Alkermes plc Reports First Quarter 2021 Financial Results

April 28, 2021

-- First Quarter Revenues of $251.4 Million Reflect Solid Performance of VIVITROL® and ARISTADA® --
-- Achieves GAAP Loss per Share of $0.14 and Basic and Diluted Non-GAAP Earnings per Share of $0.11, Supported by Disciplined Expense Management --
-- Financial Expectations for 2021 Reiterated --

DUBLIN, April 28, 2021 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the first quarter of 2021.

"Our first quarter results reflect solid execution against our strategy to grow revenues and actively manage our cost structure. As the country begins to see signs of recovery from the pandemic, we believe we are well-positioned to efficiently manage our business and to achieve our long-term profitability targets," commented Iain Brown, Chief Financial Officer of Alkermes. "Today, we are reiterating our financial expectations for 2021, as we continue to position VIVITROL® and ARISTADA® for long-term growth, prepare for the anticipated launch of LYBALVI™, advance the clinical development program for nemvaleukin and invest in our neuroscience and oncology development pipeline."

Quarter Ended March 31, 2021 Financial Results

Revenues

- Total revenues for the quarter were $251.4 million. This compared to $246.2 million for the same period in the prior year.
- Net sales of proprietary products for the quarter were $130.0 million, compared to $129.7 million for the same period in the prior year.
  - Net sales of VIVITROL were $74.5 million, compared to $78.8 million for the same period in the prior year, representing a decrease of approximately 5%, primarily due to COVID-19-related disruptions.
  - Net sales of ARISTADA[i] were $55.4 million, compared to $51.0 million for the same period in the prior year, representing an increase of approximately 9%.
- Manufacturing and royalty revenues for the quarter were $119.8 million, compared to $116.3 million for the same period in the prior year.
  - Manufacturing and royalty revenues from RISPERDAL CONSTA®, INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® were $75.7 million, compared to $82.2 million for the same period in the prior year.
  - Manufacturing and royalty revenues from VUMERITY® were $13.4 million, compared to $1.7 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses for the quarter were $267.9 million, compared to $283.6 million for the same period in the prior year.
  - Cost of Goods Manufactured and Sold were $41.0 million, compared to $47.2 million for the same period in the prior year.
  - Research and Development (R&D) expenses were $92.3 million, compared to $93.3 million for the same period in the prior year.
  - Selling, General and Administrative (SG&A) expenses were $125.2 million, compared to $133.4 million for the same period in the prior year.

Profitability

- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $22.4 million for the quarter, or a basic and diluted GAAP loss per share of $0.14. This compared to GAAP net loss of $38.7 million, or a basic and diluted GAAP loss per share of $0.24, for the same period in the prior year.
- Non-GAAP net income was $17.8 million for the quarter, or a non-GAAP basic and diluted earnings per share of $0.11. This compared to non-GAAP net income of $1.7 million, or a non-GAAP basic and diluted earnings per share of $0.01 for the same period in the prior year.

Balance Sheet

- At March 31, 2021, the company recorded cash, cash equivalents and total investments of $627.4 million, compared to $659.8 million at Dec. 31, 2020, driven primarily by the company's operating results and changes in working capital. The

company's total debt outstanding as of March 31, 2021 was $297.7 million, following the March 2021 refinancing of the company's term loan, which extended its maturity date to March 2026.

Financial Expectations for 2021

Alkermes reiterates its financial expectations for 2021, and the assumptions underlying such expectations, as set forth in its press release dated Feb. 11, 2021.

"We are intensely focused on increasing Alkermes' value through the combination of scientific and business excellence. The first few months of 2021 were highlighted by important advancements in our nemvaleukin immuno-oncology program, including receipt of orphan drug designation for mucosal melanoma, initiation of ARTISTRY-6, a phase 2 trial to further evaluate nemvaleukin's monotherapy utility in melanoma, entry into a clinical trial and supply agreement with MSD (a tradename of Merck & Co., Inc. Kenilworth, NJ, USA) in platinum-resistant ovarian cancer, and achievement of the first partial response in platinum-resistant ovarian cancer in the ARTISTRY-2 subcutaneous dosing study. At our recent Investor Day, we also introduced new assets from our pipeline, including our CoREST-selective HDAC inhibitor program, our orexin 2 receptor agonist program and our platform of engineered cytokines, including our tumor-targeted, split IL-12 fusion protein," said Richard Pops, Chief Executive Officer of Alkermes. "Coupled with expected growth of our commercial portfolio, including the potential launch of LYBALVI™ and growth of VUMERITY®, and a focus on efficiency, cost management and strong governance, we have the potential to drive significant growth and value creation in 2021 and beyond."

Recent Events:

Nemvaleukin alfa ("nemvaleukin", formerly referred to as ALKS 4230)

- In March 2021, nemvaleukin, the company's investigational engineered interleukin-2 (IL-2) variant immunotherapy, was granted orphan drug designation for the treatment of mucosal melanoma by the U.S. Food and Drug Administration (FDA).
- In April 2021, the company entered into a clinical trial collaboration and supply agreement with MSD (a tradename of Merck & Co., Inc. Kenilworth, NJ, USA) for a planned phase 3 study to evaluate nemvaleukin in combination with KEYTRUDA® (pembrolizumab), in comparison to investigator choice chemotherapy in patients with platinum-resistant ovarian cancer. The study is planned to initiate in the second half of 2021.
- In April 2021, the company initiated ARTISTRY-6, a global phase 2 study evaluating the anti-tumor activity, safety and tolerability of intravenous nemvaleukin monotherapy in patients with mucosal melanoma. The study also includes a cohort of patients with advanced cutaneous melanoma who will receive subcutaneous (SC) nemvaleukin with intent to establish monotherapy proof-of-concept with SC dosing.

