Alkermes Plc Reports First Quarter 2019 Financial Results

April 25, 2019

-- First Quarter Revenues of $223.1 Million, Primarily Driven by ~8% Year-Over-Year Growth of Proprietary Product Net Sales --

-- Company Reports GAAP Net Loss per Share of $0.62 and Non-GAAP Net Loss per Share of $0.17 --

-- Company Reiterating Financial Expectations for 2019 --

DUBLIN, April 25, 2019 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the first quarter of 2019.

"Our first quarter results reflect the diversity of our business, as the growth of VIVITROL® net sales and royalty revenues from INVEGA SUSTENNA® offset a decline in AMPYRA® royalties, following generic entry in the market. As is typical, during the first quarter we saw the effect of seasonal inventory fluctuations and deductible resets for commercial payer plans impact net sales of our proprietary commercial products, which decreased sequentially. In particular, ARISTADA® net sales were impacted more than anticipated by inventory fluctuations which masked underlying prescription growth of approximately 5% compared to last quarter," commented James Frates, Chief Financial Officer of Alkermes. "Today, we are reiterating our financial expectations for 2019, as we continue to position VIVITROL and ARISTADA for long-term growth, invest in our development pipeline and prepare for the potential launch of ALKS 3831."

"The first few months of 2019 were highlighted by the presentation of important new data from large clinical trials of both ALKS 3831 and ARISTADA at the 2019 Congress of the Schizophrenia International Research Society. These innovative studies demonstrated the clear antipsychotic efficacy of our medicines along with our intended patient-focused attributes relating to safety and tolerability. Our recently announced ALPINE study results also provide information useful to clinicians making treatment decisions for their patients," commented Richard Pops, Chief Executive Officer of Alkermes. "Looking ahead, we are focused on executing both commercially and across our development pipeline. With the planned submission of the New Drug Application for ALKS 3831 mid-year, expected regulatory action for diroximel fumarate for multiple sclerosis in the fourth quarter, and increasing momentum in the ALKS 4230 immuno-oncology program, we have a number of key milestones ahead and look forward to updating you on our progress throughout the year."

Quarter Ended Mar. 31, 2019 Financial Highlights

- Total revenues for the quarter were $223.1 million, compared to $225.2 million for the same period in the prior year, reflecting the growth in our proprietary product net sales and an offsetting decrease in AMPYRA[i] revenues following generic entry into the market in 2018.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $96.4 million for the quarter, or a basic and diluted GAAP net loss per share of $0.62. This compared to GAAP net loss of $62.5 million, or a basic and diluted GAAP net loss per share of $0.40 for the same period in the prior year.
- Non-GAAP net loss was $26.0 million for the quarter, or a non-GAAP basic and diluted net loss per share of $0.17. This compared to non-GAAP net loss of $14.2 million, or a non-GAAP basic and diluted net loss per share of $0.09 for the same period in the prior year.

Quarter Ended Mar. 31, 2019 Financial Results

Revenues

- Net sales of VIVITROL were $69.2 million, compared to $62.7 million for the same period in the prior year, representing an increase of approximately 10%.
- Net sales of ARISTADA[ii] were $30.3 million, compared to $29.2 million for the same period in the prior year, representing an increase of approximately 4%.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were $75.6 million, compared to $68.8 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA/FAMPYRA® were $12.2 million, compared to $28.3 million for the same period in the prior year due to generic competition to AMPYRA entering the market in late 2018.
- Research and development revenues from the collaboration with Biogen for diroximel fumarate (BIIB098) were $13.9 million, compared to $17.5 million for the same period in the prior year.

Costs and Expenses

- Operating expenses were $299.1 million, compared to $287.0 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 $22.6 million charge due to a decrease in the fair value of contingent

consideration, related to Recro Pharma, Inc.'s receipt of a second complete response letter from the United States (U.S.) Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for IV Meloxicam.

Financial Expectations for 2019

Alkermes reiterates its financial expectations for 2019 set forth in its press release dated Feb. 14, 2019.

Recent Events:

- Leadership
  - Appointed Todd Nichols to the role of Senior Vice President of Sales and Marketing. Mr. Nichols joins Alkermes from Celgene and his responsibilities will include leading global commercial activities, including marketing and sales of VIVITROL and ARISTADA, as well as developing and executing the commercial strategy for ALKS 3831 and other development candidates.
- ARISTADA
  - The U.S. Department of Veterans Affairs recently added ARISTADA and ARISTADA INITIO® to its National Formulary at parity with other long-acting injectable atypical antipsychotics.
  - Announced positive topline results from ALPINE (**A**ripiprazole **L**auroxil and **P**aliperidone palmitate: **IN**itiation **E**ffectiveness), a six-month study evaluating the efficacy, safety and tolerability of ARISTADA and INVEGA SUSTENNA, when used to initiate patients experiencing an acute exacerbation of schizophrenia in the hospital and maintain treatment in an outpatient setting. Results were presented at the 2019 Congress of the Schizophrenia International Research Society (SIRS).
- ALKS 3831
  - Presented new data at SIRS from the phase 3 ALKS 3831 ENLIGHTEN-2 six-month weight study and interim results from the ENLIGHTEN-2 52-week safety extension study.
- Diroximel fumarate
  - Announced that the FDA accepted for review the NDA for diroximel fumarate. If approved, Biogen intends to market diroximel fumarate under the brand name VUMERITY ™, which has been conditionally accepted by the FDA and would be confirmed upon approval.
- ALKS 4230
  - Initiated ARTISTRY-2, a new clinical study of ALKS 4230 administered subcutaneously as monotherapy and in combination with the PD-1 inhibitor KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors.
  - Announced a research collaboration with Clovis to evaluate ALKS 4230 in combination with rucaparib, Clovis' marketed PARP inhibitor, and lucitanib, Clovis' investigational tyrosine kinase inhibitor.

