



## Alkermes plc Reports Second Quarter Fiscal 2012 Financial Results

November 3, 2011

***-- Financial Results Reflect Successful Completion of Merger With EDT on Sept. 16, 2011, and Include 14 Days of EDT Results --***

***-- Second Quarter Revenues Grew More Than 46% Year-Over-Year to \$72.0 Million, Reflecting Growth and Expansion of Commercial Product Portfolio --***

***-- Company Reports Adjusted EBITDA of \$13.3 Million for Second Quarter --***

***-- Company Expects Significant Increase in Revenues and Positive Adjusted EBITDA for Fiscal Year 2012, Underscoring Financially Transformative Nature of Merger --***

DUBLIN, Nov 03, 2011 (BUSINESS WIRE) -- [Alkermes plc](#) (NASDAQ: ALKS) today reported financial results for its second quarter of fiscal 2012, which ended on Sept. 30, 2011. These are the first financial results released by Alkermes plc (Alkermes) following the successful completion on Sept. 16, 2011, of the merger of Alkermes, Inc. with Elan Drug Technologies (EDT). Alkermes is a new, growing, global leader in central nervous system (CNS) therapeutics, characterized by its broad portfolio of commercial products and robust pipeline of new product candidates.

"This quarter marks the beginning of a new phase of growth for Alkermes, as we begin to realize the financially transformative effects of the EDT transaction. We are now fully executing on our strategy to build Alkermes for growth in both the near- and long-term. In the near-term, we will see the growth in revenues from the expansion of our portfolio of commercial products. Over the long-term, we will realize the value of our advancing pipeline of new drug candidates," commented Richard Pops, Chief Executive Officer of Alkermes. "We are committed to our vision of building Alkermes plc as a global leader in the development of innovative products for a broad range of CNS diseases for the benefit of patients and healthcare systems around the world."

### **Second Quarter Fiscal 2012 Financial Results**

These financial results reflect a full quarter of operations of Alkermes, Inc. and 14 days of operations of the former EDT business, together with the consolidated balance sheet as of Sept. 30, 2011.

For the quarter ended Sept. 30, 2011, the company reported a net loss of \$22.3 million, or a basic and diluted loss per share of \$0.22, based on U.S. Generally Accepted Accounting Principles (GAAP).

As a complement to GAAP results, the company is also providing a non-GAAP measure of Adjusted EBITDA, which the company believes better indicates underlying trends in ongoing operations. Adjusted EBITDA excludes from GAAP results the following: interest expense, taxes, depreciation, amortization, share-based compensation expense and certain noncash or nonrecurring items, such as merger-related expenses.

For the second quarter of fiscal 2012, the company reported Adjusted EBITDA of \$13.3 million, or a basic and diluted Adjusted EBITDA per share of \$0.13 and \$0.12, respectively. This result includes \$3.4 million of Adjusted EBITDA from EDT for the 14-day period following the close of the merger. The reconciliation between GAAP net loss and Adjusted EBITDA for the second quarters of fiscal 2012 and 2011 is provided in the tables at the end of this press release.

"Our second quarter results were driven by the strong performance of our long-acting atypical antipsychotic franchise, as well as growing sales of VIVITROL<sup>®</sup> and milestone revenue triggered by the EU launch of BYDUREON<sup>™</sup>," commented James Frates, Chief Financial Officer of Alkermes. "Next quarter, we will report the first complete quarter of financial results of our combined organization, which will more fully reflect our diverse product portfolio. Moving forward, we will continue to focus on growing revenues and delivering on our Adjusted EBITDA goals."

