



Alkermes plc Reports Second Quarter Fiscal 2013 Financial Results

November 1, 2012

— *Company Improves Guidance for Fiscal 2013, With \$25 Million Increase in Non-GAAP Net Income Guidance to a Range of \$120 Million to \$140 Million* —

— *Second Quarter Revenues Grew to \$124.0 Million, a 72% Increase Year-Over-Year, Reflecting Growth in Key Products in Diversified Portfolio* —

— *Second Quarter Non-GAAP Diluted EPS Grew to \$0.17 from \$0.07 for the Same Period in Prior Fiscal Year* —

DUBLIN--(BUSINESS WIRE)--Nov. 1, 2012-- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for its second quarter of fiscal 2013, which ended Sept. 30, 2012, and the company provided improved financial expectations for its fiscal year 2013, which will be the first full fiscal year of the combined company, Alkermes plc (Alkermes), following the completion of the merger of Alkermes, Inc. with Elan Drug Technologies (EDT) on Sept. 16, 2011.

"We reported a very strong quarter in what is shaping up to be a very strong year. The financial power of our commercial product portfolio is becoming even more apparent in our improved guidance and in the recent upgrade of our credit ratings," commented Richard Pops, Chief Executive Officer of Alkermes. "We are building an exciting biopharmaceutical company characterized by a diversified portfolio of products generating growing cash flows and a pipeline of valuable late-stage candidates."

Second Quarter Fiscal 2013 Highlights

- Total revenues for the second quarter of fiscal 2013 increased more than 72% to \$124.0 million, compared to the same period in fiscal 2012, which was attributable to the expansion of the company's commercial product portfolio as a result of the merger and growth from the company's key commercial products. Total revenues of \$72.0 million for the same period in fiscal 2012 included results for Alkermes, Inc. and 14 days of operations of the former EDT business.
- Based on accounting principles generally accepted in the U.S. (GAAP), Alkermes reported a net loss of \$16.7 million, or a basic and diluted loss per share of \$0.13, for the second quarter of fiscal 2013. This compared to a GAAP net loss of \$22.3 million, or a basic and diluted loss per share of \$0.22, for the same period in fiscal 2012.
- Included in the GAAP net loss for the second quarter of fiscal 2013 was a one-time charge of \$12.1 million related to the refinancing of the company's debt in September 2012. The company successfully refinanced its previously outstanding senior secured term loans and reduced the company's overall debt outstanding. The new term loans have a lower blended interest rate of approximately 4.4% compared to the prior blended interest rate of approximately 7.6%, and the refinancing is expected to result in savings of approximately \$18 million in cash interest annually.
- The company reported non-GAAP¹ net income of \$23.7 million, or non-GAAP diluted earnings per share (EPS) of \$0.17, for the second quarter of fiscal 2013. This compared to non-GAAP net income of \$7.1 million, or a non-GAAP diluted EPS of \$0.07, for the same period in fiscal 2012.

"Our second fiscal quarter results clearly demonstrate the financial strength and growth potential that we envisioned when we created Alkermes plc. Our key commercial product portfolio generated strong revenues this quarter, and we are positioned for record financial results this fiscal year," commented James Frates, Chief Financial Officer of Alkermes. "In September, we updated our expectations for improved non-GAAP net income and free cash flow for fiscal 2013, reflecting the impact of the successful refinancing of the term loans used to fund the merger. Today, we are further improving our financial expectations for fiscal 2013 based on strong operational performance in the first six months, and we now expect Alkermes to generate between \$120 million and \$140 million in non-GAAP net income this fiscal year."

Second Quarter Fiscal 2013 Financial Results

It should be noted that comparative financial information provided below includes 14 days of revenues and operating expenses from the former EDT business during the second quarter of fiscal 2012.

Revenues

- Manufacturing and royalty revenues from the company's long-acting atypical antipsychotic franchise, RISPERDAL[®] CONSTA[®] and INVEGA[®] SUSTENNA[®]/XEPLION[®], were \$50.3 million for the second quarter of fiscal 2013, compared to \$44.9 million for the same period in fiscal 2012. Worldwide end-market sales of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION for the second quarter of fiscal 2013 were approximately \$564 million and grew approximately 15% compared to the same period in fiscal 2012.

