



Alkermes plc Reports Third Quarter 2014 Financial Results

October 29, 2014

— Third Quarter 2014 Revenues Grew 14% Year-Over-Year to \$160.0 Million —

— Non-GAAP Diluted EPS of \$0.03 for Third Quarter —

— CNS Pipeline Continues to Advance With Lead Product Candidate, Aripiprazole Lauroxil, Assigned FDA Action Date of Aug. 22, 2015 —

DUBLIN--(BUSINESS WIRE)--Oct. 29, 2014-- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for the third quarter of 2014.

"We enter the fourth quarter with strong momentum, and on the threshold of multiple data readouts for one of the most exciting and robust pipelines of new CNS medicines in the industry," said Richard Pops, Chief Executive Officer of Alkermes. "Our most advanced candidate, aripiprazole lauroxil for the treatment of schizophrenia, builds on our experience in the increasingly important long-acting injectable antipsychotic class. Following the acceptance of the aripiprazole lauroxil NDA last week, we are keenly focused on preparing for its introduction and expanding the awareness of the benefits of long-acting antipsychotics for patients, physicians and the community."

"This quarter's results demonstrate Alkermes' strong financial and operational position, with a robust portfolio of commercial products generating significant revenue funding the development of our pipeline of CNS candidates. Further, our strong balance sheet gives us the ability to control the development of our pipeline," commented James Frates, Chief Financial Officer of Alkermes. "We have all the elements and resources in place to advance our novel candidates and look forward to reporting substantial progress in the coming months."

Quarter Ended Sept. 30, 2014 Financial Highlights

- Total revenues for the quarter were \$160.0 million, compared to \$139.8 million for the same period in the prior year.
- Non-GAAP net income was \$3.9 million, or a non-GAAP diluted earnings per share (EPS) of \$0.03, for the quarter. This compared to non-GAAP net income of \$31.8 million, or a non-GAAP diluted EPS of \$0.22, for the same period in the prior year.
- GAAP net loss was \$40.0 million, or a basic and diluted GAAP net loss per share of \$0.27, for the quarter. This compared to GAAP net loss of \$7.8 million, or a basic and diluted GAAP net loss per share of \$0.06, for the same period in the prior year.
- Free cash flow was an outflow of \$5.0 million for the quarter, compared to an inflow of \$26.2 million for the same period in the prior year.

Quarter Ended Sept. 30, 2014 Financial Results

Revenues

- Manufacturing and royalty revenues from the company's long-acting atypical antipsychotic franchise, RISPERDAL[®] CONSTA[®] and INVEGA[®] SUSTENNA[®]/XEPLION[®], were \$68.5 million, compared to \$62.6 million for the same period in the prior year, representing an increase of approximately 9%.
- Manufacturing and royalty revenues from AMPYRA[®]/FAMPYRA^{®1} were \$16.5 million, compared to \$12.6 million for the same period in the prior year, representing an increase of approximately 31%.
- Net sales of VIVITROL[®] were \$25.8 million, compared to \$19.2 million for the same period in the prior year, representing an increase of approximately 34%.
- Royalty revenue from BYDUREON[®] was \$10.3 million, compared to \$7.0 million for the same period in the prior year, representing an increase of approximately 46%.
- In addition, results for the quarter included RITALIN LA[®]/FOCALIN XR[®] revenues of \$8.7 million, VERELAN[®] revenues of \$6.3 million and EMEND[®] revenues of \$4.4 million. This compared to RITALIN LA/FOCALIN XR revenues of \$9.2 million, VERELAN revenues of \$4.4 million and EMEND revenues of \$3.0 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were \$192.7 million for the quarter, compared to \$143.7 million for the same period in the prior year. This included Research and Development (R&D) expense of \$78.3 million, compared to \$45.9 million for the same period in the prior year. This increase was driven by a substantial increase in the number of late-stage clinical studies that the company is conducting.
- The company reported an income tax provision of \$3.5 million for the quarter, compared to an income tax provision of \$0.2 million for the same period in the prior year.

Balance Sheet

At Sept. 30, 2014, Alkermes had cash and total investments of \$716.3 million, compared to \$713.9 million at June 30, 2014. At Sept. 30, 2014, the company's total debt outstanding was \$359.6 million.

Financial Expectations

Alkermes is updating its financial expectations for 2014 as a result of the acquisition of Civitas Therapeutics, Inc. (Civitas) by Acorda Therapeutics, Inc. This transaction is expected to improve GAAP net loss for Alkermes by approximately \$40 million, to a range of \$50 million to \$70 million. The following outlines Alkermes' updated financial expectations for 2014.

