Alkermes plc Reports Financial Results for the Year Ended Dec. 31, 2015 and Provides Financial Expectations for 2016

February 25, 2016

—Revenues of $628 Million, GAAP Loss Per Share of $1.52 and Non-GAAP Diluted Loss Per Share of $0.36 Reported for Calendar 2015 —

—VIVITROL® Net Sales Grew by 53% Year-Over-Year to $144.4 Million —

—2016 Revenues Expected to Grow by 15% to 20%, Driven by Continuing Growth of VIVITROL and Launch of ARISTADA® Into Rapidly Growing Long-Acting Antipsychotic Market —

—Pivotal Clinical Programs Underway for Late-Stage CNS Pipeline for Schizophrenia, Multiple Sclerosis and Major Depressive Disorder —

DUBLIN--(BUSINESS WIRE)--Feb. 25, 2016-- Alkermes plc (NASDAQ: ALKS) today reported financial results for the twelve months ended Dec. 31, 2015 and provided financial expectations for 2016.

“Alkermes has a diversified CNS business poised for significant growth over the coming years. In 2015, we continued to successfully execute on our business plan, highlighted by the robust revenue growth of VIVITROL® and the launch of our novel, long-acting antipsychotic ARISTADA® for the treatment of schizophrenia,” said Richard Pops, Chief Executive Officer of Alkermes. “Looking ahead to 2016, we expect to achieve continued revenue growth and to make significant advances across our pipeline. We will continue to enroll the pivotal clinical studies of ALKS 3831 for schizophrenia and ALKS 8700 for multiple sclerosis; obtain the first clinical data for ALKS 7119, our CNS candidate for Alzheimer’s agitation, and RDB 1450, our immuno-oncology candidate; and report results from the FORWARD-5 efficacy study of ALKS 5461 for major depressive disorder by year-end.”

“Our financial results in 2015 were driven by the strong performance of VIVITROL, the approval and launch of ARISTADA into a rapidly growing long-acting antipsychotic market, and the continued strength of our base business,” commented James Frates, Chief Financial Officer of Alkermes. “In 2016, we expect our business to continue to grow, led by VIVITROL and ARISTADA. Together with our solid royalty and manufacturing base business, these proprietary products are expected to drive revenue growth of 15 to 20 percent.”

Quarter Ended Dec. 31, 2015 Financial Highlights

- Total revenues for the quarter were $163.1 million. This compared to $175.2 million for the same period in the prior year, or $156.7 million excluding $18.5 million of revenues from the products associated with the Gainesville manufacturing facility that was divested in April 2015 (“the Gainesville Divestiture”).
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $69.4 million, or a basic and diluted GAAP loss per share of $0.46, for the quarter and reflected increased investment in the company’s advancing late-stage pipeline and commercial infrastructure. This compared to GAAP net income of $30.5 million, or a basic GAAP earnings per share (EPS) of $0.21 and a diluted GAAP EPS of $0.20 for the same period in the prior year, or GAAP net income of $25.2 million, or a basic EPS of $0.17 and a diluted EPS of $0.16, excluding $5.3 million of GAAP net income related to the Gainesville Divestiture.
- Non-GAAP net loss was $22.6 million, or a non-GAAP basic and diluted loss per share of $0.15 for the quarter. This compared to non-GAAP net income of $16.8 million, or a non-GAAP basic and diluted EPS of $0.11 for the same period in the prior year, or non-GAAP net income of $9.0 million, or a non-GAAP basic and diluted EPS of $0.06, excluding $7.8 million of non-GAAP net income related to the Gainesville Divestiture.

Quarter Ended Dec. 31, 2015 Financial Results

Revenues

- Net sales of VIVITROL were $38.2 million, compared to $29.7 million for the same period in the prior year, representing an increase of 29%. On a unit basis, sales grew 43% compared to the same period in the prior year. Compared to the third quarter of 2015, VIVITROL grew 7% on a unit basis, driven by increased adoption by treatment systems, while net sales grew 1% as the company increased accruals for Medicaid rebates to reflect the increasing volume of VIVITROL units covered by Medicaid.
- Net sales of ARISTADA were $4.6 million, following its launch in October 2015.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA® were $75.1 million, compared to $70.3 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®[1] were $19.1 million, compared to $24.3 million for the same period in the prior year, due primarily to the timing of shipments.
- Royalty revenue from BYDUREON® was $12.2 million, compared to $9.8 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were $230.2 million for the quarter ended Dec. 31, 2015, reflecting increased investment in the company's development pipeline and the launch of ARISTADA. This compared to $190.8 million for the same period in the prior year, or $177.4 million excluding $13.4 million of operating expenses related to the Gainesville Divestiture.

