



Alkermes plc Reports First Quarter 2023 Financial Results

April 26, 2023

— First Quarter Revenues of \$287.6 Million Reflect Strong Performance of Proprietary Product Portfolio —

— GAAP Loss per Share of \$0.25 and Basic and Diluted Non-GAAP Earnings per Share of \$0.01 —

— Planned Separation of Oncology Business Expected to be Completed in Second Half of 2023 —

— Second Favorable Interim Award Received in Janssen Arbitration —

— Financial Expectations for 2023 Reiterated —

DUBLIN, April 26, 2023 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today reported financial results for the first quarter of 2023.

"During the first quarter we made continued progress across our portfolio, including strong commercial execution driving growth for our proprietary products – LYBALVI[®], VIVITROL[®] and ARISTADA[®] – and important progress in the development of ALKS 2680, our orexin 2 receptor agonist, which is now poised to enter a phase 1b proof-of-concept study in patients with narcolepsy and idiopathic hypersomnia, with data expected later this year," said Richard Pops, Chief Executive Officer of Alkermes. "In addition, we made significant operational and strategic advances in the planned separation of our oncology business, which remains on track for completion in the second half of this year. We remain sharply focused on executing our strategic priorities to create significant value for shareholders."

"Our strong first quarter financial results were driven by 25% growth year-over-year in proprietary product net sales and continued focus on disciplined management of our cost structure," commented Iain Brown, Chief Financial Officer of Alkermes. "Today, we are reiterating our financial expectations for 2023 and believe we are in a strong financial position to continue to execute our strategic priorities, including further driving the launch of LYBALVI, advancing our orexin 2 receptor agonist clinical development program and completing the planned separation of the oncology business later this year."

Quarter Ended March 31, 2023 Financial Results

Revenues

- Total revenues for the quarter were \$287.6 million, compared to \$278.5 million for the same period in the prior year.

- Net sales of proprietary products for the quarter increased approximately 25% to \$214.7 million, compared to \$171.3 million for the same period in the prior year.

- Net sales of VIVITROL were \$96.7 million, compared to \$84.9 million for the same period in the prior year, representing an increase of approximately 14%.
- Net sales of ARISTADAⁱ were \$80.1 million, compared to \$72.5 million for the same period in the prior year, representing an increase of approximately 10%.
- Net sales of LYBALVI were \$38.0 million, compared to \$13.9 million for the same period in the prior year, representing an increase of approximately 173%.

- Manufacturing and royalty revenues for the quarter were \$72.9 million, compared to \$105.2 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 \$13.6 million, compared to \$37.1 million for the same period in the prior year. This decrease was driven primarily by Janssen Pharmaceutica N.V.'s (Janssen), a subsidiary of Johnson & Johnson, partial termination of the license agreement related to sales of the long-acting INVEGA products in the United States (U.S.), effective Feb. 2, 2022.
- Manufacturing and royalty revenues from VUMERITY[®] for the quarter were \$28.9 million, compared to \$30.6 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses for the quarter were \$335.1 million, compared to \$305.1 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 \$58.2 million, compared to \$55.2 million for the same period in the prior year.
- Research and Development (R&D) expenses were \$93.6 million, compared to \$96.0 million for the same period in the prior year.
- Selling, General and Administrative (SG&A) expenses were \$174.5 million, compared to \$145.1 million for the same period

in the prior year, primarily reflecting increased investment to support the launch of LYBALVI.

Profitability

- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was \$41.8 million for the quarter, or a basic and diluted GAAP loss per share of \$0.25. This compared to GAAP net loss of \$35.9 million, or a basic and diluted GAAP loss per share of \$0.22, for the same period in the prior year.

- Non-GAAP net income was \$2.4 million for the quarter, or a non-GAAP basic and diluted earnings per share of \$0.01. This compared to non-GAAP net income of \$19.6 million, or a non-GAAP basic and diluted earnings per share of \$0.12, for the same period in the prior year.

Balance Sheet

- At March 31, 2023, the company recorded cash, cash equivalents and total investments of \$692.5 million, compared to \$740.1 million at Dec. 31, 2022. The company's total debt outstanding as of March 31, 2023 was \$292.6 million.

Financial Expectations for 2023

Alkermes reiterates its financial expectations for 2023, as set forth in its press release dated Feb. 16, 2023.

Separation of Oncology Business

Alkermes continues to make meaningful progress on the previously announced planned separation of the company's oncology business. 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.

- As previously announced, in April, Alkermes submitted a confidential draft Form 10 registration statement to the United States Securities and Exchange Commission (SEC) in connection with the planned separation of its oncology business into an independent, publicly-traded company. Upon completion of the planned separation, the new company would be known as Mural Oncology plc.

- 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.

