

# Alkermes plc Reports Financial Results for the Year Ended Dec. 31, 2014 and Provides Financial Expectations for 2015

February 24, 2015

-Record Revenues of \$618.8 Million and Non-GAAP Diluted EPS of \$0.35 for Calendar 2014 -

-Preparing for Launch of Aripiprazole Lauroxil and Advancing Pivotal Development Programs for ALKS 5461, ALKS 3831 and ALKS 8700 -

DUBLIN--(BUSINESS WIRE)--Feb. 24, 2015-- Alkermes plc (NASDAQ: ALKS) today reported financial results for the twelve months ended Dec. 31, 2014 and provided financial expectations for 2015.

"We had a tremendous year of achievement in 2014, marked by successful execution of our ambitious business plan and exciting clinical validation of our development pipeline, as we continue on our path to create a major biopharmaceutical company. In the last two months, the momentum has continued as we reported positive data for three potential blockbuster opportunities: ALKS 5461 in major depressive disorder, ALKS 3831 in schizophrenia and ALKS 8700 for multiple sclerosis," said Richard Pops, Chief Executive Officer of Alkermes. "We have major opportunities ahead in 2015, as we advance this pipeline of valuable CNS medicines. We are preparing to launch aripiprazole lauroxil as an important new treatment option for patients with schizophrenia and their caregivers, and we look forward to continued clinical progress across the rest of our development pipeline in 2015."

"Our financial results for 2014 were ahead of expectations, demonstrating our successful performance and the strength of our business model. We ended the year with more than \$800 million in cash and investments, which provides the financial flexibility to further execute on our strategic plan, including resources to invest in a remarkable late-stage pipeline that we control entirely," commented James Frates, Chief Financial Officer of Alkermes. "Our financial expectations for 2015 reflect investments in this increasingly valuable late-stage pipeline, as well as significant investment in our commercial organization in preparation for the launch of aripiprazole lauroxil later this year."

# Quarter Ended Dec. 31, 2014 Financial Highlights

- Total revenues for the quarter grew 13% to \$175.2 million from \$154.5 million for the same period in the prior year.
- Non-GAAP net income was \$16.8 million, or a non-GAAP diluted earnings per share (EPS) of \$0.11 for the quarter. This
  compared to non-GAAP net income of \$39.9 million, or a non-GAAP diluted EPS of \$0.27, for the same period in the prior
  year and reflected increased investment in the company's rapidly advancing late-stage pipeline and commercial
  infrastructure.
- GAAP net income was \$30.5 million, or a basic GAAP EPS of \$0.21 and a diluted GAAP EPS of \$0.20, for the quarter, including approximately \$60 million that Alkermes earned related to the acquisition of Civitas Therapeutics, Inc. (Civitas) by Acorda Therapeutics, Inc. This compared to GAAP net income of \$18.1 million, or a basic GAAP EPS of \$0.13 and diluted GAAP EPS of \$0.12, for the same period in the prior year.
- Free cash flow was \$3.5 million for the quarter, compared to \$30.0 million for the same period in the prior year.

### Quarter Ended Dec. 31, 2014 Financial Results

# Revenues

- Manufacturing and royalty revenues from the company's long-acting atypical antipsychotic franchise, RISPERDAL<sup>®</sup> CONSTA<sup>®</sup> and INVEGA<sup>®</sup> SUSTENNA<sup>®</sup>/XEPLION<sup>®</sup>, were \$70.3 million, compared to \$71.2 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA<sup>®</sup>/FAMPYRA<sup>®1</sup> were \$24.3 million, compared to \$18.6 million for the same period in the prior year.
- Net sales of VIVITROL<sup>®</sup> were \$29.7 million, compared to \$20.6 million for the same period in the prior year, representing an increase of 44%.
- Royalty revenue from BYDUREON® was \$9.8 million, compared to \$7.7 million for the same period in the prior year.

Costs and Expenses

- Operating expenses for the quarter ended Dec. 31, 2014 were \$190.8 million, compared to \$148.6 million for the same period in the prior year, reflecting increased investment in the company's rapidly advancing development pipeline and prelaunch activities for aripiprazole lauroxil.
- Income tax expense for the quarter ended Dec. 31, 2014 was \$10.3 million, compared to an income tax benefit of \$15.2 million for the same period in the prior year.