Calendar Year 2015 Financial Highlights

- Total revenues were $628.3 million in calendar 2015, which included VIVITROL net sales of $144.4 million and ARISTADA net sales of $4.6 million. This compared to total revenues of $618.8 million for calendar 2014. Please see the tables at the end of this press release for a detailed breakdown of the revenues from our key commercial products. Excluding the Gainesville Divestiture, 2015 total revenues were $608.6 million in calendar 2015, compared to total revenues of $545.8 million in calendar 2014.
- GAAP net loss was $227.2 million, or a basic and diluted GAAP loss per share of $1.52, for calendar 2015 and reflected increased investment in the company's advancing late-stage pipeline and the launch of ARISTADA in October 2015. This compared to a GAAP net loss of $30.1 million, or a basic and diluted GAAP loss per share of $0.21, for calendar 2014. Excluding the Gainesville Divestiture, GAAP net loss was $231.7 million, or a basic and diluted loss per share of $1.55, in calendar 2015, compared to a GAAP net loss of $53.7 million, or a basic and diluted GAAP loss per share of $0.37, in calendar 2014.
- Non-GAAP net loss was $53.2 million, or a non-GAAP basic and diluted loss per share of $0.36, for calendar 2015. This compared to non-GAAP net income of $54.6 million, or a non-GAAP basic EPS of $0.38 and a non-GAAP diluted EPS of $0.35, for calendar 2014. Excluding the Gainesville Divestiture, non-GAAP net loss was $59.5 million, or a non-GAAP basic and diluted loss per share of $0.40, in calendar 2015, compared to a non-GAAP net income of $19.4 million, or a basic and diluted EPS of $0.13, in calendar 2014.
- At Dec. 31, 2015, Alkermes recorded cash and total investments of $798.8 million, compared to $801.6 million at Dec. 31, 2014. At Dec. 31, 2015, the company's total debt outstanding was $349.9 million.

Financial Expectations for 2016

The following outlines the company's financial expectations for 2016, which include continued investment in the pipeline and a full year of expenses related to the ARISTADA commercial launch. 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:** The company expects total revenues to range from $700 million to $750 million, a 15% to 20% increase from 2015 excluding revenues derived from the Gainesville Divestiture, driven by continuing growth of VIVITROL and the ongoing launch of ARISTADA. Included in this total revenue expectation, Alkermes expects VIVITROL net sales to range from $180 million to $200 million. For ARISTADA, the company expects to provide net product revenue guidance during 2016 after gaining additional experience from the launch.
- **Cost of Goods Manufactured and Sold:** The company expects cost of goods manufactured and sold to range from $125 million to $135 million.
- **Research and Development (R&D) Expenses:** The company expects R&D expenses to range from $370 million to $400 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company expects SG&A expenses to range from $360 million to $390 million.
- **Amortization of Intangible Assets:** The company expects amortization of intangibles to be approximately $60 million.
- **Net Interest Expense:** The company expects net interest expense to be approximately $10 million.
- **Income Tax Expense:** The company expects income tax expense of up to $10 million.
- **GAAP Net Loss:** The company expects a GAAP net loss to be in the range of $225 million to $255 million, or a basic and diluted loss per share of $1.48 to $1.68, based on a weighted average basic and diluted share count of approximately 152 million shares outstanding.
- **Non-GAAP Net Loss:** The company expects a non-GAAP net loss to be in the range of $25 million to $55 million, and non-GAAP basic and diluted loss per share to be between $0.16 and $0.36.
- **Capital Expenditures:** The company expects capital expenditures to be approximately $45 million.

Conference Call

Alkermes will host a conference call at 8:30 a.m. EST (1:30 p.m. GMT) on Thursday, Feb. 25, 2016, 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. EST (4:00 p.m. GMT) on Thursday, Feb. 25, 2016, through 5:00 p.m. EST (10:00 p.m. GMT) on Thursday, March 3, 2016, 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 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 (loss) and non-GAAP diluted earnings (loss) per share. 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.

Non-GAAP net income (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.

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 (loss) and non-GAAP diluted earnings (loss) per share 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 in this press release 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 clinical development activities. 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; the results of such clinical development activities may not be positive, or 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 "Risk Factors" in the company's Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2015, and in any other subsequent filings made by the company with the Securities and Exchange Commission ("SEC") and 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.

VIVITROL® is a registered trademark of Alkermes, Inc.; ARISTADA® is a registered trademark of Alkermes Pharma Ireland Limited; RISPERDAL CONSTA®, INVEGA SUSTENNA®, XEPLION® and INVEGA TRINZA® are registered trademarks of Johnson & Johnson; AMPYRA® and FAMPYRA® are registered trademarks of Acorda Therapeutics, Inc.; BYDUREON® is a registered trademark of Amylin Pharmaceuticals, LLC.

