



Alkermes plc Reports Second Quarter 2014 Financial Results

July 31, 2014

—Revenues Grew Approximately 11% Year-Over-Year to \$153.4 Million —

—Non-GAAP Diluted EPS of \$0.11 for Second Quarter —

—Company Increases Expectation for 2014 R&D Investment, Driven by Faster Initiation of Key Clinical Studies for Late-Stage Pipeline Candidates —

—Company On Track to Submit Aripiprazole Lauroxil NDA in Third Quarter of 2014 —

DUBLIN--(BUSINESS WIRE)--Jul. 31, 2014-- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for the second quarter of 2014.

"These quarterly results reflect the strength of our commercial business and the progress we are making to advance Alkermes' pipeline of innovative CNS medicines. We expect this valuable, late-stage pipeline to fuel significant future growth, and we are in the strong position to drive new product development with robust and reliable revenue streams and significant cash on the balance sheet," commented James Frates, Chief Financial Officer of Alkermes. "Today, we are updating our financial expectations for 2014 to reflect our results year-to-date and investment in R&D activities that have accelerated since we originally provided expectations in February."

"At Alkermes, we are focused on the development of important new CNS medicines that are designed to benefit patients, providers, payers and society," said Richard Pops, Chief Executive Officer of Alkermes. "With the upcoming NDA submission for aripiprazole lauroxil, the pivotal program well underway for ALKS 5461, and important new data expected for ALKS 3831, ALKS 8700 and ALKS 7106 in the next several months, we are executing on our strategy and making rapid progress to bring these new medicines to patients."

Quarter Ended June 30, 2014 Financial Highlights

- Total revenues for the quarter were \$153.4 million, compared to \$138.6 million for the same period in the prior year.
- Non-GAAP net income was \$17.7 million, or a non-GAAP diluted earnings per share (EPS) of \$0.11, for the quarter. This compared to non-GAAP net income of \$42.9 million, or a non-GAAP diluted EPS of \$0.30, for the same period in the prior year.
- GAAP net income was \$3.7 million, or a basic GAAP EPS of \$0.03 and a diluted GAAP EPS of \$0.02, for the quarter. These results included a gain of \$15.3 million related to the sale of Alkermes' stake in Acceleron Pharma Inc. and a gain of \$12.3 million related to the sale of property, plant and equipment. This compared to GAAP net income of \$7.3 million, or a basic and diluted GAAP EPS of \$0.05, for the same period in the prior year.
- Free cash flow was \$12.0 million for the quarter, compared to \$39.2 million for the same period in the prior year.

Quarter Ended June 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 \$60.0 million, compared to \$56.2 million for the same period in the prior year, representing an increase of approximately 7%.
- Manufacturing and royalty revenues from AMPYRA[®]/FAMPYRA^{®1} were \$19.5 million, compared to \$19.9 million for the same period in the prior year.
- Net sales of VIVITROL[®] were \$21.6 million, compared to \$17.4 million for the same period in the prior year, representing an increase of approximately 24%.
- Royalty revenue from BYDUREON[®] was \$8.8 million, compared to \$5.4 million for the same period in the prior year.
- Additionally, results for the quarter included RITALIN LA[®]/FOCALIN XR[®] revenues of \$10.9 million, EMEND[®] revenues of \$5.1 million and VERELAN[®] revenues of \$6.6 million. This compared to RITALIN LA/FOCALIN XR revenues of \$11.2 million, EMEND revenues of \$3.3 million and VERELAN revenues of \$6.5 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were \$176.2 million for the quarter, compared to \$125.1 million for the same period in the prior year.

This includes Research and Development (R&D) expense of \$67.2 million, compared to \$33.5 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 benefit of \$1.5 million for the quarter, compared to an income tax provision of \$2.7 million for the same period in the prior year.

Balance Sheet

At June 30, 2014, Alkermes had cash and total investments of \$713.9 million, compared to \$701.8 million at March 31, 2014. At June 30, 2014, the company's total debt outstanding was \$361.1 million.

