



Alkermes plc Reports Second Quarter 2024 Financial Results

July 24, 2024

— Second Quarter Revenues of \$399.1 Million —

— Net Sales of Proprietary Products Increased Approximately 16% Year-Over-Year —

— GAAP Net Income from Continuing Operations of \$94.7 Million and Diluted GAAP Earnings per Share from Continuing Operations of \$0.55 —

— Company Reiterates 2024 Financial Expectations —

DUBLIN, July 24, 2024 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today reported financial results for the second quarter of 2024.

"Our second quarter results reflect solid execution across our business, delivering double-digit, year-over-year growth for our proprietary commercial product portfolio and robust profitability. We enter the second half of the year in a strong financial position with clear operational priorities to drive the performance of our commercial portfolio and advance our neuroscience development pipeline, including the phase 2 program for ALKS 2680 in narcolepsy type 1 and type 2," said Richard Pops, Chief Executive Officer of Alkermes. "As a profitable, mid-cap biotech growth company with multiple commercial products and a development pipeline with significant value potential, we are executing our plan to become a leader in the field of neuroscience."

Key Financial Highlights

Revenues

<i>(In millions)</i>	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2024	2023	2024	2023
Total Revenues	\$ 399.1	\$ 617.4*	\$ 749.5	\$ 905.0*
Total Proprietary Net Sales	\$ 269.3	\$ 231.5	\$ 502.8	\$ 446.2
VIVITROL [®]	\$ 111.9	\$ 102.1	\$ 209.5	\$ 198.7
ARISTADA ^{®i}	\$ 86.0	\$ 82.4	\$ 164.9	\$ 162.5
LYBALVI [®]	\$ 71.4	\$ 47.0	\$ 128.4	\$ 85.0

Profitability

<i>(In millions)</i>	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2024	2023	2024	2023
GAAP Net Income From Continuing Operations	\$ 94.7	\$ 279.1	\$ 133.6	\$ 267.1
GAAP Net Loss From Discontinued Operations	\$ (3.3)	\$ (42.0)	\$ (5.4)	\$ (71.8)
GAAP Net Income	\$ 91.4	\$ 237.1*	\$ 128.2	\$ 195.2*
Non-GAAP Net Income From Continuing Operations	\$ 123.4	\$ 134.3	\$ 199.6	\$ 164.4
Non-GAAP Net Loss From Discontinued Operations	\$ (3.3)	\$ (40.0)	\$ (5.4)	\$ (67.7)
Non-GAAP Net Income	\$ 120.1	\$ 94.3	\$ 194.2	\$ 96.7
EBITDA From Continuing Operations	\$ 118.6	\$ 299.1	\$ 170.1	\$ 306.2
EBITDA From Discontinued Operations	\$ (3.9)	\$ (41.4)	\$ (6.4)	\$ (77.4)
EBITDA	\$ 114.7	\$ 257.7*	\$ 163.7	\$ 228.9*

*As a result of the successful resolution of the arbitration with Janssen Pharmaceutica N.V., the three months ended June 30, 2023 included approximately \$245.5 million of back royalties (and related interest) related to U.S. net sales of long-acting INVEGA[®] products (consisting of \$195.4 million for 2022 and \$50.1 million for the first quarter of 2023) that would ordinarily have been recognized in prior periods.

Revenue Highlights

LYBALVI

- Revenues for the quarter were \$71.4 million.
- Revenues and total prescriptions for the quarter grew 52% and 44%, respectively, compared to the second quarter of

2023.

ARISTADA¹

- Revenues for the quarter were \$86.0 million.
- New to brand prescriptions for the quarter grew 6% sequentially compared to the first quarter of 2024.

VIVITROL

- Revenues for the quarter were \$111.9 million.
- Revenues for the quarter grew 10% compared to the second quarter of 2023, driven by the alcohol dependence indication.

Manufacturing & Royalty Revenues

- Royalty revenues from INVEGA SUSTENNA[®]/XEPLION[®], INVEGA TRINZA[®]/TREVICTA[®] and INVEGA HAFYERA[®]/BYANLI[®] for the quarter were \$78.7 million.
- VUMERITY[®] manufacturing and royalty revenues for the quarter were \$35.2 million.

Key Operating Expenses

Please see Note 1 below for details regarding discontinued operations.