[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 Idec, under a licensing agreement with Acorda Therapeutics, as FAMPYRA® (prolonged-release fampridine tablets).

(tables follow)

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	Three Months Ended December 31, 2015	Three Months Ended December 31, 2014
Revenues:		
Manufacturing and royalty revenues	$ 119,310	$ 143,202
Product sales, net	42,816	29,684
Research and development revenues	972	2,275
Total Revenues	163,098	175,161
Expenses:		
Cost of goods manufactured and sold	34,791	46,368
Research and development	93,686	74,433

Selling, general and administrative	87,472	54,804
Amortization of acquired intangible assets	14,206	15,244
Total Expenses	230,155	190,849
Operating Loss	(67,057)	(15,688)
Other (Expense) Income, net:		
Interest income	1,010	592
Interest expense	(3,319)	(3,333)
Gain on the Gainesville Transaction	(301)	-
Decrease in the fair value of contingent consideration	(5,000)	-
Gain on sale of property, plant and equipment	2,407	29,612
Gain on sale of investment in Civitas Therapeutics, Inc.	-	29,564
Other (expense) income, net	(533)	33
Total Other (Expense) Income, net	(5,736)	56,468
(Loss) Income Before Income Taxes	(72,793)	40,780
Income Tax (Benefit) Provision	(3,411)	10,266
Net (Loss) Income — GAAP	$ (69,382)	$ 30,514
(Loss) Earnings Per Share:		
GAAP (loss) earnings per share — basic	$ (0.46)	$ 0.21
GAAP (loss) earnings per share — diluted	$ (0.46)	$ 0.20
Non-GAAP (loss) earnings per share — basic and diluted	$ (0.15)	$ 0.11
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP	150,330	146,882
Diluted — GAAP	150,330	155,527
Basic — Non-GAAP	150,330	146,882
Diluted — Non-GAAP	150,330	155,527

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

Net (Loss) Income — GAAP	$ (69,382)	$ 30,514
Adjustments:		
Share-based compensation expense	22,869	13,341
Amortization expense	14,206	15,244
Depreciation expense	7,575	10,124
Non-cash taxes	(2,790)	7,324
Non-cash net interest expense	233	237
Deferred revenue	542	(390)
Decrease in the fair value of contingent consideration	5,000	-
Decrease in the fair value of common stock warrants	860	-
Gain on the Gainesville Transaction	301	-
Net gain on transactions with equity method investee	(397)	(29,961)
Gain on sale of property, plant and equipment	(1,646)	(29,612)
Non-GAAP Net (Loss) Income	$ (22,629)	$ 16,821

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Year Ended December 31, 2015	Year Ended December 31, 2014
Revenues:		
Manufacturing and royalty revenues	$ 475,288	$ 516,876
Product sales, net	149,028	94,160
Research and development revenues	4,019	7,753
Total Revenues	628,335	618,789
Expenses:		
Cost of goods manufactured and sold	138,989	175,832
Research and development	344,404	272,043
Selling, general and administrative	311,558	199,905
Amortization of acquired intangible assets	57,685	58,153
Total Expenses	852,636	705,933
Operating Loss	(224,301)	(87,144)
Other Income, net:		
Interest income	3,330	1,972

Interest expense	(13,247)	(13,430)
Gain on the Gainesville Transaction	9,636	-
Decrease in the fair value of contingent consideration	(2,300)	-
Gain on sale of property, plant and equipment	2,862	41,933
Gain on sale of investment in Civitas Therapeutics, Inc.	-	29,564
Gain on sale of investment in Acceleron Pharma Inc.	-	15,296
Other income (expense), net	15	(2,220)
Total Other Income, net	296	73,115
Loss Before Income Taxes	(224,005)	(14,029)
Income Tax Provision	3,158	16,032
Net Loss — GAAP	$ (227,163)	$ (30,061)
(Loss) Earnings Per Share:		
GAAP loss per share — basic and diluted	$ (1.52)	$ (0.21)
Non-GAAP (loss) earnings per share — basic	$ (0.36)	$ 0.38
Non-GAAP (loss) earnings per share — diluted	$ (0.36)	$ 0.35
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and Diluted — GAAP	149,206	145,274
Basic — Non-GAAP	149,206	145,274
Diluted — Non-GAAP	149,206	154,415