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, Apr. 25, 2019, 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 +1 877 407 2988 for U.S. callers and +1 201 389 0923 for international callers. In addition, a replay of the conference call will be available from 11:00 a.m. ET (4:00 p.m. BST) on Thursday, Apr. 25, 2019, through Thursday, May 2, 2019, and may be accessed by visiting Alkermes' website or by dialing +1 877 660 6853 for U.S. callers and +1 201 612 7415 for international callers. The replay access code is 13690081.

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, multiple sclerosis and oncology. 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 loss and non-GAAP basic and diluted 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 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 loss and non-GAAP basic and diluted 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 loss and non-GAAP basic and diluted 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: the company's future financial and operating performance, business plans or prospects; expectations concerning continued revenue growth from the company's commercial products, including the growth of VIVITROL, ARISTADA and ARISTADA INITIO; expectations concerning the company's continued investment in its development pipeline and commercial capabilities and the value that can be derived therefrom; the potential therapeutic and commercial value of the company's marketed and development products; expectations concerning the timing and results of clinical development and regulatory activities, including the planned submission of an NDA for ALKS 3831, the FDA's anticipated action with respect to the NDA for diroximel fumarate, and increasing momentum in the ALKS 4230 development program; and expectations concerning investment in commercial activities, including the potential launch of ALKS 3831. 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; 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.

(tables follow)

[i] AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg is developed and marketed in the U.S. by Acorda. Biogen Inc. markets this product as FAMPYRA® (prolonged-release fampridine tablets) outside the U.S. under a licensing agreement with Acorda.

[ii] The term "ARISTADA" as used in this press release refers to ARISTADA and ARISTADA INITIO, unless the context indicates otherwise.

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	**Three Months Ended March 31, 2019**	**Three Months Ended March 31, 2018**
Revenues:		
Manufacturing and royalty revenues	$ 108,915	$ 114,601
Product sales, net	99,481	91,842
Research and development revenue	14,706	18,707
Total Revenues	223,102	225,150
Expenses:		
Cost of goods manufactured and sold	45,361	44,476
Research and development	102,570	108,346
Selling, general and administrative	141,220	118,147
Amortization of acquired intangible assets	9,952	16,069
Total Expenses	299,103	287,038
Operating Loss	(76,001)	(61,888)
Other Expense, net:		
Interest income	3,570	1,485
Interest expense	(3,500)	(5,487)
Change in the fair value of contingent consideration	(22,600)	(1,900)
Other expense, net	(1,721)	792
Total Other Expense, net	(24,251)	(5,110)
Loss Before Income Taxes	(100,252)	(66,998)
Income Tax Benefit	(3,854)	(4,493)
Net Loss — GAAP	$ (96,398)	$ (62,505)

Net Loss Per Share:

GAAP net loss per share — basic and diluted	$ (0.62)	$ (0.40)
Non-GAAP net loss per share — basic and diluted	$ (0.17)	$ (0.09)
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP and Non-GAAP	156,336	154,424

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

Net Loss — GAAP	$ (96,398)	$ (62,505)
Adjustments:		
Share-based compensation expense	24,616	20,042
Amortization expense	9,952	16,069
Depreciation expense	9,690	9,653
Change in the fair value of contingent consideration	22,600	1,900
Income tax effect related to reconciling items	2,972	(5,178)
Non-cash net interest expense	169	191
Change in the fair value of warrants and equity method investments	433	(302)
Restructuring expense	—	3,598
Debt refinancing charge	—	2,298
Non-GAAP Net Loss	$ (25,966)	$ (14,234)

Condensed Consolidated Balance Sheets (In thousands)	**March 31, 2019**	**December 31, 2018**
Cash, cash equivalents and total investments	$ 625,133	$ 620,039
Receivables	222,811	292,223
Contract assets	8,447	8,230
Inventory	92,861	90,196
Prepaid expenses and other current assets	56,492	53,308
Property, plant and equipment, net	320,004	309,987
Intangible assets, net and goodwill	273,922	283,874
Other assets	156,866	167,150
Total Assets	$ 1,756,536	$ 1,825,007
Long-term debt — current portion	$ 2,843	$ 2,843
Other current liabilities	324,842	336,931
Long-term debt	275,923	276,465
Contract liabilities — long-term	11,342	9,525
Other long-term liabilities	39,445	27,958
Total shareholders' equity	1,102,141	1,171,285
Total Liabilities and Shareholders' Equity	$ 1,756,536	$ 1,825,007
Ordinary shares outstanding (in thousands)	156,885	155,757

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 months ended March 31, 2019, which the company intends to file in April 2019.

Alkermes Contacts:
For Investors: Sandy Coombs +1 781 609 6377
For Media: Matthew Henson +1 781 609 6637

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