UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 2, 2022

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**001-35299**	**98-1007018**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Connaught House, 1 Burlington Road
Dublin 4, Ireland D04 C5Y6
(Address of principal executive offices)

Registrant's telephone number, including area code: + 353-1-772-8000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Ordinary shares, $0.01 par value	ALKS	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 2, 2022, Alkermes plc (the "Company") announced financial results for the three and nine months ended September 30, 2022 and updated certain financial expectations for the year ending December 31, 2022. Copies of the related press release and the investor presentation to be displayed during the Company's conference call on November 2, 2022 discussing such financial results and financial expectations are furnished herewith as Exhibit 99.1 and Exhibit 99.2, respectively. This information, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On November 2, 2022, the Company issued a press release announcing its intent, as approved by its board of directors, to explore a separation of its commercial-stage neuroscience business and development-stage oncology business. The Company 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. Copies of the investor presentation to be displayed during the Company's conference call on November 2, 2022 discussing such potential separation and the related press release are furnished herewith as Exhibit 99.2 and Exhibit 99.3, respectively. This information, including Exhibits 99.2 and 99.3, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Alkermes plc on November 2, 2022 announcing financial results for the three and nine months ended September 30, 2022 and updated financial expectations for the year ending December 31, 2022.
99.2	Investor presentation to be displayed by Alkermes plc on November 2, 2022.
99.3	Press release issued by Alkermes plc on November 2, 2022 announcing its intent to explore a separation of its neuroscience and oncology businesses.
104	Cover page interactive data file (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALKERMES PLC

Date: November 2, 2022

By: /s/ Iain M. Brown
Iain M. Brown
Senior Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

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

Alkermes plc Reports Third Quarter 2022 Financial Results

— 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 — 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.

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

(tables follow)

[1] 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

Alkermes plc and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Balance Sheets (In thousands)	September 30, 2022	December 31, 2021
Cash, cash equivalents and total investments	$ 747,110	$ 765,741
Receivables	257,173	313,193
Inventory	166,296	150,335
Contract assets	10,105	13,363
Prepaid expenses and other current assets	40,041	48,967
Property, plant and equipment, net	326,350	341,054
Intangible assets, net and goodwill	139,718	166,916
Other assets	255,106	224,915
Total Assets	$ 1,941,899	$ 2,024,484
Long-term debt — current portion	$ 3,000	$ 3,000
Other current liabilities	466,555	468,286
Long-term debt	290,904	292,804
Other long-term liabilities	138,586	147,810
Total shareholders' equity	1,042,854	1,112,584
Total Liabilities and Shareholders' Equity	$ 1,941,899	$ 2,024,484
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.

Alkermes plc and Subsidiaries
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	(Loss) Earnings Per Share
Projected Net Loss — GAAP	$ (170.0)	164	$ (1.04)
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	$ 0.24

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

Proposed Separation of Oncology Business & Third Quarter 2022 Financial Results

November 2, 2022

Forward-Looking Statements and Non-GAAP Financial Information

Certain statements set forth in this presentation 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: Alkermes plc's (the "Company") expectations concerning its future financial, commercial and operating performance, business plans or prospects, including its assumptions regarding royalty payments on sales of XEPLION®, TREVICTA® and BYANNLI ® outside the U.S. through December 2022, and expectations concerning revenue growth, value creation and profitability; the Company's plans to separate its neuroscience and oncology businesses, including the anticipated timing, structure, costs and benefits of the proposed separation and expectations concerning the anticipated business profiles and 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 and product candidates, including the broad potential clinical utility of nemvaleukin. The Company cautions that forward-looking statements are inherently uncertain. The forward-looking statements contained in this presentation 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, assumptions and uncertainties. These risks, assumptions and uncertainties include, among others: the Company may not be able to achieve its targeted financial and profitability metrics in a timely manner or at all; the impacts of the ongoing COVID-19 pandemic and continued efforts to mitigate its spread on the Company's business, results of operations or financial condition; 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 neuroscience and oncology businesses; disruption to the Company's operations resulting from the planned 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 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 the arbitration proceedings with Janssen Pharmaceutica N.V. ("Janssen") and so-called "Paragraph IV" litigation or 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 other regulatory authorities may not agree with the Company's regulatory approval strategies or components of the Company's marketing applications and 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, assumptions 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 September 30, 2022, which are available on the SEC's website at www.sec.gov, and on the Company's website at www.alkermes.com in the 'Investors – SEC filings' section. 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 presentation.

