Alkermes plc Reports Third Quarter 2022 Financial Results

November 2, 2022

— Third Quarter Revenues of $252.4 Million Reflect Strong Year-Over-Year Growth of Proprietary Commercial Product Portfolio —

— GAAP Loss per Share of $0.39 and Non-GAAP Earnings per Share of $0.02 —

— Company Announces Intent to Separate Oncology Business —

— Company Updates Financial Expectations for Full-Year 2022 —

DUBLIN, Nov. 2, 2022 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today reported financial results for the third quarter of 2022 and updated certain financial expectations for full-year 2022. Alkermes today also announced its intent, as approved by its Board of Directors (the Board), to explore a separation of its commercial-stage neuroscience business and development-stage oncology business.

"One year into the launch of LYBALVI®, we have gained confidence in its commercial potential and the opportunity it represents to be an important, long-term value driver for Alkermes. Our teams have made excellent progress in raising awareness of LYBALVI, establishing and expanding the foundation of prescribers, and driving patient access to this important new medicine," said Richard Pops, Chief Executive Officer of Alkermes. "We are proving the value of our distinctive commercial capabilities with the growth of our three proprietary products in complex and dynamic markets. At the same time, we've progressed our oncology portfolio with nemvaleukin in potential registration-enabling studies and our pipeline of preclinical engineered cytokines advancing behind it. As the value propositions for each of our neuroscience and oncology businesses have come more clearly into focus, separating the oncology business represents an important opportunity to unlock value for each business and position both for success."

"Our third quarter results demonstrate strong year-over-year growth of our proprietary commercial product portfolio and our continued focus on operational efficiency. The addition of LYBALVI to our portfolio of proprietary commercial products has highlighted the operating leverage we have built into the business and the growth potential it represents," commented Iain Brown, Chief Financial Officer of Alkermes. "As we approach the end of the year, we are pleased to raise certain of our financial expectations for 2022, primarily reflecting the strong performance of LYBALVI. We remain in a strong financial position to advance our strategic priorities with a focus on execution and driving shareholder value as we work to separate our neuroscience and oncology businesses."

Quarter Ended Sept. 30, 2022 Financial Results

Revenues

- Total revenues for the quarter were $252.4 million, compared to $294.1 million for the same period in the prior year.

- Net sales of proprietary products for the quarter were $199.4 million, compared to $157.7 million for the same period in the prior year.

  - Net sales of VIVITROL® were $96.5 million, compared to $88.8 million for the same period in the prior year, representing an increase of approximately 9%.
  - Net sales of ARISTADA®i were $75.7 million, compared to $68.9 million for the same period in the prior year, representing an increase of approximately 10%.
  - Net sales of LYBALVI were $27.1 million, following its commercial launch in October 2021.

- Manufacturing and royalty revenues for the quarter were $52.9 million, primarily driven by royalty revenues from long-acting INVEGA® products and VUMERITY®, partially offset by a one-time revenue reversal related to AMPYRA®. Manufacturing and royalty revenues were $136.3 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) were $26.7 million, compared to $79.3 million for the same period in the prior year. This decrease was driven primarily by Janssen Pharmaceutica N.V.'s 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 were $26.3 million, compared to $26.7 million for the same period in the prior year.
  - The company recorded a one-time reversal of royalty revenue of approximately $21.5 million in the quarter due to the outcome of recent arbitration proceedings related to agreements pertaining to AMPYRA, which includes a $16.5 million arbitration award and other royalty revenue that was previously recognized.

Costs and Expenses

- Total operating expenses for the quarter were $313.0 million, compared to $313.8 million for the same period in the prior year.

- Cost of Goods Manufactured and Sold was $50.6 million, compared to $49.6 million for the same period in the prior year.
- Research and Development (R&D) expenses were $100.4 million, compared to $118.4 million for the same period in the prior year. R&D expenses for the third quarter of 2021 included the accrual of a $25.0 million development milestone payment.
- Selling, General and Administrative (SG&A) expenses were $152.8 million, compared to $136.2 million for the same period in the prior year, reflecting increased investment in the launch of LYBALVI.

Profitability

- Net loss according to generally accepted accounting principles in the U.S. (GAAP) was $64.0 million for the quarter, or a basic and diluted GAAP loss per share of $0.39. This compared to GAAP net loss of $29.0 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 $3.5 million for the quarter, or a non-GAAP basic and diluted earnings per share of $0.02. This compared to non-GAAP net income of $23.6 million for the quarter, or a non-GAAP basic earnings per share of $0.15 and non-GAAP diluted earnings per share of $0.14, for the same period in the prior year.

Balance Sheet

- At Sept. 30, 2022, the company recorded cash, cash equivalents and total investments of $747.1 million, compared to $760.0 million at June 30, 2022. The company's total debt outstanding as of Sept. 30, 2022 was $293.9 million.

