

# Alkermes plc Reports Third Quarter Fiscal 2012 Financial Results

February 2, 2012

- Third Quarter Revenues Grew to \$126 Million, More Than 185% Year-Over-Year, Reflecting First Full Quarter of Alkermes plc Results Following Merger With EDT -
- Third Quarter Adjusted EBITDA Grew to \$29.7 Million -
- Company Increases Revenue and Adjusted EBITDA Guidance for Fiscal 2012 -

DUBLIN--(BUSINESS WIRE)--Feb. 2, 2012-- Alkermes plc (NASDAQ: ALKS) today reported financial results for its third quarter of fiscal 2012, which ended on Dec. 31, 2011. The third quarter results reflect the first full quarter 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.

"These quarterly results demonstrate the powerful financial and operational entity Alkermes plc has become. We are now well-positioned to build a major biotech company. Our financial strength is driven by a significant and diverse commercial portfolio with five key products that will deliver growth in the near-term, while our promising late-stage pipeline of candidates reflects our world-class science and focused research and development strategy," commented Richard Pops, Chief Executive Officer of Alkermes. "2012 will be an important year for Alkermes, with catalysts driving growth across the commercial portfolio and progress in our pipeline."

### Third Quarter Fiscal 2012 Financial Results

Based on U.S. Generally Accepted Accounting Principles (GAAP), for the quarter ended Dec. 31, 2011, Alkermes reported a net loss of \$14.8 million, or a basic and diluted loss per share of \$0.11.

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: net interest expense, taxes, depreciation, amortization, share-based compensation expense and merger-related expenses.

For the third quarter of fiscal 2012, the company reported Adjusted EBITDA of \$29.7 million, or a basic and diluted Adjusted EBITDA per share of \$0.23 and \$0.22, respectively. This compares to an Adjusted EBITDA loss of \$4.1 million, or a basic and diluted Adjusted EBITDA loss per share of \$0.04 for the same period in fiscal 2011. The reconciliation between GAAP net loss and Adjusted EBITDA for the third quarters of fiscal 2012 and 2011 is provided in the tables at the end of this press release.

"Our third quarter results were driven by the strong performance of our key commercial products, with particularly robust growth from our long-acting atypical antipsychotic franchise and AMPYRA<sup>®</sup>, as well as strong contributions from a number of our mature products," commented James Frates, Chief Financial Officer of Alkermes. "Today we are adjusting our financial expectations for fiscal 2012 to reflect stronger than anticipated revenues and our consistent financial discipline. We continue to focus on delivering on our Adjusted EBITDA goals, and we look forward to providing expectations for the upcoming fiscal year when we report our fiscal 2012 year-end financial results in May 2012."

### Revenues

Total revenues for the third quarter of fiscal 2012 were \$125.6 million, compared to \$44.0 million for Alkermes, Inc. for the same period of 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>/XEPLION<sup>®</sup>; AMPYRA/FAMPYRA<sup>®</sup>; VIVITROL<sup>®</sup>; and BYDUREON <sup>™</sup>.

- Manufacturing and royalty revenues from the company's long-acting atypical antipsychotic franchise, RISPERDAL
  CONSTA and INVEGA SUSTENNA/XEPLION, were \$47.6 million for the third quarter of fiscal 2012, compared to \$35.2
  million from RISPERDAL CONSTA alone for the same period of fiscal 2011. According to Johnson & Johnson, worldwide
  sales of RISPERDAL CONSTA and INVEGA SUSTENNA grew nearly 20% operationally during the quarter as compared
  to the same period in fiscal 2011 due to increased combined market share.
- Manufacturing and royalty revenues from AMPYRA/FAMPYRA were \$10.2 million for the third quarter of fiscal 2012. For
  the quarter ended Dec. 31, 2011, U.S. unaudited net sales of AMPYRA reported by Acorda Therapeutics, Inc. (Acorda)
  were approximately \$57 million. Alkermes, Inc. did not record any revenues for AMPYRA/FAMPYRA for the same period of
  fiscal 2011. For the calendar year ended Dec. 31, 2011, unaudited net sales of AMPYRA in the U.S. reported by Acorda
  were approximately \$210 million.
- Net sales for VIVITROL were \$10.6 million for the third quarter of fiscal 2012, compared to \$7.7 million for the same period of fiscal 2011, representing a 38% increase year-over-year, and compared to \$9.9 million for the second quarter of fiscal 2012, representing a 7% sequential quarterly increase. This marks the tenth consecutive quarter of growth for VIVITROL.
- Royalty revenue from BYDUREON was \$0.3 million in the third quarter of fiscal 2012. BYDUREON was commercially launched in certain EU countries in the second half of calendar 2011.
- Additionally, third quarter fiscal 2012 results included TRICOR® 145 revenues of \$15.7 million, RITALIN LA®/FOCALIN XR® revenues of \$11.6 million and VERELAN® revenues of \$6.6 million. These products already face, or are expected to