### Calendar Year 2014 Financial Highlights

- Total revenues were \$618.8 million in calendar 2014, which included VIVITROL net sales of \$94.2 million. This compared to total revenues of \$596.3 million for calendar 2013, which included \$30.0 million of one-time intellectual property license revenue. Please see the tables at the end of this press release for a detailed breakdown of the revenues from our key commercial products.
- Non-GAAP net income was \$54.6 million, or a non-GAAP diluted EPS of \$0.35, for calendar 2014. This compared to non-GAAP net income of \$170.7 million, or a non-GAAP diluted EPS of \$1.19, for calendar 2013 and reflected increased investment in the company's rapidly advancing late-stage pipeline and commercial infrastructure.
- GAAP net loss was \$30.1 million, or a basic and diluted GAAP loss per share of \$0.21, for calendar 2014. This compared to a GAAP net income of \$20.6 million, or a basic GAAP EPS of \$0.15 and diluted GAAP EPS of \$0.14, for calendar 2013.
- Free cash flow was \$20.9 million for calendar 2014, compared to \$143.4 million for calendar 2013.
- At Dec. 31, 2014, Alkermes recorded cash and total investments of \$801.6 million, compared to \$450.0 million at Dec. 31, 2013. The increase in cash reflects the company's active management of the business and was primarily driven by gross proceeds of \$250.0 million related to the sale of Alkermes' ordinary shares through a registered direct offering in January 2014. Additionally, the company received net proceeds of approximately \$96 million from the sale of its stakes in Civitas and Acceleron Pharma Inc. and from the sale of two buildings in Athlone, Ireland. At Dec. 31, 2014, the company's total debt outstanding was \$358.0 million.

### **Financial Expectations for 2015**

The following outlines the company's financial expectations for 2015. The following statements are forward-looking, and actual results may differ materially. Please see "Note Regarding Forward-Looking Statements" at the end of this press release for risks that could cause results to differ materially from these forward-looking statements.

- **Revenues:** The company expects total revenues to range from \$640 million to \$670 million. Included in this total revenue expectation, Alkermes expects VIVITROL net sales to range from \$125 million to \$135 million and net sales from the anticipated launch of aripiprazole lauroxil to range from \$5 million to \$10 million.
- Cost of Goods Manufactured and Sold: The company expects cost of goods manufactured and sold to range from \$155 million to \$165 million.
- Research and Development (R&D) Expenses: The company expects R&D expenses to range from \$345 million to \$365 million.
- Selling, General and Administrative (SG&A) Expenses: The company expects SG&A expenses to range from \$310 million to \$330 million.
- Amortization of Intangible Assets: The company expects amortization of intangibles to be approximately \$65 million.
- Net Interest Expense: The company expects net interest expense to range from \$10 million to \$15 million.
- Income Tax Expense: The company expects income tax expense to range from \$10 million to \$15 million.
- GAAP Net Loss: The company expects a GAAP net loss in the range of \$255 million to \$285 million, or a basic and diluted loss per share of \$1.70 to \$1.90, based on a weighted average basic and diluted share count of approximately 150 million shares outstanding.
- Non-GAAP Net Loss: The company expects a non-GAAP net loss in the range of \$40 million to \$60 million, and non-GAAP basic and diluted EPS to range from \$0.27 to \$0.40.
- Capital Expenditures: The company expects capital expenditures to be approximately \$55 million.
- Free Cash Flow: The company expects a free cash outflow in the range of \$95 million to \$115 million.

### **Conference Call**

Alkermes will host a conference call at 8:30 a.m. EST (1:30 p.m. GMT) on Tuesday, Feb. 24, 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. EST (4:00 p.m. GMT) on Tuesday, Feb. 24, 2015, through 5:00 p.m. EST (10:00 p.m. GMT) on Tuesday, March 3, 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 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, depression 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 manufacturing facilities in Gainesville, Georgia and Wilmington, Ohio. For more information, please visit Alkermes' website at <u>www.alkermes.com</u>.