Financial Expectations

Alkermes is updating its financial expectations to reflect increased investment in R&D for 2014, partially offset by the gain on the sale of its investment in Acceleron Pharma Inc. This change in R&D expense is expected to reduce non-GAAP net income by \$35 million to a range of \$30 million to \$50 million. The following outlines Alkermes' financial expectations for the year ending Dec. 31, 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 now expects R&D expenses to range from \$260 million to \$280 million, up from a range of \$225 million to \$245 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 \$25 million to \$30 million, up from a range of \$10 million to \$15 million.
- **Net Income Tax Expense:** The company continues to expect net income tax expense to range from \$10 million to \$15 million.
- **GAAP Net Loss:** The company now expects the GAAP net loss to range from \$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. This compares to previous expectations of a GAAP net loss in the range of \$70 to \$90 million, or a basic and diluted loss per share of approximately \$0.48 to \$0.61, based on weighted average basic and diluted share counts of approximately 147 million shares outstanding.
- **Non-GAAP Net Income:** The company now expects 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. This compares to previous expectations of non-GAAP net income in the range of \$65 million to \$85 million and non-GAAP diluted EPS in the range of \$0.41 to \$0.54, based on a weighted average diluted share count of approximately 157 million shares outstanding.
- **Capital Expenditures:** The company now expects capital expenditures to be approximately \$30 million, down from an expectation of approximately \$35 million.
- **Free Cash Flow:** The company now expects free cash flow of up to \$20 million, down from a range of \$30 million to \$50 million.

Conference Call

Alkermes will host a conference call at 8:30 a.m. EDT (1:30 p.m. BST) on Thursday, July 31, 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 (4:00 p.m. BST) on Thursday, July 31, 2014, through 5:00 p.m. EDT (10:00 p.m. BST) on Thursday, August 7, 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. These statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, many of which are beyond the company's control, which could cause actual results to differ materially from those contemplated in these forward-looking statements.

These risks and uncertainties include, among others: whether clinical development activities will be completed on time or at all and whether the results of such activities will 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; whether the company, and its partners, are able to continue to successfully commercialize its products; whether there will 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 possibility of adverse decisions by the U.S. Food and Drug Administration or regulatory authorities outside the U.S. regarding the company's products; the possibility that 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, 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[®] is a registered trademark of Alkermes, Inc.; RISPERDAL[®] CONSTA[®], INVEGA[®] SUSTENNA[®] and XEPLION[®] are registered trademarks of Johnson & Johnson Corporation; AMPYRA[®] and FAMPYRA[®] are registered trademarks of Acorda Therapeutics, Inc.; BYDUREON[®] is a registered trademark of Amylin Pharmaceuticals, LLC; TRICOR[®] is a registered trademark of Fournier Industrie et Sante Corporation; 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 Alkermes Pharma Ireland 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).

Alkermes plc and Subsidiaries Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013
Revenues:		
Manufacturing and royalty revenues	\$ 130,366	\$ 119,788

Product sales, net	21,595	17,379
Research and development revenues	1,463	1,464
Total Revenues	153,424	138,631
Expenses:		
Cost of goods manufactured and sold	43,290	45,991
Research and development	67,207	33,462
Selling, general and administrative	50,663	32,933
Amortization of acquired intangible assets	15,089	12,716
Total Expenses	176,249	125,102
Operating (Loss) Income	(22,825)	13,529
Other Income (Expense), net:		
Interest income	323	161
Interest expense	(3,385)	(3,468)
Gain on sale of investment in Acceleron Pharma Inc.	15,296	-
Gain on sale of property, plant and equipment	12,285	-
Other income (expense), net	518	(170)
Total Other Income (Expense), net	25,037	(3,477)
Income Before Income Taxes	2,212	10,052
Income Tax (Benefit) Provision	(1,523)	2,718
Net Income — GAAP	\$ 3,735	\$ 7,334

Earnings Per Share:

GAAP earnings per share — basic	\$ 0.03	\$ 0.05
GAAP earnings per share — diluted	\$ 0.02	\$ 0.05
Non-GAAP earnings per share — basic	\$ 0.12	\$ 0.32
Non-GAAP earnings per share — diluted	\$ 0.11	\$ 0.30

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP and Non-GAAP	144,913	134,602
Diluted — GAAP and Non-GAAP	154,300	143,369

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

Net Income — GAAP	\$ 3,735	\$ 7,334
Adjustments:		
Share-based compensation expense	19,337	8,809
Amortization expense	15,089	12,716
Depreciation expense	9,844	11,011
Non-cash net interest expense	239	268
Non-cash taxes	(2,207)	2,814
Deferred revenue	(338)	(97)
Net loss on transactions with equity method investee	(396)	-
Gain on sale of investment in Acceleron Pharma Inc.	(15,296)	-
Gain on sale of property, plant and equipment	(12,285)	-
Non-GAAP Net Income	\$ 17,722	\$ 42,855
Capital expenditures	5,753	3,625
Free Cash Flow	\$ 11,969	\$ 39,230