- Manufacturing and royalty revenues from AMPYRA[®]/FAMPYRA^{®2} were \$5.0 million for the second quarter of fiscal 2013, compared to \$0.6 million for the same period in fiscal 2012. End-market sales of AMPYRA by Acorda Therapeutics, Inc. in the U.S. for the second quarter of fiscal 2013 were approximately \$69.8 million and grew approximately 28% compared to the same period in fiscal 2012.
- Net sales of VIVITROL[®] were \$15.2 million for the second quarter of fiscal 2013, compared to \$9.9 million for the same period in fiscal 2012. During the quarter, Alkermes changed its revenue recognition policy for VIVITROL net sales, following the establishment of a product return history. Prior to the second quarter of fiscal 2013, net sales were recognized when the product left the distribution channel. Beginning in the second quarter of fiscal 2013, the company recognizes net sales upon product shipment into the distribution channel. This change in accounting policy resulted in a one-time increase of \$1.7 million in VIVITROL net sales in the second quarter of fiscal 2013. Excluding this adjustment, net sales of VIVITROL were \$13.5 million and grew approximately 36% compared to the same period in fiscal 2012.
- Royalty revenue from BYDUREON[®] was \$3.3 million for the second quarter of fiscal 2013, compared to \$0.1 million for the same period in fiscal 2012. The royalty revenue for the second quarter was \$3.7 million based on estimated end-market sales of approximately \$46 million, partially offset by a \$0.4 million true-up from the previous quarter.
- Additionally, second quarter fiscal 2013 results included TRICOR[®] 145 revenues of \$12.5 million and RITALIN LA[®]/FOCALIN XR[®] revenues of \$9.1 million.

Costs and Expenses

- Operating expenses for the second quarter of fiscal 2013 were \$118.6 million, which included expenses associated with the advancement of pipeline candidates in later-stage clinical trials and expenses associated with the former EDT business. This compared to operating expenses of \$83.7 million for the same period in fiscal 2012.
- Net interest expense for the second quarter of fiscal 2013 was \$22.4 million, which included a one-time charge of \$12.1 million related to refinancing the company's debt in September 2012. This compared to net interest expense of \$7.2 million for the same period in fiscal 2012.

Balance Sheet

At Sept. 30, 2012, Alkermes recorded cash and total investments of \$208.2 million compared to \$231.9 million at June 30, 2012, and \$246.1 million at March 31, 2012. The reduction in cash in the second quarter was primarily due to the use of approximately \$83 million to reduce total debt outstanding and for expenses associated with the refinancing. At Sept. 30, 2012, the company had total debt outstanding on the balance sheet of \$370.6 million, down from \$444.2 million as of June 30, 2012.

Financial Expectations for Fiscal 2013

Alkermes is improving its financial expectations for fiscal 2013, reflecting increased revenue expectations from the company's product portfolio and decreased expense expectations. These factors are expected to result in an increase in non-GAAP net income of \$25 million to a range of \$120 million to \$140 million. The following outlines Alkermes' financial expectations for the fiscal year ending March 31, 2013.

- **Revenues:** Alkermes now expects total revenues to range from \$510 million to \$540 million, up from a range of \$490 million to \$530 million. The company continues to expect VIVITROL net sales to range from \$45 million to \$55 million and continues to expect milestone revenues, unrelated to key clinical development candidates, to range from \$20 million to \$30 million.
- **Cost of Goods Manufactured:** The company now expects cost of goods manufactured to range from \$160 million to \$170 million, down from a range of \$170 million to \$180 million.
- **Research and Development (R&D) Expenses:** The company now expects R&D expenses to range from \$150 million to \$160 million, down from a range of \$155 million to \$165 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company continues to expect SG&A expenses to range from \$120 million to \$130 million.
- **Amortization of Intangible Assets:** The company continues to expect amortization of intangibles to range from \$40 million to \$45 million.
- **Net Interest Expense:** The company continues to expect net interest expense to range from \$35 million to \$40 million.
- **Net Income Tax Expense:** The company now expects net income tax expense to range from \$5 million to \$10 million, compared to previous expectations of a nominal tax charge in fiscal 2013.
- **Share-Based Compensation Expense:** The company continues to expect share-based compensation expense, included in the operating expenses above, to range from \$35 million to \$40 million.

