Alkermes plc Reports Third Quarter 2017 Financial Results

October 26, 2017

—Third Quarter Total Revenues Increased 21% Year-Over-Year to $217.4 Million, GAAP Loss per Share of $0.24 and Non-GAAP Earnings per Share of $0.03 —

— Sales of Proprietary Products Increased 34% Year-Over-Year —

— Portfolio of CNS Medicines Continues to Progress to Support Goal of Providing Patient-Centered Treatment Options for Addiction and Serious Mental Illness —

— Company Updates Financial Expectations for 2017—

DUBLIN--(BUSINESS WIRE)--Oct. 26, 2017-- Alkermes plc (NASDAQ: ALKS) today reported financial results for the third quarter of 2017.

"Our third quarter results reflect solid year-over-year topline growth of more than twenty percent and disciplined expense management. We continue to focus on executing on our business strategy to grow our commercial products and invest in the late-stage development programs that we expect will be the growth drivers for the future," commented James Frates, Chief Financial Officer of Alkermes. "As we head into the final months of the year, today we are reiterating our guidance for non-GAAP results and improving guidance for GAAP net loss. These expectations reflect reduced revenues, largely due to VIVITROL® sales growth being slightly lower than expected in the third quarter, offset by lower cost forecasts."

"VIVITROL and ARISTADA® both operate in markets where there remains significant unmet patient need. With new health and economic data being generated to support the long-term potential of these important medicines, we continue to progress VIVITROL and ARISTADA and work toward ensuring access for the patients that need these medicines," said Richard Pops, Chief Executive Officer of Alkermes. "Looking ahead, 2018 will be a transformative year for Alkermes' proprietary development pipeline, with key events across the development portfolio, highlighted by FDA review of the ALKS 5461 NDA, the phase 3 data readout for ALKS 3831, submission of the ALKS 8700 NDA and important phase 1 data for ALKS 4230."

Quarter Ended Sept. 30, 2017 Highlights

- Total revenues for the quarter were $217.4 million. This compared to $180.2 million for the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $36.3 million, or a basic and diluted GAAP loss per share of $0.24, for the quarter. This compared to GAAP net loss of $62.7 million, or a basic and diluted GAAP loss per share of $0.41, for the same period in the prior year.
- Non-GAAP net income was $4.2 million, or a non-GAAP basic and diluted earnings per share of $0.03. This compared to non-GAAP net loss of $14.1 million, or a non-GAAP basic and diluted loss per share of $0.09, for the same period in the prior year.

Quarter Ended Sept. 30, 2017 Financial Results

Revenues

- Net sales of VIVITROL were $69.2 million, compared to $55.8 million for the same period in the prior year.
- Net sales of ARISTADA were $24.5 million, compared to $14.0 million for the same period in the prior year.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were $79.4 million, compared to $73.3 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®[1] were $24.5 million, compared to $12.9 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were $255.7 million, compared to $241.4 million for the same period in the prior year, reflecting increased investment in the company's development pipeline and commercial organization.

Balance Sheet
At Sept. 30, 2017, Alkermes had cash and total investments of $568.9 million, compared to $560.8 million at June 30, 2017. At Sept. 30, 2017, the company's total debt outstanding was $282.0 million.

Financial Expectations
Alkermes is updating its financial expectations for 2017 to reflect year-to-date results and expectations for the fourth quarter of 2017. The following outlines Alkermes' updated financial expectations for 2017.

- **Revenues:** The company now expects total revenues to range from $850 million to $880 million, reduced from a previous range of $870 million to $920 million. Included in this total revenue expectation, the company now expects VIVITROL net

sales to range from $265 million to $275 million, reduced from a previous range of $280 million to $300 million.

- **Cost of Goods Manufactured and Sold:** The company continues to expect cost of goods manufactured and sold to range from $150 million to $160 million.
- **Research and Development (R&D) Expenses:** The company now expects R&D expenses to range from $400 million to $420 million, reduced from $405 million to $435 million, reflecting the timing of certain expenses related to various ongoing programs.
- **Selling, General and Administrative (SG&A) Expenses:** The company now expects SG&A expenses to range from $410 million to $430 million, reduced from $425 million to $455 million, reflecting disciplined expense management and the timing of certain commercial initiatives.
- **Amortization of Intangible Assets:** The company continues to expect amortization of intangibles to be approximately $60 million.
- **Net Interest Expense:** The company continues to expect net interest expense to be approximately $10 million.
- **Other Income, Net:** The company now expects net other income of approximately $10 million.
- **Income Tax Benefit:** The company now expects an income tax benefit of approximately $5 million, improved from an income tax expense of up to $10 million.
- **GAAP Net Loss:** The company now expects GAAP net loss to range from $160 million to $190 million, or a basic and diluted loss per share of $1.04 to $1.23, based on a weighted average basic and diluted share count of approximately 154 million shares outstanding. This compares to previous expectations of GAAP net loss in the range of $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 continues to expect 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 now expects capital expenditures to range from $50 million to $60 million, reduced from $70 million to $80 million.

Conference Call

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:30 a.m. ET (1:30 p.m. BST) on Thursday, Oct. 26, 2017, to discuss these financial results and provide an update on the company. The webcast player may be accessed on the Investors section of Alkermes' website at www.alkermes.com. 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. A replay of the conference call will be available from 11:00 a.m. ET (4:00 p.m. BST) on Thursday, Oct. 26, 2017 through 5:00 p.m. ET (9:00 p.m. GMT) on Thursday, Nov. 2, 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, are useful in identifying underlying trends in ongoing operations. However, non-GAAP net income (loss) and non-GAAP basic and 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 basic and 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; 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 marketed and development products and patient access to such products; and expectations concerning the timing and results of clinical development activities, including the phase 3 data readout for ALKS 3831, phase 1 data readout for ALKS 4230, the timing of the submission of the NDA for ALKS 8700, and the timing of the submission and FDA review of the NDA for ALKS 5461. You are cautioned 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, which may lead to competition from generic drug manufacturers; 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 our 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 Annual Report on Form 10-K for the year ended Dec. 31, 2016 and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and June 30, 2017 and in subsequent filings made by the company with the U.S. 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 hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements 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.

