



Alkermes plc Reports Third Quarter 2023 Financial Results

October 25, 2023

—Third Quarter Revenues of \$380.9 Million; Net Sales of Proprietary Products Increased Approximately 16% Year-Over-Year —

—GAAP Net Income of \$47.8 Million and Non-GAAP Net Income of \$109.5 Million —

—Company Reiterates Financial Expectations for Full-Year 2023 —

—Separation of Oncology Business Expected to be Completed in November 2023 —

DUBLIN, Oct. 25, 2023 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today reported financial results for the third quarter of 2023.

"With solid performance across our proprietary commercial portfolio, the successful settlement of the VIVITROL[®] patent litigation, and progress toward completion of the separation of our oncology business, we have made significant strides to evolve the business into a pure-play neuroscience company with the potential to generate strong profitability and cash flow," said Richard Pops, Chief Executive Officer of Alkermes. "Our presentation at this week's World Sleep Congress of the first-in-human safety and tolerability data and initial proof-of-concept data for ALKS 2680, our investigational, orexin 2 receptor agonist for the treatment of narcolepsy, represents an important milestone for that development program. We look forward to sharing additional data from the phase 1 study and advancing ALKS 2680 into a planned phase 2 program next year."

"Our third quarter results demonstrate the financial strength of the business, driven by top-line year-over-year growth, strategic capital allocation and our focus on delivering value to shareholders," commented Iain Brown, Chief Financial Officer of Alkermes. "Upon planned completion of the separation of the oncology business in the coming weeks, the remaining neuroscience business will be positioned to deliver enhanced profitability as we focus on growing our proprietary commercial products and advancing the key programs that we believe will drive future growth."

Quarter Ended Sept. 30, 2023 Financial Results

Revenues

- Total revenues for the quarter were \$380.9 million, compared to \$252.4 million for the same period in the prior year.
- Net sales of proprietary products for the quarter increased approximately 16% to \$231.8 million, compared to \$199.4 million for the same period in the prior year.
 - Net sales of VIVITROL were \$99.3 million, compared to \$96.5 million for the same period in the prior year, representing an increase of approximately 3%.
 - Net sales of ARISTADA[®] were \$81.8 million, compared to \$75.7 million for the same period in the prior year, representing an increase of approximately 8%.
 - Net sales of LYBALVI[®] were \$50.7 million, compared to \$27.1 million for the same period in the prior year, representing an increase of approximately 87%.
- Manufacturing and royalty revenues for the quarter were \$149.1 million, compared to \$52.9 million for the same period in the prior year.
 - Royalty revenues from INVEGA SUSTENNA[®]/XEPLION[®], INVEGA TRINZA[®]/TREVICTA[®] and INVEGA HAFYERA[®]/BYANLI[®] for the quarter were \$76.1 million. The company recorded royalty revenues from these products of \$26.7 million for the same period in the prior year. This increase was driven by the favorable resolution of the arbitration proceedings related to these products in the second quarter of 2023.
 - Manufacturing and royalty revenues from VUMERITY[®] for the quarter were \$34.6 million, compared to \$26.3 million for the same period in the prior year.

Costs and Expenses

- Total operating expenses for the quarter were \$337.1 million, compared to \$313.0 million for the same period in the prior year. This 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 \$61.5 million, compared to \$50.6 million for the same period in the prior year.
 - Research and Development (R&D) expenses were \$97.1 million, compared to \$100.4 million for the same period in the prior year.
 - Selling, General and Administrative (SG&A) expenses were \$169.4 million, compared to \$152.8 million for the same period in the prior year.

Profitability

- Net income according to generally accepted accounting principles in the U.S. (GAAP) was \$47.8 million for the quarter, or a GAAP basic earnings per share of \$0.29 and diluted earnings per share of \$0.28, based on 166.6 million and 171.9 million shares outstanding, respectively. This compared to GAAP net loss of \$64.0 million, or a basic and diluted GAAP loss per share of \$0.39, for the same period in the prior year.