(In millions)	Three Months Ended		Six Months Ended	
	June 30,	June 30,	June 30,	June 30,
	2024	2023	2024	2023
R&D Expense – Continuing Operations	\$ 59.6	\$ 68.2	\$ 127.3	\$ 132.0
R&D Expense – Discontinued Operations	\$ 3.9	\$ 32.6	\$ 6.4	\$ 62.4
SG&A Expense – Continuing Operations	\$ 168.1	\$ 195.8	\$ 347.9	\$ 363.6
SG&A Expense – Discontinued Operations	\$ -	\$ 9.5	\$ -	\$ 16.1

Balance Sheet

At June 30, 2024, the company recorded cash, cash equivalents and total investments of \$962.5 million, compared to \$807.8 million at March 31, 2024. The company's total debt outstanding as of June 30, 2024 was \$289.5 million.

Share Repurchase Program

During the second quarter of 2024, the company repurchased approximately 3.5 million of the company's ordinary shares under the share repurchase program authorized in February 2024, at a total purchase price of \$84.7 million. As of June 30, 2024, the company had \$315.3 million (exclusive of any fees, commissions or other expenses related to such repurchases) remaining under the program.

Financial Expectations for 2024

Alkermes reiterates its financial expectations for 2024, as set forth in its press release dated Feb. 15, 2024.

Recent Events

- In April 2024, the company announced [positive topline results](#) from the narcolepsy type 2 and idiopathic hypersomnia cohorts in its phase 1b proof-of-concept study evaluating ALKS 2680, the company's novel, investigational, oral orexin 2 receptor (OX2R) agonist in development as a once-daily treatment for narcolepsy.
- In April 2024, the company announced initiation of its Vibrance-1 phase 2 study of ALKS 2680 in patients with narcolepsy type 1.
- In May 2024, the company completed the sale of its development and manufacturing facility in Athlone, Ireland to Novo Nordisk. Alkermes received a cash payment for the facility and certain related assets of approximately \$91 million.
- In May and June 2024, the company presented research related to its psychiatry franchise products—LYBALVI (olanzapine and samidorphan) and ARISTADA (aripiprazole lauroxil)—at several scientific conferences. The conferences included: American Psychiatric Association (APA) Annual Meeting, American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, and Psych Congress Elevate.
- In June 2024, the company presented new research related to ALKS 2680 and narcolepsy, including new data from the full narcolepsy type 1 cohort in its phase 1b, proof-of-concept study evaluating ALKS 2680, at SLEEP 2024, the 38th annual meeting of the Associated Professional Sleep Societies (APSS).

Notes and Explanations

1. The company determined that upon the separation of its oncology business, completed on Nov. 15, 2023, the oncology business met the criteria for discontinued operations in accordance with Financial Accounting Standards Board Accounting Standards Codification 205, *Discontinued Operations*. Accordingly, the accompanying selected financial information has been updated to present the results of the oncology business as discontinued operations for the three and six months ended June 30, 2023.

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 24, 2024, 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 global biopharmaceutical company that seeks to develop innovative medicines in the field of neuroscience. The company has a portfolio of proprietary commercial products for the treatment of alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of clinical and preclinical candidates in development for neurological disorders, including narcolepsy. Headquartered in Ireland, Alkermes also has a corporate office and research and development center in Massachusetts and a manufacturing facility in 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 generally accepted accounting principles in the U.S. (GAAP), including non-GAAP net income and EBITDA. 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. EBITDA represents earnings before interest, tax, depreciation and amortization; earnings include share-based compensation expense.

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 EBITDA 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 EBITDA 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 profitability; and the potential therapeutic and commercial value of ALKS 2680 and the company's development pipeline. 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: whether the company is able to sustain profitability; 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 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, 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; BYANLI®, 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.