Non-GAAP Financial Measures: This presentation 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 non-GAAP earnings per share. 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. 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. Reconciliations of non-GAAP financial measures to the most directly comparable GAAP financial measures, to the extent reasonably determinable, can be found in the Appendix of this presentation.

Note Regarding Trademarks: The Company and its affiliates are the owners of various U.S. federal trademark registrations (®) and other trademarks (™), including ARISTADA®, ARISTADA INITIO®, LYBALVI® and VIVITROL®. Any other trademarks referred to in this presentation are the property of their respective owners. Appearances of such other trademarks herein should not be construed as any indicator that their respective owners will not assert their rights thereto.

Agenda

- **Introduction**
  Sandy Coombs, SVP, Investor Relations & Corporate Affairs
- **Proposed Separation of Oncology Business**
  Richard Pops, Chief Executive Officer
- **Q3 2022 Financial Results**
  Iain Brown, Chief Financial Officer
- **Q3 2022 Commercial Review**
  Todd Nichols, Chief Commercial Officer
- **Q&A**

Alkermes Today

Significant, diverse revenues with new growth opportunities

LYBALVI® olanzapine and samidorphan

ARISTADA® aripiprazole lauroxil

Vivitrol® (naltrexone for extended-release injectable suspension) 380 mg/vial

VUMERITY® (diroximel fumarate)

Licensed to and commercialized by Biogen (royalty & manufacturing revenue)

Pipeline of novel development candidates designed to target significant unmet needs

Neuroscience		Oncology	
ALKS 2680	• Phase 1 • Narcolepsy	**Nemvaleukin Alfa**	• Phase 2/3 • Advanced solid tumors
HDAC Inhibitors	• Preclinical • Neurology/neuropsychiatry	**IL-12 IL-18**	• Preclinical • Advanced solid tumors

Clear Value Propositions for Neuroscience and Oncology

Neuroscience

- Commercial progress
  - Strong uptake of LYBALVI® one year into launch
  - Continued growth of VIVITROL® and ARISTADA®
- Pipeline advancements
  - ALKS 2680: Orexin 2 receptor agonist, entering phase 1; Proof-of-Concept study data expected in 2023
- Profitability
  - Established commercial infrastructure that provides opportunity to drive operating leverage and profitability
- Strong investor focus on neuroscience and profitable biopharmaceutical companies

Oncology

- Late-stage development asset
  - Nemvaleukin alfa: novel, investigational, engineered IL-2 variant and potential first-in-class cancer immunotherapy
    - Potential registration-enabling studies underway in two difficult-to-treat tumor types
    - Potential to be used in a wider range of combinations and tumor types
- Protein engineering capabilities and pipeline
  - Additional preclinical engineered cytokines: IL-12 and IL-18
- Enhanced value proposition of biologics post-Inflation Reduction Act

Exploring Separation of Oncology Business as Part of Ongoing Board-Level Review of Strategic Alternatives

Separation of the oncology business expected to drive benefits for both neuroscience and oncology businesses

- Drive a sharp strategic focus with distinct management teams with relevant therapeutic expertise
- Simplify capital allocation decision-making and increase flexibility
- Enable capital markets to better assess value, performance and potential, and attract a long-term shareholder base suited to each business

Post-Separation Alkermes‡
Pure-Play, Commercial-Stage Neuroscience Company

Builds on Alkermes heritage of innovation and excellence in neuroscience

Proprietary Products

- Topline primarily driven by growth of proprietary commercial products in addiction and psychiatry

Vivitrol (naltrexone for extended-release injectable suspension) ARISTADA (aripiprazole lauroxil extended-release injectable suspension) LYBALVI (olanzapine and samidorphan)