- **GAAP Net Loss:** The company now expects a reduced GAAP net loss to range from break-even to \$15 million, or a basic and diluted loss per share of approximately \$0.00 to \$0.11, based on a weighted average basic and diluted share count of approximately 132 million shares outstanding. This compares to previous expectations of a GAAP net loss in the range of \$20 million to \$40 million, or a basic and diluted loss per share of approximately \$0.15 to \$0.30.
- **Capital Expenditures:** The company continues to expect capital expenditures to be approximately \$25 million.
- **Non-GAAP Net Income:** The company now expects non-GAAP net income to range from \$120 million to \$140 million, and non-GAAP diluted EPS to range from \$0.88 to \$1.02, based on a weighted average diluted share count of approximately 137 million shares outstanding. This compares to previous expectations of non-GAAP net income in the range of \$95 million to \$115 million and non-GAAP diluted EPS in the range of \$0.69 to \$0.84.
- **Free Cash Flow:** The company now expects free cash flow to range from \$95 million to \$115 million, up from a range of \$70 million to \$90 million.

Conference Call

Alkermes will host a conference call at 8:30 a.m. EDT (12:30 p.m. GMT) on Thursday, Nov. 1, 2012, 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 11:30 a.m. EDT (3:30 p.m. GMT) on Thursday, Nov. 1, 2012, through 5:00 p.m. EST (10:00 p.m. GMT) on Thursday, Nov. 8, 2012, 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.

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; and the therapeutic value of the company's products. 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: the commercial markets and demand for the company's products may not be as large as the company anticipates; reimbursement for the company's products may change; the possibility of adverse decisions by the U.S. Food and Drug Administration (FDA) or regulatory authorities outside the U.S. 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 that could cause the FDA or regulatory authorities outside the U.S. to require post-approval studies or removal of the company's products from the market; and those risks described in the company's Annual Report on Form 10-K for the year ended March 31, 2012, and in other filings made by the company with the Securities and Exchange Commission ("SEC") and which are available at 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 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, Inc.; TRICOR[®] is a registered trademark of Fournier Industrie et Sante Corporation; and RITALIN LA[®] and FOCALIN XR[®] are registered trademarks of Novartis AG Corporation.

¹As a complement to GAAP results, the company is providing non-GAAP net income (loss) and non-GAAP diluted earnings (loss) per share, which the company believes better indicate underlying trends in ongoing operations and cash flows. Non-GAAP net income (loss) adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation; amortization; depreciation; non-cash net interest expense; non-cash tax expense; deferred revenue; and certain other one-time items.

²AMPYRA[®] (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)

	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011
Condensed Consolidated Statements of Operations - GAAP		
(In thousands, except per share data)		
Revenues:		
Manufacturing and royalty revenues	\$ 107,327	\$ 54,039
Product sales, net	15,192	9,887
Research and development revenue	1,459	8,052
Total Revenues	123,978	71,978
Expenses:		
Cost of goods manufactured and sold	41,491	17,530
Research and development	35,088	28,160
Selling, general and administrative	31,428	36,234
Amortization of acquired intangible assets	10,547	1,817
Total Expenses	118,554	83,741
Operating Income (Loss)	5,424	(11,763)
Other (Expense), net:		
Interest income	216	383
Interest expense	(22,648)	(7,561)
Other income, net	723	336
Total Other (Expense), net	(21,709)	(6,842)
(Loss) Before Income Taxes	(16,285)	(18,605)
Income Tax Provision	422	3,650
Net (Loss) — GAAP	\$ (16,707)	\$ (22,255)

(Loss) Earnings Per Share:

GAAP (loss) per share — basic and diluted	\$ (0.13)	\$ (0.22)
Non-GAAP earnings per share — basic	\$ 0.18	\$ 0.07
Non-GAAP earnings per share — diluted	\$ 0.17	\$ 0.07

Weighted Average Number of Ordinary Shares Outstanding:

Basic and diluted — GAAP	131,067	102,474
Basic — Non-GAAP	131,067	102,474
Diluted — Non-GAAP	136,217	106,646