Financial Expectations for 2022

The following updated financial expectations for 2022 primarily reflect LYBALVI's launch performance to date, the company's current assumption that it will continue to receive royalty payments related to sales of the long-acting INVEGA products outside the U.S. through the end of the year and the impact of the AMPYRA royalty revenue reversal. All line items are according to GAAP, except as otherwise noted.

In millions (except per share amounts)	**Current 2022 Expectation** (Provided 11/2/22)	**Prior 2022 Expectation** (Provided 7/27/22)
Total Revenue	$1,070 – $1,120	$1,050 – $1,120
VIVITROL Net Sales	$370 – $380	$365 – $385
ARISTADA Net Sales	$300 – $310	$295 – $315
LYBALVI Net Sales	$88 – $95	$75 – $90
INVEGA Franchise Royalties*	$115 – $120	$95 – $100
Other revenues	$197 – $215	$220 – $230
Cost of Goods Sold	$220 – $230	$215 – $225
R&D Expenses	$385 – $400	$380 – $400
SG&A Expenses	$590 – $605	$575 – $605
Amortization of Intangible Assets	~$35	~$35
Interest Expense, Net	$5 – $10	$5 – $10
Other Expense, Net	~$20	~$15
Income Tax Benefit	$10 – $15	$10 – $15
GAAP Net Loss	($155) – ($185)	($145) – ($175)
GAAP Net Loss per Share[+]	($0.95) – ($1.13)	($0.88) – ($1.07)
Non-GAAP Net Income	$25 – $55	$15 – $45
Non-GAAP Earnings Per Share[+]	$0.15 – $0.33	$0.09 – $0.27
Capital Expenditures	$35 – $40	$35 – $40

*Reflects royalties related to sales of INVEGA SUSTENNA/INVEGA TRINZA/INVEGA HAFYERA in the U.S. through January 2022 and royalties related to sales of XEPLION/ TREVICTA/BYANNLI through December 2022.

[+] Current 2022 per share expectations are calculated based on a weighted average basic share count of approximately 164.0 million shares outstanding and a weighted average diluted share count of approximately 169.0 million shares outstanding.

Recent Events:

Psychiatry

- In September 2022, the company presented clinical, epidemiology and health economics and outcomes research related to its psychiatry portfolio at Psych Congress 2022.

Corporate

- In November 2022, the company announced approval by the Board to explore a separation of its commercial-stage neuroscience business and development-stage oncology business. The company, together with the Board and external financial and legal advisors, plans to explore a separation of the oncology business into an independent, publicly-traded company as part of an ongoing review of strategic alternatives for the oncology business. The separation, if consummated, is expected to be completed in the second half of 2023.
- In September 2022, 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.

Conference Call

Alkermes will host a conference call and webcast presentation with accompanying slides at 8:00 a.m. ET (12:00 p.m. GMT) on Wednesday, Nov. 2, 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 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 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 assumptions regarding royalty payments on sales of the long-acting INVEGA products outside the U.S., its commitment and plans to drive shareholder value, and its ability to execute on its strategic priorities; the company's plans to explore separation of its neuroscience and oncology businesses, including the anticipated timing, structure and benefits of a potential separation and expectations concerning the future financial and operating performance, business plans or prospects of the two businesses, if separated; 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 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 potential separation; the company may be unable to make, on a timely or cost-effective basis, the changes necessary to separately operate its neuroscience and oncology businesses; the potential separation or announcement thereof 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, or other disputes related to the company's products or products using the company's proprietary technologies, including the arbitration proceedings with Janssen Pharmaceutica N.V.; 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), including the company's Quarterly Report on Form 10-Q for the quarter ended Sept. 30, 2022, 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.

Biogen Inc., used by Alkermes under license; and AMPYRA® is a registered trademark of Acorda Therapeutics, Inc.