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, 2024	Three Months Ended June 30, 2023
Revenues:		
Product sales, net	\$ 269,273	\$ 231,477
Manufacturing and royalty revenues	129,858	385,913
Research and development revenue	—	7

Total Revenues	399,131	617,397
Expenses:		
Cost of goods manufactured and sold	61,472	63,249
Research and development	59,649	68,225
Selling, general and administrative	168,113	195,756
Amortization of acquired intangible assets	14	8,898
Total Expenses	289,248	336,128
Operating Income	109,883	281,269
Other Income, net:		
Interest income	10,735	6,769
Interest expense	(5,952)	(5,684)
Other income (expense), net	2,053	(525)
Total Other Income, net	6,836	560
Income Before Income Taxes	116,719	281,829
Income Tax Provision	22,061	2,728
Net Income From Continuing Operations	94,658	279,101
Loss From Discontinued Operations — Net of Tax	(3,300)	(42,036)
Net Income — GAAP	\$ 91,358	\$ 237,065

GAAP Earnings (Loss) Per Ordinary Share - Basic:

From continuing operations	\$ 0.56	\$ 1.68
From discontinued operations	\$ (0.02)	\$ (0.25)
From net income	\$ 0.54	\$ 1.43

GAAP Earnings (Loss) Per Ordinary Share - Diluted:

From continuing operations	\$ 0.55	\$ 1.63
From discontinued operations	\$ (0.02)	\$ (0.25)
From net income	\$ 0.53	\$ 1.38

Weighted Average Number of Ordinary Shares Outstanding:

Basic — GAAP and Non-GAAP	168,321	166,279
Diluted — GAAP and Non-GAAP	170,977	171,553

Condensed Consolidated Statements of Operations - GAAP (Continued) (In thousands, except per share data)	Three Months	Three Months
	Ended	Ended
	June 30, 2024	June 30, 2023
An itemized reconciliation between net income from continuing operations on a GAAP basis and EBITDA is as follows:		
Net Income from Continuing Operations	\$ 94,658	\$ 279,101
Adjustments:		
Depreciation expense	6,644	9,426
Amortization expense	14	8,898
Interest income	(10,735)	(6,769)
Interest expense	5,952	5,684
Income tax provision	22,061	2,728
EBITDA from Continuing Operations	118,594	299,068
EBITDA from Discontinued Operations	(3,913)	(41,388)
EBITDA	\$ 114,681	\$ 257,680

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

Net Income from Continuing Operations	\$ 94,658	\$ 279,101
Adjustments:		
Share-based compensation expense	20,601	27,187
Depreciation expense	6,644	9,426
Amortization expense	14	8,898
Non-cash net interest expense	114	115
Separation expense	813	5,857
Income tax effect related to reconciling items	2,060	816
Gain on sale of Athlone manufacturing facility	(1,462)	—
Final award in the Janssen arbitration (2022 back royalties and interest)	—	(197,092)

Non-GAAP Net Income from Continuing Operations	123,442	134,308
Non-GAAP Net Loss from Discontinued Operations	(3,300)	(40,031)
Non-GAAP Net Income	<u>\$ 120,142</u>	<u>\$ 94,277</u>
Non-GAAP diluted earnings per ordinary share from continuing operations	\$ 0.72	\$ 0.78
Non-GAAP diluted loss per ordinary share from discontinued operations	\$ (0.02)	\$ (0.23)
Non-GAAP diluted earnings per ordinary share from net income	\$ 0.70	\$ 0.55

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, 2024	Six Months Ended June 30, 2023
Revenues:		
Product sales, net	\$ 502,809	\$ 446,204
Manufacturing and royalty revenues	246,691	458,775
Research and development revenue	3	13
Total Revenues	<u>749,503</u>	<u>904,992</u>
Expenses:		
Cost of goods manufactured and sold	120,116	121,413
Research and development	127,260	131,995
Selling, general and administrative	347,862	363,589
Amortization of acquired intangible assets	1,073	17,698
Total Expenses	<u>596,311</u>	<u>634,695</u>
Operating Income	<u>153,192</u>	<u>270,297</u>
Other Income, net:		
Interest income	20,134	11,735
Interest expense	(11,930)	(10,972)
Other income (expense), net	2,235	(564)
Total Other Income, net	<u>10,439</u>	<u>199</u>
Income Before Income Taxes	<u>163,631</u>	<u>270,496</u>
Income Tax Provision	<u>30,025</u>	<u>3,445</u>
Net Income From Continuing Operations	<u>133,606</u>	<u>267,051</u>
Loss From Discontinued Operations — Net of Tax	<u>(5,420)</u>	<u>(71,831)</u>
Net Income — GAAP	<u>\$ 128,186</u>	<u>\$ 195,220</u>
GAAP Earnings (Loss) Per Ordinary Share - Basic:		
From continuing operations	\$ 0.79	\$ 1.61
From discontinued operations	\$ (0.03)	\$ (0.43)
From net income	\$ 0.76	\$ 1.18
GAAP Earnings (Loss) Per Ordinary Share - Diluted:		
From continuing operations	\$ 0.78	\$ 1.56
From discontinued operations	\$ (0.03)	\$ (0.42)
From net income	\$ 0.75	\$ 1.14
Weighted Average Number of Ordinary Shares Outstanding:		
Basic — GAAP and Non-GAAP	168,152	165,686
Diluted — GAAP and Non-GAAP	171,960	170,747

