Alkermes plc Reports Financial Results for the Year Ended Dec. 31, 2016 and Provides Financial Expectations for 2017

February 15, 2017

—Record Revenues of $746 Million, GAAP Loss Per Share of $1.38 and Non-GAAP Loss Per Share of $0.07 Reported for 2016 —

—VIVITROL® Net Sales Grew by 45% Year-Over-Year to $209.0 Million —

—2017 Total Revenues Expected to Grow by Approximately 20%, Driven by Continuing Volume Growth of VIVITROL and ARISTADA® —

—Company Plans to Submit New Drug Application for ALKS 5461 in 2017 —

DUBLIN--(BUSINESS WIRE)--Feb. 15, 2017-- Alkermes plc (NASDAQ: ALKS) today reported financial results for the twelve months ended Dec. 31, 2016 and provided financial expectations for 2017.

"Our 2016 financial results reflect the strong growth of our proprietary commercial products and demonstrate the power and breadth of the Alkermes business," commented James Frates, Chief Financial Officer of Alkermes. "We enter 2017 in a strong financial position and expect total revenues to grow approximately 20%, driven by the robust volume growth of VIVITROL® and ARISTADA®. In 2017, we are making additional investments that will drive the future growth of Alkermes, including in our development pipeline, the commercial organization for ALKS 5461 and expanded VIVITROL manufacturing capabilities to support expected demand into the 2020s."

"We have built Alkermes to thrive in an increasingly challenging biopharmaceutical industry. Our base business of FDA-approved medicines is significant and growing, led by VIVITROL and ARISTADA. We have identified our next phase of growth based on a remarkable, late-stage, phase 3 portfolio. Our focus on large, chronic diseases of the CNS coupled with our approach to selecting, developing, and commercializing medicines is unique and built for a complex public health environment," said Richard Pops, Chief Executive Officer of Alkermes. "2017 will bring an unprecedented level of activity across all of the major areas of Alkermes. Our proprietary commercial products, VIVITROL and ARISTADA, will continue their growth as we bring new and distinctive features to patients and providers. For ARISTADA, we expect approval and launch of the two-month dose mid-year, which will be the only two-month option available in the long-acting injectable antipsychotic market. Our late-stage pipeline will continue to evolve rapidly, highlighted by the planned NDA submission for ALKS 5461 in major depressive disorder, the completion of the pivotal efficacy study of ALKS 3831 in schizophrenia, and completion of the required elements for registration of ALKS 8700 in multiple sclerosis."

Quarter Ended Dec. 31, 2016 Financial Highlights

- Total revenues for the quarter were $213.5 million. This compared to $163.1 million for the same period in the prior year, representing an increase of 31%.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $21.1 million, or a basic and diluted GAAP loss per share of $0.14. This compared to GAAP net loss of $69.4 million, or a basic and diluted GAAP loss per share of $0.46 for the same period in the prior year.
- Non-GAAP net income was $23.3 million, or a non-GAAP basic and diluted earnings per share of $0.15 for the quarter. This compared to non-GAAP net loss of $21.0 million, or a non-GAAP basic and diluted loss per share of $0.14 for the same period in the prior year.

Quarter Ended Dec. 31, 2016 Financial Results

Revenues

- Net sales of VIVITROL were $62.1 million, compared to $38.2 million for the same period in the prior year, representing an increase of 62%. On a unit basis, sales grew 67% compared to the same period in the prior year.
- Net sales of ARISTADA were $17.3 million, up from $4.6 million in the fourth quarter of 2015, which was the quarter of launch.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were $74.0 million, compared to $75.1 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®[1] were $32.3 million, representing a 69% increase compared to $19.1 million for the same period in the prior year.
- Royalty revenue from BYDUREON® was $11.3 million, compared to $12.2 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were $237.1 million for the quarter ended Dec. 31, 2016, compared to $230.2 million for the same period in the prior year.

Calendar Year 2016 Financial Highlights

- Total revenues increased 19% to $745.7 million in 2016, which included VIVITROL net sales of $209.0 million and ARISTADA net sales of $47.2 million. This compared to total revenues of $628.3 million for 2015. Please see the tables at the end of this press release for a detailed breakdown of the revenues from our key commercial products.
- GAAP net loss was $208.4 million, or a basic and diluted GAAP loss per share of $1.38, for 2016. This compared to a GAAP net loss of $227.2 million, or a basic and diluted GAAP loss per share of $1.52, for 2015.
- Non-GAAP net loss was $10.3 million, or a non-GAAP basic and diluted loss per share of $0.07, for 2016. This compared to non-GAAP net loss of $56.8 million, or a non-GAAP basic and diluted loss per share of $0.38, for 2015.
- At Dec. 31, 2016, Alkermes recorded cash and total investments of $619.2 million, compared to $798.8 million at Dec. 31, 2015. At Dec. 31, 2016, the company's total debt outstanding was $283.7 million, compared to $349.9 million at Dec. 31, 2015.