face in the near term, generic competition.

### Costs and Expenses

Operating expenses for the third quarter of fiscal 2012 were \$130.6 million. This compared to operating expenses of \$55.9 million for the same period of fiscal 2011 for Alkermes, Inc. The increase was mainly the result of: a \$29.9 million increase in cost of goods sold, in line with the increase in revenues from manufactured products; an \$18.0 million increase in Research and Development (R&D) expenses due largely to the inclusion of expenses associated with the former EDT business and the advancement of pipeline candidates into later-stage development; a \$15.0 million increase in Selling, General and Administrative (SG&A) expenses due primarily to the inclusion of expenses associated with the former EDT business and \$4.4 million of merger-related expenses; and \$11.9 million of amortization of intangibles associated with the acquisition of EDT. Net interest expense for the third quarter of fiscal 2012 was \$10.1 million, including \$10.5 million of interest expense on the \$450 million of term loans secured to fund the acquisition.

#### **Balance Sheet**

As of Dec. 31, 2011, Alkermes had cash and total investments of \$234.0 million, compared to \$294.7 million for Alkermes, Inc. at March 31, 2011. The decrease in cash and total investments was primarily due to the use of \$50 million to fund the acquisition of EDT. At Dec. 31, 2011, Alkermes plc had \$1.5 billion in total assets, reflecting the combination of Alkermes, Inc. and EDT, compared with total assets of Alkermes, Inc. at March 31, 2011, of \$452.4 million.

#### **Financial Expectations for Fiscal 2012**

Alkermes is increasing its revenue expectations and maintaining its expense expectations for fiscal 2012, resulting in an improvement in GAAP net loss and Adjusted EBITDA expectations. These revised financial expectations are outlined below and include the anticipated results for the full fiscal year of Alkermes, Inc. and for the former 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 press release for risks that could cause results to differ materially from these forward-looking statements.

- Revenues: Alkermes expects total revenues to range from \$370 million to \$400 million, up from a range of \$350 million to \$380 million.
- Cost of Goods Manufactured: The company continues to expect cost of goods manufactured to range from \$120 million to \$130 million.
- R&D Expenses: The company continues to expect R&D expenses to range from \$135 million to \$145 million.
- SG&A Expenses: The company continues to expect SG&A expenses to range from \$130 million to \$140 million.
- Amortization of Intangible Assets: The company continues to expect amortization of intangibles to range from \$25 million to \$30 million.
- Net Interest Expense: The company continues to expect net interest expense to range from \$25 million to \$27 million.
- Net Income Tax Expense: The company continues to expect 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 \$70 million to \$82 million, or a basic and diluted loss per share of approximately \$0.61 to \$0.71, 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 \$90 million to \$102 million, or a basic and diluted loss per share of approximately \$0.78 to \$0.89.
- Share-Based Compensation Expense: The company continues to expect share-based compensation expense, included in the operating expenses above, to range from \$30 million to \$35 million.
- Adjusted EBITDA: The company expects Adjusted EBITDA to range from \$65 million to \$75 million, or a basic Adjusted EBITDA per share of \$0.57 to \$0.65, based on a weighted average basic share count of approximately 115 million shares outstanding, or a diluted Adjusted EBITDA per share of \$0.54 to \$0.63, based on a weighted average diluted share count of approximately 120 million shares outstanding. This compares to a prior expectation of Adjusted EBITDA in the range of \$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.

