Alkermes plc Reports Second Quarter 2023 Financial Results

July 26, 2023

—Second Quarter Revenues of $617.4 Million Reflect Strong Performance of Proprietary Product Portfolio and Reinstatement of Long-Acting INVEGA® Product Royalties —

—Net Sales of Proprietary Products Increased Approximately 21% Year-Over-Year —

—Prevailed in Janssen Arbitration; Recorded $248.4 Million in Back Royalties and Interest —

—GAAP Net Income of $237.1 Million and Non-GAAP Net Income of $94.3 Million —

—Financial Expectations for Full-Year 2023 Reiterated —

DUBLIN, July 26, 2023 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the second quarter of 2023.

"The second quarter clearly demonstrated Alkermes' strong execution against our strategic priorities. We generated double-digit growth of our proprietary commercial products, advanced our development pipeline, and progressed the planned separation of our oncology business," said Richard Pops, Chief Executive Officer of Alkermes. "As we enter the second half of the year, we are well positioned to continue to make meaningful progress across the business and drive shareholder value."

"Our second quarter results reflect solid execution across our portfolio, highlighted by 21% year-over-year growth of our proprietary commercial products and reinstatement of the long-acting INVEGA product royalties in the U.S.," commented Iain Brown, Chief Financial Officer of Alkermes. "We are in a strong financial position with more than $907 million of cash and total investments and, today, we are reiterating our financial expectations for 2023 that were provided in June following receipt of the favorable final award in our arbitration with Janssen. We continue to expect royalty revenues from Janssen for these long-acting INVEGA products to be incrementally accretive to Alkermes' bottom line in 2023 and beyond, as we continue to manage our business to drive profitability for the benefit of Alkermes' shareholders."

Quarter Ended June 30, 2023 Financial Results

Revenues

- Total revenues for the quarter were $617.4 million, compared to $276.2 million for the same period in the prior year. Total revenues in the second quarter of 2023 included $248.4 million of back royalties and associated interest related to the successful outcome of the company's arbitration with Janssen Pharmaceutica N.V. (Janssen), a subsidiary of Johnson & Johnson.

- Net sales of proprietary products for the quarter increased approximately 21% to $231.5 million, compared to $190.8 million for the same period in the prior year.

- Net sales of VIVITROL® were $102.1 million, compared to $96.1 million for the same period in the prior year, representing an increase of approximately 6%.
- Net sales of ARISTADA®ⁱ were $82.4 million, compared to $74.6 million for the same period in the prior year, representing an increase of approximately 10%.
- Net sales of LYBALVI® were $47.0 million, compared to $20.1 million for the same period in the prior year, representing an increase of approximately 134%.

- Manufacturing and royalty revenues for the quarter were $385.9 million, compared to $85.3 million for the same period in the prior year.

- Royalty revenues from INVEGA SUSTENNA®/XEPLION®, INVEGA TRINZA®/TREVICTA® and INVEGA HAFYERA®/BYANNLI® (the long-acting INVEGA products) for the quarter were $321.2 million, which included $195.4 million and $50.2 million of back royalties and associated interest related to U.S. net sales of these products in 2022 and in the first quarter of 2023, respectively. The company recorded royalty revenues from these products of $26.6 million for the same period in the prior year.
- Manufacturing and royalty revenues from VUMERITY® for the quarter were $32.3 million, compared to $26.2 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses for the quarter were $378.2 million, compared to $310.7 million for the same period in the prior year. The increase was driven primarily by investment in the launch of LYBALVI and expenses associated with the planned separation of the oncology business.

- Cost of Goods Manufactured and Sold was $63.3 million, compared to $58.4 million for the same period in the prior year.
- Research and Development (R&D) expenses were $100.8 million, compared to $92.9 million for the same period in the

prior year, primarily reflecting acceleration in recruitment for the nemvaleukin alfa (nemvaleukin) clinical studies and investment in the ALKS 2680 phase 1 study.
- Selling, General and Administrative (SG&A) expenses were $205.3 million, compared to $150.4 million for the same period in the prior year, primarily reflecting increased investment in the direct-to-consumer advertising campaign to support the launch of LYBALVI and certain expenses related to the planned separation of the oncology business.

Profitability

- Net income according to generally accepted accounting principles in the U.S. (GAAP) was $237.1 million for the quarter, or a GAAP basic earnings per share of $1.43 and diluted earnings per share of $1.38, based on 166.3 million and 171.6 million shares outstanding, respectively. This compared to GAAP net loss of $30.1 million, or a basic and diluted GAAP loss per share of $0.18, for the same period in the prior year.

- Non-GAAP net income was $94.3 million for the quarter, or a non-GAAP basic earnings per share of $0.57 and diluted earnings per share of $0.55, based on 166.3 million and 171.6 million shares outstanding, respectively. Non-GAAP net income excluded back royalties and associated interest paid in the quarter of approximately $197.1 million related to 2022 U.S. net sales of the long-acting INVEGA products and CABENUVA®. This compared to non-GAAP net income of $10.5 million, or a non-GAAP basic and diluted earnings per share of $0.06 for the same period in the prior year.

