



## Alkermes plc Reports Third Quarter 2015 Financial Results

October 29, 2015

— Third Quarter Revenues of \$152.7 Million and Non-GAAP Diluted Loss Per Share of \$0.18 —

— Commercial Launch of ARISTADA™ Underway Following FDA Approval for the Treatment of Schizophrenia on Oct. 5, 2015 —

— ALKS 3831 for Schizophrenia and ALKS 8700 for Multiple Sclerosis to Commence Registration Studies Before Year-End —

DUBLIN--(BUSINESS WIRE)--Oct. 29, 2015-- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for the third quarter of 2015.

"Earlier this month, the FDA approved ARISTADA™ as the first long-acting atypical antipsychotic for the treatment of schizophrenia with both once-monthly and six-week dosing. Our nationwide commercial launch is underway and we are delighted to bring this important new treatment option to patients and the treatment community," said Richard Pops, Chief Executive Officer of Alkermes. "Alkermes has a number of important milestones ahead that will drive the growth of the company. Based on our recent discussions with the FDA, we have determined the design of the pivotal programs for both ALKS 3831 in schizophrenia and ALKS 8700 in multiple sclerosis and expect to initiate both before year-end. The pivotal program for ALKS 5461 in major depressive disorder is advancing rapidly, and we expect data from the first core efficacy study in the first quarter of 2016."

"We are pleased by our solid financial performance during the third quarter and are on track with our financial expectations for the remainder of 2015. The approval of ARISTADA further strengthens our commercial portfolio and represents a major financial opportunity for Alkermes," commented James Frates, Chief Financial Officer of Alkermes. "Heading into 2016, we are well-positioned to invest in our development plans for our late-stage pipeline, the launch of ARISTADA and drive the growth of VIVITROL®."

### **Quarter Ended Sept. 30, 2015 Highlights**

- Total revenues for the quarter were \$152.7 million compared to \$160.0 million for the same period in the prior year, or \$143.2 million excluding \$16.8 million of revenues from the products associated with the Gainesville manufacturing facility that was divested in April 2015.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$81.0 million, or a basic and diluted GAAP loss per share of \$0.54, for the quarter. This compared to GAAP net loss of \$40.0 million, or a basic and diluted GAAP loss per share of \$0.27, for the same period in the prior year, or \$34.5 million, or a basic and diluted loss per share of \$0.24, excluding \$5.5 million of GAAP net income related to the Gainesville facility and associated products.
- Non-GAAP net loss was \$26.2 million, or a non-GAAP diluted loss per share of \$0.18 for the quarter. This compared to non-GAAP net income of \$3.9 million, or a non-GAAP diluted earnings per share of \$0.03, for the same period in the prior year, or a non-GAAP net loss of \$3.5 million, or a non-GAAP basic and diluted loss per share of \$0.02, excluding \$7.4 million of non-GAAP net income related to the Gainesville facility and associated products.

### **Quarter Ended Sept. 30, 2015 Financial Results**

#### **Revenues**

- Manufacturing and royalty revenues from RISPERDAL CONSTA® and INVEGA SUSTENNA®/XEPLION® were \$67.6 million, compared to \$68.5 million for the same period in the prior year.
- Net sales of VIVITROL were \$37.9 million, compared to \$25.8 million for the same period in the prior year, representing an increase of approximately 47%.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®<sup>1</sup> were \$22.1 million, compared to \$16.5 million for the same period in the prior year.
- Royalty revenue from BYDUREON® was \$13.0 million, compared to \$10.3 million for the same period in the prior year.

#### **Costs and Expenses**

- Operating expenses were \$230.1 million, reflecting increased investment in the company's rapidly advancing development pipeline and pre-launch activities for ARISTADA, and included \$13.9 million of share-based compensation expense related to the partial vesting of a performance-based equity grant related to the approval of ARISTADA. This compared to \$192.7 million for the same period in the prior year, or \$180.0 million excluding \$12.7 million of operating expenses related to the Gainesville facility and associated products.

- Income tax provision was \$3.0 million, compared to \$3.5 million for the same period in the prior year.

#### **Balance Sheet**

At Sept. 30, 2015, Alkermes had cash and total investments of \$815.5 million, compared to \$801.6 million at Dec. 31, 2014. At Sept. 30, 2015, the company's total debt outstanding was \$353.2 million.

#### **Conference Call**

Alkermes will host a conference call at 8:30 a.m. EDT (12:30 p.m. GMT) on Thursday, Oct. 29, 2015, 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. EDT (3:00 p.m. GMT) on Thursday, Oct. 29, 2015, through 5:00 p.m. EST (10:00 p.m. GMT) on Thursday, Nov. 5, 2015, 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](http://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 or loss, non-GAAP diluted earnings or loss per share and free cash flow. 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.

