Alkermes plc Reports First Quarter 2022 Financial Results

April 27, 2022

— First Quarter Revenues of $278.5 Million Reflect Strong Performance of LYBALVI®, ARISTADA® and VIVITROL® —

— GAAP Loss per Share of $0.22 and Basic and Diluted Non-GAAP Earnings per Share of $0.12 —

— Financial Expectations for 2022 Reiterated —

DUBLIN, April 27, 2022 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the first quarter of 2022.

"Our strong first quarter results reflect continued momentum across the business, and a sharp operational focus that provides a solid foundation to drive further growth of our proprietary products and advance our pipeline of development programs in 2022. As we execute on our launch strategy for LYBALVI®, we are particularly encouraged by early utilization trends and feedback from healthcare providers that underscore LYBALVI's value proposition in the oral antipsychotic market," said Richard Pops, Chief Executive Officer of Alkermes. "With our focus on disciplined allocation of capital, strong corporate governance, and our commitment to long-term profitability targets, we are delivering on our commitment to efficiently drive growth and actively managing the business to create value for our shareholders in 2022 and beyond."

Quarter Ended March 31, 2022 Financial Results

Revenues

- Total revenues for the quarter were $278.5 million, compared to $251.4 million for the same period in the prior year.

- Net sales of proprietary products for the quarter were $171.3 million, compared to $130.0 million for the same period in the prior year.

  - Net sales of VIVITROL® were $84.9 million, compared to $74.5 million for the same period in the prior year, representing an increase of approximately 14%.
  - Net sales of ARISTADA®i were $72.5 million, compared to $55.4 million for the same period in the prior year, representing an increase of approximately 31%.
  - Net sales of LYBALVI were $13.9 million, following its commercial launch in October 2021.

- Manufacturing and royalty revenues for the quarter were $105.2 million, compared to $119.8 million for the same period in the prior year.

  - Royalty revenues from INVEGA SUSTENNA®/XEPLION®, INVEGA TRINZA®/TREVICTA® and INVEGA HAFYERA® (the long-acting INVEGA products) were $37.1 million, compared to $61.6 million for the same period in the prior year. This includes approximately one month of royalty payments related to sales of the long-acting INVEGA products in the United States (U.S.), compared to three months in the same period in the prior year. This decrease was driven primarily by Janssen Pharmaceutica N.V.'s (Janssen) partial termination of the license agreement related to sales of long-acting INVEGA products in the U.S., which took effect starting in February of 2022.

    ° In April 2022, the company commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of the license agreement in the U.S. and Janssen's royalty and other obligations under the agreement.

  - Manufacturing and royalty revenues from RISPERDAL CONSTA® were $17.4 million, compared to $14.2 million for the same period in the prior year.
  - Manufacturing and royalty revenues from VUMERITY® were $30.6 million, compared to $13.4 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses for the quarter were $305.1 million, compared to $267.9 million for the same period in the prior year, primarily reflecting increased investment to support the commercial launch of LYBALVI.

  - Cost of Goods Manufactured and Sold were $55.2 million, compared to $41.0 million for the same period in the prior year.
  - Research and Development (R&D) expenses were $96.0 million, compared to $92.3 million for the same period in the prior year.
  - Selling, General and Administrative (SG&A) expenses were $145.1 million, compared to $125.2 million for the same period in the prior year.

- Other Expense, Net for the quarter included a reduction of $19.1 million in the fair value of contingent consideration related to increased risk of

non-payment of certain milestone payments by Baudax Bio, Inc. in light of its disclosures regarding its ability to continue as a going concern.

Profitability

- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $35.9 million for the quarter, or a basic and diluted GAAP loss per share of $0.22. This compared to GAAP net loss of $22.4 million, or a basic and diluted GAAP loss per share of $0.14, for the same period in the prior year.

- Non-GAAP net income was $19.6 million for the quarter, or a non-GAAP basic and diluted earnings per share of $0.12. This compared to non-GAAP net income of $17.8 million for the quarter, or a non-GAAP basic and diluted earnings per share of $0.11, for the same period in the prior year.

Balance Sheet

- At March 31, 2022, the company recorded cash, cash equivalents and total investments of $758.7 million, compared to $765.7 million at Dec. 31, 2021. The company's total debt outstanding as of March 31, 2022 was $295.2 million.

"Our first quarter results demonstrate the strength of our proprietary commercial product portfolio and our continued focus on efficient management of our cost structure. We are in a strong financial position to execute on our strategic priorities and work toward achievement of our long-term profitability targets," commented Iain Brown, Chief Financial Officer of Alkermes. "Today, we are reiterating our financial expectations for 2022, as we focus on efficiently driving growth of LYBALVI, ARISTADA and VIVITROL, and advancing our development pipeline."

Financial Expectations for 2022

Alkermes reiterates its financial expectations for 2022, and the assumptions underlying such expectations, as set forth in its press release dated Feb. 16, 2022.

Recent Events:

Oncology

- In February 2022, the company presented new data from the ongoing phase 1/2 ARTISTRY-1 clinical trial for nemvaleukin alfa (nemvaleukin), the company's novel, investigational, engineered interleukin-2 (IL-2) variant immunotherapy, at the American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium. The presentation included updated data from the monotherapy arm of ARTISTRY-1 in patients with advanced renal cell carcinoma (RCC), including patients who were checkpoint inhibitor-pretreated.
- In March 2022, the company presented nemvaleukin data from ARTISTRY-1 in patients with platinum-resistant ovarian cancer (PROC) in an oral plenary session at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting on Women's Cancer. The company also presented a trial-in-progress poster from the ongoing phase 3 ARTISTRY-7 global study evaluating the efficacy, safety and tolerability of IV nemvaleukin in combination with pembrolizumab compared to investigator's choice chemotherapy in patients with platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer.

