Alkermes plc Reports Second Quarter 2015 Financial Results

July 30, 2015

—Second Quarter Revenues of $151.4 Million and Non-GAAP Diluted Loss Per Share of $0.09 —

—Alkermes Unveils ARISTADA™ as Proposed Brand Name for Aripiprazole Lauroxil; Final Launch Preparations Underway in Advance of Aug. 22, 2015 PDUFA Date —

—Company Improves Financial Expectations for 2015 Driven by Strong VIVITROL® Performance —

DUBLIN--(BUSINESS WIRE)--Jul. 30, 2015-- Alkermes plc (NASDAQ: ALKS) today reported financial results for the second quarter of 2015.

"With the PDUFA date for ARISTADA™, our proposed brand name for aripiprazole lauroxil, just a few weeks away, we are in the midst of final launch preparations for this important potential new treatment option for patients with schizophrenia. Our field sales force is in position, our comprehensive patient support services are ready and launch quantities have been manufactured," said Richard Pops, Chief Executive Officer of Alkermes. "ARISTADA, our long-acting atypical antipsychotic product candidate for schizophrenia, is leading the next wave of Alkermes' emerging blockbusters that offer innovative treatment options for chronic CNS diseases that affect millions of people. Our late-stage pipeline of product candidates, including ALKS 5461 in depression, ALKS 3831 in schizophrenia, and ALKS 8700 in multiple sclerosis, has been purposefully designed to address areas of major unmet medical need and to be responsive to today's regulatory and payer environments."

"Our second quarter financial results were driven by the strong revenues from our core portfolio of commercial products, important investments in the development of our late-stage CNS pipeline and the launch preparations for ARISTADA," commented James Frates, Chief Financial Officer of Alkermes. "Today we are improving our financial expectations for the remainder of 2015, driven by the accelerating quarterly growth in net sales of VIVITROL®, our long-acting injectable medication for the treatment of opioid dependence and alcohol dependence."

Quarter Ended June 30, 2015 Highlights

- Total revenues for the quarter were $151.4 million compared to $153.4 million for the same period in the prior year. The prior year period included $21.1 million of revenues from the products associated with the Gainesville manufacturing facility that was divested in April 2015.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $46.1 million, or a basic and diluted GAAP loss per share of $0.31, for the quarter. This compared to GAAP net income of $3.7 million, or a basic GAAP earnings per share (EPS) of $0.03 and a diluted GAAP EPS of $0.02, for the same period in the prior year, which included GAAP net income of $7.3 million related to the Gainesville facility and associated products and $27.6 million of net income from two one-time transactions.
- Non-GAAP net loss was $13.6 million, or a non-GAAP diluted loss per share of $0.09 for the quarter. This compared to non-GAAP net income of $17.7 million, or a non-GAAP diluted EPS of $0.11, for the same period in the prior year, which included non-GAAP net income of $10.6 million related to the Gainesville facility and associated products.
- On April 10, 2015, Alkermes closed the transaction to divest its Gainesville, Ga. facility and associated products, as well as rights to IV/IM and parenteral forms of Meloxicam (Meloxicam), to Recro Pharma, Inc. (Recro) in exchange for gross proceeds of $54 million and future payments related to Meloxicam, including milestone payments of up to $120 million and low double-digit royalties on net sales. Alkermes recorded a gain on this transaction of $9.9 million during the second quarter, which was recorded as a component of other income, net.

Quarter Ended June 30, 2015 Financial Results

Revenues

- Manufacturing and royalty revenues from the company's long-acting atypical antipsychotic franchise, RISPERDAL® CONSTA® and INVEGA® SUSTENNA®/XEPLION®, were $60.8 million, compared to $60.0 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®[1] were $26.9 million, compared to $19.5 million for the same period in the prior year.
- Net sales of VIVITROL were $37.2 million, compared to $21.6 million for the same period in the prior year, representing an increase of approximately 72%.

- Royalty revenue from BYDUREON® was $11.1 million, compared to $8.8 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were $203.9 million, reflecting increased investment in the company's rapidly advancing central nervous system (CNS) development pipeline and pre-launch activities for ARISTADA. This compared to $176.2 million for the same period in the prior year, which included $13.2 million related to the Gainesville facility and associated products.
- Income tax provision was $3.1 million, compared to an income tax benefit of $1.5 million for the same period in the prior year.

