

# Alkermes plc Reports First Quarter Fiscal 2013 Financial Results

# July 26, 2012

- First Quarter Revenues Grew to \$152.2 Million, a 146% Increase Year-Over-Year -
- First Quarter Non-GAAP Diluted EPS Grew to \$0.39 from \$0.04 for the Same Period in Prior Fiscal Year -

DUBLIN--(BUSINESS WIRE)--Jul. 26, 2012-- Alkermes plc (NASDAQ: ALKS) today reported financial results for its first quarter of fiscal 2013, which ended June 30, 2012, and reiterated 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.

"Our first quarter results highlight Alkermes' transformation to a business generating growing revenues and earnings. These results also demonstrate the strength of our business model with revenues coming from a diversified portfolio of important medications," commented Richard Pops, Chief Executive Officer of Alkermes. "Our company is in a stronger position than ever before with solid financial performance and a broad portfolio of unique commercial and pipeline products."

## First Quarter Fiscal 2013 Highlights

- Total revenues for the first quarter increased 146% to \$152.2 million, which reflected the expansion of the company's commercial product portfolio as a result of the merger and the inclusion of \$20.0 million of intellectual property license revenue unrelated to our key clinical development programs. This compared to total revenues of \$61.9 million for the same period in the prior fiscal year for Alkermes, Inc.
- Based on accounting principles generally accepted in the U.S. (GAAP), Alkermes reported net income of \$22.4 million, or a basic and diluted earnings per share (EPS) of \$0.17, for the quarter. This compared to a GAAP net loss of \$13.2 million, or a basic and diluted loss per share of \$0.14, for the same period in the prior fiscal year for Alkermes, Inc.
- The company reported non-GAAP<sup>1</sup> net income of \$53.0 million, or a non-GAAP diluted EPS of \$0.39. This compared to non-GAAP net income of \$3.6 million, or a non-GAAP diluted EPS of \$0.04, for the same period in the prior fiscal year for Alkermes, Inc.

"The business is performing as we expected with growing revenue streams from our key commercial products and continued contributions from the legacy portfolio during the quarter. For the remainder of the fiscal year, we expect to see growing contributions from the key products while contributions from the legacy products become less significant," commented James Frates, Chief Financial Officer of Alkermes. "Looking forward, we see the business on a steady course for achieving the financial expectations for fiscal year 2013 that we set forth in May."

## First Quarter Fiscal 2013 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 \$47.9 million for the first quarter of fiscal 2013. This compared to \$48.5 million in manufacturing and royalty revenues from RISPERDAL CONSTA alone for the same period of fiscal 2012, which were driven by unusually high manufacturing revenues due to the timing of shipments. Worldwide end-market sales of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION for the first quarter of fiscal 2013 were approximately \$550 million and grew more than 14% year-over-year.
- Manufacturing and royalty revenues from AMPYRA<sup>®</sup>/FAMPYRA<sup>®2</sup> were \$17.1 million for the first quarter of fiscal 2013. Alkermes, Inc. did not record any revenues from AMPYRA/FAMPYRA for the same period of fiscal 2012.
- Net sales of VIVITROL<sup>®</sup> were \$12.4 million for the first quarter of fiscal 2013, compared to \$9.7 million for the same period of fiscal 2012, representing an increase of approximately 28% year-over-year and the 12<sup>th</sup> consecutive quarter of growth.
- Royalty revenue from BYDUREON <sup>™</sup> was \$3.0 million for the first quarter of fiscal 2013. Alkermes did not record any royalty revenues from BYDUREON for the same period of fiscal 2012.
- Additionally, first quarter fiscal 2013 results included TRICOR<sup>®</sup> 145 revenues of \$12.0 million, RITALIN LA<sup>®</sup>/FOCALIN XR<sup>®</sup> revenues of \$10.9 million and VERELAN<sup>®</sup> revenues of \$6.0 million. Alkermes, Inc. did not record any revenues from these products for the same period of fiscal 2012.
- Manufacturing and royalty revenues in the first quarter of fiscal 2013 also included \$20.0 million of intellectual property license revenue unrelated to our key development programs.

Costs and Expenses

• Operating expenses for the first quarter of fiscal 2013 were \$120.1 million. This compared to operating expenses of \$75.8 million for the same period of fiscal 2012 for Alkermes, Inc. The increase was primarily related to the inclusion of expenses

associated with the former EDT business and the advancement of pipeline candidates into later stages of development.

• Net interest expense for the first quarter of fiscal 2013 was \$9.9 million, including \$10.2 million of interest expense on the term loans secured to fund the merger.

## **Balance Sheet**

• At June 30, 2012, Alkermes recorded cash and total investments of \$231.9 million, compared to \$246.1 million at March 31, 2012. The decrease was primarily driven by changes in working capital, notably the increase in receivables due to the timing of receipts from collaborative partners, including the \$20.0 million of license revenue.

#### **Conference Call**

Alkermes will host a conference call at 8:30 a.m. EDT (1:30 p.m. BST) on Thursday, July 26, 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 (4:30 p.m. BST) on Thursday, July 26, 2012, through 5:00 p.m. EDT (10:00 p.m. BST) on August 2, 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 http://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 five key commercial products; and the therapeutic value of the company's products. 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; the company's business is subject to significant risk and uncertainties, and there can be no assurance that its actual results will not differ materially from its expectations.