Financial Expectations for 2017

The following outlines the company's financial expectations for 2017, which include investments in commercial infrastructure in preparation for the expected launch of ALKS 5461 in 2018 and in Alkermes' pipeline of late-stage development candidates. 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 $870 million to $920 million, a 17% to 23% increase from 2016, driven by continuing growth of VIVITROL and ARISTADA. Included in this total revenue expectation, Alkermes expects VIVITROL net sales to range from $280 million to $300 million.
- **Cost of Goods Manufactured and Sold:** The company expects cost of goods manufactured and sold to range from $150 million to $160 million.
- **Research and Development (R&D) Expenses:** The company expects R&D expenses to range from $405 million to $435 million.
- **Selling, General and Administrative (SG&A) Expenses:** The company expects SG&A expenses to range from $425 million to $455 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 GAAP net loss to range from $180 million to $210 million, or a basic and diluted loss per share of $1.17 to $1.36, based on a weighted average basic and diluted share count of approximately 154 million shares outstanding.
- **Non-GAAP Net Income (Loss):** The company expects its non-GAAP financial measure to be in the range of non-GAAP net loss of $15 million to non-GAAP net income of $15 million. This equates to a non-GAAP basic loss per share of $0.10 to a non-GAAP basic income per share of $0.10, based on a weighted average basic share count of approximately 154 million shares outstanding, and a non-GAAP diluted loss per share of $0.10 to a non-GAAP diluted income per share of $0.09, based on a weighted average diluted share count of approximately 161 million shares outstanding.
- **Capital Expenditures:** The company expects capital expenditures to range from $70 million to $80 million.

Conference Call

Alkermes will host a conference call at 8:30 a.m. ET (1:30 p.m. GMT) on Wednesday, Feb. 15, 2017, to discuss these financial results and provide an update on the company. The conference call may be accessed by visiting Alkermes' website or 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. ET (4:00 p.m. GMT) on Wednesday, Feb. 15, 2017, through 5:00 p.m. ET (10:00 p.m. GMT) on Wednesday, Feb. 22, 2017, 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; certain other one-time or non-cash items; and the income tax effect of these reconciling items.

The company's management and board of directors utilize these non-GAAP financial measures to evaluate the company's performance. The company provides these non-GAAP measures of the company's performance to investors because 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. 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. Further, non-GAAP net income (loss) and non-GAAP diluted earnings (loss) per share should not be considered measures of our liquidity.

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, including the launch of ALKS 5461; the likelihood of continued revenue growth from the company's commercial products, including the growth of VIVITROL and ARISTADA; the therapeutic and commercial value of the company's products; and expectations concerning the timing and results of clinical development activities, including the timing of the NDA submission for ALKS 5461. 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: the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to any of our products; data from clinical trials may be interpreted by the U.S. Food and Drug Administration ("FDA") in different ways than we interpret it; the FDA may not agree with our regulatory approval strategies or components of our filings, such as clinical trial designs; 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 FDA 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 most recent Annual Report on Form 10-K, 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®, INVEGA TRINZA® and TREVICTA® 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, 2016	Three Months Ended December 31, 2015
Revenues:		
Manufacturing and royalty revenues	$ 133,804	$ 119,310
Product sales, net	79,451	42,816
Research and development revenues	259	972
Total Revenues	213,514	163,098
Expenses:		
Cost of goods manufactured and sold	34,957	34,791
Research and development	89,627	93,686
Selling, general and administrative	97,145	87,472
Amortization of acquired intangible assets	15,322	14,206
Total Expenses	237,051	230,155
Operating Loss	(23,537)	(67,057)
Other Expense, net:		
Interest income	835	1,010
Interest expense	(4,896)	(3,319)
Loss on the Gainesville Transaction	-	(301)

Change in the fair value of contingent consideration	4,800	(5,000)
Other (expense) income, net	(1,515)	1,874
Total Other Expense, net	(776)	(5,736)
Loss Before Income Taxes	(24,313)	(72,793)
Income Tax Benefit	(3,172)	(3,411)
Net Loss — GAAP	$ (21,141)	$ (69,382)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	$ (0.14)	$ (0.46)
Non-GAAP net earnings (loss) per share — basic and diluted	$ 0.15	$ (0.14)
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	152,148	150,330
Basic — Non-GAAP	152,148	150,330
Diluted — Non-GAAP	159,212	150,330

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

Net Loss — GAAP	$ (21,141)	$ (69,382)
Adjustments:		
Share-based compensation expense	19,783	22,869
Amortization expense	15,322	14,206
Depreciation expense	9,326	7,575
Income tax effect related to reconciling items	1,636	(618)
Non-cash net interest expense	194	233
Loss on warrants and equity method investments	866	463
Loss on debt refinancing	2,075	-
Change in the fair value of contingent consideration	(4,800)	5,000
Loss on the Gainesville Transaction	-	301
Gain on sale of property, plant and equipment	-	(1,646)
Non-GAAP Net Income (Loss)	$ 23,261	$ (20,999)