### **Conference Call**

Alkermes will host a conference call at 8:30 a.m. EST (1:30 p.m. GMT) on Thursday, Feb. 2, 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. EST (4:30 p.m. GMT) on Thursday, Feb. 2, 2012, through 5:00 p.m. EST (10:00 p.m. GMT) on Thursday, Feb. 9, 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 and manufacturing facilities in Athlone, Ireland; Gainesville, Georgia; and Wilmington, Ohio. For more information, please visit Alkermes' website at <a href="http://www.alkermes.com">http://www.alkermes.com</a>.

#### **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 commercial markets and demand for our products may not be as large as the company anticipates; reimbursement for our products may change; 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 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 the U.S. Food and Drug Administration (FDA) or regulatory authorities outside the U.S. 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 regulatory authorities outside the U.S. to require post-approval studies or require removal of the company's products from the market; and those risks described in the company's Registration Statement on Form S-4 (commission file number 333-175078), which was declared effective by the Securities and Exchange Commission (SEC) on August 4, 2011, and in other filings made by the company with the SEC and which are available at the SEC's website at <a href="http://www.sec.gov">http://www.sec.gov</a>. 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.

Acorda is developing and marketing AMPYRA in the U.S. under a licensing agreement with Alkermes. AMPYRA is marketed outside the U.S. as FAMPYRA by Biogen Idec under a licensing agreement from Acorda.

VIVITROL<sup>®</sup> is a registered trademark of Alkermes, Inc.; RISPERDAL<sup>®</sup> CONSTA<sup>®</sup> and INVEGA<sup>®</sup> SUSTENNA<sup>®</sup> 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<sup>®</sup> and FOCALIN XR<sup>®</sup> are registered trademarks of Novartis AG Corporation; and VERELAN<sup>®</sup> is a registered trademark of Elan Pharma International Limited.

# Alkermes plc and Subsidiaries Selected Financial Information (Unaudited)

	Three Months Ended	Three Months
Condensed Consolidated Statements of Operations CAAD	December 31,	Ended December 31,
Condensed Consolidated Statements of Operations - GAAP	2011	2010
(In thousands, except per share data) Revenues:	2011	2010
	¢ 440 700	Ф 2E 022
Manufacturing and royalty revenues	\$ 112,780	\$ 35,932
Product sales, net	10,597	7,729
Research and development revenue	2,266	314
Total Revenues	125,643	43,975
Expenses:	40.750	40.000
Cost of goods manufactured and sold	42,752	12,860
Research and development	40,493	22,503
Selling, general and administrative	35,469	20,521
Amortization of acquired intangible assets	11,896	-
Total Expenses	130,610	55,884
Operating Loss	(4,967)	(11,909)
Other (Expense) Income, net:		
Interest income	350	650
Interest expense	(10,458)	-
Other income (expense), net	345	(83)
Total Other (Expense) Income, net	(9,763)	567
Loss Before Income Taxes	(14,730)	(11,342)
Income Tax Provision	98	41
Net Loss - GAAP	\$ (14,828)	\$ (11,383)
(Loss) Earnings Per Share:		
GAAP loss per share - basic and diluted	\$ (0.11)	\$ (0.12)
Adjusted EBITDA per share - basic (Non-GAAP)	\$ 0.23	\$ (0.04)
Adjusted EBITDA per share - diluted (Non-GAAP)	\$ 0.22	\$ (0.04)

Basic and diluted	129,670	95,667
Weighted Average Number of Common Shares Outstanding - Adjusted EBITDA (Non-GAAP)		
Basic	129,670	95,667
Diluted	133,617	95,667
An itemized reconciliation between net loss on a GAAP basis and Adjusted EBITDA is as follows:		
Net Loss - GAAP	\$ (14,828)	\$ (11,383)
Adjustments:		
Share-based compensation included in cost of goods manufactured and sold	801	385
Share-based compensation included in R&D	2,470	1,573
Share-based compensation included in SG&A	5,760	3,834
Depreciation included in cost of goods manufactured and sold	6,926	1,066
Depreciation included in R&D	1,675	757
Depreciation included in SG&A	380	325
Amortization of acquired intangible assets	11,896	-
Net interest expense (income)	10,108	(650)
Income tax provision	98	41
Costs incurred related to the merger with Elan Drug Technologies, included in SG&A	4,447	-
Adjusted EBITDA - Non-GAAP	\$ 29,733	\$ (4,052)