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

Net (Loss) — GAAP	\$ (16,707)	\$ (22,255)
Adjustments:		
Non-cash net interest expense	2,092	1,684
Non-cash taxes	(846)	3,646
Depreciation expense	8,264	2,653
Amortization expense	10,547	1,817
Share-based compensation	10,447	7,052
Deferred revenue	(1,206)	(277)
Loss on debt refinancing	12,129	-
Change in method of revenue recognition for VIVITROL product sales	(1,013)	-
Merger-related costs	-	12,783
Non-GAAP Net Income	\$ 23,707	\$ 7,103

	Six Months Ended September 30, 2012	Six Months Ended September 30, 2011
Condensed Consolidated Statements of Operations - GAAP		
(In thousands, except per share data)		
Revenues:		
Manufacturing and royalty revenues	\$ 245,707	\$ 102,979
Product sales, net	27,564	19,573
Research and development revenue	2,946	11,309

Total Revenues	276,217	133,861
Expenses:		
Cost of goods manufactured and sold	83,561	33,749
Research and development	72,894	56,210
Selling, general and administrative	61,212	67,731
Amortization of acquired intangible assets	20,981	1,817
Total Expenses	238,648	159,507
Operating Income (Loss)	37,569	(25,646)
Other (Expense), net:		
Interest income	515	885
Interest expense	(32,818)	(7,561)
Other income, net	1,646	425
Total Other (Expense), net	(30,657)	(6,251)
Income (Loss) Before Income Taxes	6,912	(31,897)
Income Tax Provision	1,186	3,596
Net Income (Loss) — GAAP	\$ 5,726	\$ (35,493)

Earnings (Loss) Per Share:

GAAP earnings (loss) per share — basic and diluted	\$ 0.04	\$ (0.36)
Non-GAAP earnings per share — basic	\$ 0.59	\$ 0.11
Non-GAAP earnings per share — diluted	\$ 0.57	\$ 0.10

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP	130,753	99,578
Diluted — GAAP	135,589	99,578
Basic — Non-GAAP	130,753	99,578
Diluted — Non-GAAP	135,589	103,706

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

Net Income (Loss) — GAAP	\$ 5,726	\$ (35,493)
Adjustments:		
Non-cash net interest expense	3,620	1,684
Non-cash taxes	(991)	3,581
Depreciation expense	15,848	4,557
Amortization expense	20,981	1,817
Share-based compensation	18,609	12,712
Deferred revenue	1,764	(474)
Loss on debt refinancing	12,129	-
Change in method of revenue recognition for VIVITROL product sales	(1,013)	-
Merger-related costs	-	22,270
Non-GAAP Net Income	\$ 76,673	\$ 10,654

Use of Non-GAAP Financial Measures

We use "non-GAAP net income" as a key indicator of the underlying financial operating performance of Alkermes plc. Non-GAAP net income is not a GAAP measure of performance and is defined as net income or loss plus or minus the non-cash portion of net interest expense and provision for or benefit from income taxes, plus depreciation and amortization of costs, share-based compensation expense, deferred revenue and other nonrecurring items. We feel that non-GAAP net income provides management and investors with a better representation of the ongoing economics of the business and reflects how we manage the business internally.

Condensed Consolidated Balance Sheets (In thousands)	September 30, 2012	March 31, 2012
Cash, cash equivalents and total investments	\$ 208,177	\$ 246,138
Receivables	101,998	96,381
Inventory	40,887	39,759
Prepaid expenses and other current assets	12,583	12,566
Property, plant and equipment, net	295,374	302,995
Intangible assets, net and goodwill	689,604	710,585
Other assets	21,924	26,793
Total Assets	\$ 1,370,547	\$ 1,435,217
Long-term debt — current portion	\$ 6,750	\$ 3,100

Other current liabilities	61,988	86,064
Long-term debt	363,847	441,360
Deferred revenue - long-term	8,845	7,578
Other long-term liabilities	44,109	43,263
Total shareholders' equity	885,008	853,852
Total Liabilities and Shareholders' Equity	\$ 1,370,547	\$ 1,435,217

Ordinary shares outstanding (in thousands)	131,568	130,177
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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 September 30, 2012, which the company intends to file in November 2012.



Source: Alkermes plc

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