Psychiatry

- In April 2022, the company presented new research from its psychiatry portfolio at the 2022 Congress of the Schizophrenia International Research Society (SIRS). The presentations included detailed results from the recently completed ENLIGHTEN-Early study of LYBALVI (olanzapine and samidorphan), a phase 3b study that evaluated the effect of LYBALVI compared to olanzapine on body weight in young adult patients (ages 16 to 39; mean age: 26 years) with schizophrenia, schizophreniform disorder or bipolar I disorder who were early in their illness.

Other

- In April 2022, the company commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of two license agreements with the company in the U.S. and Janssen's royalty and other obligations under the agreements. Under these agreements, Janssen received access and rights to Alkermes' small particle pharmaceutical compound technology, known as NanoCrystal® Technology, which enabled the development and commercialization of a number of successful products, such as INVEGA SUSTENNA, INVEGA TRINZA, INVEGA HAFYERA and CABENUVA®. Janssen partially terminated these agreements in the United States effective as of February 2022.

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 27, 2022, 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 27, 2022, through Wednesday, May 4, 2022, 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 13727838.

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 alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurodegenerative disorders and cancer. Headquartered in Dublin, Ireland, Alkermes 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 certain one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; change in the fair value of contingent consideration; 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 financial 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 the company's 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 its future financial and operating performance, business plans or prospects, including its commitment and plans to drive, and ability to achieve, growth, long-term profitability and shareholder value creation, and its ability to execute on its strategic priorities; and the potential therapeutic and commercial value of the company's products. 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 efforts to manage its cost structure may not yield the intended results; the company may not be able to achieve long-term profitability or its profitability targets in a timely manner or at all; the impacts of the ongoing COVID-19 pandemic 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 marketed products; the unfavorable outcome of arbitration or litigation, including so-called "Paragraph IV" litigation and other patent litigation, or other disputes related to the company's products or products using the company's proprietary technologies, including the arbitration proceedings with Janssen; 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; the U.S. Food and Drug Administration (FDA) may not agree with the company's regulatory approval strategies or components of the company's marketing applications; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company's products; 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, 2021 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] 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, 2022	Three Months Ended March 31, 2021
Revenues:		
Product sales, net	$ 171,268	$ 129,963

Manufacturing and royalty revenues	105,170	119,847
License revenue	2,000	1,500
Research and development revenue	107	119
Total Revenues	278,545	251,429
Expenses:		
Cost of goods manufactured and sold	55,159	41,020
Research and development	95,953	92,268
Selling, general and administrative	145,052	125,168
Amortization of acquired intangible assets	8,966	9,406
Total Expenses	305,130	267,862
Operating Loss	(26,585)	(16,433)
Other Expense, net:		
Interest income	573	864
Interest expense	(2,350)	(3,970)
Change in the fair value of contingent consideration	(19,067)	1,278
Other income (expense), net	2,431	(391)
Total Other Expense, net	(18,413)	(2,219)
Loss Before Income Taxes	(44,998)	(18,652)
(Benefit) Provision for Income Taxes	(9,095)	3,766
Net Loss — GAAP	$ (35,903)	$ (22,418)
(Loss) Earnings Per Share:		
GAAP loss per share — basic and diluted	$ (0.22)	$ (0.14)
Non-GAAP earnings per share — basic and diluted	$ 0.12	$ 0.11
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	162,483	159,634
Basic — Non-GAAP	162,483	159,634
Diluted — Non-GAAP	166,616	162,332

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

Net Loss — GAAP	$ (35,903)	$ (22,418)
Adjustments:		
Share-based compensation expense	18,343	15,451
Depreciation expense	10,231	10,237
Amortization expense	8,966	9,406
Income tax effect related to reconciling items	(1,193)	4,178
Non-cash net interest expense	117	118
Change in the fair value of contingent consideration	19,067	(1,278)
Debt refinancing charge	—	2,109
Non-GAAP Net Income	$ 19,628	$ 17,803

Condensed Consolidated Balance Sheets (In thousands)	**March 31, 2022**	**December 31, 2021**
Cash, cash equivalents and total investments	$ 758,697	$ 765,741
Receivables	249,942	313,193
Inventory	154,786	150,335
Contract assets	20,212	13,363
Prepaid expenses and other current assets	61,018	48,967
Property, plant and equipment, net	336,740	341,054
Intangible assets, net and goodwill	157,950	166,916
Other assets	238,500	224,915
Total Assets	$ 1,977,845	$ 2,024,484
Long-term debt — current portion	$ 3,000	$ 3,000
Other current liabilities	459,361	468,286
Long-term debt	292,171	292,804
Contract liabilities — long-term		
Other long-term liabilities	147,923	147,810
Total shareholders' equity	1,075,390	1,112,584
Total Liabilities and Shareholders' Equity	$ 1,977,845	$ 2,024,484
Ordinary shares outstanding (in thousands)	163,212	161,937

plc's Quarterly Report on Form 10-Q for the three months ended March 31, 2022, which the company intends to file in April 2022.

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