### **Revenues**

Total revenues for the second quarter of fiscal 2012 were \$72.0 million, compared to \$49.2 million for Alkermes, Inc. for the same period in fiscal 2011. Alkermes plc earns revenues from a broad portfolio of products, including five key growth products: RISPERDAL<sup>®</sup> CONSTA<sup>®</sup>, INVEGA<sup>®</sup> SUSTENNA<sup>®</sup>, AMPYRA<sup>®</sup>, VIVITROL and BYDUREON. Alkermes, Inc. revenues were in line with the company's expectations:

- Manufacturing and royalty revenues from RISPERDAL CONSTA were \$44.3 million for the second quarter of fiscal 2012, compared to \$42.0 million for the same period in fiscal 2011.
- Net sales for VIVITROL were \$9.9 million for the second quarter of fiscal 2012, compared to \$6.5 million for the same period in fiscal 2011, representing a 52.8% increase year-over-year, and compared to \$9.7 million for the first quarter of fiscal 2012, representing a 2.1% sequential quarterly increase. This marks the ninth consecutive quarter of growth for VIVITROL.

- Research & Development (R&D) revenues for the second quarter of fiscal 2012 included a \$7.0 million milestone payment in connection with the launch of BYDUREON in the EU.

The EDT portfolio contributed \$9.1 million to the second quarter fiscal 2012 revenues during the 14-day period following the close of the merger.

#### Costs and Expenses

Operating expenses for the second quarter of fiscal 2012 were \$83.7 million, compared to \$56.3 million for the same period of fiscal 2011. The increase was mainly the result of: \$12.8 million of merger-related expenses included in Selling, General & Administrative (SG&A) expenses; \$6.8 million of costs and expenses associated with 14 days of the EDT business; a \$4.0 million increase in SG&A expenses for Alkermes, Inc. due to a \$1.4 million increase in share-based compensation expense and an increase in promotional efforts associated with VIVITROL's launch in the opioid dependence indication; a \$3.3 million increase in Alkermes, Inc.'s R&D expenses due largely to the advancement of pipeline candidates into later-stage development; and \$1.8 million of amortization of intangibles. Net interest expense for the second quarter of fiscal 2012 was \$7.2 million, due primarily to interest expense on the \$450 million of term loans secured on June 30, 2011, to fund the merger.

#### Balance Sheet

At Sept. 30, 2011, Alkermes had \$1.5 billion in total assets, reflecting the combination of Alkermes, Inc. and EDT, compared with total assets of Alkermes, Inc. on March 31, 2011, of \$452.4 million. As of Sept. 30, 2011, Alkermes had cash and total investments of \$240.6 million, compared to \$294.7 million at March 31, 2011.

#### Financial Expectations for Fiscal 2012

Alkermes' financial expectations for the fiscal year ending March 31, 2012, are outlined below and include the anticipated results for the full fiscal year of Alkermes, Inc. and for the EDT business from Sept. 16, 2011 through March 31, 2012. The following statements are forward-looking, and actual results may differ materially. Please see "Note Regarding Forward-Looking Statements" at the end of this release for risks that could cause results to differ materially from these forward-looking statements.