## **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 Statements of Operations - GAAP	Nine Months Ended December 31,	Nine Months Ended December 31,
(In thousands, except per share data)	2011	2010
Revenues:		
Manufacturing and royalty revenues	\$ 215,759	\$ 114,363
Product sales, net	30,170	20,402
Research and development revenue	13,575	737
Total Revenues	259,504	135,502
Expenses:		
Cost of goods manufactured and sold	76,501	39,436
Research and development	96,703	69,412
Selling, general and administrative	103,200	58,683
Amortization of acquired intangible assets	13,713	-
Total Expenses	290,117	167,531
Operating Loss	(30,613)	(32,029)
Other (Expense), net:		
Interest income	1,235	2,175
Interest expense	(18,019)	(3,298)
Other income (expense), net	770	(266)
Total Other (Expense), net	(16,014)	(1,389)
Loss Before Income Taxes	(46,627)	(33,418)
Income Tax Provision (Benefit)	3,694	(960)
Net Loss - GAAP	\$ (50,321)	\$ (32,458)
(Loss) Earnings Per Share:		
GAAP loss per share - basic and diluted	\$ (0.46)	\$ (0.34)
Adjusted EBITDA per share - basic (Non-GAAP)	\$ 0.42	\$ (0.09)
Adjusted EBITDA per share - diluted (Non-GAAP)	\$ 0.40	\$ (0.09)
		, ,
Weighted Average Number of Common Shares Outstanding - GAAP:		
Basic and diluted	109,645	95,502

Weighted Average Number of Common Shares Outstanding - Adjusted EBITDA (Non-GAAP)		
Basic	109,645	95,502
Diluted	113,727	95,502
An itemized reconciliation between net loss on a GAAP basis and Adjusted EBITDA is as follows:		
Net Loss - GAAP	\$ (50,321)	\$ (32,458)
Adjustments:		
Share-based compensation included in cost of goods manufactured and sold	1,886	1,271
Share-based compensation included in R&D	6,714	4,726
Share-based compensation included in SG&A	13,143	9,199
Depreciation included in cost of goods manufactured and sold	9,325	3,111
Depreciation included in R&D	3,252	2,121
Depreciation included in SG&A	961	978
Amortization of acquired intangible assets	13,713	-
Net interest expense	16,784	1,123
Income tax provision (benefit)	3,694	(960)
Costs incurred related to the merger with Elan Drug Technologies, included in SG&A	26,718	-
Costs related to the redemption of the non-recourse 7% Notes	-	2,168
Adjusted EBITDA - Non-GAAP	\$ 45,869	\$ (8,721)
	D 1 04	
Condensed Consolidated Balance Sheets	December 31,	March 31,
(In thousands)	2011	2011
Cash, cash equivalents and total investments	\$ 233,952	\$ 294,730
Receivables	104,684	22,969
Inventory	46,109	20,425
Prepaid expenses and other current assets	10,916	8,244
Property, plant and equipment, net	302,612	95,020
Intangible assets, net and goodwill	780,987	-
Other assets	26,567	11,060
Total Assets	\$ 1,505,827	\$ 452,448
Long-term debt - current portion	\$ 3,100	\$ -
Other current liabilities	94,096	48,057
Deferred revenue - long-term	4,697	4,837
Long-term debt	441,668	-
Other long-term liabilities	57,413	7,536
	004.050	000 040
Total shareholders' equity	904,853	392,018
Total shareholders' equity  Total Liabilities and Shareholders' Equity	904,853 \$ 1,505,827	392,018 \$ 452,448

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 nine months ended December 31, 2011, which the company intends to file in February 2012.

129,747

95,702

Source: Alkermes plc

Alkermes Contacts: For Investors: Rebecca Peterson, +1 781 609 6378 For Media: Jennifer Snyder, +1 781 609 6166

Common shares outstanding (in thousands)