive treatment of major depressive disorder, data from the pivotal antipsychotic efficacy study for ALKS 3831 in schizophrenia and completion of the clinical registration requirements for ALKS 8700 in multiple sclerosis expected before year-end."

Quarter Ended March 31, 2017 Highlights

- Total revenues for the quarter were \$191.8 million. This compared to \$156.8 million for the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$68.9 million, or a basic and diluted GAAP loss per share of \$0.45, for the quarter and reflected increased investment in the company's advancing late-stage pipeline and commercial infrastructure. This compared to GAAP net loss of \$77.4 million, or a basic and diluted GAAP loss per share of \$0.51 for the same period in the prior year.
- Non-GAAP net loss was \$27.9 million, or a non-GAAP basic and diluted loss per share of \$0.18 for the quarter. This compared to non-GAAP net loss of \$17.9 million, or a non-GAAP diluted loss per share of \$0.12, for the same period in the prior year.

Quarter Ended March 31, 2017 Financial Results

Revenues

- Net sales of VIVITROL were \$58.5 million, compared to \$43.8 million for the same period in the prior year, representing an increase of approximately 33.4%.
- Net sales of ARISTADA were \$18.0 million, compared to \$5.5 million for the same period in the prior year.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were \$60.0 million, compared to \$54.7 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®¹ were \$29.2 million, compared to \$28.2 million for the same period in the prior year.
- Royalty revenue from BYDUREON® was \$12.3 million, compared to \$10.5 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were \$262.6 million, compared to \$233.7 million for the same period in the prior year, reflecting increased investment in the company's commercial infrastructure and higher cost of goods manufactured and sold reflecting increased manufacturing activity at our site in Ohio.

Balance Sheet

At March 31, 2017, Alkermes had cash and total investments of \$589.4 million, compared to \$619.2 million at December 31, 2016. At March 31, 2017, the company's total debt outstanding was \$283.1 million.

Financial Expectations

Alkermes reiterates its financial expectations for 2017 set forth in its press release dated Feb. 15, 2017.

Conference Call

Alkermes will host a conference call at 8:30 a.m. ET (1:30 p.m. BST) on Thursday, April 27, 2017, to discuss these financial results and provide an update on the company. The conference call may be accessed by visiting Alkermes' website or by dialing +1 888 424 8151 for U.S. callers and +1 847 585 4422 for international callers. The conference call ID number is 6037988. In addition, a replay of the conference call will be available from 11:00 a.m. ET (4:00 p.m. BST) on Thursday, April 27, 2017 through 5:00 p.m. ET (10:00 p.m. BST) on Thursday, May 4, 2017, and may be accessed by visiting Alkermes' website or by dialing +1 888 843 7419 for U.S. callers and +1 630 652 3042 for international callers. The replay access code is 6037988.

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. 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 generally accepted accounting principles in the U.S. (GAAP), including non-GAAP net income (loss) and non-GAAP diluted 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; 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, better indicate underlying trends in ongoing operations. However, non-GAAP net income (loss) and non-GAAP diluted 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 diluted earnings (loss) per share should not be considered measures of our liquidity.

A reconciliation of 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: future financial and operating performance, business plans or prospects; the likelihood of continued revenue growth from the company's commercial products, including the growth of VIVITROL and ARISTADA; the therapeutic and commercial value of the company's products; and expectations concerning the timing and results of clinical development activities, including the NDA submission for ALKS 5461, data from a pivotal efficacy study for ALKS 3831, the launch of the two-month dose of ARISTADA, and completion of the pivotal registration requirements for ALKS 8700. 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: the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to any of our products, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the U.S. Food and Drug Administration ("FDA") in different ways than we interpret it; the FDA may not agree with our regulatory approval strategies or components of our filings, such as clinical trial designs; 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 in a timely manner; the company, and its partners, may not be able to continue to successfully commercialize its 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 Annual Report on Form 10-K for the year ended Dec. 31, 2016 and Quarterly Report on Form 10-Q for the quarter ended Mar. 31, 2017 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 they are made. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking information contained in this press release.