- **Revenues:** Alkermes expects total revenues to range from \$350 million to \$380 million, up from a range of \$205 million to \$229 million. These revenue expectations include no changes from the Alkermes, Inc. guidance provided on May 18, 2011, and reflect additional revenues from the EDT portfolio.
- **Cost of Goods Manufactured:** The company expects total cost of goods manufactured to range from \$120 million to \$130 million, up from a range of \$46 million to \$57 million, driven by the expansion of the product portfolio.
- **R&D Expenses:** The company expects R&D expenses to range from \$135 million to \$145 million, up from a range of \$110 million to \$125 million. This expectation is based on product candidates moving into later-stage development.
- **SG&A Expenses:** The company expects SG&A expenses to range from \$130 million to \$140 million, up from a range of \$85 million to \$95 million. These expectations include \$25 million to \$30 million of merger-related expenses.
- **Amortization of Intangible Assets:** The company expects amortization of intangibles to range from \$25 million to \$30 million.
- **Net Interest Expense:** The company expects net interest expense to range from \$25 million to \$27 million, revised from net interest income of up to \$3 million, due to interest charges on the \$450 million of term loans secured on June 30, 2011, to fund the merger.
- **Net Income Tax Expense:** The company expects net income tax expense to range from \$5 million to \$10 million.
- **GAAP Net Loss:** The company expects a GAAP net loss in the range of \$90 million to \$102 million, or a basic and diluted loss per share of approximately \$0.78 to \$0.89. This loss per share is based on a weighted average basic and diluted share count of approximately 115 million shares outstanding. This compares to previous expectations of a GAAP net loss in the range of \$36 million to \$45 million for Alkermes, Inc., or a basic and diluted loss per share of approximately \$0.38 to \$0.47. This loss per share was based on a weighted average basic and diluted share count of approximately 96 million shares outstanding.
- **Share-based Compensation Expense:** The company expects share-based compensation expense, included in the operating expenses above, to range from \$30 million to \$35 million, up from a range of \$20 million to \$25 million.
- **Adjusted EBITDA:** The company expects Adjusted EBITDA to range from \$45 million to \$55 million, or a basic Adjusted EBITDA per share of \$0.39 to \$0.48, based on a weighted average basic share count of approximately 115 million shares outstanding, or a diluted Adjusted EBITDA per share of \$0.38 to \$0.46, based on a weighted average diluted share count of approximately 120 million shares outstanding. This compares to a prior expectation of an Adjusted EBITDA loss of \$7 million to \$13 million for Alkermes, Inc., or a basic and diluted loss per share of \$0.07 to \$0.14, based on a weighted average basic and diluted share count of approximately 96 million shares outstanding.

#### Conference Call

Alkermes will host a conference call at 8:30 a.m. EDT (12:30 p.m. GMT) on Thursday, November 3, 2011, 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, November 3, 2011, through 5:00 p.m. EST (10:00 p.m. GMT) on Thursday, November 10, 2011, 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 and manufacturing facilities in Athlone, Ireland; Gainesville, Georgia; and Wilmington, Ohio. For more information, please visit Alkermes' website at [www.alkermes.com](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; the timing, funding and feasibility of development activities for its product candidates; 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 company's ability to successfully conduct clinical trials in a timely and cost-effective manner; the possibility that the anticipated benefits from the recently completed merger of Alkermes, Inc. and EDT cannot or will not be fully realized; the possibility that costs or difficulties related to integration of the former Alkermes, Inc. and EDT businesses will be greater than expected; the possibility that clinical trial results for the company's products will not be predictive of real-world results or of results in subsequent clinical trials; decisions by foreign regulatory authorities or the U.S. Food and Drug Administration (FDA) regarding the company's products; the risk 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 that could cause the FDA or foreign regulatory authorities to require post-approval studies or require removal of the company's products from the market; and those risks described in our Registration Statement on Form S-4 (commission file number 333-175078) which was declared effective by the SEC on August 4, 2011, Alkermes, Inc.'s Annual Report on Form 10-K, as amended, for the year ended March 31, 2011 and in other filings made by the company with the SEC and which are available at the SEC's website at [www.sec.gov](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 trademark of Alkermes, Inc.; RISPERDAL® CONSTA® and INVEGA® SUSTENNA® are trademarks of Janssen Pharmaceuticals, Inc.; AMPYRA® is a trademark of Acorda Therapeutics, Inc.; and BYDUREON™ is a trademark of Amylin Pharmaceuticals, Inc.