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 company may not fully realize the anticipated benefits from the merger of Alkermes, Inc. and EDT; 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 http://www.sec.gov. 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<sup>®</sup> is a registered trademark of Johnson & Johnson Corporation; AMPYRA<sup>®</sup> and FAMPYRA<sup>®</sup> are registered trademarks of Acorda Therapeutics, Inc.; BYDUREON<sup>™</sup> is a trademark of Amylin Pharmaceuticals, Inc.; TRICOR<sup>®</sup> 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 Elan Pharma International Limited.

<sup>1</sup>As 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.

<sup>2</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® (prolonged-release fampridine tablets).

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

Revenues:

|  | Three Months | Three Months |  |
|--|--------------|--------------|--|
|  | Ended        | Ended        |  |
| Condensed Consolidated Statements of Operations - GAAP | June 30,     | June 30,     |  |
| (In thousands, except per share data)                  | 2012         | 2011         |  |
| Pevenues:  |              |              |  |

| Manufacturing and royalty revenues  | \$ 138,380           |   | \$ 48,940        |   |
|---|----------------------|---|------------------|---|
| Product sales, net  | \$ 130,300<br>12,372 |   | 9,686            |   |
| Research and development revenue  | 1,487                |   | 3,257            |   |
| Total Revenues  | 152,239              |   | 61,883           |   |
| Expenses:   | 152,259              |   | 01,005           |   |
| Cost of goods manufactured and sold   | 42,070               |   | 16,219           |   |
| Research and development  | 37,806               |   | 28,050           |   |
| Selling, general and administrative   | 29,784               |   | 20,000<br>31,497 |   |
| Amortization of acquired intangible assets  | 10,434               |   | -                |   |
| Total Expenses  | 120,094              |   | 75,766           |   |
| Operating Income (Loss)   | 32,145               |   | (13,883          | ) |
| Other (Expense) Income, net:  | 52,145               |   | (13,005          | ) |
| Interest income   | 299                  |   | 502              |   |
| Interest expense  | (10,170              | ) | -                |   |
| Other income (expense), net   | 923                  | ) | -<br>89          |   |
|   | 923<br>(8,948        | ` | 69<br>591        |   |
| Total Other (Expense) Income, net   | (0,940)<br>23,197    | ) | (13,292          | ` |
| Income (Loss) Before Income Taxes   | 23,197<br>764        |   | (13,292)<br>(54) | ) |
| Income Tax Provision (Benefit)  | -                    |   | •                | ) |
| Net Income (Loss) - GAAP  | \$ 22,433            |   | \$ (13,238       | ) |
| Earnings (Loss) Per Share:  |                      |   |                  |   |
| GAAP earnings (loss) per share - basic and diluted  | \$ 0.17              |   | \$ (0.14         | ) |
| Non-GAAP earnings per share - basic   | \$ 0.41              |   | \$ 0.04          |   |
| Non-GAAP earnings per share - diluted   | \$ 0.39              |   | \$ 0.04          |   |
| Weighted Average Number of Ordinary Shares Outstanding  |                      |   |                  |   |
| Weighted Average Number of Ordinary Shares Outstanding:<br>Basic - GAAP                                     | 120 424              |   | 06 640           |   |
| Diluted - GAAP  | 130,434<br>134,945   |   | 96,649<br>96,649 |   |
| Basic - Non-GAAP  | 130,434              |   | 96,649<br>96,649 |   |
| Diluted - Non-GAAP  | -                    |   | -                |   |
| Diluted - Noti-GAAP   | 134,945              |   | 100,736          |   |
| An itemized reconciliation between net income (loss) on a GAAP basis and non-GAAP net income is as follows: |                      |   |                  |   |
| Net Income (Loss) - GAAP  | \$ 22,433            |   | \$ (13,238       | ) |
| Adjustments:  |                      |   |                  |   |
| Non-cash net interest expense   | 1,528                |   | -                |   |
| Non-cash taxes  | (145                 | ) | (65              | ) |
| Depreciation expense  | 7,584                |   | 1,908            |   |
| Amortization expense  | 10,434               |   | -                |   |
| Share-based compensation  | 8,162                |   | 5,660            |   |
| Deferred revenue  | 2,970                |   | (197             | ) |
| Merger-related costs  | -                    |   | 9,487            |   |
| Non-GAAP Net Income   | \$ 52,966            |   | \$ 3,555         |   |
|   |                      |   |                  |   |

## **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        | June 30,     | March 31,    |
|--|--------------|--------------|
| (In thousands)                               | 2012         | 2012         |
| Cash, cash equivalents and total investments | \$ 231,930   | \$ 246,138   |
| Receivables                                  | 135,656      | 96,381       |
| Inventory                                    | 41,442       | 39,759       |
| Prepaid expenses and other current assets    | 10,939       | 12,566       |
| Property, plant and equipment, net           | 299,536      | 302,995      |
| Intangible assets, net and goodwill          | 700,151      | 710,585      |
| Other assets                                 | 26,013       | 26,793       |
| Total Assets                                 | \$ 1,445,667 | \$ 1,435,217 |
| Long-term debt - current portion             | \$ 3,100     | \$ 3,100     |

| Other current liabilities                  | 68,139       | 86,064       |
|--|--------------|--------------|
| Long-term debt                             | 441,083      | 441,360      |
| Deferred revenue - long-term               | 8,146        | 7,578        |
| Other long-term liabilities                | 42,713       | 43,263       |
| Total shareholders' equity                 | 882,486      | 853,852      |
| Total Liabilities and Shareholders' Equity | \$ 1,445,667 | \$ 1,435,217 |
|  |              |              |
| Ordinary shares outstanding (in thousands) | 130,730      | 130,177      |

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 months ended June 30, 2012, which the company intends to file in July 2012.

Source: Alkermes plc

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