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

Net Loss — GAAP	$ (227,163)	$ (30,061)
Adjustments:		
Share-based compensation expense	97,342	59,579
Amortization expense	57,685	58,153
Depreciation expense	27,911	39,934
Non-cash taxes	1,409	12,379
Non-cash net interest expense	938	954
Deferred revenue	(630)	(997)
Gain on the Gainesville Transaction	(9,636)	-
Decrease in the fair value of contingent consideration	2,300	-
Decrease in the fair value of common stock warrants	302	-
Net gain on transactions with equity method investee	(1,588)	(28,119)
Gain on sale of property, plant and equipment	(2,101)	(41,933)
Gain on sale of investment in Acceleron Pharma Inc.	-	(15,296)
Non-GAAP Net (Loss) Income	$ (53,231)	$ 54,593

Condensed Consolidated Balance Sheets (In thousands)	December 31, 2015	December 31, 2014
Cash, cash equivalents and total investments	$ 798,849	$ 801,646
Receivables	155,487	151,551
Inventory	38,411	51,357
Prepaid expenses and other current assets	26,286	42,719
Property, plant and equipment, net	254,819	265,740
Intangible assets, net and goodwill	472,059	573,624
Other assets	109,833	32,421
Total Assets	$ 1,855,744	$ 1,919,058
Long-term debt — current portion	$ 65,737	$ 6,750
Other current liabilities	170,470	123,832
Long-term debt	284,207	349,006
Deferred revenue — long-term	7,975	11,801
Other long-term liabilities	13,080	30,832
Total shareholders' equity	1,314,275	1,396,837
Total Liabilities and Shareholders' Equity	$ 1,855,744	$ 1,919,058
Ordinary shares outstanding (in thousands)	150,701	147,539

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in Alkermes plc's Annual Report on Form 10-K for the year ended December 31, 2015, which the company intends to file in February 2016.

Revenues for Calendar Year 2015 and 2014

(In thousands)	Three Months Ended March 31, 2015	Three Months Ended June 30, 2015	Three Months Ended September 30, 2015	Three Months Ended December 31, 2015	**Year Ended December 31, 2015**
Revenues:					
PARTNERED LONG-ACTING ANTIPSYCHOTICS (1)	$ 46,864	$ 60,841	$ 67,606	$ 75,074	**$ 250,385**
AMPYRA/FAMPYRA	36,549	26,939	22,132	19,116	**104,736**
BYDUREON	9,800	11,081	13,039	12,195	**46,115**
VIVITROL	31,137	37,172	37,903	38,227	**144,439**
ARISTADA	-	-	-	4,589	**4,589**
Key Commercial Product Revenues	**124,350**	**136,033**	**140,680**	**149,201**	**550,264**
Legacy Product Revenues (2)	17,314	13,737	11,295	12,925	**55,271**
Gainesville Revenues	19,167	565	-	-	**19,732**
Research and Development Revenues	383	1,035	678	972	**3,068**
Total Revenues	**$ 161,214**	**$ 151,370**	**$ 152,653**	**$ 163,098**	**$ 628,335**
Total Revenues excluding Gainesville Revenues	*$ 142,047*	*$ 150,805*	*$ 152,653*	*$ 163,098*	*$ 608,603*

	Three Months Ended March 31, 2014	Three Months Ended June 30, 2014	Three Months Ended September 30, 2014	Three Months Ended December 31, 2014	**Year Ended December 31, 2014**
Revenues:					
PARTNERED LONG-ACTING ANTIPSYCHOTICS (1)	$ 49,608	$ 60,001	$ 68,472	$ 70,311	**$ 248,392**
AMPYRA/FAMPYRA	20,631	19,518	16,503	24,273	**80,925**
BYDUREON	7,700	8,784	10,254	9,849	**36,587**
VIVITROL	17,079	21,595	25,802	29,684	**94,160**
Key Commercial Product Revenues	**95,018**	**109,898**	**121,031**	**134,117**	**460,064**
Legacy Product Revenues (2)	16,952	21,396	21,203	21,058	**80,609**
Gainesville Revenues	16,623	21,067	16,833	18,448	**72,971**
Research and Development Revenues	1,619	1,063	925	1,538	**5,145**
Total Revenues	**$ 130,212**	**$ 153,424**	**$ 159,992**	**$ 175,161**	**$ 618,789**
Total Revenues excluding Gainesville Revenues	*$ 113,589*	*$ 132,357*	*$ 143,159*	*$ 156,713*	*$ 545,818*

(1) - Includes RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA.

(2) - Includes legacy product revenues excluding product revenues sold as part of the Gainesville transaction.

2016 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)/Earnings Per Share
Projected Net Loss — GAAP	$ (240.0)	152	$ (1.58)
Adjustments:			
Non-cash net interest expense	1.0		
Non-cash taxes	(5.0)		
Depreciation expense	32.5		
Amortization expense	60.0		
Share-based compensation expense	112.5		
Deferred revenue	(1.0)		
Projected Non-GAAP Net Loss	$ (40.0)	152	$ (0.26)

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

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