### **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.

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, 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, including regulatory approval of aripiprazole lauroxil. 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: 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 "Risk Factors" in the company's Transition Report on Form 10-K for the fiscal period ended Dec. 31, 2013, and in any 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<sup>®</sup> is a registered trademark of Alkermes, Inc.; RISPERDAL<sup>®</sup> CONSTA<sup>®</sup>, INVEGA<sup>®</sup> SUSTENNA<sup>®</sup> and XEPLION<sup>®</sup> are registered trademarks of Johnson & Johnson Corporation; AMPYRA<sup>®</sup> and FAMPYRA<sup>®</sup> are registered trademarks of Acorda Therapeutics, Inc.; BYDUREON<sup>®</sup> 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 Idec, under a licensing agreement with Acorda Therapeutics, as FAMPYRA<sup>®</sup> (prolonged-release fampridine tablets).

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

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended December 31, 2014	Three Months Ended December 31, 2013
Revenues:		
Manufacturing and royalty revenues	\$ 143,202	\$ 132,680
Product sales, net	29,684	20,609
Research and development revenues	2,275	1,189
Total Revenues	175,161	154,478
Expenses:		
Cost of goods manufactured and sold	46,368	42,892
Research and development	74,433	48,716
Selling, general and administrative	54,804	44,171
Amortization of acquired intangible assets	15,244	12,856
Total Expenses	190,849	148,635
Operating (Loss) Income	(15,688)	5,843
Other Income (Expense), net:		
Interest income	592	255
Interest expense	(3,333 )	(3,434 )

Gain on sale of property, plant and equipment Gain on sale of investment in Civitas Therapeutics, Inc. Other income, net Total Other Income (Expense), net Income Before Income Taxes Income Tax Provision (Benefit) <b>Net Income — GAAP</b>	29,612 29,564 33 56,468 40,780 10,266 \$ 30,514		- 210 (2,969 2,874 (15,203 \$ 18,077	) )
Earnings Per Share:				
GAAP earnings per share — basic	\$ 0.21		\$ 0.13	
GAAP earnings per share — diluted	\$ 0.20		\$ 0.12	
Non-GAAP earnings per share — basic	\$ 0.11		\$ 0.29	
Non-GAAP earnings per share — diluted	\$ 0.11		\$ 0.27	
Weighted Average Number of Ordinary Shares Outstanding:	1 10 000		407 450	
Basic — GAAP	146,882		137,158	
Diluted — GAAP	155,527		146,304	
Basic — Non-GAAP	146,882		137,158	
Diluted — Non-GAAP	155,527		146,304	
An itemized reconciliation between net income on a GAAP basis and non-GAAP net income is as follows:				
Net Income — GAAP	\$ 30,514		\$ 18,077	
Adjustments:	+ ,		+ ,	
Amortization expense	15,244		12,856	
Share-based compensation expense	13,341		10,391	
Depreciation expense	10,124		10,532	
Non-cash taxes	7,324		(15,616	)
Non-cash net interest expense	237		243	
Deferred revenue	(390	)	3,381	
Gain on sale of property, plant and equipment	(29,612	)	-	
Net gain on transactions with equity method investee	(29,961	)	-	
Non-GAAP Net Income	\$ 16,821	-	\$ 39,864	
Capital expenditures	(13,325	)	(9,856	)
Free Cash Flow	\$ 3,496	-	\$ 30,008	-

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Year Ended December 31, 2014	Year Ended December 31, 2013	
Revenues:			
Manufacturing and royalty revenues	\$ 516,876	\$ 517,958	
Product sales, net	94,160	71,841	
Research and development revenues	7,753	6,534	
Total Revenues	618,789	596,333	
Expenses:			
Cost of goods manufactured and sold	175,832	182,297	
Research and development	272,043	163,925	
Selling, general and administrative	199,905	151,237	
Amortization of acquired intangible assets	58,153	48,750	
Restructuring	-	12,300	
Impairment of long-lived assets	-	3,346	
Total Expenses	705,933	561,855	
Operating (Loss) Income	(87,144 )	34,478	
Other Income (Expense), net:			
Interest income	1,972	882	
Interest expense	(13,430)	(21,852 )	
Gain on sale of property, plant and equipment	41,933	-	
Gain on sale of investment in Civitas Therapeutics, Inc.	29,564	-	
Gain on sale of investment in Acceleron Pharma Inc.	15,296	-	
Other (expense), net	(2,220)	(245)	
Total Other Income (Expense), net	73,115	(21,215 )	
(Loss) Income Before Income Taxes	(14,029 )	13,263	