Balance Sheet

At June 30, 2015, Alkermes had cash and total investments of $832.4 million, compared to $801.6 million at Dec. 31, 2014. At June 30, 2015, the company's total debt outstanding was $354.8 million.

Financial Expectations

Alkermes is updating its financial expectations for 2015 as a result of accelerating growth trends for VIVITROL, which are driving a $10 million increase in expected revenues and $8 million improvement in expected non-GAAP net loss. The following outlines Alkermes' updated financial expectations for 2015.

- **Revenues:** Alkermes now expects total revenues to range from $610 million to $640 million, up from the previous range of $600 million to $630 million.
  - Alkermes now expects VIVITROL net sales to range from $135 million to $145 million, up from a previous range of $125 million to $135 million.
  - The company continues to expect net sales from the anticipated launch of ARISTADA to range from $5 million to $10 million.
- **Cost of Goods Manufactured and Sold:** The company continues to expect cost of goods manufactured and sold to range from $130 million to $140 million.
- **R&D Expenses:** The company continues to expect R&D expenses to range from $345 million to $365 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company continues to expect SG&A expenses to range from $310 million to $330 million.
- **Amortization of Intangible Assets:** The company now expects amortization of intangible assets of approximately $60 million, reduced from the previous expectation of approximately $65 million.
- **Net Interest Expense:** The company continues to expect net interest expense to range from $10 million to $15 million.
- **Other Income, Net:** The company now expects other income, net to range from $10 million to $15 million, driven primarily by the gain on the sale of the Gainesville facility and associated products during the second quarter and changes in the fair value of the contingent consideration and warrants received as part of the transaction.
- **Net Income Tax Expense:** The company continues to expect net income tax expense to range from $10 million to $15 million.
- **GAAP Net Loss:** The company now expects GAAP net loss to range from $245 million to $270 million, or a basic and diluted loss per share of $1.63 to $1.80, based on weighted average basic and diluted share counts of approximately 150 million shares outstanding. This compares to previous expectations of GAAP net loss in the range of $270 million to $300 million, or a basic and diluted loss per share of approximately $1.80 to $2.00, based on weighted average basic and diluted share counts of approximately 150 million shares outstanding.
- **Non-GAAP Net Loss:** The company now expects non-GAAP net loss to range from $47 million to $67 million, or a basic and diluted loss per share of $0.31 to $0.45, based on weighted average basic and diluted share counts of approximately 150 million shares outstanding. This compares to previous expectations of non-GAAP net loss in the range of $55 million to $75 million, or a non-GAAP diluted loss per share of $0.37 to $0.50, based on a weighted average diluted share count of approximately 150 million shares outstanding.
- **Capital Expenditures:** The company continues to expect capital expenditures to be approximately $50 million.
- **Free Cash Outflow:** The company now expects free cash outflow to range from $97 million to $117 million. This compares to previous expectations of free cash outflow in the range of $105 million to $125 million.

Conference Call

Alkermes will host a conference call at 8:30 a.m. EDT (1:30 p.m. BST) on Thursday, July 30, 2015, 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 11:00 a.m. EDT (4:00 p.m. BST) on Thursday, July 30, 2015, through 5:00 p.m. EDT (10:00 p.m. BST) on Thursday, August 6, 2015, 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

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Non-GAAP Financial Measures

This press release includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principles in the U.S. (GAAP), including non-GAAP net income or loss, non-GAAP diluted earnings or loss per share and free cash flow. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Management defines its non-GAAP financial measures as follows:

- Non-GAAP net income or loss adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; non-cash tax expense; deferred revenue; and certain other one-time or non-cash items.
- Free cash flow represents non-GAAP net income or loss less capital expenditures.

The company's management believes that these non-GAAP financial measures, when viewed with the company's results under GAAP and the accompanying reconciliations, better indicate underlying trends in ongoing operations and cash flows. However, non-GAAP net income or loss, non-GAAP diluted earnings or loss per share and free cash flow are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance.

