



Alkermes plc Reports Third Quarter 2016 Financial Results

November 2, 2016

—Third Quarter Revenues Increased 18% Year-Over-Year to \$180.2 Million;
GAAP Loss per Share of \$0.41 and Non-GAAP Loss per Share of \$0.09 —

—VIVITROL[®] Net Sales Grew 47% Year-Over-Year to \$55.8 Million —

—ARISTADA[®] Launch Progressing; Revenues Grow In Line With Expectations —

DUBLIN--(BUSINESS WIRE)--Nov. 2, 2016-- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for the third quarter of 2016.

“Our third quarter results demonstrate the value of our highly-diversified commercial portfolio, and were driven by the strong growth of our proprietary products, VIVITROL[®] and ARISTADA[®],” commented James Frates, Chief Financial Officer of Alkermes. “As we approach year-end, we remain well-positioned to execute on our business strategy and are reiterating our 2016 financial expectations provided in July.”

“We are at an unprecedented place in Alkermes’ evolution, with two proprietary products growing in their markets, ALKS 5461 advancing at full speed, and two additional late-stage candidates well into their pivotal programs,” stated Richard Pops, Chief Executive Officer of Alkermes. “VIVITROL for opioid and alcohol dependence and ARISTADA for schizophrenia are important, distinctive medicines in their disease areas and are the foundation of our future growth. With the positive results of FORWARD-5 for ALKS 5461 for major depressive disorder in hand, Alkermes’ next potential growth driver is coming more clearly into focus.”

Quarter Ended Sept. 30, 2016 Highlights

- Total revenues for the quarter were \$180.2 million. This compared to \$152.7 million for the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$62.7 million, or a basic and diluted GAAP loss per share of \$0.41, for the quarter, which reflected increased investment in the company’s advancing late-stage pipeline and commercial infrastructure. This compared to GAAP net loss of \$81.0 million, or a basic and diluted GAAP loss per share of \$0.54, for the same period in the prior year.
- Non-GAAP net loss was \$14.1 million, or a non-GAAP basic and diluted loss per share of \$0.09, for the quarter. This compared to non-GAAP net loss of \$28.8 million, or a non-GAAP basic and diluted loss per share of \$0.19, for the same period in the prior year.

Quarter Ended Sept. 30, 2016 Financial Results

Revenues

- Net sales of VIVITROL were \$55.8 million, compared to \$37.9 million for the same period in the prior year, representing an increase of approximately 47%.
- Net sales of ARISTADA were \$14.0 million, up from \$10.3 million in the second quarter of 2016.
- Manufacturing revenues from RISPERDAL CONSTA[®] (risperidone) and royalty revenues from RISPERDAL CONSTA, INVEGA SUSTENNA[®]/XEPLION[®] (paliperidone palmitate) and INVEGA TRINZA[®]/TREVICTA[®] (paliperidone palmitate) were \$73.3 million, compared to \$67.6 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA[®]/FAMPYRA[®] were \$12.9 million, compared to \$22.1 million for the same period in the prior year, primarily due to the timing of manufacturing shipments.
- Royalty revenue from BYDUREON[®] was \$11.6 million, compared to \$13.0 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were \$241.4 million, reflecting increased investment in the company’s development pipeline, the continued launch of ARISTADA and growth of VIVITROL. Operating expenses for the quarter ended Sept. 30, 2015 were \$230.1 million.

Balance Sheet

At Sept. 30, 2016, Alkermes had cash and total investments of \$624.6 million, compared to \$798.8 million at Dec. 31, 2015. On Sept. 26, 2016 the company retired \$60 million of maturing debt. In October 2016, the company extended the maturity date of the approximately \$286 million outstanding

term loan by two years to Sept. 25, 2021.

Financial Expectations

Alkermes reiterates its Financial Expectations for 2016 set forth in its press release dated July 28, 2016.

