



Alkermes plc Reports Financial Results for Quarter Ended Sept. 30, 2013

October 31, 2013

— Quarterly Revenues of \$139.8 Million Driven by 38% Year-Over-Year Growth From Portfolio of Five Key Commercial Products —

— Non-GAAP Diluted EPS of \$0.22 —

— Late-Stage CNS Pipeline Progress Includes Enrollment Completion for Aripiprazole Lauroxil Pivotal Study and Fast Track Designation for ALKS 5461 —

DUBLIN--(BUSINESS WIRE)--Oct. 31, 2013-- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for the quarter ended Sept. 30, 2013. This is the second quarter of the nine-month period ending Dec. 31, 2013, as the company transitions to reporting on a calendar year basis.

“Against a backdrop of another quarter of solid financial performance, Alkermes is advancing one of the most important CNS pipelines in the biopharmaceutical industry,” commented Richard Pops, Chief Executive Officer of Alkermes. “During the quarter, we achieved key milestones for our most advanced programs. Looking forward, 2014 will be an important year for this late-stage pipeline as we obtain phase 3 results for aripiprazole lauroxil and prepare for the NDA submission and launch, as well as initiate the phase 3 program for ALKS 5461, which has been granted Fast Track status for the adjunctive treatment of major depressive disorder.”

“This quarter’s financial results demonstrate the power of our business model to generate substantial cash flows while also providing the resources to invest in our advancing pipeline,” commented James Frates, Chief Financial Officer of Alkermes. “Our commercial portfolio demonstrated another strong quarter with 38% year-over-year revenue growth from our key products.”

Quarter Ended Sept. 30, 2013 Highlights

- Total revenues for the quarter were \$139.8 million, compared to total revenues of \$124.0 million for the same period in the prior year.
- Revenues from the company’s five key commercial products for the quarter grew 38% to \$101.5 million, from \$73.8 million for the same period in the prior year.
- Non-GAAP net income for the quarter was \$31.8 million, or a non-GAAP diluted earnings per share (EPS) of \$0.22. This compared to non-GAAP net income of \$23.7 million, or a non-GAAP diluted EPS of \$0.17, for the same period in the prior year.
- GAAP net loss for the quarter was \$7.8 million, or a basic and diluted GAAP loss per share of \$0.06. This compared to GAAP net loss of \$16.7 million, or a basic and diluted GAAP loss per share of \$0.13, for the same period in the prior year.
- Free cash flow for the quarter was \$26.2 million, compared to \$19.2 million for the same period in the prior year.

Quarter Ended Sept. 30, 2013 Financial Results

Revenues

- Manufacturing and royalty revenues from the company’s long-acting atypical antipsychotic franchise, RISPERDAL[®] CONSTA[®] and INVEGA[®] SUSTENNA[®]/XEPLION[®], were \$62.6 million, compared to \$50.3 million for the same period in the prior year. Worldwide end-market sales of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION were approximately \$650 million, compared to approximately \$563 million in the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA[®]/FAMPYRA^{®1} were \$12.6 million, compared to \$5.0 million for the same period in the prior year.
- Net sales of VIVITROL[®] were \$19.2 million, compared to \$15.2 million for the same period in the prior year, representing an increase of approximately 26% year over year.
- Royalty revenue from BYDUREON[®] was \$7.0 million, compared to \$3.3 million for the same period in the prior year.
- Results for the quarter included RITALIN LA[®]/FOCALIN XR[®] revenues of \$9.2 million, VERELAN[®] revenues of \$4.4 million and TRICOR[®] 145 revenues of \$3.5 million. This compared to RITALIN LA/FOCALIN XR revenues of \$9.1 million, VERELAN revenues of \$5.8 million and TRICOR 145 revenues of \$12.5 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were \$143.7 million, compared to operating expenses of \$118.6 million for the same period in the prior year.
- Net interest expense was \$3.2 million, compared to net interest expense of \$22.4 million for the same period in the prior year. The reduction was driven by the successful refinancing and repricing of the company's term loans completed in 2012 and 2013, respectively.

Balance Sheet

- At Sept. 30, 2013, Alkermes recorded cash and total investments of \$395.2 million, compared to \$325.0 million at June 30, 2013, and \$304.2 million at March 31, 2013.

Financial Expectations for Nine Months Ending Dec. 31, 2013

- The company reiterated all of its financial expectations for the nine-month period ending Dec. 31, 2013, (originally provided on May 23, 2013) except for Selling, General and Administrative expense, which the company now expects to be in the range of \$105 million to \$115 million, up from the previous range of \$95 million to \$105 million, reflecting increased commercial activity in preparation for the aripiprazole lauroxil launch and activities related to the VIVITROL label update.
- The company reiterated its expectations for non-GAAP net income to be in the range of \$85 million to \$105 million for the nine-month period ending Dec. 31, 2013, and expects to be in the upper end of that range.

Conference Call

Alkermes will host a conference call at 8:00 a.m. EDT (12:00 p.m. GMT) on Thursday, Oct. 31, 2013, 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. 31, 2013, through 5:00 p.m. EST (10:00 p.m. GMT) on Nov. 7, 2013, 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 our 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, 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 the company's expectations concerning the timing and results of our 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: clinical development activities may not be completed on time or at all, and the results of such activities may not be successful, predictive of real-world results or of results in subsequent clinical trials; the company, and its partners, may not be

able to continue to successfully commercialize its products; 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 described in the Alkermes plc Annual Report for the year ended March 31, 2013, and in other 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, may occur. 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 any forward-looking information contained in this press release.