- Non-GAAP net income was \$109.5 million for the quarter, or a non-GAAP basic earnings per share of \$0.66 and diluted earnings per share of \$0.64, based on 166.6 million and 171.9 million shares outstanding, respectively. This compared to non-GAAP net income of \$3.5 million, or a non-GAAP basic and diluted earnings per share of \$0.02, for the same period in the prior year.

Balance Sheet

- At Sept. 30, 2023, the company recorded cash, cash equivalents and total investments of \$995.6 million, compared to \$907.2 million at June 30, 2023. The company's total debt outstanding as of Sept. 30, 2023 was \$291.4 million.

Financial Expectations for 2023

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

Separation of Oncology Business

- Alkermes expects to complete the separation of its oncology business into a new, independent publicly-traded company, Mural Oncology plc (Mural), in November 2023, subject to various customary conditions, including final approval from Alkermes' board of directors. Alkermes expects to capitalize Mural with cash of \$275 million upon completion of the separation.

- In October 2023, members of Mural's designated management team held an investor webcast to provide an overview of its pipeline and strategy. A replay is available on the Investors section of Alkermes' website at www.alkermes.com.

Recent Events

Neuroscience

- In October 2023, the company presented initial phase 1 clinical data related to ALKS 2680, the company's novel, investigational orexin 2 receptor agonist in development for the treatment of narcolepsy, at the World Sleep Congress. The presentation included safety and tolerability data from single- and multiple-ascending dose evaluations in healthy volunteers and initial Maintenance of Wakefulness Test proof-of-concept data in four patients with narcolepsy type 1.

- In September 2023, the company presented multiple posters highlighting real-world and clinical data related to its psychiatry portfolio at Psych Congress 2023.

Corporate

- In September 2023, the company published its latest Corporate Responsibility Report, which details how the company integrates environmental, social and governance considerations into its business. A copy of the report is available on the Responsibility section of Alkermes' website.

- In August 2023, the company entered into a settlement agreement with Teva Pharmaceuticals USA, Inc. (Teva) to resolve the patent litigation between the parties related to VIVITROL. Pursuant to the terms of the settlement agreement, the company has granted Teva a license under the company's U.S. Patent No. 7,919,499 to market a generic version of VIVITROL in the United States beginning Jan. 15, 2027, or earlier under certain customary circumstances.

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, Oct. 25, 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 cash flow and to create value for shareholders; the company's plans and expected timelines for the clinical development activities for ALKS 2680, including initiation of the phase 2 study and presentation of additional data; and the company's expectations regarding the timing for completion, capitalization, structure, and anticipated benefits of the planned separation of its oncology business. 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 on the anticipated timeline 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 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; 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	
	September 30, 2023	September 30, 2022
Revenues:		
Product sales, net	\$ 231,822	\$ 199,380
Manufacturing and royalty revenues	149,113	52,941
Research and development revenue	3	36
Total Revenues	<u>380,938</u>	<u>252,357</u>
Expenses:		
Cost of goods manufactured and sold	61,509	50,625
Research and development	97,140	100,430
Selling, general and administrative	169,446	152,777
Amortization of acquired intangible assets	8,995	9,166
Total Expenses	<u>337,090</u>	<u>312,998</u>
Operating Income (Loss)	<u>43,848</u>	<u>(60,641)</u>
Other Income (Expense), net:		
Interest income	9,370	2,239
Interest expense	(6,006)	(3,552)
Other income (expense) , net	149	(1,861)
Change in the fair value of contingent consideration	—	(3,553)
Total Other Income (Expense), net	<u>3,513</u>	<u>(6,727)</u>

Income (Loss) Before Income Taxes	47,361	(67,368)
Income Tax Benefit	(397)	(3,394)
Net Income (Loss) — GAAP	\$ 47,758	\$ (63,974)

Earnings (Loss) Per Share:

GAAP earnings (loss) per share — basic	\$ 0.29	\$ (0.39)
GAAP earnings (loss) per share — diluted	\$ 0.28	\$ (0.39)
Non-GAAP earnings per share — basic	\$ 0.66	\$ 0.02
Non-GAAP earnings per share — diluted	\$ 0.64	\$ 0.02