Conference Call

Alkermes will host a conference call at 8:30 a.m. ET (12:30 p.m. GMT) on Wednesday, Nov. 2, 2016, to discuss these financial results and provide an update on the company. The conference call may be accessed 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 (3:00 p.m. GMT) on Wednesday, Nov. 2, 2016, through 5:00 p.m. ET (10:00 p.m. GMT) on Wednesday, Nov. 9, 2016, 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

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 loss in the three and nine months ended Sept. 30, 2016 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 revenue growth from the company's marketed products; the therapeutic and commercial value of the company's marketed and development products; and expectations concerning the timing and results of clinical development activities and regulatory authority interactions. 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; 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 such 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 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 fiscal year ended Dec. 31, 2015, and in any other subsequent filings made by the company with the U.S. Securities and Exchange Commission (SEC) and 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; RISPEDAL CONSTA[®], INVEGA SUSTENNA[®], XEPLION[®], INVEGA TRINZA[®] and TREVICTA[®] are registered trademarks of Johnson & Johnson and its affiliates; 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)

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015
Condensed Consolidated Statements of Operations - GAAP		
(In thousands, except per share data)		
Revenues:		
Manufacturing and royalty revenues	\$ 110,250	\$ 114,072
Product sales, net	69,802	37,903
Research and development revenues	189	678
Total Revenues	180,241	152,653
Expenses:		
Cost of goods manufactured and sold	35,456	33,806
Research and development	99,444	92,558
Selling, general and administrative	91,145	89,497
Amortization of acquired intangible assets	15,323	14,207
Total Expenses	241,368	230,068
Operating Loss	(61,127)	(77,415)
Other Expense, net:		
Interest income	912	865
Interest expense	(3,375)	(3,325)
Gain on Gainesville Transaction	-	26
Change in the fair value of contingent consideration	(1,000)	1,200
Other (expense) income, net	(752)	629
Total Other Expense, net	(4,215)	(605)
Loss Before Income Taxes	(65,342)	(78,020)
Income Tax (Benefit) Provision	(2,655)	2,995
Net Loss — GAAP	\$ (62,687)	\$ (81,015)
Net Loss Per Share:		
GAAP net loss per share — basic and diluted	\$ (0.41)	\$ (0.54)
Non-GAAP net loss per share — basic and diluted	\$ (0.09)	\$ (0.19)
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP and Non-GAAP	151,652	149,512
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net loss is as follows:		
Net Loss — GAAP	\$ (62,687)	\$ (81,015)
Adjustments:		
Share-based compensation expense	23,726	35,267
Amortization expense	15,323	14,207
Depreciation expense	8,497	6,486
Income tax effect related to reconciling items	(673)	(2,344)
Non-cash net interest expense	231	234
Loss (gain) on warrants and equity method investments	521	(79)
Change in the fair value of contingent consideration	1,000	(1,200)
Gain on Gainesville Transaction	-	(26)
Gain on sale of property, plant and equipment	-	(341)
Non-GAAP Net Loss	\$ (14,062)	\$ (28,811)
	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Condensed Consolidated Statements of Operations - GAAP		
(In thousands, except per share data)		
Revenues:		
Manufacturing and royalty revenues	\$ 353,444	\$ 355,978
Product sales, net	176,695	106,212

Research and development revenues	2,042	3,047
Total Revenues	532,181	465,237
Expenses:		
Cost of goods manufactured and sold	97,165	104,198
Research and development	297,523	250,718
Selling, general and administrative	276,985	224,086
Amortization of acquired intangible assets	45,636	43,479
Total Expenses	717,309	622,481
Operating Loss	(185,128)	(157,244)
Other (Expense) Income, net:		
Interest income	2,917	2,320
Interest expense	(9,993)	(9,928)
Gain on Gainesville Transaction	-	9,937
Change in the fair value of contingent consideration	3,100	2,700
Other (expense) income, net	(970)	1,003
Total Other (Expense) Income, net	(4,946)	6,032
Loss Before Income Taxes	(190,074)	(151,212)
Income Tax (Benefit) Provision	(2,771)	6,569
Net Loss — GAAP	\$ (187,303)	\$ (157,781)

Net Loss Per Share:

GAAP net loss per share — basic and diluted	<u>\$ (1.24)</u>	<u>\$ (1.06)</u>
Non-GAAP net loss per share — basic and diluted	<u>\$ (0.22)</u>	<u>\$ (0.24)</u>

Weighted Average Number of Ordinary Shares Outstanding:

Basic and diluted — GAAP and Non-GAAP	<u>151,261</u>	<u>148,828</u>
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An itemized reconciliation between net loss on a GAAP basis and non-GAAP net loss is as follows:

