Alkermes Plc Reports Second Quarter 2018 Financial Results

July 26, 2018

-- Second Quarter Revenues Increase to $304.6 Million, Driven by License Revenues and 24% Year-Over-Year Growth of Proprietary Product Net Sales --

-- Company Reports GAAP Net Loss per Share of $0.21 and Diluted Non-GAAP Earnings per Share of $0.29 --

-- Company Reiterates Financial Expectations for 2018 --

DUBLIN, July 26, 2018 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the second quarter of 2018.

"Our strong second quarter results were driven by the solid growth of our proprietary commercial products, the continued strength of our royalty and manufacturing business, as well as the receipt of a $50 million payment related to our collaboration with Biogen for BIIB098," commented James Frates, Chief Financial Officer of Alkermes. "The business is performing as planned and today we are reiterating our financial expectations for 2018. As we head into a catalyst-rich second half of the year, we are well-positioned financially to drive value, grow our portfolio of commercial products and advance our late-stage pipeline."

Quarter Ended June 30, 2018 Financial Highlights

- Total revenues for the quarter were $304.6 million. This compared to $218.8 million for the same period in the prior year, representing an increase of 39%. Proprietary product net sales for VIVITROL® and ARISTADA® were $109.8 million for the quarter, reflecting a 24% increase compared to the same period in the prior year.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $32.6 million for the quarter, or a basic and diluted GAAP net loss per share of $0.21. This compared to GAAP net loss of $43.0 million, or a basic and diluted GAAP net loss per share of $0.28, for the same period in the prior year.
- Non-GAAP net income was $45.6 million for the quarter, or non-GAAP basic and diluted earnings per share of $0.29. This compared to non-GAAP net income of $1.2 million, or non-GAAP basic and diluted earnings per share of $0.01, for the same period in the prior year.

"VIVITROL and ARISTADA continue to demonstrate solid growth and perform in-line with our expectations. Our proprietary commercial portfolio is a key growth driver for Alkermes, and we are confident about the prospects ahead for these important products," stated Jim Robinson, President and Chief Operating Officer of Alkermes. "In particular, the launch of ARISTADA INITIO™ is an important opportunity to support continuity of care and address a critical unmet need for patients, as ARISTADA is now the first and only long-acting atypical antipsychotic that can be fully dosed on day one for up to two months. ARISTADA INITIO represents a key addition to the treatment paradigm for schizophrenia and provides a platform to further expand utilization of ARISTADA."

Quarter Ended June 30, 2018 Financial Results

Revenues

- Net sales of VIVITROL were $76.2 million, compared to $66.1 million for the same period in the prior year, representing an increase of approximately 15%.
- Net sales of ARISTADA were $33.6 million, compared to $22.7 million for the same period in the prior year, representing an increase of approximately 48%.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were $85.2 million, compared to $82.2 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA®/FAMPYRA®[1] were $19.7 million, compared to $25.3 million for the same period in the prior year.
- License revenues from the collaboration with Biogen for BIIB098 (formerly ALKS 8700) were $48.3 million.
- Research and development revenues were $18.3 million, of which $17.2 million related to the collaboration with Biogen for BIIB098.

Costs and Expenses

- Operating expenses were $304.7 million, compared to $263.4 million for the same period in the prior year, primarily reflecting increased investment in the commercialization of VIVITROL and ARISTADA.
- Other expense during the quarter included a $19.6 million charge due to a decrease in the fair value of contingent consideration, related to Recro Pharma, Inc.'s receipt of a complete response letter from the United States (U.S.) Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for IV Meloxicam.

"With a growing proprietary commercial portfolio and partnered royalty and manufacturing business approaching $1 billion in revenue in 2018, Alkermes is in a strong position to create significant long-term value. As we head into the second half of 2018, we are on the threshold of important

value inflections across our development portfolio," said Richard Pops, Chief Executive Officer of Alkermes. "For ALKS 5461 for major depressive disorder, the regulatory review is underway and we are preparing for an Advisory Committee meeting in the fourth quarter. For ALKS 3831 for schizophrenia, enrollment of the ENLIGHTEN-2 pivotal study is complete and we expect topline data in the fourth quarter of 2018. In addition, we are on track to submit the NDA for BIIB098 toward year-end, and we look forward to presenting initial data from the ALKS 4230 phase 1 study and expanding into combination therapy later this year."

Recent Events:

- ARISTADA INITIO: Following recent FDA approval, ARISTADA INITIO is now commercially available. The ARISTADA INITIO regimen[2] provides physicians with an opportunity to initiate patients onto any dose of ARISTADA on day one.
- ALKS 5461: Data on the long-term safety, tolerability and durability of antidepressant effect of ALKS 5461 were presented at the American Psychiatric Association (APA) and American Society of Clinical Psychopharmacology (ASCP) annual meetings.
- ALKS 3831: The company presented data from the ALKS 3831 preclinical program and phase 1 translational medicine study evaluating the metabolic profile of ALKS 3831 compared to olanzapine.
- BIIB098: Alkermes received a $50 million payment from Biogen in June 2018. This payment follows Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098.

Financial Expectations for 2018
Alkermes reiterates its financial expectations for 2018 set forth in its press release dated April 26, 2018.