[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 September 30, 2017	Three Months Ended September 30, 2016
Revenues:		
Manufacturing and royalty revenues	$ 122,677	$ 110,250
Product sales, net	93,681	69,802
Research and development revenues	1,027	189
Total Revenues	217,385	180,241
Expenses:		
Cost of goods manufactured and sold	36,054	35,456
Research and development	104,411	99,444
Selling, general and administrative	99,633	91,145
Amortization of acquired intangible assets	15,643	15,323
Total Expenses	255,741	241,368
Operating Loss	(38,356)	(61,127)
Other Income (Expense), net:		
Interest income	1,173	912
Interest expense	(3,129)	(3,375)
Change in the fair value of contingent consideration	13,600	(1,000)
Other expense, net	(9,078)	(752)
Total Other Income (Expense), net	2,566	(4,215)
Loss Before Income Taxes	(35,790)	(65,342)
Provision (Benefit) for Income Taxes	486	(2,655)
Net Loss — GAAP	$ (36,276)	$ (62,687)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	$ (0.24)	$ (0.41)
Non-GAAP earnings (loss) per share — basic and diluted	$ 0.03	$ (0.09)

Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	153,684	151,652
Basic — Non-GAAP	153,684	151,652
Diluted — Non-GAAP	159,989	151,652
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income (loss) is as follows:		
Net Loss — GAAP	$ (36,276)	$ (62,687)
Adjustments:		
Share-based compensation expense	19,487	23,726
Amortization expense	15,643	15,323
Depreciation expense	9,394	8,497
Non-cash net interest expense	192	231
Other-than-temporary impairment of equity method investment	10,471	-
Change in the fair value of warrants and equity method investments	(303)	521
Change in the fair value of contingent consideration	(13,600)	1,000
Income tax effect related to reconciling items	(844)	(673)
Non-GAAP Net Income (Loss)	$ 4,164	$ (14,062)

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Revenues:		
Manufacturing and royalty revenues	$ 366,608	$ 353,444
Product sales, net	258,893	176,695
Research and development revenues	2,503	2,042
Total Revenues	628,004	532,181
Expenses:		
Cost of goods manufactured and sold	116,241	97,165
Research and development	308,399	297,523
Selling, general and administrative	310,682	276,985
Amortization of acquired intangible assets	46,417	45,636
Total Expenses	781,739	717,309
Operating Loss	(153,735)	(185,128)
Other Expense, net:		
Interest income	3,287	2,917
Interest expense	(8,816)	(9,993)
Change in the fair value of contingent consideration	15,900	3,100
Other expense, net	(10,696)	(970)
Total Other Expense, net	(325)	(4,946)
Loss Before Income Taxes	(154,060)	(190,074)
Income Tax Benefit	(5,904)	(2,771)
Net Loss — GAAP	$ (148,156)	$ (187,303)
Net Loss Per Share:		
GAAP net loss per share — basic and diluted	$ (0.97)	$ (1.24)
Non-GAAP net loss per share — basic and diluted	$ (0.15)	$ (0.22)
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP and Non-GAAP	153,263	151,261
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net loss is as follows:		
Net Loss — GAAP	$ (148,156)	$ (187,303)
Adjustments:		
Share-based compensation expense	63,336	74,613
Amortization expense	46,417	45,636
Depreciation expense	26,889	23,972
Change in the fair value of warrants and equity method investments	2,760	1,264
Non-cash net interest expense	578	694
Other-than-temporary impairment of equity method investment	10,471	-
Increase in the fair value of contingent consideration	(15,900)	(3,100)

Income tax effect related to reconciling items	(8,896)	616
Upfront license option payment to Reset Therapeutics, Inc. charged to R&D expense	-	10,000
Non-GAAP Net Loss	$ (22,501)	$ (33,608)

Condensed Consolidated Balance Sheets	September 30,	December 31,
(In thousands)	2017	2016
Cash, cash equivalents and total investments	$ 568,850	$ 619,165
Receivables	207,537	191,102
Inventory	85,027	62,998
Prepaid expenses and other current assets	38,888	39,344
Property, plant and equipment, net	270,666	264,785
Intangible assets, net and goodwill	364,683	411,100
Other assets	212,675	137,929
Total Assets	$ 1,748,326	$ 1,726,423
Long-term debt — current portion	$ 3,000	$ 3,000
Other current liabilities	253,014	208,993
Long-term debt	278,994	280,666
Deferred revenue — long-term	6,132	7,122
Other long-term liabilities	19,906	17,161
Total shareholders' equity	1,187,280	1,209,481
Total Liabilities and Shareholders' Equity	$ 1,748,326	$ 1,726,423
Ordinary shares outstanding (in thousands)	153,746	152,431

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 September 30, 2017, which the company intends to file in October 2017.

Alkermes plc and Subsidiaries
2017 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	$ (175.0)	154	$ (1.14)
Adjustments:			
Share-based compensation expense	85.0		
Amortization expense	60.0		
Depreciation expense	37.5		
Other-than-temporary impairment of equity method investment	10.5		
Change in the fair value of warrants and equity method investments	2.0		
Non-cash net interest expense	1.0		
Increase in the fair value of contingent consideration	(16.0)		
Income tax effect related to reconciling items	(5.0)		
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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Source: Alkermes plc

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