Net Loss — GAAP	\$ (187,303)	\$ (157,781)
Adjustments:		
Share-based compensation expense	74,613	74,473
Amortization expense	45,636	43,479
Depreciation expense	23,972	20,336
Income tax effect related to reconciling items	616	(2,204)
Loss (gain) on warrants and equity method investments	1,264	(1,749)
Non-cash net interest expense	694	705
Upfront license option payment to Reset Therapeutics, Inc. charged to R&D expense	10,000	-
Change in the fair value of contingent consideration	(3,100)	(2,700)
Gain on Gainesville Transaction	-	(9,937)
Gain on sale of property, plant and equipment	-	(455)
Non-GAAP Net Loss	<u>\$ (33,608)</u>	<u>\$ (35,833)</u>

Pursuant to compliance and disclosure interpretations published by the SEC in May 2016, the Company made certain changes to how it presents non-GAAP net loss. The Company no longer adjusts the deferred revenue recognized in the period and now reflects the tax effect of the reconciling items, as opposed to the non-cash taxes, as was previously the case. The Company revised its prior period presentation to reflect its current period presentation.

Condensed Consolidated Balance Sheets (In thousands)	September 30,	December 31,
	2016	2015
Cash, cash equivalents and total investments	\$ 624,605	\$ 798,849
Receivables	177,446	155,487
Inventory	54,155	38,411
Prepaid expenses and other current assets	26,204	26,286
Property, plant and equipment, net	262,181	254,819
Intangible assets, net and goodwill	426,423	472,059
Other assets	136,362	109,833
Total Assets	<u>\$ 1,707,376</u>	<u>\$ 1,855,744</u>
Long-term debt — current portion	\$ 3,000	\$ 65,737
Other current liabilities	187,240	170,470

Long-term debt	282,576	284,207
Deferred revenue — long-term	7,660	7,975
Other long-term liabilities	17,206	13,080
Total shareholders' equity	<u>1,209,694</u>	<u>1,314,275</u>
Total Liabilities and Shareholders' Equity	<u>\$ 1,707,376</u>	<u>\$ 1,855,744</u>

Ordinary shares outstanding (in thousands)	151,805	150,701
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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, 2016, which the company intends to file in November 2016.

Non-GAAP Reconciliation from Prior to Current Presentation

Pursuant to compliance and disclosure interpretations published by the SEC in May 2016, the Company made certain changes to how it presents non-GAAP net loss. The Company no longer adjusts the deferred revenue recognized in the period and now reflects the tax effect of the reconciling items, as opposed to the non-cash taxes, as was previously the case. The Company revised its prior period presentation to reflect its current period presentation. The following reconciliation shows the effect of this change in presentation of non-GAAP net income (loss) for each of the quarters in the year ended December 31, 2015, the year ended December 31, 2015 and the quarter ended March 31, 2016:

	Three Months Ended March 31, 2015	Three Months Ended June 30, 2015	Three Months Ended September 30, 2015	Three Months Ended December 31, 2015	Year Ended December 31, 2015	Three Months Ended March 31, 2016
Non-GAAP Net Income (Loss) — as previously reported	\$ 9,157	\$ (13,585)	\$ (26,174)	\$ (22,629)	\$ (53,231)	\$ (24,566)
Removal of the adjustment for deferred revenue	328	460	384	(542)	630	442
Removal of the adjustment for non-cash taxes	(488)	(3,034)	(677)	2,790	(1,409)	2,863
Adjustment for the income tax effect of other non-GAAP adjustments	2,671	(2,531)	(2,344)	(618)	(2,822)	3,340
Non-GAAP Net Income (Loss) — revised	<u>\$ 11,668</u>	<u>\$ (18,690)</u>	<u>\$ (28,811)</u>	<u>\$ (20,999)</u>	<u>\$ (56,832)</u>	<u>\$ (17,921)</u>
Net Increase (Decrease) From Previously Reported Non-GAAP Net Income (Loss)	<u>\$ 2,511</u>	<u>\$ (5,105)</u>	<u>\$ (2,637)</u>	<u>\$ 1,630</u>	<u>\$ (3,601)</u>	<u>\$ 6,645</u>



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Source: Alkermes plc

Alkermes plc
For Investors:
Sandy Coombs, +1 781-609-6377
or
Eva Stroynowski, +1 781-609-6823
or
For Media:
Jennifer Snyder, +1 781-609-6166