	Six Months Ended	Six Months Ended
Condensed Consolidated Statements of Operations - GAAP	June 30,	June 30,
(In thousands, except per share data)	2014	2013
Revenues:		
Manufacturing and royalty revenues	\$ 241,646	\$ 266,707
Product sales, net	38,674	32,005
Research and development revenues	3,316	3,341
Total Revenues	283,636	302,053
Expenses:		
Cost of goods manufactured and sold	82,129	93,982

Research and development	119,347	69,262
Selling, general and administrative	93,213	67,612
Amortization of acquired intangible assets	27,665	23,038
Restructuring	-	12,300
Impairment of long-lived assets	-	3,346
Total Expenses	322,354	269,540
Operating (Loss) Income	(38,718)	32,513
Other Income (Expense), net:		
Interest income	834	332
Interest expense	(6,741)	(14,941)
Gain on sale of investment in Acceleron Pharma Inc.	15,296	-
Gain on sale of property, plant and equipment	12,285	-
Other (expense) income, net	(1,332)	14
Total Other Income (Expense), net	20,342	(14,595)
(Loss) Income Before Income Taxes	(18,376)	17,918
Income Tax Provision	2,243	7,585
Net (Loss) Income — GAAP	\$ (20,619)	\$ 10,333

(Loss) Earnings Per Share:

GAAP (loss) earnings per share — basic	\$ (0.14)	\$ 0.08
GAAP (loss) earnings per share — diluted	\$ (0.14)	\$ 0.07
Non-GAAP earnings per share — basic	\$ 0.24	\$ 0.74
Non-GAAP earnings per share — diluted	\$ 0.22	\$ 0.70

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP	144,140	133,941
Diluted — GAAP	144,140	141,822
Basic — Non-GAAP	144,140	133,941
Diluted — Non-GAAP	153,833	141,822

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

Net (Loss) Income — GAAP	\$ (20,619)	\$ 10,333
Adjustments:		
Share-based compensation expense	32,757	16,690
Amortization expense	27,665	23,038
Depreciation expense	19,821	19,010
Non-cash net interest expense	479	568
Non-cash taxes	1,415	7,257
Deferred revenue	(1,303)	(975)
Net loss on transactions with equity method investee	1,239	-
Gain on sale of investment in Acceleron Pharma Inc.	(15,296)	-
Gain on sale of property, plant and equipment	(12,285)	-
Restructuring	-	12,300
Loss on debt repricing	-	7,541
Impairment of long-lived assets	-	3,346
Non-GAAP Net Income	\$ 33,873	\$ 99,108
Capital expenditures	11,438	11,884
Free Cash Flow	\$ 22,435	\$ 87,224

Condensed Consolidated Balance Sheets (In thousands)	June 30, 2014	December 31, 2013
Cash, cash equivalents and total investments	\$ 713,894	\$ 449,995
Receivables	139,316	134,154
Inventory	57,066	46,218
Prepaid expenses and other current assets	52,048	27,535
Property, plant and equipment, net	264,247	274,490
Intangible assets, net and goodwill	602,640	630,305
Other assets	28,381	14,891

Total Assets	<u>\$ 1,857,592</u>	<u>\$ 1,577,588</u>
Long-term debt — current portion	\$ 6,750	\$ 6,750
Other current liabilities	95,410	94,147
Long-term debt	354,382	357,543
Deferred revenue — long-term	11,507	12,213
Other long-term liabilities	37,718	41,749
Total shareholders' equity	<u>1,351,825</u>	<u>1,065,186</u>
Total Liabilities and Shareholders' Equity	<u>\$ 1,857,592</u>	<u>\$ 1,577,588</u>

Ordinary shares outstanding (in thousands)	145,664	137,793
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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 six months ended June 30, 2014, which the company intends to file in July 2014.

Alkermes plc and Subsidiaries
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	\$ (100.0)	145	\$ (0.69)
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)		
Deferred revenue	(2.0)		
Projected Non-GAAP Net Income	<u>\$ 40.0</u>	155	<u>\$ 0.26</u>
Capital expenditures	(30.0)		
Projected Free Cash Flow	<u>\$ 10.0</u>		

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



Source: Alkermes plc

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