Management defines its non-GAAP financial measures as follows:

- Non-GAAP net income or 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; non-cash tax expense; deferred revenue; and certain other one-time or non-cash items.
- Free cash flow represents non-GAAP net income or loss less capital expenditures.

The company's 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 and cash flows. However, non-GAAP net income or loss, non-GAAP diluted earnings or loss per share and free cash flow are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance.

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 above may 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; the therapeutic and commercial value of the company's products; and expectations concerning the timing and results of development activities, including the timing of the commencement of the pivotal programs for ALKS 3831 and ALKS 8700 and the receipt of data from the first core efficacy study of ALKS 5461. 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 impact of litigation, including litigation against regulatory authorities, in respect of our products; clinical development activities may not be completed on time or at all and the results of such activities may not be 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 U.S. Food and Drug Administration 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 "Item 1A. Risk Factors" in the company's Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014 and under the heading "Item 1A. Risk Factors" in the company's Quarterly Report on Form 10-Q for the fiscal quarter ended Sept. 30, 2015, and in any other subsequent filings made by the company with the Securities and Exchange Commission ("SEC"), which are available on the SEC's website at [www.sec.gov](http://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.

ARISTADA™ is a trademark of Alkermes Pharma Ireland Limited; VIVITROL® is a registered trademark of Alkermes, Inc. RISPERDAL CONSTA®, INVEGA SUSTENNA® and XEPLION® 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.

<sup>1</sup>AMPYRA<sup>®</sup> (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 International GmbH, under a licensing agreement with Acorda Therapeutics, Inc., as FAMPYRA<sup>®</sup> (prolonged-release fampridine tablets).

(tables follow)

**Alkermes plc and Subsidiaries**  
**Selected Financial Information (Unaudited)**

<b>Condensed Consolidated Statements of Operations - GAAP</b> <b>(In thousands, except per share data)</b>	Three Months Ended September 30, 2015	Three Months Ended September 30, 2014
Revenues:		
Manufacturing and royalty revenues	\$ 114,072	\$ 132,028
Product sales, net	37,903	25,802
Research and development revenues	678	2,162
Total Revenues	<u>152,653</u>	<u>159,992</u>
Expenses:		
Cost of goods manufactured and sold	33,806	47,335
Research and development	92,558	78,263
Selling, general and administrative	89,497	51,888
Amortization of acquired intangible assets	14,207	15,244
Total Expenses	<u>230,068</u>	<u>192,730</u>
Operating Loss	<u>(77,415)</u>	<u>(32,738)</u>
Other Expense, net:		
Interest income	865	546
Interest expense	(3,325)	(3,356)
Gain on the Gainesville Transaction	26	-
Increase in the fair value of contingent consideration	1,200	-
Gain on sale of property, plant and equipment	-	36
Other income (expense), net	629	(921)
Total Other Expense, net	<u>(605)</u>	<u>(3,695)</u>
Loss Before Income Taxes	<u>(78,020)</u>	<u>(36,433)</u>
Income Tax Provision	<u>2,995</u>	<u>3,523</u>
<b>Net Loss — GAAP</b>	<u>\$ (81,015)</u>	<u>\$ (39,956)</u>
<b>(Loss) Earnings Per Share:</b>		
GAAP loss per share — basic and diluted	<u>\$ (0.54)</u>	<u>\$ (0.27)</u>
Non-GAAP (loss) earnings per share — basic and diluted	<u>\$ (0.18)</u>	<u>\$ 0.03</u>
<b>Weighted Average Number of Ordinary Shares Outstanding:</b>		
Basic and diluted — GAAP	<u>149,512</u>	<u>145,896</u>
Basic — Non-GAAP	<u>149,512</u>	<u>145,896</u>
Diluted — Non-GAAP	<u>149,512</u>	<u>154,399</u>
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net (loss) income is as follows:		
<b>Net Loss — GAAP</b>	<u>\$ (81,015)</u>	<u>\$ (39,956)</u>
Adjustments:		
Share-based compensation expense	35,267	13,481
Amortization expense	14,207	15,244
Depreciation expense	6,486	9,989
Non-cash taxes	677	3,640
Non-cash net interest expense	234	238
Deferred revenue	(725)	696
Net (gain) loss on transactions with equity method investee	(397)	603
Gain on the Gainesville Transaction	(26)	-
Increase in the fair value of contingent consideration	(1,200)	-
Change in the fair value of common stock warrants	318	-