Balance Sheet

- At June 30, 2023, the company recorded cash, cash equivalents and total investments of $907.2 million, compared to $692.5 million at March 31, 2023. The company's total debt outstanding as of June 30, 2023 was $292.0 million.

Financial Expectations for 2023

Alkermes reiterated its financial expectations for 2023, as set forth in its press release dated June 6, 2023.

Separation of Oncology Business

Alkermes continues to make meaningful progress on the previously announced planned separation of its oncology business into a new, independent publicly-traded company. The separation would allow Alkermes to maintain its focus on researching, developing and commercializing therapies for people living with complex neurological conditions and is expected to accelerate and enhance the profitability of the remaining neuroscience business.

- In June 2023, Alkermes appointed Caroline J. Loew, Ph.D., as the chief executive officer designate of Mural Oncology plc (Mural Oncology), the new independent public company to be established upon the planned separation of Alkermes' oncology business. Dr. Loew joined Alkermes in June as a strategic advisor and will transition to CEO of Mural Oncology upon completion of the separation.

- Alkermes continues to expect to complete the separation in the second half of 2023, subject to various customary conditions, including final approval from Alkermes' board of directors and receipt of a private letter ruling from the IRS and/or a tax opinion from the company's tax advisor.

Recent Events

Corporate

- In June 2023, the company received a final award (the Final Award) from the arbitral tribunal in its arbitration proceedings with Janssen. In connection with the Final Award, the company raised its financial expectations for 2023 by approximately $425 million, reflecting back royalties and associated interest paid related to 2022 U.S. net sales of the long-acting INVEGA products and CABENUVA and anticipated royalty revenues related to 2023 global net sales of these products. Further details regarding the Final Award can be found here.

- In June 2023, the company announced that at its 2023 annual general meeting of shareholders, the company's shareholders voted to re-elect all seven of Alkermes' director nominees – Emily Peterson Alva, Shane M. Cooke, Richard B. Gaynor, M.D., Cato T. Laurencin, M.D., Ph.D., Brian P. McKeon, Richard F. Pops and Christopher I. Wright, M.D., Ph.D., and approve all other company proposals presented.

Neuroscience

- In May 2023, the company initiated a phase 1b proof-of-concept study of ALKS 2680, the company's orexin 2 receptor agonist, which is in clinical development for the treatment of narcolepsy and other hypersomnia conditions.

- In May and June 2023, the company presented research related to its psychiatry portfolio at four scientific conferences. The conferences included: Schizophrenia International Research Society (SIRS) Annual Congress, International Society for Bipolar Disorders (ISBD) Annual Conference, American Psychiatric Association (APA) Annual Meeting, and American Society of Clinical Psychopharmacology (ASCP) Annual Meeting.

Oncology

- In June 2023, the company presented trial-in-progress posters from the actively recruiting phase 2 ARTISTRY-6 clinical trial and phase 3 ARTISTRY-7 clinical trial for nemvaleukin, the company's novel, investigational, engineered interleukin-2 (IL-2) variant immunotherapy, at the American Society of Clinical Oncology (ASCO) Annual Meeting.

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, July 26, 2023, 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 may be accessed by visiting Alkermes' website.

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 neurological disorders and cancer. Headquartered in Dublin, Ireland, Alkermes has a research and development 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 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 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 and non-GAAP basic and diluted 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 earnings 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 ability to drive profitability and create value for shareholders; the company's expectations regarding the future royalties to be received from Janssen; the company's expectations regarding the timing, structure, anticipated benefits and other impacts of the planned separation of its oncology business; and the therapeutic and commercial potential 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 may not ultimately separate its oncology business during 2023 or at all; unanticipated developments, costs or difficulties that may delay or otherwise negatively affect the planned separation of the company's oncology business; the planned separation may adversely impact the company's ability to attract or retain key personnel; the unfavorable outcome of arbitration or litigation, including so-called "Paragraph IV" litigation and other patent litigation which may lead to competition from generic drug manufacturers, or other disputes related to the company's products or products using the company's proprietary technologies; 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) or regulatory authorities outside the U.S. 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 or support revenue growth from such 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, 2022 and the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 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®, ARISTADA INITIO® and LYBALVI® are registered trademarks of Alkermes Pharma Ireland Limited, used by Alkermes, Inc. under license; BYANNLI®, INVEGA®, INVEGA HAFYERA®, INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA® and XEPLION® are registered trademarks of Johnson & Johnson or its affiliated companies; CABENUVA® is a registered trademark of ViiV Healthcare UK (No.3) Limited; and VUMERITY® is a registered trademark of Biogen MA Inc., used by Alkermes under license.

