Alkermes Plc Reports Second Quarter 2019 Financial Results

July 25, 2019

-- Second Quarter Revenues of $279.9 Million, Primarily Driven by Approximately 24% Year-Over-Year Growth of Proprietary Product Net Sales --

-- Company Reports GAAP Net Loss per Share of $0.27 and Non-GAAP Net Income per Share of $0.09 --

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

"Our second quarter results reflect the growth of VIVITROL® and ARISTADA®, driven by underlying unit demand and continued upside from our royalty and manufacturing business. While driving revenue expansion, we are making important investments to further accelerate growth of VIVITROL and ARISTADA, and continue to invest in our research & development programs. These investments are designed to support sustainable, long-term growth," commented James Frates, Chief Financial Officer of Alkermes. "Based on our results through the second quarter, today we are adjusting our expectations for ARISTADA net sales for 2019, to a range of $200 million to $210 million. While we remain encouraged by positive momentum in prescription trends and expected growth opportunities as we enter into the second half of the year, we are fine-tuning our guidance to reflect the current growth trajectory. Importantly, the financial expectations that we provided in February for the rest of our business, including our expectations for total revenues for the year, remain intact."

"The second quarter was highlighted by important data presentations for ARISTADA and ALKS 3831, as we work to establish Alkermes as a leader in schizophrenia. We also made substantial progress in our ALKS 4230 ARTISTRY immuno-oncology program, as we advanced our recommended phase 2 dose into the monotherapy expansion stage of our ARTISTRY-1 study in patients with renal cell carcinoma or melanoma," commented Richard Pops, Chief Executive Officer of Alkermes. "Looking ahead, we expect to make important pipeline progress throughout the remainder of the year, with regulatory action for VUMERITY™, the planned submission of the NDA for ALKS 3831 for both schizophrenia and bipolar I disorder, and the first efficacy data for ALKS 4230, all expected before year-end."

Quarter Ended June 30, 2019 Financial Highlights

- Total revenues for the quarter were $279.9 million, compared to $304.6 million for the same period in the prior year, reflecting growth in our proprietary product net sales, partially offset by a decrease in AMPYRA[i] revenues following generic entry in 2018. In addition, the quarter ended June 30, 2018 included $48.3 million of license revenue from the collaboration with Biogen for diroximel fumarate.
- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $42.0 million for the quarter, or a basic and diluted GAAP net loss per share of $0.27. This compared to GAAP net loss of $32.6 million, or a basic and diluted GAAP net loss per share of $0.21, for the same period in the prior year.
- Non-GAAP net income was $13.7 million for the quarter, or a non-GAAP basic and diluted net earnings per share of $0.09. This compared to non-GAAP net income of $45.6 million, or a non-GAAP basic and diluted net earnings per share of $0.29, for the same period in the prior year.

Quarter Ended June 30, 2019 Financial Results

Revenues

- Net sales of VIVITROL were $88.2 million, compared to $76.2 million for the same period in the prior year, representing an increase of approximately 16%.
- Net sales of ARISTADA[ii] were $48.4 million, compared to $33.6 million for the same period in the prior year, representing an increase of approximately 44%.
- Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were $91.9 million, compared to $85.2 million for the same period in the prior year.
- Manufacturing and royalty revenues from AMPYRA/FAMPYRA® were $9.8 million, compared to $19.7 million for the same period in the prior year, due to generic competition to AMPYRA entering the market in 2018.
- Research and development revenues were $14.3 million, compared to $18.3 million for the same period in the prior year. These revenues were primarily related to the collaboration with Biogen for diroximel fumarate.
- License revenue was $1.0 million. This compared to $48.3 million for the same period in the prior year, which reflected receipt of a payment from Biogen under the collaboration for diroximel fumarate.

Costs and Expenses

- Operating expenses were $315.8 million, compared to $304.7 million for the same period in the prior year, primarily reflecting increased investment in the commercialization of VIVITROL and ARISTADA and in the development of ALKS 4230.