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, July 26, 2018, to discuss these financial results and provide an update on the company. The webcast 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. 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 26, 2018, through 5:00 p.m. ET (10:00 p.m. BST) on Thursday, Aug. 2, 2018, 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 basic and 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 potential therapeutic and commercial value of the company's marketed and development products, and payer coverage of, and patient access to, such products; expectations concerning the timing and results of clinical development and regulatory activities, including the timing of the phase 3 clinical trial (ENLIGHTEN-2) data readout for ALKS 3831, the timing of the submission of the NDA for BIIB098, the timing of initial data from the ALKS 4230 phase 1 study and the expansion of the study into combination therapy, and the outcome and timing of the FDA's review of the NDA for ALKS 5461; and expectations concerning the timing and results of commercial activities, including the launch of ARISTADA INITIO. 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 or products using our proprietary technologies, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the FDA in different ways than we interpret it; the FDA may not agree with our regulatory approval strategies or components of our filings for our products, including our clinical trial designs, conduct and methodologies and, for ALKS 5461, evidence of efficacy and adequacy of bridging to buprenorphine; 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 licensees may not be able to continue to successfully commercialize their 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 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 and ARISTADA INITIO™ is a 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).

[2]ARISTADA INITIO was approved by the FDA for the initiation of ARISTADA, a long-acting injectable atypical antipsychotic for the treatment of schizophrenia in adults. The ARISTADA INITIO regimen consists of ARISTADA INITIO plus a single 30 mg dose of oral aripiprazole.

(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, 2018	Three Months Ended June 30, 2017
Revenues:		
Manufacturing and royalty revenues	$ 128,241	$ 129,252
Product sales, net	109,807	88,756
License revenues	48,250	-
Research and development revenues	18,344	833
Total Revenues	304,642	218,841
Expenses:		
Cost of goods manufactured and sold	43,417	39,775
Research and development	106,823	99,153
Selling, general and administrative	138,257	108,950
Amortization of acquired intangible assets	16,247	15,472
Total Expenses	304,744	263,350
Operating Loss	(102)	(44,509)
Other Expense, net:		
Interest income	1,900	1,171
Interest expense	(3,126)	(2,923)
Change in the fair value of contingent consideration	(19,600)	700
Other expense, net	(3,517)	(119)
Total Other Expense, net	(24,343)	(1,171)
Loss Before Income Taxes	(24,445)	(45,680)
Income Tax Provision (Benefit)	8,204	(2,681)
Net Loss — GAAP	$ (32,649)	$ (42,999)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	$ (0.21)	$ (0.28)
Non-GAAP earnings per share — basic and diluted	$ 0.29	$ 0.01
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	155,176	153,392
Basic — Non-GAAP	155,176	153,392
Diluted — Non-GAAP	159,761	160,307
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:		
Net Loss — GAAP	$ (32,649)	$ (42,999)
Adjustments:		
Share-based compensation expense	30,933	22,680
Amortization expense	16,247	15,472
Depreciation expense	9,521	9,034

Change in the fair value of warrants and equity method investments	1,269	1,611
Non-cash net interest expense	170	193
Change in the fair value of contingent consideration	19,600	(700)
Income tax effect related to reconciling items	512	(4,102)
Non-GAAP Net Income	$ 45,603	$ 1,189

Condensed Consolidated Statements of Operations - GAAP **(In thousands, except per share data)**	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Revenues:		
Manufacturing and royalty revenues	$ 242,842	$ 243,931
Product sales, net	201,649	165,212
License revenues	48,250	-
Research and development revenues	37,051	1,476
Total Revenues	529,792	410,619
Expenses:		
Cost of goods manufactured and sold	87,893	80,187
Research and development	215,169	203,988
Selling, general and administrative	256,404	211,049
Amortization of acquired intangible assets	32,316	30,774
Total Expenses	591,782	525,998
Operating Loss	(61,990)	(115,379)
Other Expense, net:		
Interest income	3,385	2,114
Interest expense	(8,613)	(5,687)
Change in the fair value of contingent consideration	(21,500)	2,300
Other expense, net	(2,725)	(1,618)
Total Other Expense, net	(29,453)	(2,891)
Loss Before Income Taxes	(91,443)	(118,270)
Income Tax Provision (Benefit)	3,711	(6,390)
Net Loss — GAAP	$ (95,154)	$ (111,880)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	$ (0.61)	$ (0.73)
Non-GAAP earnings (loss) per share — basic and diluted	$ 0.20	$ (0.17)
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	154,802	153,050
Basic — Non-GAAP	154,802	153,050
Diluted — Non-GAAP	160,472	153,050

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

Net Loss — GAAP	$ (95,154)	$ (111,880)
Adjustments:		
Share-based compensation expense	50,975	43,849
Amortization expense	32,316	30,774
Depreciation expense	19,174	17,495
Change in the fair value of warrants and equity method investments	967	3,063
Non-cash net interest expense	361	386
Change in the fair value of contingent consideration	21,500	(2,300)
Income tax effect related to reconciling items	(4,666)	(8,052)
Restructuring expense	3,598	-
Debt refinacing charge	2,298	-
Non-GAAP Net Income (Loss)	$ 31,369	$ (26,665)

Condensed Consolidated Balance Sheets **(In thousands)**	June 30, 2018	December 31, 2017
Cash, cash equivalents and total investments	$ 560,519	$ 590,716
Receivables	255,230	233,590
Contract assets	14,582	-
Inventory	87,165	93,275
Prepaid expenses and other current assets	49,639	48,475
Property, plant and equipment, net	296,635	284,736

Intangible assets, net and goodwill	316,725	349,041
Other assets	170,991	197,394
Total Assets	$ 1,751,486	$ 1,797,227
Long-term debt — current portion	$ 2,843	$ 3,000
Other current liabilities	284,630	288,122
Long-term debt	277,548	278,436
Deferred revenue — long-term	5,857	5,657
Other long-term liabilities	22,453	19,204
Total shareholders' equity	1,158,155	1,202,808
Total Liabilities and Shareholders' Equity	$ 1,751,486	$ 1,797,227

Ordinary shares outstanding (in thousands)	155,303	154,009

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, 2018, which the company intends to file in July 2018.

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