

# Alkermes plc Reports Third Quarter Fiscal 2013 Financial Results

## January 31, 2013

- Company Improves Guidance for Fiscal 2013, Driven by Stronger Revenues and Lower Expenses -
- Third Quarter Non-GAAP Diluted EPS Grew td\$0.34 from \$0.10 for the Same Period in Prior Fiscal Year -

DUBLIN--(BUSINESS WIRE)--Jan. 31, 2013-- Alkermes plc (NASDAQ: ALKS) today reported financial results for its third quarter of fiscal 2013, which ended Dec. 31, 2012, and improved financial expectations for its fiscal year 2013.

"With results now spanning an entire year, the power of Alkermes plc is becoming evident. Our strong financial performance was driven by our five key commercial products, which grew 33% year-over-year," commented James Frates, Chief Financial Officer of Alkermes. "Today, we are again improving our financial expectations for fiscal 2013, based on our robust operational performance across the business. We now expect Alkermes to generate between \$135 million and \$155 million in non-GAAP net income this fiscal year."

### Third Quarter Fiscal 2013 Highlights

- Total revenues for the third quarter of fiscal 2013 increased 8.2% to \$135.9 million, compared to the same period in fiscal 2012, which was attributable primarily to growth from the company's key commercial products.
- Based on accounting principles generally accepted in the U.S. (GAAP), Alkermes reported net income of \$16.3 million, or a basic and diluted earnings per share (EPS) of \$0.12, for the third quarter of fiscal 2013. This compared to a GAAP net loss of \$14.8 million, or a basic and diluted loss per share of \$0.11, for the same period in fiscal 2012.
- The company reported non-GAAP<sup>1</sup> net income of \$46.5 million, or a non-GAAP diluted EPS of \$0.34, for the third quarter of fiscal 2013. This compared to non-GAAP net income of \$12.8 million, or a non-GAAP diluted EPS of \$0.10, for the same period in fiscal 2012.

"This quarter demonstrates the strength of Alkermes' business model, which is characterized by two robust portfolios – our commercial products and our development pipeline. The quarterly financial results underscore our ability to hit financial goals while investing in a promising pipeline," commented Richard Pops, Chief Executive Officer of Alkermes. "As we move into 2013, we are excited by how our late-stage pipeline is taking shape, with interesting new medicines that have blockbuster potential and many important data readouts this year."

#### Third 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 \$52.5 million for the third quarter of fiscal 2013, compared to \$47.6 million for the same period in fiscal 2012. Worldwide end-market sales of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION for the third quarter of fiscal 2013 were approximately \$586 million and grew approximately 13% compared to the same period in fiscal 2012.
- Manufacturing and royalty revenues from AMPYRA<sup>®</sup>/FAMPYRA<sup>®2</sup> were \$18.4 million for the third quarter of fiscal 2013, compared to \$10.6 million for the same period in fiscal 2012. Unaudited end-market sales of AMPYRA by Acorda Therapeutics, Inc. in the U.S. for the third quarter of fiscal 2013 were approximately \$73 million and grew approximately 28% compared to the same period in fiscal 2012. End-market sales of FAMPYRA by Biogen Idec for the third quarter of fiscal 2013 were approximately 1% compared to the same period in fiscal 2012.
- Net sales of VIVITROL<sup>®</sup> were \$15.9 million for the third quarter of fiscal 2013, compared to \$10.6 million for the same period in fiscal 2012, representing an increase of approximately 50%.
- Royalty revenue from BYDUREON<sup>®</sup> was \$5.3 million for the third quarter of fiscal 2013, based on estimated end-market net sales of approximately \$65 million. This compared to royalty revenue of \$0.3 million for the same period in fiscal 2012.
- Additionally, third quarter fiscal 2013 results included RITALIN LA<sup>®</sup>/FOCALIN XR<sup>®</sup> revenues of \$9.8 million and TRICOR<sup>®</sup> 145 revenues of \$6.8 million. This compared to RITALIN LA/FOCALIN XR revenues of \$11.6 million and TRICOR 145 revenues of \$15.7 million for the same period in fiscal 2012.

Costs and Expenses

- Operating expenses for the third quarter of fiscal 2013 were \$110.6 million, compared to operating expenses of \$130.6 million for the same period in fiscal 2012. This reduction was due primarily to the timing of clinical trial expenses and the inclusion of certain merger-related expenses in fiscal 2012.
- Net interest expense for the third quarter of fiscal 2013 was \$4.5 million. This compared to net interest expense of \$10.1 million for the same period in fiscal 2012. This reduction was due primarily to the successful refinancing of Alkermes'

### **Balance Sheet**

At Dec. 31, 2012, Alkermes recorded cash and total investments of \$239.3 million, compared to \$208.2 million at Sept. 30, 2012, and \$246.1 million at March 31, 2012.