Financial Expectations for 2019

Alkermes is adjusting its financial expectations for ARISTADA net sales in 2019 based on year-to-date results. The company now expects ARISTADA net sales to range from $200 million to $210 million, decreased from its previous expectation of $210 million to $230 million. Alkermes anticipates that this slightly lower expectation for ARISTADA net sales will be offset by upside from royalty and manufacturing revenues and reiterates the remainder of its financial expectations for 2019 set forth in its press release dated Feb. 14, 2019, including its expectation for total revenues in the range of $1.14

billion to $1.19 billion, as well as GAAP net loss in the range of $135 million to $165 million and Non-GAAP net income in the range of $40 million to $70 million.

Recent Events:

- ARISTADA
  - Presented new safety and tolerability data from the ALPINE (**A**ripiprazole **L**auroxil and **P**aliperidone palmitate: **IN**itiation **E**ffectiveness) study at the American Society of Clinical Psychopharmacology (ASCP) annual meeting, which underscored the clinical utility of ARISTADA and long-acting therapies for schizophrenia.
- ALKS 3831
  - Following completion of a pre-New Drug Application (NDA) meeting with the FDA, announced plans to expand the ALKS 3831 NDA to include an indication for the treatment of bipolar I disorder, in addition to the treatment of schizophrenia. The NDA for ALKS 3831 will include data from the completed ALKS 3831 ENLIGHTEN clinical development program in patients with schizophrenia as well as pharmacokinetic bridging data comparing ALKS 3831 and ZYPREXA® (olanzapine).
- VUMERITY (diroximel fumarate)
  - Biogen presented new interim tolerability data from the ongoing open-label, pivotal EVOLVE-MS-1 study in people with relapsing multiple sclerosis at the annual meeting of the Consortium of Multiple Sclerosis Centers (CMSC).
- ALKS 4230
  - Initiated monotherapy expansion phase of ARTISTRY-1 to evaluate the efficacy, safety and tolerability of ALKS 4230 in treating patients with renal cell carcinoma or melanoma, following selection of the recommended phase 2 dose in the dose-escalation stage of ARTISTRY-1.

Conference Call

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:00 a.m. ET (1:00 p.m. BST) on Thursday, July 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, July 25, 2019, through Thursday, Aug. 1, 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 13691972.

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases and oncology. 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 cancer. 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 GAAP, including non-GAAP net income and non-GAAP basic and diluted net earnings 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 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; change in the fair value of contingent consideration; change in the fair value of warrants and equity method investments; 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 and non-GAAP basic and diluted net earnings 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 and non-GAAP basic and diluted net earnings per share should not be considered measures of our liquidity.

A reconciliation of certain 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 business plans or prospects; the company's expectations concerning future financial and operating performance, including expectations of continued revenue growth from the company's commercial products and products for which the company receives royalties; expectations concerning the company's continued investment in its development pipeline and commercial products and 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, details and results of the company's clinical development activities, including obtaining the first efficacy data for ALKS 4230; and the company's expectations and timelines for regulatory activities and interactions with the U.S. Food and Drug Administration ("FDA"), including actions by the FDA relating to the company's NDA submission for VUMERITY (diroximel fumarate), the company's submission of an NDA for ALKS 3831, the expected data to be contained in such NDA for ALKS 3831 and the adequacy of such data to serve as the basis of an NDA for ALKS 3831 for the treatment of schizophrenia and the treatment of bipolar I disorder. 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 adequacy of the data included to support the proposed indications; 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® and ARISTADA INITIO® are registered trademarks of Alkermes Pharma Ireland Limited and VUMERITY ™is a trademark of Alkermes Pharma Ireland Limited; RISPERDAL CONSTA®, INVEGA SUSTENNA®, XEPLION®, INVEGA TRINZA® and TREVICTA® are registered trademarks of Johnson & Johnson; and AMPYRA® and FAMPYRA® are registered trademarks of Acorda Therapeutics, Inc.; ZYPREXA® is a registered trademark of Eli Lilly & Company.