Psychiatry

- In April 2021, the company presented new research from its psychiatry portfolio at the 2021 Congress of the Schizophrenia International Research Society (SIRS), which took place virtually April 17-21, 2021. The company's presentations included new exploratory analyses from its phase 3 ENLIGHTEN-2 study of LYBALVI.

Corporate

- In March 2021, Alkermes held a virtual Investor Day to discuss the company's research and development strategy and portfolio, including updates from its nemvaleukin development program and introduction of new preclinical neuroscience and immuno-oncology programs. The company also provided an update on the implementation of its Value Enhancement Plan announced in December 2020.

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 Wednesday, April 28, 2021, 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 Wednesday, April 28, 2021, through Wednesday, May 5, 2021, 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 conference ID is 13718854.

About Alkermes plc

Alkermes plc is a fully-integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on addiction and schizophrenia, and a pipeline of product candidates in development for schizophrenia, bipolar I disorder, neurodegenerative disorders 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 (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: the company's expectations concerning future financial and operating performance, business plans or prospects, including the expected drivers of future growth and value creation and the company's ability to efficiently manage its business and achieve its long-term profitability targets; the potential therapeutic and commercial value of the company's marketed and development products; the potential approval of the new drug application (NDA) for LYBALVI; expectations concerning the company's future development activities, including plans and expected timing for initiation of a phase 3 study to evaluate nemvaleukin in combination with KEYTRUDA, and investment in the company's neuroscience and oncology development pipeline; and expectations concerning the company's commercial activities, including preparations for the anticipated launch of LYBALVI. The company cautions that forward-looking statements are inherently uncertain. 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 company's management of its cost structure may not yield the intended results; the company may not be able to achieve its targeted profitability metrics in a timely manner or at all; the impacts of the ongoing COVID-19 pandemic and continued efforts to mitigate its spread on the company's business, results of operations or financial condition, including impacts on healthcare systems and on patient and healthcare provider access to the company's commercial products and impacts on the regulatory agencies with which the company interacts in the development, review, approval and commercialization of its medicines; the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to 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 the adequacy of the data and other information included in our submissions to support the FDA's requirements for approval; clinical development activities may not be completed on time or at all; the results of the company's development activities may not be positive, or predictive of final results from such activities, results of future development activities or real-world results; regulatory submissions may not occur or be submitted in a timely manner; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products, including the NDA for LYBALVI; 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 government payers; 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, 2020 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; LYBALVI™ is a trademark of Alkermes Pharma Ireland Limited; KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA; RISPERDAL CONSTA®, INVEGA SUSTENNA®, XEPLION®, INVEGA TRINZA® and TREVICTA® are registered trademarks of Johnson & Johnson; and VUMERITY® is a registered trademark of Biogen Inc., used by Alkermes under license.

(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 March 31, 2021**	**Three Months Ended March 31, 2020**
Revenues:		
Product sales, net	$ 129,963	$ 129,726
Manufacturing and royalty revenues	119,847	116,251
License revenue	1,500	—
Research and development revenue	120	243
Total Revenues	251,430	246,220
Expenses:		
Cost of goods manufactured and sold	41,020	47,211
Research and development	92,268	93,279
Selling, general and administrative	125,168	133,372
Amortization of acquired intangible assets	9,406	9,728
Total Expenses	267,862	283,590
Operating Loss	(16,432)	(37,370)

Other (Expense) Income, net:				
Interest income		864		2,760
Interest expense		(3,970)		(2,857)
Change in the fair value of contingent consideration		1,278		6,800
Other expense, net		(393)		(658)
Total Other (Expense) Income, net		(2,221)		6,045
Loss Before Income Taxes		(18,653)		(31,325)
Provision for Income Taxes		3,765		7,329
Net Loss — GAAP	$	(22,418)	$	(38,654)
(Loss) Earnings Per Share:				
GAAP loss per share — basic and diluted	$	(0.14)	$	(0.24)
Non-GAAP earnings per share — basic and diluted	$	0.11	$	0.01
Weighted Average Number of Ordinary Shares Outstanding:				
Basic and diluted — GAAP		159,634		158,095
Basic — Non-GAAP		159,634		158,095
Diluted — Non-GAAP		162,332		159,038

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

Net Loss — GAAP	$	(22,418)	$	(38,654)
Adjustments:				
Share-based compensation expense		15,451		19,812
Depreciation expense		10,237		10,881
Amortization expense		9,406		9,728
Debt refinancing charge		2,109		—
Income tax effect related to reconciling items		4,178		5,920
Non-cash net interest expense		118		167
Change in the fair value of contingent consideration		(1,278)		(6,800)
Acquisition of IPR&D		—		674
Non-GAAP Net Income	$	17,803	$	1,728

Condensed Consolidated Balance Sheets (In thousands)	**March 31, 2021**		**December 31, 2020**	
Cash, cash equivalents and total investments	$	627,443	$	659,807
Receivables		243,514		275,143
Contract assets		9,279		14,401
Inventory		134,178		125,738
Prepaid expenses and other current assets		78,043		60,662
Property, plant and equipment, net		346,327		350,003
Intangible assets, net and goodwill		194,658		204,064
Other assets		244,779		259,912
Total Assets	$	1,878,221	$	1,949,730
Long-term debt — current portion	$	3,000	$	2,843
Other current liabilities		362,842		435,415
Long-term debt		294,702		272,118
Contract liabilities — long-term		14,745		16,397
Other long-term liabilities		151,777		155,975
Total shareholders' equity		1,051,155		1,066,982
Total Liabilities and Shareholders' Equity	$	1,878,221	$	1,949,730
Ordinary shares outstanding (in thousands)		160,198		159,161

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, 2021, which the company intends to file in April 2021.

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

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