(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, 2022**	**Three Months Ended September 30, 2021**
Revenues:		
Product sales, net	$ 199,380	$ 157,737
Manufacturing and royalty revenues	52,941	136,294
Research and development revenue	36	110
Total Revenues	252,357	294,141
Expenses:		
Cost of goods manufactured and sold	50,625	49,561
Research and development	100,430	118,411
Selling, general and administrative	152,777	136,213
Amortization of acquired intangible assets	9,166	9,615
Total Expenses	312,998	313,800
Operating Loss	(60,641)	(19,659)
Other Expense, net:		
Interest income	2,239	468
Interest expense	(3,552)	(2,437)
Change in the fair value of contingent consideration	(3,553)	(5,195)
Other (expense) income, net	(1,861)	288
Total Other Expense, net	(6,727)	(6,876)
Loss Before Income Taxes	(67,368)	(26,535)
(Benefit) Provision for Income Taxes	(3,394)	2,453
Net Loss — GAAP	$ (63,974)	$ (28,988)
(Loss) Earnings Per Share:		
GAAP loss per share — basic and diluted	$ (0.39)	$ (0.18)
Non-GAAP earnings per share — basic	$ 0.02	$ 0.15
Non-GAAP earnings per share — diluted	$ 0.02	$ 0.14
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	164,282	161,456
Basic — Non-GAAP	164,282	161,456
Diluted — Non-GAAP	168,762	166,758
An itemized reconciliation between net loss on a GAAP basis and non-GAAP net income is as follows:		
Net Loss — GAAP	$ (63,974)	$ (28,988)
Adjustments:		
Share-based compensation expense	26,051	25,600
Depreciation expense	10,431	9,775
Amortization expense	9,166	9,615
Legal settlement	15,905	—
Income tax effect related to reconciling items	(17)	2,243
Non-cash net interest expense	116	117
Reduction in the fair value of contingent consideration and other related assets	5,835	5,195
Non-GAAP Net Income	$ 3,513	$ 23,557

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, 2022**	**Nine Months Ended September 30, 2021**
Revenues:		
Product sales, net	$ 561,435	$ 448,508
Manufacturing and royalty revenues	243,437	398,435
License revenue	2,000	1,500

Research and development revenue	249	845
Total Revenues	807,121	849,288
Expenses:		
Cost of goods manufactured and sold	164,144	143,705
Research and development	289,256	308,152
Selling, general and administrative	448,206	400,569
Amortization of acquired intangible assets	27,198	28,532
Total Expenses	928,804	880,958
Operating Loss	(121,683)	(31,670)
Other Expense, net:		
Interest income	3,708	1,955
Interest expense	(8,271)	(8,814)
Change in the fair value of contingent consideration	(21,750)	(677)
Other income (expense), net	2,380	(327)
Total Other Expense, net	(23,933)	(7,863)
Loss Before Income Taxes	(145,616)	(39,533)
(Benefit) Provision for Income Taxes	(15,603)	9,509
Net Loss — GAAP	$ (130,013)	$ (49,042)
(Loss) Earnings Per Share:		
GAAP loss per share — basic and diluted	$ (0.79)	$ (0.31)
Non-GAAP earnings per share — basic	$ 0.21	$ 0.56
Non-GAAP earnings per share — diluted	$ 0.20	$ 0.55
Weighted Average Number of Ordinary Shares Outstanding:		
Basic and diluted — GAAP	163,541	160,642
Basic — Non-GAAP	163,541	160,642
Diluted — Non-GAAP	167,687	164,077

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

Net Loss — GAAP	$ (130,013)	$ (49,042)
Adjustments:		
Share-based compensation expense	67,771	68,603
Depreciation expense	30,988	28,978
Amortization expense	27,198	28,532
Legal settlement	15,905	—
Income tax effect related to reconciling items	(2,593)	10,349
Non-cash net interest expense	350	352
Reduction in the fair value of contingent consideration and other related assets	24,032	677
Debt refinancing charge	—	2,109
Non-GAAP Net Income	$ 33,638	$ 90,558

Condensed Consolidated Balance Sheets (In thousands)	**September 30, 2022**	**December 31, 2021**
Cash, cash equivalents and total investments	$ -	$ -
Receivables	-	-
Inventory	-	-
Contract assets	-	-
Prepaid expenses and other current assets	-	-
Property, plant and equipment, net	(8,666)	-
Intangible assets, net and goodwill	-	-
Other assets	1	-
Total Assets	$ (8,665)	$ -
Long-term debt — current portion	$ -	$ -
Other current liabilities	-	-
Long-term debt	-	-
Contract liabilities — long-term		
Other long-term liabilities	(6,384)	(1)
Total shareholders' equity	(2,282)	-
Total Liabilities and Shareholders' Equity	$ (8,666)	$ (1)
Ordinary shares outstanding (in thousands)	164,303	161,937

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, 2022, which the company intends to file in November 2022.

2022 Guidance — GAAP to Non-GAAP Adjustments

An itemized reconciliation between projected loss per share on a GAAP basis and projected earnings per share on a non-GAAP basis is as follows:

(In millions, except per share data)	Amount	Shares
Projected Net Loss — GAAP	$ (170.0)	164
Adjustments:		
Share-based compensation expense	91.0	
Depreciation expense	40.0	
Amortization expense	35.0	
Change in the fair value of contingent consideration	24.0	
Legal settlement	16.0	
Income tax effect related to reconciling items	3.0	
Non-cash net interest expense	1.0	
Projected Net Income — Non-GAAP	$ 40.0	169

Projected GAAP and non-GAAP measures reflect mid-points within ranges of estimated guidance.

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