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	Year Ended December 31, 2016	Year Ended December 31, 2015
Revenues:		
Manufacturing and royalty revenues	$ 487,247	$ 475,288
Product sales, net	256,146	149,028
Research and development revenues	2,301	4,019
Total Revenues	745,694	628,335
Expenses:		
Cost of goods manufactured and sold	132,122	138,989
Research and development	387,148	344,404
Selling, general and administrative	374,130	311,558
Amortization of acquired intangible assets	60,959	57,685
Total Expenses	954,359	852,636
Operating Loss	(208,665)	(224,301)
Other (Expense) Income, net:		
Interest income	3,752	3,330
Interest expense	(14,889)	(13,247)
Gain on the Gainesville Transaction	-	9,636
Change in the fair value of contingent consideration	7,900	(2,300)
Other (expense) income, net	(2,485)	2,877
Total Other (Expense) Income, net	(5,722)	296
Loss Before Income Taxes	(214,387)	(224,005)
Income Tax (Benefit) Provision	(5,943)	3,158
Net Loss — GAAP	$ (208,444)	$ (227,163)
Net Loss Per Share:		
GAAP net loss per share — basic and diluted	$ (1.38)	$ (1.52)
Non-GAAP net loss per share — basic and diluted	$ (0.07)	$ (0.38)
Weighted Average Number of Ordinary Shares Outstanding:		

Basic and diluted — GAAP and Non-GAAP	151,484	149,206
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net loss is as follows:		
Net Loss — GAAP	$ (208,444)	$ (227,163)
Adjustments:		
Share-based compensation expense	94,396	97,342
Amortization expense	60,958	57,685
Depreciation expense	33,298	27,911
Income tax effect related to reconciling items	2,252	(2,822)
Loss (gain) on warrants and equity method investments	2,130	(1,286)
Non-cash net interest expense	888	938
Upfront license option payment to Reset Therapeutics, Inc. charged to R&D expense	10,000	-
Loss on debt refinancing	2,075	
Change in the fair value of contingent consideration	(7,900)	2,300
Gain on the Gainesville Transaction	-	(9,636)
Gain on sale of property, plant and equipment	-	(2,101)
Non-GAAP Net Loss	$ (10,347)	$ (56,832)

Pursuant to compliance and disclosure interpretations published by the SEC in May 2016, the Company made certain changes to how it presents non-GAAP net loss. The Company no longer adjusts the deferred revenue recognized in the period and now reflects the tax effect of the reconciling items, as opposed to the non-cash taxes, as was previously the case. The Company revised its prior period presentation to reflect its current period presentation.

Condensed Consolidated Balance Sheets	December 31,	December 31,
(In thousands)	2016	2015
Cash, cash equivalents and total investments	$ 619,164	$ 798,849
Receivables	191,102	155,487
Inventory	62,998	38,411
Prepaid expenses and other current assets	39,345	26,286
Property, plant and equipment, net	264,785	254,819
Intangible assets, net and goodwill	411,100	472,059
Other assets	137,929	109,833
Total Assets	$ 1,726,423	$ 1,855,744
Long-term debt — current portion	$ 3,000	$ 65,737
Other current liabilities	208,993	170,470
Long-term debt	280,666	284,207
Deferred revenue — long-term	7,122	7,975
Other long-term liabilities	17,161	13,080
Total shareholders' equity	1,209,481	1,314,275
Total Liabilities and Shareholders' Equity	$ 1,726,423	$ 1,855,744
Ordinary shares outstanding (in thousands)	152,431	150,701

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, 2016, which the company intends to file in February 2017.

Revenues for Calendar Year 2016 and 2015

(In thousands)	Three Months Ended March 31, 2016	Three Months Ended June 30, 2016	Three Months Ended September 30, 2016	Three Months Ended December 31, 2016	**Year Ended December 31, 2016**
Revenues:					
PARTNERED LONG-ACTING ANTIPSYCHOTICS [1]	$ 54,667	$ 69,578	$ 73,251	$ 73,967	**$ 271,463**
AMPYRA/FAMPYRA	28,194	40,848	12,897	32,254	**114,193**
BYDUREON	10,533	12,303	11,554	11,256	**45,646**
VIVITROL	43,827	47,242	55,804	62,109	**208,982**

ARISTADA	5,547	10,277	13,998	17,342	**47,164**
Key Commercial Product Revenues	**142,768**	**180,248**	**167,504**	**196,928**	**687,448**
Legacy Product Revenues [2]	12,765	14,305	12,548	16,327	**55,945**
Research and Development Revenues	1,241	612	189	259	**2,301**
Total Revenues	**$ 156,774**	**$ 195,165**	**$ 180,241**	**$ 213,514**	**$ 745,694**

(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*

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

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

2017 Guidance — GAAP to Non-GAAP Adjustments

An itemized reconciliation between projected loss per share on a GAAP basis and projected earnings (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	$ (195.0)	154	$ (1.27)
Adjustments:			
Non-cash net interest expense	1.0		
Income tax effect related to reconciling items	1.5		
Depreciation expense	37.5		
Amortization expense	60.0		
Share-based compensation expense	95.0		
Projected Non-GAAP Net Income (Loss)	$ -	161	$ -

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

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