(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 June 30, 2023**	**Three Months Ended June 30, 2022**
Revenues:		
Product sales, net	$ 231,477	$ 190,787

Manufacturing and royalty revenues	385,913	85,326
Research and development revenue	7	106
Total Revenues	617,397	276,219
Expenses:		
Cost of goods manufactured and sold	63,260	58,360
Research and development	100,788	92,873
Selling, general and administrative	205,258	150,377
Amortization of acquired intangible assets	8,898	9,066
Total Expenses	378,204	310,676
Operating Income (Loss)	239,193	(34,457)
Other Income, net:		
Interest income	6,769	896
Interest expense	(5,684)	(2,369)
Other (expense) income, net	(525)	1,810
Change in the fair value of contingent consideration	—	870
Total Other Income, net	560	1,207
Income (Loss) Before Income Taxes	239,753	(33,250)
Income Tax Provision (Benefit)	2,688	(3,114)
Net Income (Loss) — GAAP	$ 237,065	$ (30,136)
Earnings (Loss) Per Share:		
GAAP earnings (loss) per share — basic	$ 1.43	$ (0.18)
GAAP earnings (loss) per share — diluted	$ 1.38	$ (0.18)
Non-GAAP earnings per share — basic	$ 0.57	$ 0.06
Non-GAAP earnings per share — diluted	$ 0.55	$ 0.06
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP and Non-GAAP	166,279	163,839
Diluted — GAAP	171,553	163,839
Diluted — Non-GAAP	171,553	168,706

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

Net Income (Loss) — GAAP	$ 237,065	$ (30,136)
Adjustments:		
Share-based compensation expense	28,504	23,377
Depreciation expense	10,114	10,326
Amortization expense	8,898	9,066
Final award in the Janssen arbitration (2022 back royalties and interest)	(197,092)	—
Separation expense	5,857	—
Income tax effect related to reconciling items	816	(1,383)
Non-cash net interest expense	115	117
Change in the fair value of contingent consideration and other related assets	—	(870)
Non-GAAP Net Income	$ 94,277	$ 10,497

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	**Six Months Ended June 30, 2023**	**Six Months Ended June 30, 2022**
Revenues:		
Product sales, net	$ 446,204	$ 362,055
Manufacturing and royalty revenues	458,775	190,496
License revenue	—	2,000
Research and development revenue	13	213
Total Revenues	904,992	554,764
Expenses:		
Cost of goods manufactured and sold	121,435	113,519
Research and development	194,425	188,826

Selling, general and administrative	379,735	295,429
Amortization of acquired intangible assets	17,698	18,032
Total Expenses	713,293	615,806
Operating Income (Loss)	191,699	(61,042)
Other Income (Expense), net:		
Interest income	11,735	1,469
Interest expense	(10,972)	(4,719)
Other (expense) income, net	(564)	4,241
Change in the fair value of contingent consideration	—	(18,197)
Total Other Income (Expense), net	199	(17,206)
Income (Loss) Before Income Taxes	191,898	(78,248)
Income Tax Benefit	(3,322)	(12,209)
Net Income (Loss) — GAAP	$ 195,220	$ (66,039)
Earnings (Loss) Per Share:		
GAAP earnings (loss) per share — basic	$ 1.18	$ (0.40)
GAAP earnings (loss) per share — diluted	$ 1.14	$ (0.40)
Non-GAAP earnings per share — basic	$ 0.58	$ 0.18
Non-GAAP earnings per share — diluted	$ 0.57	$ 0.18
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP and Non-GAAP	165,686	163,165
Diluted — GAAP	170,747	163,165
Diluted — Non-GAAP	170,747	167,372

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

Net Income (Loss) — GAAP	$ 195,220	$ (66,039)
Adjustments:		
Share-based compensation expense	51,147	41,720
Depreciation expense	20,028	20,557
Amortization expense	17,698	18,032
Final award in the Janssen arbitration (2022 back royalties and interest)	(197,092)	0
Separation expense	9,640	—
Income tax effect related to reconciling items	(179)	(2,576)
Non-cash net interest expense	231	234
Reduction in the fair value of contingent consideration and other related assets	—	18,197
Non-GAAP Net Income	$ 96,693	$ 30,125

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	**June 30, 2023**	**December 31, 2022**
Cash, cash equivalents and total investments	$ 907,176	$ 740,075
Receivables	334,478	287,967
Inventory	189,372	181,418
Contract assets	—	8,929
Prepaid expenses and other current assets	44,452	43,527
Property, plant and equipment, net	323,801	325,361
Intangible assets, net and goodwill	112,855	130,553
Deferred tax assets	153,152	115,602
Other assets	121,898	130,546
Total Assets	$ 2,187,184	$ 1,963,978
Accounts payable and accrued expenses	$ 465,691	$ 472,204
Long-term debt — current portion	3,000	3,000
Other current liabilities	18,494	22,538
Long-term debt	289,001	290,270
Other long-term liabilities	130,561	132,213

Total shareholders' equity	1,280,437	1,043,753
Total Liabilities and Shareholders' Equity	$ 2,187,184	$ 1,963,978
Ordinary shares outstanding (in thousands)	166,498	164,377

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, 2023, which the company intends to file in July 2023.

Alkermes Contacts:
For Investors: Sandy Coombs +1 781 609 6377
For Media: Katie Joyce +1 781 249 8927



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