A reconciliation of GAAP to non-GAAP financial measures has been provided in the tables included in this press release.

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, as amended, 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 expectations concerning the timing and results of development activities, including regulatory approval of ARISTADA (aripiprazole lauroxil) and advancement of the company's product candidates. The company cautions that forward-looking statements are inherently uncertain. 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 and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: clinical development activities may not be completed on time or at all and the results of such activities may not be predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted in a timely manner; the company, and its partners, may not be able to continue to successfully commercialize its products; there may be a reduction in payment rate or reimbursement for the company's products or an increase in the company's financial obligations to governmental payers; the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions 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; and those risks and uncertainties described under the heading "Item 1A. Risk Factors" in the company's Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014, under the heading "Item 1A. Risk Factors" in the company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, and in any other subsequent filings made by the company with the Securities and Exchange Commission ("SEC"), which are available on 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 or revising any forward-looking information contained in this press release.

[1]AMPYRA® (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 International GmbH, under a licensing agreement with Acorda Therapeutics, Inc., as FAMPYRA® (prolonged-release fampridine tablets).

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014
Revenues:		
Manufacturing and royalty revenues	$ 113,162	$ 130,366
Product sales, net	37,172	21,595
Research and development revenues	1,036	1,463
Total Revenues	151,370	153,424
Expenses:		
Cost of goods manufactured and sold	30,418	43,290
Research and development	87,882	67,207
Selling, general and administrative	71,539	50,663
Amortization of acquired intangible assets	14,052	15,089
Total Expenses	203,891	176,249
Operating Loss	(52,521)	(22,825)
Other Income, net:		
Interest income	795	323
Interest expense	(3,315)	(3,385)
Gain on Gainesville Transaction	9,911	-
Increase in the fair value of contingent consideration	1,500	-
Gain on sale of property, plant and equipment	-	12,285
Other income, net	585	518
Gain on sale of investment in Acceleron Pharma Inc.	-	15,296
Total Other Income, net	9,476	25,037
(Loss) Income Before Income Taxes	(43,045)	2,212
Income Tax Provision (Benefit)	3,064	(1,523)
Net (Loss) Income — GAAP	$ (46,109)	$ 3,735
(Loss) Earnings Per Share:		
GAAP (loss) earnings per share — basic	$ (0.31)	$ 0.03
GAAP (loss) earnings per share — diluted	$ (0.31)	$ 0.02
Non-GAAP (loss) earnings per share — basic	$ (0.09)	$ 0.12
Non-GAAP (loss) earnings per share — diluted	$ (0.09)	$ 0.11
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP	148,867	144,913
Diluted — GAAP	148,867	154,300
Basic — Non-GAAP	148,867	144,140
Diluted — Non-GAAP	148,867	153,833
An itemized reconciliation between net (loss) income on a GAAP basis and non-GAAP net (loss) income is as follows:		
Net (Loss) Income — GAAP	$ (46,109)	$ 3,735
Adjustments:		
Share-based compensation expense	21,877	19,337
Amortization expense	14,052	15,089
Depreciation expense	6,584	9,844
Non-cash net interest expense	235	239
Non-cash taxes	3,034	(2,207)
Deferred revenue	(574)	(338)
Net loss on transactions with equity method investee	(397)	(396)
Gain on Gainesville Transaction	(9,911)	-
Increase in the fair value of contingent consideration	(1,500)	-
Change in the fair value of common stock warrants	(876)	-
Gain on sale of investment in Acceleron Pharma Inc.	-	(15,296)
Gain on sale of property, plant and equipment	-	(12,285)
Non-GAAP Net (Loss) Income	$ (13,585)	$ 17,722