Recent Events

Corporate

- In April 2023, the company received a second favorable interim award (the Second Interim Award) from the arbitral tribunal (the Tribunal) in the company's arbitration proceedings with Janssen in respect of Janssen's partial termination in the U.S. of two license agreements with the company. The Second Interim Award, which builds on the first interim award that was issued in December 2022, provides that back royalties related to 2022 of approximately \$194 million (inclusive of interest) are due to the company under the two agreements, and that a separate Know-How Royalty (as defined in the applicable license agreement) term applies for each of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA.

Neuroscience

- In February 2023, the company initiated a multiple ascending dose cohort in the phase 1 study of its ALKS 2680 orexin 2 receptor agonist, which is in clinical development for the treatment of narcolepsy and other hypersomnia conditions.

- In March 2023, the company announced the publication of results from its phase 3 ENLIGHTEN-Early study of LYBALVI in the peer-reviewed publication, the *Journal of Clinical Psychiatry*. ENLIGHTEN-Early 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.

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 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 (loss) and non-GAAP basic and diluted (loss) 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 (loss) 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 (loss) income and non-GAAP basic and diluted (loss) 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 (loss) income and non-GAAP basic and diluted (loss) 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 execute on its strategic priorities and create value for shareholders; the company's expectations regarding the royalties and interest due to the company and royalty terms under the license agreements with Janssen; the company's expectations regarding the timing, structure, anticipated benefits and other impacts of the planned separation of the oncology business; timelines, plans and expectations for development activities relating to ALKS 2680; 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 a potential separation of the company's neuroscience and oncology businesses; disruption to the company's operations resulting from the planned separation; the planned separation may adversely impact the company's ability to attract or retain key personnel; the terms of the final award to be issued by the Tribunal may differ from the terms of the interim awards issued by the Tribunal and may be challenged by Janssen; 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; 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; 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 and in subsequent filings made by the company with the 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; BYANNL®, INVEGA®, INVEGA HAFYERA®, INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA® and XEPLION® are registered trademarks of Johnson & Johnson or its affiliated companies; 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	
	March 31, 2023	March 31, 2022
Revenues:		
Product sales, net	\$ 214,727	\$ 171,268
Manufacturing and royalty revenues	72,862	105,170
License revenue	—	2,000
Research and development revenue	6	107
Total Revenues	287,595	278,545
Expenses:		
Cost of goods manufactured and sold	58,175	55,159
Research and development	93,637	95,953
Selling, general and administrative	174,477	145,052
Amortization of acquired intangible assets	8,800	8,966

Total Expenses	335,089	305,130
Operating Loss	(47,494)	(26,585)
Other Expense, net:		
Interest income	4,966	573
Interest expense	(5,288)	(2,350)
Change in the fair value of contingent consideration	—	(19,067)
Other (expense) income, net	(39)	2,431
Total Other Expense, net	(361)	(18,413)
Loss Before Income Taxes	(47,855)	(44,998)
Income tax benefit	(6,010)	(9,095)
Net Loss — GAAP	\$ (41,845)	\$ (35,903)

(Loss) Earnings Per Share:

GAAP loss per share — basic and diluted	\$ (0.25)	\$ (0.22)
Non-GAAP earnings per share — basic and diluted	\$ 0.01	\$ 0.12

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP and Non-GAAP	165,085	162,483
Diluted — GAAP	165,085	162,483
Diluted — Non-GAAP	170,270	166,616

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

Net Loss — GAAP	\$ (41,845)	\$ (35,903)
Adjustments:		
Share-based compensation expense	22,643	18,343
Depreciation expense	9,914	10,231
Amortization expense	8,800	8,966
Separation expense	3,783	—
Income tax effect related to reconciling items	(995)	(1,193)
Non-cash net interest expense	116	117
Change in the fair value of contingent consideration and other related assets	—	19,067
Non-GAAP Net Income	\$ 2,416	\$ 19,628

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	March 31 2023	December 31, 2022
Cash, cash equivalents and total investments	\$ 692,542	\$ 740,075
Receivables	269,178	287,967
Inventory	184,984	181,418
Contract assets	8,429	8,929
Prepaid expenses and other current assets	47,008	43,527
Property, plant and equipment, net	321,109	325,361
Intangible assets, net and goodwill	121,753	130,553
Deferred tax assets	151,232	115,602
Other assets	126,492	130,546
Total Assets	\$ 1,922,727	\$ 1,963,978
Accounts payable and accrued expenses	\$ 472,413	\$ 472,204
Long-term debt — current portion	3,000	3,000
Other current liabilities	17,497	22,538
Long-term debt	289,635	290,270
Other long-term liabilities	134,606	132,213
Total shareholders' equity	1,005,576	1,043,753
Total Liabilities and Shareholders' Equity	\$ 1,922,727	\$ 1,963,978
Ordinary shares outstanding (in thousands)	166,059	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 months ended March 31, 2023, which the company intends to file in April 2023.

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