(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 June 30, 2019**	**Three Months Ended June 30, 2018**
Revenues:		
Manufacturing and royalty revenues	$ 127,897	$ 128,241
Product sales, net	136,635	109,807
Research and development revenue	14,340	18,344
License revenue	1,000	48,250
Total Revenues	279,872	304,642
Expenses:		
Cost of goods manufactured and sold	46,223	43,417
Research and development	104,435	106,823
Selling, general and administrative	155,075	138,257
Amortization of acquired intangible assets	10,062	16,247
Total Expenses	315,795	304,744
Operating Loss	(35,923)	(102)
Other Expense, net:		
Interest income	3,706	1,900
Interest expense	(3,520)	(3,126)
Change in the fair value of contingent consideration	(6,500)	(19,600)
Other income (expense), net	1,851	(3,517)
Total Other Expense, net	(4,463)	(24,343)
Loss Before Income Taxes	(40,386)	(24,445)
Income Tax Provision	1,604	8,204
Net Loss — GAAP	$ (41,990)	$ (32,649)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	$ (0.27)	$ (0.21)
Non-GAAP net earnings per share — basic and diluted	$ 0.09	$ 0.29
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	156,991	155,176
Basic — Non-GAAP	156,991	155,176
Diluted — Non-GAAP	158,987	159,761

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

Net Loss — GAAP	$ (41,990)	$ (32,649)
Adjustments:		
Share-based compensation expense	28,245	30,933
Amortization expense	10,062	16,247
Depreciation expense	9,852	9,521
Change in the fair value of contingent consideration	6,500	19,600
Income tax effect related to reconciling items	2,043	512
Non-cash net interest expense	168	170
Change in the fair value of warrants and equity method investments	(1,134)	1,269
Non-GAAP Net Income	$ 13,746	$ 45,603

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	**Six Months Ended June 30, 2019**	**Six Months Ended June 30, 2018**
Revenues:		
Manufacturing and royalty revenues	$ 236,812	$ 242,842
Product sales, net	236,116	201,649
Research and development revenue	29,046	37,051
License revenue	1,000	48,250
Total Revenues	502,974	529,792
Expenses:		
Cost of goods manufactured and sold	91,584	87,893
Research and development	207,005	215,169
Selling, general and administrative	296,295	256,404
Amortization of acquired intangible assets	20,014	32,316
Total Expenses	614,898	591,782
Operating Loss	(111,924)	(61,990)
Other Expense, net:		
Interest income	7,276	3,385
Interest expense	(7,020)	(8,613)
Change in the fair value of contingent consideration	(29,100)	(21,500)
Other income (expense), net	130	(2,725)
Total Other Expense, net	(28,714)	(29,453)
Loss Before Income Taxes	(140,638)	(91,443)
Income Tax (Benefit) Provision	(2,250)	3,711
Net Loss — GAAP	$ (138,388)	$ (95,154)
Net (Loss) Earnings Per Share:		
GAAP net loss per share — basic and diluted	$ (0.88)	$ (0.61)
Non-GAAP net (loss) earnings per share — basic and diluted	$ (0.08)	$ 0.20
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	156,665	154,802
Basic — Non-GAAP	156,665	154,802
Diluted — Non-GAAP	156,665	160,472

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

Net Loss — GAAP	$ (138,388)	$ (95,154)
Adjustments:		
Share-based compensation expense	52,861	50,975
Amortization expense	20,014	32,316
Depreciation expense	19,542	19,174
Change in the fair value of contingent consideration	29,100	21,500
Income tax effect related to reconciling items	5,015	(4,666)
Non-cash net interest expense	337	361
Change in the fair value of warrants and equity method investments	(701)	967
Restructuring expense	—	3,598
Debt refinancing charge	—	2,298
Non-GAAP Net (Loss) Income	$ (12,220)	$ 31,369

Condensed Consolidated Balance Sheets (In thousands)	June 30, 2019	December 31, 2018
Cash, cash equivalents and total investments	$ 593,593	$ 620,039
Receivables	261,226	292,223
Contract assets	12,690	8,230
Inventory	94,780	90,196
Prepaid expenses and other current assets	55,607	53,308
Property, plant and equipment, net	326,230	309,987
Intangible assets, net and goodwill	263,859	283,874
Other assets	143,766	167,150
Total Assets	$ 1,751,751	$ 1,825,007
Long-term debt — current portion	$ 2,843	$ 2,843
Other current liabilities	331,303	336,931
Long-term debt	275,381	276,465
Contract liabilities — long-term	11,621	9,525
Other long-term liabilities	39,435	27,958
Total shareholders' equity	1,091,168	1,171,285
Total Liabilities and Shareholders' Equity	$ 1,751,751	$ 1,825,007
Ordinary shares outstanding (in thousands)	157,097	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 and six months ended June 30, 2019, which the company intends to file in July 2019.

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