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP and Non-GAAP	166,607	164,282
Diluted — GAAP	171,903	164,282
Diluted — Non-GAAP	171,903	168,762

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

Net Income (Loss) — GAAP	\$ 47,758	\$ (63,974)
Adjustments:		
Share-based compensation expense	23,915	26,051
Depreciation expense	9,665	10,431
Amortization expense	8,995	9,166
Separation expense	9,640	—
Restructuring expense	5,938	—
Income tax effect related to reconciling items	3,511	(17)
Non-cash net interest expense	115	116
Legal settlement	—	15,905
Change in the fair value of contingent consideration and other related assets	—	5,835
Non-GAAP Net Income	\$ 109,537	\$ 3,513

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations - GAAP (In thousands, except per share data)	Nine Months Ended	
	September 30, 2023	September 30, 2022
Revenues:		
Product sales, net	\$ 678,026	\$ 561,435
Manufacturing and royalty revenues	607,888	243,437
Research and development revenue	16	249
License revenue	—	2,000
Total Revenues	1,285,930	807,121
Expenses:		
Cost of goods manufactured and sold	182,944	164,144
Research and development	291,565	289,256
Selling, general and administrative	549,181	448,206
Amortization of acquired intangible assets	26,693	27,198
Total Expenses	1,050,383	928,804
Operating Income (Loss)	235,547	(121,683)
Other Income (Expense), net:		
Interest income	21,105	3,708
Interest expense	(16,978)	(8,271)
Other (expense) income, net	(415)	2,380
Change in the fair value of contingent consideration	—	(21,750)
Total Other Income (Expense), net	3,712	(23,933)
Income (Loss) Before Income Taxes	239,259	(145,616)
Income Tax Benefit	(3,719)	(15,603)
Net Income (Loss) — GAAP	\$ 242,978	\$ (130,013)

Earnings (Loss) Per Share:

GAAP earnings (loss) per share — basic	\$	1.46	\$	(0.79)
GAAP earnings (loss) per share — diluted	\$	1.42	\$	(0.79)
Non-GAAP earnings per share — basic	\$	1.24	\$	0.21
Non-GAAP earnings per share — diluted	\$	1.21	\$	0.20

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP and Non-GAAP	165,996	163,541
Diluted — GAAP	170,981	163,541
Diluted — Non-GAAP	170,981	167,687

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

Net Income (Loss) — GAAP	\$	242,978	\$	(130,013)
Adjustments:				
Share-based compensation expense		75,062		67,771
Depreciation expense		29,693		30,988
Amortization expense		26,693		27,198
Separation expense		19,280		—
Restructuring expense		5,938		—
Income tax effect related to reconciling items		3,332		(2,593)
Non-cash net interest expense		346		350
Final award in the Janssen arbitration (2022 back royalties and interest)		(197,092)		—
Legal settlement		—		15,905
Reduction in the fair value of contingent consideration and other related assets		—		24,032
Non-GAAP Net Income	\$	206,230	\$	33,638

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets **September 30, December 31,**
(In thousands)

	2023	2022
Cash, cash equivalents and total investments	\$ 995,581	\$ 740,075
Receivables	337,697	287,967
Inventory	192,186	181,418
Contract assets	2,766	8,929
Prepaid expenses and other current assets	42,982	43,527
Property, plant and equipment, net	327,517	325,361
Intangible assets, net and goodwill	103,860	130,553
Deferred tax assets	162,184	115,602
Other assets	114,458	130,546
Total Assets	\$ 2,279,231	\$ 1,963,978
Accounts payable and accrued expenses	\$ 481,587	\$ 472,204
Long-term debt — current portion	3,000	3,000
Other current liabilities	18,520	22,538
Long-term debt	288,366	290,270
Other long-term liabilities	132,175	132,213
Total shareholders' equity	1,355,583	1,043,753
Total Liabilities and Shareholders' Equity	\$ 2,279,231	\$ 1,963,978
Ordinary shares outstanding (in thousands)	166,714	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 nine months ended September 30, 2023, which the company intends to file in October 2023.

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