#### **Financial Expectations for Fiscal 2013**

Alkermes is improving its financial expectations for fiscal 2013, reflecting increased net sales expectations for VIVITROL and decreased research and development (R&D) expense expectations. These factors are expected to increase non-GAAP net income by \$15 million to a range of \$135 million to \$155 million. The following outlines Alkermes' financial expectations for the fiscal year ending March 31, 2013.

- Revenues: Alkermes now expects total revenues to range from \$520 million to \$545 million, up from a range of \$510 million to \$540 million. The company now expects VIVITROL net sales to range from \$55 million to \$60 million, up from a range of \$45 million to \$55 million. The company 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 continues to expect cost of goods manufactured to range from \$160 million to \$170 million.
- **R&D Expenses:** The company now expects R&D expenses to range from \$140 million to \$150 million, down from a range of \$150 million to \$160 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 continues to expect net income tax expense to range from \$5 million to \$10 million.
- 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 Income: The company now expects GAAP net income to range from break-even to positive \$15 million, or a basic and diluted EPS of approximately \$0.00 to \$0.11, based on weighted average basic and diluted share counts of approximately 132 million and 137 million shares outstanding, respectively. This compares to previous expectations of a GAAP net loss in the range of break-even to \$15 million, or a basic and diluted loss per share of approximately \$0.00 to \$0.11.
- Capital Expenditures: The company now expects capital expenditures to be approximately \$20 million, down from approximately \$25 million.
- Non-GAAP Net Income: The company now expects non-GAAP net income to range from \$135 million to \$155 million, and non-GAAP diluted EPS to range from \$0.99 to \$1.13. This compares to previous expectations of non-GAAP net income in the range of \$120 million to \$140 million and non-GAAP diluted EPS in the range of \$0.88 to \$1.02.
- Free Cash Flow: The company now expects free cash flow to range from \$115 million to \$135 million, up from a range of \$95 million to \$115 million.

## **Conference Call**

Alkermes will host a conference call at 8:30 a.m. EST (1:30 p.m. GMT) on Thursday, Jan. 31, 2013, to discuss these financial results and provide an update on the company. The conference call will be webcast on the investor relations section of Alkermes' website at <u>www.alkermes.com</u> or 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, Jan. 31, 2013, through 5:00 p.m. EST (10:00 p.m. GMT) on Thursday, Feb. 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 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; the therapeutic and commercial value of the company's products; and our 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: whether the company, and its partners, are able to continue to successfully commercialize and develop its products; 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; whether clinical development activities will be completed on time or at all and whether the results of such activities will be predictive of real-world results or of results in subsequent clinical trials; 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 <a href="https://www.sec.gov">www.sec.gov</a>. 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 they are made. The information or responsibility for updating any forward-looking information contained in this press release.

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 registered trademark of Amylin Pharmaceuticals, LLC; TRICOR<sup>®</sup> is a registered trademark of Fournier Industrie et Sante Corporation; and RITALIN LA<sup>®</sup> and FOCALIN XR<sup>®</sup> are registered trademarks of Novartis AG Corporation.

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

(tables follow)

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

			Three Months	
	Ended	Ended	~ /	
Condensed Consolidated Statements of Operations - GAAP	December 31,	,		
(In thousands, except per share data)	2012	2011		
Revenues:	<b>•</b> • • • • • <b>•</b> •	<b>•</b> • • • <b>• •</b> • • • • • • • • • • •		
Manufacturing and royalty revenues	\$ 118,274	\$ 112,780		
Product sales, net	15,917	10,597		
Research and development revenue	1,718	2,266		
Total Revenues	135,909	125,643	125,643	
Expenses:				
Cost of goods manufactured and sold	38,914	-	42,752	
Research and development	31,319	40,493		
Selling, general and administrative	29,867	35,469		
Amortization of acquired intangible assets	10,549	11,896		
Total Expenses	110,649	130,610		
Operating Income (Loss)	25,260	(4,967	)	
Other (Expense), net:				
Interest income	155	350		
Interest expense	(4,703)	(10,458	)	
Other income, net	(49)	345		
Total Other (Expense), net	(4,597)	(9,763	)	
Income (Loss) Before Income Taxes	20,663	(14,730	)	
Income Tax Provision	4,405	98		
Net Income (Loss) — GAAP	\$ 16,258	\$ (14,828	)	
(Loss) Earnings Per Share:				
GAAP earnings (loss) per share — basic	\$ 0.12	\$ (0.11	)	
GAAP earnings (loss) per share — diluted	\$ 0.12	\$ (0.11	)	
Non-GAAP earnings per share — basic	\$ 0.35	\$ 0.10		
Non-GAAP earnings per share — diluted	\$ 0.34	\$ 0.10		
Weighted Average Number of Ordinary Shares Outstanding:				
Basic — GAAP	132,097	129,670		