VIVITROL[®] is a registered trademark of Alkermes, Inc.; ARISTADA[®] is a registered trademark of Alkermes Pharma Ireland Limited; RISPERDAL CONSTA[®], INVEGA SUSTENNA[®], XEPLION[®], INVEGA TRINZA[®] and TREVICTA[®] are registered trademarks of Johnson & Johnson; AMPYRA[®] and FAMPYRA[®] are registered trademarks of Acorda Therapeutics, Inc.; BYDUREON[®] is a registered trademark of Amylin Pharmaceuticals, LLC.

¹AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg is developed and marketed in the U.S. by Acorda Therapeutics, Inc. and outside the U.S. by Biogen Idec, under a licensing agreement with Acorda Therapeutics, as FAMPYRA[®] (prolonged-release fampridine tablets).

(tables follow)

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
(In thousands, except per share data)		
Revenues:		
Manufacturing and royalty revenues	\$ 114,679	\$ 106,159
Product sales, net	76,456	49,374
Research and development revenues	643	1,241
Total Revenues	191,778	156,774
Expenses:		
Cost of goods manufactured and sold	40,412	27,711
Research and development	104,835	101,072
Selling, general and administrative	102,099	89,719
Amortization of acquired intangible assets	15,302	15,156
Total Expenses	262,648	233,658
Operating Loss	(70,870)	(76,884)
Other Expense, net:		
Interest income	943	1,011
Interest expense	(2,764)	(3,295)
Increase in the fair value of contingent consideration	1,600	1,900
Other (expense) income, net	(1,499)	249
Total Other Expense, net	(1,720)	(135)
Loss Before Income Taxes	(72,590)	(77,019)
Income Tax (Benefit) Provision	(3,709)	404
Net Loss — GAAP	\$ (68,881)	\$ (77,423)
Loss Per Share:		
GAAP loss per share — basic and diluted	<u>\$ (0.45)</u>	<u>\$ (0.51)</u>
Non-GAAP loss per share — basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.12)</u>
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and Diluted — GAAP and Non-GAAP	<u>152,704</u>	<u>150,825</u>

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

Net Loss — GAAP	\$ (68,881)	\$ (77,423)
Adjustments:		
Share-based compensation expense	21,169	24,256
Amortization expense	15,302	15,156
Depreciation expense	8,461	7,548
Loss on warrants and equity method investment	1,452	870
Non-cash net interest expense	193	232
Increase in the fair value of contingent consideration	(1,600)	(1,900)
Income tax effect related to reconciling items	(3,950)	3,340
Upfront license option payment to Reset Therapeutics, Inc. charged to R&D expense	-	10,000
Non-GAAP Net Loss	<u>\$ (27,854)</u>	<u>\$ (17,921)</u>

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets	March 31,	December 31,
(In thousands)	2017	2016
Cash, cash equivalents and total investments	\$ 589,373	\$ 619,165
Receivables	176,487	191,102

Inventory	63,666	62,998
Prepaid expenses and other current assets	42,279	39,344
Property, plant and equipment, net	264,915	264,785
Intangible assets, net and goodwill	395,798	411,100
Other assets	197,309	137,929
Total Assets	\$ 1,729,827	\$ 1,726,423
Long-term debt — current portion	\$ 3,000	\$ 3,000
Other current liabilities	207,742	208,993
Long-term debt	280,109	280,666
Deferred revenue — long-term	6,522	7,122
Other long-term liabilities	15,750	17,161
Total shareholders' equity	1,216,704	1,209,481
Total Liabilities and Shareholders' Equity	\$ 1,729,827	\$ 1,726,423
Ordinary shares outstanding (in thousands)	153,123	152,431

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 months ended March 31, 2017, which the company intends to file in April 2017.



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