(tables follow)

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

<b>Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)</b>	Three Months Ended September 30, 2011	Three Months Ended September 30, 2010
Revenues:		
Manufacturing and royalty revenues	\$ 54,039	\$ 42,623
Product sales, net	9,887	6,469
Research and development revenue	8,052	155
<b>Total Revenues</b>	<b>71,978</b>	<b>49,247</b>
Expenses:		
Cost of goods manufactured and sold	17,530	13,911
Research and development	28,160	23,932
Selling, general and administrative	36,234	18,436
Amortization of acquired intangible assets	1,817	-
<b>Total Expenses</b>	<b>83,741</b>	<b>56,279</b>
Operating Loss	(11,763)	(7,032)
Other (Expense), net:		
Interest income	383	673
Interest expense	(7,561)	(2,168)
Other income (expense), net	336	(82)
<b>Total Other (Expense), net</b>	<b>(6,842)</b>	<b>(1,577)</b>
Loss Before Income Taxes	(18,605)	(8,609)
Income Tax Provision (Benefit)	3,650	(943)
<b>Net Loss -- GAAP</b>	<b>\$ (22,255)</b>	<b>\$ (7,666)</b>

**(Loss) Earnings Per Share:**

GAAP loss per share -- basic and diluted	\$ (0.22)	\$ (0.08)
Adjusted EBITDA per share -- basic (Non-GAAP)	\$ 0.13	\$ 0.01
Adjusted EBITDA per share -- diluted (Non-GAAP)	\$ 0.12	\$ 0.01

**Weighted Average Number of Common Shares Outstanding -- GAAP:**

Basic and diluted	102,474	95,511
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**Weighted Average Number of Common Shares Outstanding -- Adjusted EBITDA (Non-GAAP)**

Basic	102,474	95,511
Diluted	106,646	97,885

An itemized reconciliation between net loss on a GAAP basis and Adjusted EBITDA is as follows:

<b>Net Loss -- GAAP</b>	\$ (22,255)	\$ (7,666)
Adjustments:		
Share-based compensation included in cost of goods manufactured and sold	529	525
Share-based compensation included in R&D	2,309	1,637
Share-based compensation included in SG&A	4,214	2,786
Depreciation included in cost of goods manufactured and sold	1,523	1,004
Depreciation included in R&D	827	695
Depreciation included in SG&A	303	318
Amortization of acquired intangible assets	1,817	-
Interest expense	7,561	-
Income tax provision (benefit)	3,650	(943)
Costs incurred related to the merger with Elan Drug Technologies, included in SG&A	12,783	-
Costs incurred related to the redemption of the non-recourse 7% Notes included in interest expense	-	2,168
<b>Adjusted EBITDA -- Non-GAAP</b>	<b>\$ 13,261</b>	<b>\$ 524</b>

**Use of Non-GAAP Financial Measures**

We use "Adjusted EBITDA" as a key indicator of financial operating performance without regard to financing methods, capital structures, taxes or historical cost basis. Adjusted EBITDA is not a GAAP measure of performance and is defined as net income or loss plus or minus interest expense, provision for or benefit from income taxes, depreciation and amortization of costs, share-based compensation expense and other noncash or nonrecurring items, such as merger-related expenses. We feel that Adjusted EBITDA 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**

<b>(In thousands)</b>	September 30, 2011	March 31, 2011
Cash, cash equivalents and total investments	\$ 240,554	\$ 294,730
Receivables	79,644	22,969
Inventory	47,118	20,425
Prepaid expenses and other current assets	13,382	8,244
Property, plant and equipment, net	304,611	95,020
Intangible assets, net and goodwill	792,972	-
Other assets	25,822	11,060
<b>Total Assets</b>	<b>\$1,504,103</b>	<b>\$ 452,448</b>
Long-term debt -- current portion	\$ 2,325	\$ -
Other current liabilities	87,999	48,057
Deferred revenue -- long-term	4,359	4,837
Long-term debt	441,859	-
Other long-term liabilities	57,881	7,536
Total shareholders' equity	909,680	392,018
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$1,504,103</b>	<b>\$ 452,448</b>
Common shares outstanding (in thousands)	129,585	95,702

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes, Inc.'s Annual Report on Form 10-K for the year ended March 31, 2011, the company's Registration Statement on Form S-4 and the company's Quarterly Report on Form 10-Q for the six months ended September 30, 2011, which the company intends to file in November 2011.



SOURCE: Alkermes

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