Alkermes plc Reports Second Quarter 2017 Financial Results

July 27, 2017

—Second Quarter Revenues Increased 12% Year-Over-Year to $218.8 Million, GAAP Loss per Share of $0.28 and Non-GAAP Earnings per Share of $0.01 —

—Net Sales of Proprietary Commercial Products, VIVITROL® and ARISTADA®, Increased 54% Year-Over-Year —

—Rolling Submission of ALKS 5461 New Drug Application to Begin in August —

DUBLIN--(BUSINESS WIRE)--Jul. 27, 2017-- Alkermes plc (NASDAQ: ALKS) today reported financial results for the second quarter of 2017.

“Our solid results this quarter demonstrate the continued strength of our business and commercial portfolio, driven by increasing demand for our proprietary products, VIVITROL® and ARISTADA®, which continue to grow robustly in their respective markets,” commented James Frates, Chief Financial Officer of Alkermes. “The financial underpinnings of our business are strong for today and into the future, as we focus on growing our commercial portfolio and the clinical development of our pipeline candidates. Today, we are reiterating our financial expectations for 2017 that we provided in February.”

“We are executing on our strategy and making rapid progress as we continue to invest in our future growth drivers. Following a pre-NDA meeting with FDA for ALKS 5461 earlier this week, we are on track to begin the rolling submission of the ALKS 5461 New Drug Application next month and expect to complete the submission by year-end 2017. We are excited to bring this important, potential, new proprietary medicine to patients struggling with major depressive disorder,” said Richard Pops, Chief Executive Officer of Alkermes. “Alkermes is grounded in our deep commitment to the treatment of addiction and serious mental illness. We continue to advance our pipeline of late-stage product candidates and were also pleased to report positive preliminary topline data from the ALKS 3831 phase 3 antipsychotic efficacy study as well as the approval and launch of the ARISTADA two-month dose in June.”

Quarter Ended June 30, 2017 Highlights

- Total revenues for the quarter were $218.8 million. This compared to $195.2 million for the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $43.0 million, or a basic and diluted GAAP loss per share of $0.28, for the quarter and reflected increased investment in the company’s commercial infrastructure and higher cost of goods manufactured and sold reflecting increased manufacturing activity. This compared to GAAP net loss of $47.2 million, or a basic and diluted GAAP loss per share of $0.31, for the same period in the prior year.
- Non-GAAP net income was $1.2 million, or a non-GAAP basic and diluted earnings per share of $0.01 for the quarter. This compared to non-GAAP net loss of $1.6 million, or a non-GAAP basic and diluted loss per share of $0.01, for the same period in the prior year.

Quarter Ended June 30, 2017 Financial Results

Revenues

- Net sales of VIVITROL were $66.1 million, compared to $47.2 million for the same period in the prior year.
- Net sales of ARISTADA were $22.7 million, compared to $10.3 million for the same period in the prior year.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were $82.2 million, compared to $69.6 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®[1] were $25.3 million, compared to $40.8 million for the same period in the prior year.
- Royalty revenue from BYDUREON® was $11.6 million, compared to $12.3 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were $263.4 million, compared to $242.3 million for the same period in the prior year, reflecting increased investment in the company’s commercial infrastructure and higher cost of goods manufactured and sold reflecting increased manufacturing activity at our site in Ohio.

Balance Sheet
At June 30, 2017, Alkermes had cash and total investments of $560.8 million, compared to $589.4 million at March 31, 2017. At June 30, 2017, the company’s total debt outstanding was $282.6 million.

Financial Expectations
Alkermes reiterates its financial expectations for 2017 set forth in its press release dated Feb. 15, 2017.

Conference Call
Alkermes will host a conference call at 8:30 a.m. ET (1:30 p.m. BST) on Thursday, July 27, 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. BST) on Thursday, July 27, 2017 through 5:00 p.m. ET (10:00 p.m. BST) on Thursday, August 3, 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; 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, including the launch and commercialization of two-month ARISTADA; and expectations concerning the timing and results of clinical development activities, including the timing of the NDA submission 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.