- **Revenues:** Alkermes continues to expect total revenues to range from \$580 million to \$610 million.
- **Cost of Goods Manufactured:** The company continues to expect cost of goods manufactured to range from \$165 million to \$175 million.
- **R&D Expenses:** The company continues to expect R&D expenses to range from \$260 million to \$280 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company continues to expect SG&A expenses to range from \$190 million to \$200 million.
- **Amortization of Intangible Assets:** The company continues to expect amortization of intangibles of approximately \$60 million.
- **Net Interest Expense:** The company continues to expect net interest expense to range from \$10 million to \$15 million.
- **Other Income (Expense), Net:** The company now expects net other income to range from \$85 million to \$90 million, up from the previous range of \$25 million to \$30 million, reflecting approximately \$60 million that Alkermes will earn related to the Civitas transaction.
- **Net Income Tax Expense:** The company now expects net income tax expense to range from \$30 million to \$35 million, up from a range \$10 million to \$15 million, reflecting an estimated \$20 million tax charge related to the Civitas transaction.
- **GAAP Net Loss:** The company now expects GAAP net loss to range from \$50 million to \$70 million, or a basic and diluted loss per share of approximately \$0.34 to \$0.48, based on weighted average basic and diluted share counts of approximately 145 million shares outstanding. This compares to previous expectations of a GAAP net loss in the range of \$90 million to \$110 million, or a basic and diluted loss per share of approximately \$0.62 to \$0.76, based on weighted average basic and diluted share counts of approximately 145 million shares outstanding.
- **Non-GAAP Net Income:** The company continues to expect non-GAAP net income to range from \$30 million to \$50 million, and non-GAAP diluted EPS to range from \$0.19 to \$0.32, based on a weighted average diluted share count of approximately 155 million shares outstanding.
- **Capital Expenditures:** The company continues to expect capital expenditures to be approximately \$30 million.
- **Free Cash Flow:** The company continues to expect free cash flow of up to \$20 million.

Conference Call

Alkermes will host a conference call at 8:30 a.m. EDT (12:30 p.m. GMT) on Wednesday, Oct. 29, 2014, 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 Wednesday, Oct. 29, 2014, through 5:00 p.m. EST (10:00 p.m. GMT) on Wednesday, Nov. 5, 2014, 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 that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and 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, non-GAAP diluted earnings 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 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 less capital expenditures.

Management believes that these non-GAAP financial measures, when viewed with its results under GAAP and the accompanying reconciliations, better indicate underlying trends in ongoing operations and cash flows. However, non-GAAP net income, non-GAAP diluted earnings 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 clinical development activities. 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 projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: 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 occur 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 “Risk Factors” in the company’s Transition Report on Form 10-K for the fiscal period ended Dec. 31, 2013, and in other subsequent filings made by the company with the 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.; RISPERDAL® CONSTA®, INVEGA® SUSTENNA® and XEPLION® are registered trademarks of Johnson & Johnson Corporation (or its affiliate); AMPYRA® and FAMPYRA® are registered trademarks of Acorda Therapeutics, Inc.; BYDUREON® is a registered trademark of Amylin Pharmaceuticals, LLC; RITALIN LA® and FOCALIN XR® are registered trademarks of Novartis AG Corporation; EMEND® is a registered trademark of Merck Sharp & Dohme Corp.; and VERELAN® is a registered trademark of Daravita Limited.

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, 2014	Three Months Ended September 30, 2013
Condensed Consolidated Statements of Operations - GAAP		
(In thousands, except per share data)		
Revenues:		
Manufacturing and royalty revenues	\$ 132,028	\$ 118,571
Product sales, net	25,802	19,227
Research and development revenues	2,162	2,004
Total Revenues	159,992	139,802
Expenses:		
Cost of goods manufactured and sold	47,335	45,423
Research and development	78,263	45,947
Selling, general and administrative	51,888	39,454
Amortization of acquired intangible assets	15,244	12,856
Total Expenses	192,730	143,680
Operating Loss	(32,738)	(3,878)
Other Expense, net:		
Interest income	546	295
Interest expense	(3,356)	(3,477)
Gain on sale of property, plant and equipment	36	-
Other expense, net	(921)	(469)
Total Other Expense, net	(3,695)	(3,651)
Loss Before Income Taxes	(36,433)	(7,529)
Income Tax Provision	3,523	233
Net Loss — GAAP	\$ (39,956)	\$ (7,762)

(Loss) Earnings Per Share:

GAAP loss per share — basic and diluted	\$ (0.27)	\$ (0.06)
Non-GAAP earnings per share — basic	\$ 0.03		\$ 0.23	
Non-GAAP earnings per share — diluted	\$ 0.03		\$ 0.22	

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP and Non-GAAP	145,896	136,106
Diluted — GAAP	145,896	136,106
Diluted — Non-GAAP	154,399	144,861