Capital expenditures	14,046	5,753
Free Cash (Outflow) Inflow	$ (27,631)	$ 11,969

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Revenues:		
Manufacturing and royalty revenues	$ 241,906	$ 241,646
Product sales, net	68,309	38,674
Research and development revenues	2,369	3,316
Total Revenues	312,584	283,636
Expenses:		
Cost of goods manufactured and sold	70,392	82,129
Research and development	158,160	119,347
Selling, general and administrative	134,589	93,213
Amortization of acquired intangible assets	29,272	27,665
Total Expenses	392,413	322,354
Operating Loss	(79,829)	(38,718)
Other Income, net:		
Interest income	1,455	834
Interest expense	(6,603)	(6,741)
Gain on Gainesville Transaction	9,911	-
Increase in the fair value of contingent consideration	1,500	-
Gain on sale of property, plant and equipment	-	12,285
Other income (expense), net	374	(1,332)
Gain on sale of investment in Acceleron Pharma Inc.	-	15,296
Total Other Income, net	6,637	20,342
Loss Before Income Taxes	(73,192)	(18,376)
Income Tax Provision	3,574	2,243
Net Loss — GAAP	$ (76,766)	$ (20,619)
(Loss) Earnings Per Share:		
GAAP loss per share — basic	$ (0.52)	$ (0.14)
GAAP loss per share — diluted	$ (0.52)	$ (0.14)
Non-GAAP (loss) earnings per share — basic	$ (0.03)	$ 0.24
Non-GAAP (loss) earnings per share — diluted	$ (0.03)	$ 0.22
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP	148,480	144,140
Diluted — GAAP	148,480	144,140
Basic — Non-GAAP	148,480	144,140
Diluted — Non-GAAP	148,480	153,833

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

Net Loss — GAAP	$ (76,766)	$ (20,619)
Adjustments:		
Share-based compensation expense	39,206	32,757
Amortization expense	29,272	27,665
Depreciation expense	13,850	19,821
Non-cash net interest expense	471	479
Non-cash taxes	3,522	1,415
Deferred revenue	(902)	(1,303)
Net loss on transactions with equity method investee	(794)	1,239
Gain on Gainesville Transaction	(9,911)	-
Increase in the fair value of contingent consideration	(1,500)	-
Change in the fair value of common stock warrants	(876)	-
Gain on sale of investment in Acceleron Pharma Inc.	-	(15,296)
Gain on sale of property, plant and equipment	-	(12,285)

Non-GAAP Net (Loss) Income	$ (4,428)	$ 33,873
Capital expenditures	24,756	11,438
Free Cash (Outflow) Inflow	$ (29,184)	$ 22,435

Condensed Consolidated Balance Sheets (In thousands)	June 30, 2015	December 31, 2014
Cash, cash equivalents and total investments	$ 832,358	$ 801,646
Receivables	135,783	151,551
Inventory	38,801	51,357
Prepaid expenses and other current assets	65,279	42,719
Property, plant and equipment, net	239,258	265,740
Intangible assets, net and goodwill	500,472	573,624
Contingent consideration	59,100	-
Other assets	43,460	34,635
Total Assets	$ 1,914,511	$ 1,921,272
Long-term debt — current portion	$ 6,750	$ 6,750
Other current liabilities	127,468	123,832
Long-term debt	348,056	351,220
Deferred revenue — long-term	7,805	11,801
Other long-term liabilities	25,441	30,832
Total shareholders' equity	1,398,991	1,396,837
Total Liabilities and Shareholders' Equity	$ 1,914,511	$ 1,921,272
Ordinary shares outstanding (in thousands)	149,304	147,539

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 June 30, 2015, which the company intends to file in July 2015.

Alkermes plc and Subsidiaries
2015 Guidance — GAAP to Non-GAAP Adjustments

An itemized reconciliation between projected loss per share on a GAAP basis and projected loss per share on a non-GAAP basis is as follows:

(In millions, except per share data)	Amount	Shares	Loss Per Share
Projected Net Loss — GAAP	$ (257.5)	150	$ (1.72)
Adjustments:			
Non-cash net interest expense	1.0		
Non-cash taxes	10.0		
Depreciation expense	35.0		
Amortization expense	60.0		
Share-based compensation expense	110.0		
Gain on Gainesville Transaction	(10.0)		
Change in fair value of contingent consideration and warrants	(2.5)		
Deferred revenue	(3.0)		
Projected Non-GAAP Net Loss	$ (57.0)	150	$ (0.38)
Capital expenditures	50.0		
Projected Free Cash Outflow	$ (107.0)		

Projected GAAP and non-GAAP measures reflect mid-points within ranges of estimated guidance.

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