[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 June 30, 2017	Three Months Ended June 30, 2016
Revenues:		
Manufacturing and royalty revenues	$ 129,252	$ 137,034
Product sales, net	88,756	57,519
Research and development revenues	833	612
Total Revenues	218,841	195,165
Expenses:		
Cost of goods manufactured and sold	39,775	33,998
Research and development	99,153	97,007
Selling, general and administrative	108,950	96,120
Amortization of acquired intangible assets	15,472	15,157
Total Expenses	263,350	242,282
Operating Loss	(44,509)	(47,117)
Other Expense, net:		
Interest income	1,171	994
Interest expense	(2,923)	(3,323)
Increase in the fair value of contingent consideration	700	2,200
Other expense, net	(119)	(467)
Total Other Expense, net	(1,171)	(596)
Loss Before Income Taxes	(45,680)	(47,713)
Income Tax Benefit	(2,681)	(520)
Net Loss — GAAP	$ (42,999)	$ (47,193)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	$ (0.28)	$ (0.31)
Non-GAAP earnings (loss) per share — basic and diluted	$ 0.01	$ (0.01)
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	153,392	151,301
Basic — Non-GAAP	153,392	151,301
Diluted — Non-GAAP	160,307	151,301
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income (loss) is as follows:		
Net Loss — GAAP	$ (42,999)	$ (47,193)
Adjustments:		
Share-based compensation expense	22,680	26,631
Amortization expense	15,472	15,157
Depreciation expense	9,034	7,927
Change in the fair value of warrants and equity method investments	1,611	(127)
Non-cash net interest expense	193	231
Increase in the fair value of contingent consideration	(700)	(2,200)
Income tax effect related to reconciling items	(4,102)	(2,051)
Non-GAAP Net Income (Loss)	$ 1,189	$ (1,625)

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Revenues:		
Manufacturing and royalty revenues	$ 243,931	$ 243,194
Product sales, net	165,212	106,893
Research and development revenues	1,476	1,853
Total Revenues	410,619	351,940
Expenses:		
Cost of goods manufactured and sold	80,187	61,709
Research and development	203,988	198,079
Selling, general and administrative	211,049	185,840

Amortization of acquired intangible assets	30,774	30,313
Total Expenses	525,998	475,941
Operating Loss	(115,379)	(124,001)
Other Expense, net:		
Interest income	2,114	2,005
Interest expense	(5,687)	(6,618)
Increase in the fair value of contingent consideration	2,300	4,100
Other expense, net	(1,618)	(218)
Total Other Expense, net	(2,891)	(731)
Loss Before Income Taxes	(118,270)	(124,732)
Income Tax Benefit	(6,390)	(116)
Net Loss — GAAP	$ (111,880)	$ (124,616)
Net Loss Per Share:		
GAAP net loss per share — basic and diluted	$ (0.73)	$ (0.82)
Non-GAAP net loss per share — basic and diluted	$ (0.17)	$ (0.13)
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP and Non-GAAP	153,050	151,063
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net loss is as follows:		
Net Loss — GAAP	$ (111,880)	$ (124,616)
Adjustments:		
Share-based compensation expense	43,849	50,887
Amortization expense	30,774	30,313
Depreciation expense	17,495	15,475
Change in the fair value of warrants and equity method investments	3,063	743
Non-cash net interest expense	386	463
Increase in the fair value of contingent consideration	(2,300)	(4,100)
Income tax effect related to reconciling items	(8,052)	1,289
Upfront license option payment to Reset Therapeutics, Inc. charged to R&D expense	-	10,000
Non-GAAP Net Loss	$ (26,665)	$ (19,546)

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 income (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	June 30,	December 31,
(In thousands)	2017	2016
Cash, cash equivalents and total investments	$ 560,831	$ 619,165
Receivables	199,709	191,102
Inventory	77,352	62,998
Prepaid expenses and other current assets	43,457	39,344
Property, plant and equipment, net	266,484	264,785
Intangible assets, net and goodwill	380,326	411,100
Other assets	203,184	137,929
Total Assets	$ 1,731,343	$1,726,423
Long-term debt — current portion	$ 3,000	$ 3,000
Other current liabilities	221,644	208,993
Long-term debt	279,552	280,666
Deferred revenue — long-term	6,782	7,122
Other long-term liabilities	18,278	17,161
Total shareholders' equity	1,202,087	1,209,481
Total Liabilities and Shareholders' Equity	$ 1,731,343	$1,726,423
Ordinary shares outstanding (in thousands)	153,650	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 six months ended June 30, 2017, which the company intends to file in July 2017.

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