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

Net Loss — GAAP	\$ (39,956)	\$ (7,762)
Adjustments:				
Share-based compensation expense	13,481		14,209	
Amortization expense	15,244		12,856	
Depreciation expense	9,989		10,818	
Non-cash net interest expense	238		267	
Non-cash taxes	3,640		612	
Deferred revenue	696		765	
Net loss on transactions with equity method investee	603		-	
Gain on sale of property, plant and equipment	(36)	-	
Non-GAAP Net Income	\$ 3,899		\$ 31,765	
Capital expenditures	8,888		5,573	
Free Cash Flow	\$ (4,989)	\$ 26,192	

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

	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013		
Condensed Consolidated Statements of Operations - GAAP				
(In thousands, except per share data)				
Revenues:				
Manufacturing and royalty revenues	\$ 373,674	\$ 385,278		
Product sales, net	64,476	51,232		
Research and development revenues	5,478	5,345		
Total Revenues	443,628	441,855		
Expenses:				
Cost of goods manufactured and sold	129,464	139,407		
Research and development	197,610	115,209		
Selling, general and administrative	145,101	107,066		
Amortization of acquired intangible assets	42,909	35,894		
Restructuring	-	12,300		
Impairment of long-lived assets	-	3,346		
Total Expenses	515,084	413,222		
Operating (Loss) Income	(71,456)	28,633	
Other Income (Expense), net:				
Interest income	1,380	627		
Interest expense	(10,097)	(18,418)
Gain on sale of investment in Acceleron Pharma Inc.	15,296	-		
Gain on sale of property, plant and equipment	12,321	-		
Other (expense) income, net	(2,253)	(455)
Total Other Income (Expense), net	16,647	(18,246)	
(Loss) Income Before Income Taxes	(54,809)	10,387	
Income Tax Provision	5,766	7,818		
Net (Loss) Income — GAAP	\$ (60,575)	\$ 2,569	

(Loss) Earnings Per Share:

GAAP (loss) earnings per share — basic and diluted	\$ (0.42)	\$ 0.02
Non-GAAP earnings per share — basic	\$ 0.26		\$ 0.97
Non-GAAP earnings per share — diluted	\$ 0.25		\$ 0.92

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP and Non-GAAP	144,732	134,670
Diluted — GAAP	144,732	143,022
Diluted — Non-GAAP	154,017	143,022

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

Net (Loss) Income — GAAP	\$ (60,575)	\$ 2,569
Adjustments:			
Share-based compensation expense	46,238		30,899
Amortization expense	42,909		35,894
Depreciation expense	29,810		29,828
Non-cash net interest expense	717		835
Non-cash taxes	5,055		7,869
Deferred revenue	(607)	(210
Net loss on transactions with equity method investee	1,842		-
Gain on sale of investment in Acceleron Pharma Inc.	(15,296)	-
Gain on sale of property, plant and equipment	(12,321)	-
Restructuring	-		12,300
Loss on debt repricing	-		7,541
Impairment of long-lived assets	-		3,346
Non-GAAP Net Income	\$ 37,772		\$ 130,871
Capital expenditures	20,326		17,457
Free Cash Flow	\$ 17,446		\$ 113,414

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

Condensed Consolidated Balance Sheets	September 30,	December 31,
(In thousands)	2014	2013
Cash, cash equivalents and total investments	\$ 716,316	\$ 449,995
Receivables	143,692	134,154
Inventory	50,471	46,218
Prepaid expenses and other current assets	46,174	27,535
Property, plant and equipment, net	262,128	274,490
Intangible assets, net and goodwill	587,396	630,305
Other assets	31,678	14,891
Total Assets	\$ 1,837,855	\$ 1,577,588
Long-term debt — current portion	\$ 6,750	\$ 6,750
Other current liabilities	103,390	94,147
Long-term debt	352,801	357,543
Deferred revenue — long-term	11,519	12,213
Other long-term liabilities	29,803	41,749
Total shareholders' equity	1,333,592	1,065,186
Total Liabilities and Shareholders' Equity	\$ 1,837,855	\$ 1,577,588
Ordinary shares outstanding (in thousands)	146,088	137,793

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, 2014, which the company intends to file in October 2014.

Alkermes plc and Subsidiaries**2014 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	\$ (60.0)	145	\$ (0.41)
Adjustments:			
Non-cash net interest expense	1.0		
Non-cash taxes	10.0		
Depreciation expense	40.0		
Amortization expense	60.0		
Share-based compensation expense	58.0		
Gain on sale of investment in Acceleron Pharma Inc.	(15.0)		
Gain on sale of property, plant and equipment	(12.0)		
Proceeds from Civitas transaction, net of taxes	(40.0)		
Deferred revenue	(2.0)		
Projected Non-GAAP Net Income	\$ 40.0	155	\$ 0.26
Capital expenditures	(30.0)		
Projected Free Cash Flow	\$ 10.0		

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

Source: Alkermes plc

Alkermes plc

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