Condensed Consolidated Statements of Operations - GAAP (Continued) (In thousands, except per share data)	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
An itemized reconciliation between net income from continuing operations on a GAAP basis and EBITDA is as follows:		
Net Income from Continuing Operations	\$ 133,606	\$ 267,051
Adjustments:		
Depreciation expense	13,641	18,810
Amortization expense	1,073	17,698

Interest income	(20,134)	(11,735)
Interest expense	11,930	10,972
Income tax provision	30,025	3,445
EBITDA from Continuing Operations	170,141	306,241
EBITDA from Discontinued Operations	(6,429)	(77,380)
EBITDA	\$ 163,712	\$ 228,861

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

Net Income from Continuing Operations	\$ 133,606	\$ 267,051
Adjustments:		
Share-based compensation expense	53,356	48,210
Depreciation expense	13,641	18,810
Amortization expense	1,073	17,698
Separation expense	1,240	9,640
Income tax effect related to reconciling items	(2,061)	(179)
Gain on sale of Athlone manufacturing facility	(1,462)	—
Final award in the Janssen arbitration (2022 back royalties and interest)	—	(197,092)
Non-cash net interest expense	228	231
Non-GAAP Net Income from Continuing Operations	199,621	164,369
Non-GAAP Net Loss from Discontinued Operations	(5,420)	(67,676)
Non-GAAP Net Income	\$ 194,201	\$ 96,693

Non-GAAP diluted earnings per ordinary share from continuing operations	\$ 1.16	\$ 0.96
Non-GAAP diluted loss per ordinary share from discontinued operations	\$ (0.03)	\$ (0.40)
Non-GAAP diluted earnings per ordinary share from net income	\$ 1.13	\$ 0.57

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	June 30, 2024	December 31, 2023
Cash, cash equivalents and total investments	\$ 962,520	\$ 813,378
Receivables	366,415	332,477
Inventory	194,731	186,406
Contract assets	3,492	706
Prepaid expenses and other current assets	101,435	98,166
Property, plant and equipment, net	222,738	226,943
Intangible assets, net and goodwill	83,945	85,018
Assets held for sale	—	94,260
Deferred tax assets	167,382	195,888
Other assets	104,184	102,981
Total Assets	\$ 2,206,842	\$ 2,136,223
Long-term debt — current portion	\$ 3,000	\$ 3,000
Other current liabilities	512,548	512,678
Long-term debt	286,459	287,730
Liabilities from discontinued operations	—	4,542
Other long-term liabilities	120,830	125,587
Total shareholders' equity	1,284,005	1,202,686
Total Liabilities and Shareholders' Equity	\$ 2,206,842	\$ 2,136,223
Ordinary shares outstanding (in thousands)	165,887	166,980

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 quarter ended June 30, 2024, which the company intends to file in July 2024.

Alkermes plc and Subsidiaries
Amounts Included in Discontinued Operations

(In thousands)	Three Months Ended March 31, 2024	Three Months Ended June 30, 2024	Six Months Ended June 30, 2024
Cost of goods manufactured and sold	\$ —	\$ —	\$ —
Research and development	2,516	3,913	6,429
Selling, general and administrative	—	—	—
Income tax benefit	(396)	(613)	(1,009)
Loss from discontinued operations, net of tax	\$ 2,120	\$ 3,300	\$ 5,420

(In thousands)	Three Months Ended March 31, 2023	Three Months Ended June 30, 2023	Six Months Ended June 30, 2023
Cost of goods manufactured and sold	\$ 11	\$ 11	\$ 22
Research and development	29,867	32,563	62,430
Selling, general and administrative	6,644	9,502	16,146
Income tax benefit	(6,727)	(40)	(6,767)
Loss from discontinued operations, net of tax	\$ 29,795	\$ 42,036	\$ 71,831

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