Income Tax Provision (Benefit)	16,032		(7,385	
Net (Loss) Income — GAAP	\$ (30,061	)	\$ 20,648	
(Loss) Earnings Per Share:				
GAAP (loss) earnings per share — basic	\$ (0.21	)	\$ 0.15	
GAAP (loss) earnings per share — diluted	\$ (0.21	)	\$ 0.14	
Non-GAAP earnings per share — basic	\$ 0.38		\$ 1.26	
Non-GAAP earnings per share — diluted	\$ 0.35		\$ 1.19	
Weighted Average Number of Ordinary Shares Outstanding:				
Basic — GAAP	145,274		135,297	
Diluted — GAAP	145,274		144,012	

145,274

154,415

135,297

144,012

)

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

Basic — Non-GAAP

Diluted - Non-GAAP

Net (Loss) Income — GAAP	\$ (30,061	)	\$ 20,648	
Adjustments:				
Share-based compensation expense	59,579		41,290	
Amortization expense	58,153		48,750	
Depreciation expense	39,934		40,360	
Non-cash taxes	12,379		(7,747	)
Non-cash net interest expense	954		1,078	
Deferred revenue	(997	)	3,171	
Gain on sale of investment in Acceleron Pharma Inc.	(15,296	)	-	
Net gain on transactions with equity method investee	(28,119	)	-	
Gain on sale of property, plant and equipment	(41,933	)	-	
Restructuring	-		12,300	
Loss on debt refinancing and repricing	-		7,541	
Impairment of long-lived assets	-		3,346	
Non-GAAP Net Income	\$ 54,593		\$ 170,737	
Capital expenditures	(33,651	)	(27,313	)
Free Cash Flow	\$ 20,942		\$ 143,424	

Condensed Consolidated Balance Sheets (In thousands)	December 31, 2014	December 31, 2013
Cash, cash equivalents and total investments	\$ 801,646	\$ 449,995
Receivables	151,551	134,154
Inventory	51,357	46,218
Prepaid expenses and other current assets	42,719	27,535
Property, plant and equipment, net	265,740	274,490
Intangible assets, net and goodwill	573,624	630,305
Other assets	34,635	14,891
Total Assets	\$ 1,921,272	\$ 1,577,588
Long-term debt — current portion	\$ 6,750	\$ 6,750
Other current liabilities	123,832	94,147
Long-term debt	351,220	357,543
Deferred revenue — long-term	11,801	12,213
Other long-term liabilities	30,832	41,749
Total shareholders' equity	1,396,837	1,065,186
Total Liabilities and Shareholders' Equity	\$ 1,921,272	\$ 1,577,588
Ordinary shares outstanding (in thousands)	147,539	137,793

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Annual Report on Form 10-K for the year ended December 31, 2014, which the company intends to file in February 2015.

# **Revenues for Calendar Year 2014**

(In thousands, except per share data)	Three Months Ended March 31, 2014	Three Months Ended June 30, 2014	Three Months Ended September 30, 2014	Three Months Ended December 31, 2014	Year Ended December 31, 2014
Revenues:					
RISPERDAL CONSTA/INVEGA SUSTENNA Franchise	\$ 49,608	\$ 60,001	\$ 68,472	\$ 70,311	\$ 248,392
AMPYRA/FAMPYRA	20,631	19,518	16,503	24,273	80,925
BYDUREON	7,700	8,784	10,254	9,849	36,587
VIVITROL	17,079	21,595	25,802	29,684	94,160
Key Commercial Product Revenues	95,018	109,898	121,031	134,117	460,064
Total Legacy Product Revenues	33,341	42,063	36,799	38,769	150,972
Research and Development Revenues	1,853	1,463	2,162	2,275	7,753
Total Revenues	\$ 130,212	\$ 153,424	\$ 159,992	\$175,161	\$ 618,789

# 2015 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	\$ (270.0	)	150	\$ (1.80	)
Adjustments:					
Non-cash net interest expense	1.0				
Non-cash taxes	10.0				
Depreciation expense	35.0				
Amortization expense	65.0				
Share-based compensation expense	110.0				
Deferred revenue	(1.0	)			
Projected Non-GAAP Net Loss	\$ (50.0	)	150	\$ (0.33	)
Capital expenditures	55.0				
Projected Free Cash Outflow	\$ (105.0	)			

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

Source: Alkermes plc

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