Gain on sale of property, plant and equipment	-	(36)
<b>Non-GAAP Net (Loss) Income</b>	<b>\$ (26,174)</b>	<b>\$ 3,899</b>
Capital expenditures	11,974	8,888
<b>Free Cash Outflow</b>	<b>\$ (38,148)</b>	<b>\$ (4,989)</b>

	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
<b>Condensed Consolidated Statements of Operations - GAAP</b>		
<b>(In thousands, except per share data)</b>		
Revenues:		
Manufacturing and royalty revenues	\$ 355,978	\$ 373,674
Product sales, net	106,212	64,476
Research and development revenues	3,047	5,478
<b>Total Revenues</b>	<b>465,237</b>	<b>443,628</b>
Expenses:		
Cost of goods manufactured and sold	104,198	129,464
Research and development	250,718	197,610
Selling, general and administrative	224,086	145,101
Amortization of acquired intangible assets	43,479	42,909
<b>Total Expenses</b>	<b>622,481</b>	<b>515,084</b>
<b>Operating Loss</b>	<b>(157,244)</b>	<b>(71,456)</b>
Other Income, net:		
Interest income	2,320	1,380
Interest expense	(9,928)	(10,097)
Gain on the Gainesville Transaction	9,937	-
Increase in the fair value of contingent consideration	2,700	-
Gain on sale of investment in Acceleron Pharma Inc.	-	15,296
Gain on sale of property, plant and equipment	-	12,321
Other income (expense), net	1,003	(2,253)
<b>Total Other Income, net</b>	<b>6,032</b>	<b>16,647</b>
<b>Loss Before Income Taxes</b>	<b>(151,212)</b>	<b>(54,809)</b>
<b>Income Tax Provision</b>	<b>6,569</b>	<b>5,766</b>
<b>Net Loss — GAAP</b>	<b>\$ (157,781)</b>	<b>\$ (60,575)</b>

**(Loss) Earnings Per Share:**

GAAP loss per share — basic and diluted	\$ (1.06)	\$ (0.42)
Non-GAAP (loss) earnings per share — basic	\$ (0.21)	\$ 0.26
Non-GAAP (loss) earnings per share — diluted	\$ (0.21)	\$ 0.25

**Weighted Average Number of Ordinary Shares Outstanding:**

Basic and diluted — GAAP	148,828	144,732
Basic — Non-GAAP	148,828	144,732
Diluted — Non-GAAP	148,828	154,017

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

<b>Net Loss — GAAP</b>	<b>\$ (157,781)</b>	<b>\$ (60,575)</b>
Adjustments:		
Share-based compensation expense	74,473	46,238
Amortization expense	43,479	42,909
Depreciation expense	20,336	29,810
Non-cash taxes	4,199	5,055
Non-cash net interest expense	705	717
Deferred revenue	(1,627)	(607)
Net (gain) loss on transactions with equity method investee	(1,191)	1,842
Gain on the Gainesville Transaction	(9,937)	-
Increase in the fair value of contingent consideration	(2,700)	-
Change in the fair value of common stock warrants	(558)	-
Gain on sale of investment in Acceleron Pharma Inc.	-	(15,296)

Gain on sale of property, plant and equipment	-	(12,321)
<b>Non-GAAP Net (Loss) Income</b>	<b>\$ (30,602)</b>	<b>\$ 37,772</b>
Capital expenditures	36,730	20,326
<b>Free Cash (Outflow) Inflow</b>	<b>\$ (67,332)</b>	<b>\$ 17,446</b>

<b>Condensed Consolidated Balance Sheets</b> <b>(In thousands)</b>	September 30, 2015	December 31, 2014
Cash, cash equivalents and total investments	\$ 815,499	\$ 801,646
Receivables	140,987	151,551
Inventory	36,783	51,357
Prepaid expenses and other current assets	50,893	42,719
Property, plant and equipment, net	242,675	265,740
Intangible assets, net and goodwill	486,266	573,624
Contingent consideration	60,300	-
Other assets	47,552	34,635
<b>Total Assets</b>	<b>\$ 1,880,955</b>	<b>\$ 1,921,272</b>
Long-term debt — current portion	\$ 66,712	\$ 6,750
Other current liabilities	133,690	123,832
Long-term debt	286,512	351,220
Deferred revenue — long-term	7,477	11,801
Other long-term liabilities	19,759	30,832
Total shareholders' equity	1,366,805	1,396,837
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 1,880,955</b>	<b>\$ 1,921,272</b>
Ordinary shares outstanding (in thousands)	149,854	147,539

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, 2015, which the company intends to file in October 2015.



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