VIVITROL® is a registered trademark of Alkermes, Inc.; RISPERDAL® CONSTA® and INVEGA® SUSTENNA® are registered trademarks of Janssen Pharmaceuticals, Inc.; XEPLION® is a registered trademark 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; 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 Inc., under a licensing agreement with Acorda Therapeutics, as FAMPYRA® (prolonged-release fampridine tablets).

(tables follow)

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012
Revenues:		
Manufacturing and royalty revenues	\$ 118,571	\$ 107,327
Product sales, net	19,227	15,192
Research and development revenue	2,004	1,459
Total Revenues	139,802	123,978
Expenses:		
Cost of goods manufactured and sold	45,423	41,491
Research and development	45,947	35,088
Selling, general and administrative	39,454	31,428
Amortization of acquired intangible assets	12,856	10,547
Total Expenses	143,680	118,554
Operating (Loss) Income	(3,878)	5,424
Other (Expense), net:		
Interest income	295	216
Interest expense	(3,477)	(22,648)
Other (expense) income, net	(469)	723
Total Other (Expense), net	(3,651)	(21,709)
(Loss) Before Income Taxes	(7,529)	(16,285)
Income Tax Provision	233	422
Net (Loss) — GAAP	\$ (7,762)	\$ (16,707)
(Loss) Earnings Per Share:		
GAAP (loss) per share — basic and diluted	\$ (0.06)	\$ (0.13)
Non-GAAP earnings per share — basic	\$ 0.23	\$ 0.18
Non-GAAP earnings per share — diluted	\$ 0.22	\$ 0.17
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and Diluted — GAAP	136,106	131,067
Basic — Non-GAAP	136,106	131,067
Diluted — Non-GAAP	144,861	136,217

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

Net (Loss) — GAAP	\$ (7,762)	\$ (16,707)
Adjustments:		

Non-cash net interest expense	267	2,092
Non-cash taxes	612	(846)
Depreciation expense	10,818	8,264
Amortization expense	12,856	10,547
Share-based compensation	14,209	10,447
Deferred revenue	765	(1,206)
Loss on debt refinancing	-	12,129
Change in method of revenue recognition for VIVITROL product sales	-	(1,013)
Non-GAAP Net Income	\$ 31,765	\$ 23,707
Capital expenditure	5,573	4,473
Free Cash Flow	\$ 26,192	\$ 19,234

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

	Six Months Ended September 30, 2013	Six Months Ended September 30, 2012
Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)		
Revenues:		
Manufacturing and royalty revenues	\$ 238,359	\$ 245,707
Product sales, net	36,606	27,564
Research and development revenue	3,468	2,946
Total Revenues	278,433	276,217
Expenses:		
Cost of goods manufactured and sold	91,414	83,561
Research and development	79,409	72,894
Selling, general and administrative	72,387	61,212
Amortization of acquired intangible assets	25,572	20,981
Total Expenses	268,782	238,648
Operating Income	9,651	37,569
Other (Expense), net:		
Interest income	456	515
Interest expense	(6,945)	(32,818)
Other income, net	(639)	1,646
Total Other (Expense), net	(7,128)	(30,657)
Income Before Income Taxes	2,523	6,912
Income Tax Provision	2,951	1,186
Net (Loss) Income — GAAP	\$ (428)	\$ 5,726

(Loss) Earnings Per Share:

GAAP (loss) earnings per share — basic and diluted	\$ (0.00)	\$ 0.04
Non-GAAP earnings per share — basic	\$ 0.55	\$ 0.59
Non-GAAP earnings per share — diluted	\$ 0.52	\$ 0.57

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP	135,358	130,753
Diluted — GAAP	135,358	135,589
Basic — Non-GAAP	135,358	130,753
Diluted — Non-GAAP	144,143	135,589

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

Net (Loss) Income — GAAP	\$ (428)	\$ 5,726
Adjustments:		
Non-cash net interest expense	535	3,620
Non-cash taxes	3,426	(991)
Depreciation expense	21,829	15,848

Amortization expense	25,572	20,981
Share-based compensation	23,018	18,609
Deferred revenue	668	1,764
Loss on debt refinancing	-	12,129
Change in method of revenue recognition for VIVITROL product sales	-	(1,013)
Non-GAAP Net Income	\$ 74,620	\$ 76,673
Capital expenditure	9,198	11,206
Free Cash Flow	\$ 65,422	\$ 65,467

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	September 30,	March 31,
	2013	2013
Cash, cash equivalents and total investments	\$ 395,241	\$ 304,179
Receivables	120,448	124,620
Inventory	40,708	43,483
Prepaid expenses and other current assets	22,998	19,133
Property, plant and equipment, net	274,377	288,435
Intangible assets, net and goodwill	643,161	668,733
Other assets	15,504	21,708
Total Assets	\$ 1,512,437	\$ 1,470,291
Long-term debt — current portion	\$ 6,750	\$ 6,750
Other current liabilities	66,967	79,180
Long-term debt	359,122	362,258
Deferred revenue — long-term	9,121	8,866
Other long-term liabilities	53,500	60,863
Total shareholders' equity	1,016,977	952,374
Total Liabilities and Shareholders' Equity	\$ 1,512,437	\$ 1,470,291
Ordinary shares outstanding (in thousands)	136,647	133,752

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 September 30, 2013, which the company intends to file in October 2013.



Source: Alkermes plc

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