Diluted — GAAP Basic — Non-GAAP Diluted — Non-GAAP	137,497 132,097 137,497	129,670 129,670 133,617	
An itemized reconciliation between net income (loss) on a GAAP basis and non-GAAP net income is as follows: <b>Net Income (Loss) — GAAP</b> Adjustments:	\$ 16,258	\$ (14,828	)
Non-cash net interest expense	496	2,853	
Non-cash taxes	3,373	(9,957	)
Depreciation expense	8,052	8,981	,
Amortization expense	10,549	11,896	
Share-based compensation	8,226	9,031	
Deferred revenue	(412)	415	
Merger-related costs	-	4,447	
Non-GAAP Net Income	\$ 46,542	\$ 12,838	
	Nine Months	Nine Month	15
	Ended	Ended	10
Condensed Consolidated Statements of Operations - GAAP	December 31,	December	31,
(In thousands, except per share data)	2012	2011	,
Revenues:			
Manufacturing and royalty revenues	\$ 363,981	\$ 215,759	
Product sales, net	43,481	30,170	
Research and development revenue	4,664	13,575	
Total Revenues	412,126	259,504	
Expenses:			
Cost of goods manufactured and sold	122,475	76,501	
Research and development	104,213	96,703	
Selling, general and administrative	91,079	103,200	
Amortization of acquired intangible assets	31,530	13,713	
Total Expenses	349,297	290,117	,
Operating Income (Loss)	62,829	(30,613	)
Other (Expense), net:	670	1,235	
Interest income	(37,521)	(18,019	١
Interest expense Other income, net	1,597	(18,019 770	)
Total Other (Expense), net	(35,254)	(16,014	)
Income (Loss) Before Income Taxes	27,575	(46,627	)
Income Tax Provision	5,591	3,694	,
Net Income (Loss) — GAAP	\$ 21,984	\$ (50,321	)
			,
Earnings (Loss) Per Share:			
GAAP earnings (loss) per share — basic	\$ 0.17	\$ (0.46	)
GAAP earnings (loss) per share — diluted	\$ 0.16	\$ (0.46	)
Non-GAAP earnings per share — basic	\$ 0.94	\$ 0.21	
Non-GAAP earnings per share — diluted	\$ 0.90	\$ 0.21	
Weighted Average Number of Ordinary Shares Outstanding: Basic — GAAP	131,202	109,645	
Diluted — GAAP	136,216	109,645	
Basic — Non-GAAP	131,202	109,645	
Diluted — Non-GAAP	136,216	113,727	
An itemized reconciliation between net income (loss) on a GAAP basis and non-GAAP net income is as follows:	¢ 21 094	¢ (EO 204	`
Net Income (Loss) — GAAP	\$ 21,984	\$ (50,321	)
Adjustments:	1 116	1 527	
Non-cash net interest expense Non-cash taxes	4,116 2,382	4,537 (6,376	)
Depreciation expense	2,302	13,538	,
Amortization expense	23,900 31,530	13,538	
Share-based compensation	26,835	21,743	
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Deferred revenue	1,352		(59	)
Loss on debt refinancing	12,129		-	
Change in method of revenue recognition for VIVITROL product sales	(1,013	)	-	
Merger-related costs	-		26,718	
Non-GAAP Net Income	\$ 123,215		\$ 23,493	

#### **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	December 31,	March 31,
(In thousands)	2012	2012
Cash, cash equivalents and total investments	\$ 239,280	\$ 246,138
Receivables	119,835	96,381
Inventory	45,686	39,759
Prepaid expenses and other current assets	12,697	12,566
Property, plant and equipment, net	292,186	302,995
Intangible assets, net and goodwill	679,055	710,585
Other assets	23,024	26,793
Total Assets	\$ 1,411,763	\$ 1,435,217
Long-term debt — current portion	\$ 6,750	\$ 3,100
Other current liabilities	70,529	86,064
Long-term debt	362,349	441,360
Deferred revenue - long-term	9,140	7,578
Other long-term liabilities	43,056	43,263
Total shareholders' equity	919,939	853,852
Total Liabilities and Shareholders' Equity	\$ 1,411,763	\$ 1,435,217
Ordinary shares outstanding (in thousands)	132,420	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 and nine months ended December 31, 2012, which the company intends to file in January 2013.

Source: Alkermes plc

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