Commercial Capabilities

- Established commercial capabilities in psychiatry and addiction
- Opportunity to capture operating leverage

Development Pipeline

- Early-stage neuroscience pipeline:
  - ALKS 2680, orexin 2 receptor agonist in phase 1
  - Portfolio of preclinical neuroscience assets

Separation expected to enhance profitability

‡ Assuming separation is effected through a spin-off of the oncology business into an independent, publicly-traded company

Post-Separation Oncology Co.‡
Pure-play, Development-Stage Oncology Company

Investment thesis anchored by potential medical and economic value of nemvaleukin alfa:

- Potential first-in-class IL-2 variant immunotherapy
- Anti-tumor activity observed both as a single agent and with checkpoint inhibitors (CPI), in CPI-unapproved tumor types and post-CPI settings
- Potential registration-enabling studies underway in mucosal melanoma* and platinum-resistant ovarian cancer**, each with FDA Fast Track Designation
- Multiple potential routes of administration/dosing schedules being investigated

Sophisticated protein engineering platform capabilities and early-stage development assets

- Tumor-targeted split IL-12 program
- IL-18 program

Nemvaleukin has **broad potential clinical utility and offers an opportunity for significant value creation** as the development program advances and expands.

Highly-experienced team with **scientific and clinical trial expertise** to efficiently advance pipeline.

Opportunity to attract **oncology-focused investors**.

* Also granted FDA Orphan Drug Designation; **In combination with pembrolizumab
‡ Assuming separation is effected through a spin-off of the oncology business into an independent, publicly-traded company

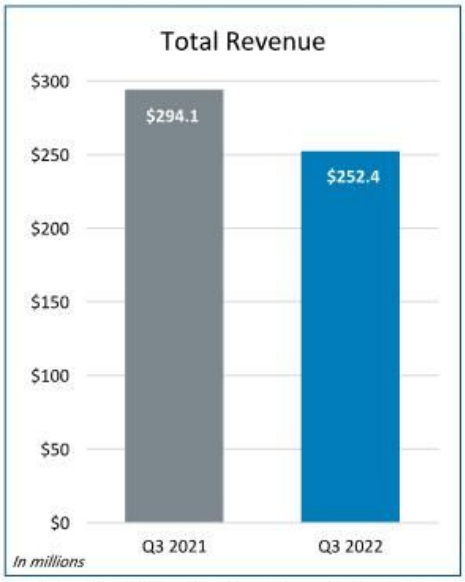
Potential Separation‡: Next Steps

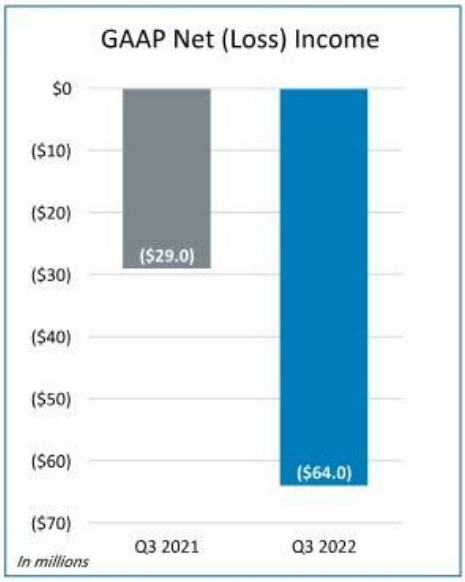
Timing	• Separation, if consummated, expected to be completed in H2 2023
Financial Expectations	• Expect to incur transactional and separation expenses prior to completion of any separation • 2023 financial expectations and long-term profitability targets for Alkermes to be discussed on February 2023 earnings call
Leadership	• Oncology Co.: Details on management and board of directors to be provided at a later date • Alkermes: Richard Pops to continue as CEO and Chairman
Location	• Oncology Co. expected to be located within Alkermes' existing Waltham, Mass. campus • Facilities and research and manufacturing operations in Wilmington, Ohio and Athlone, Ireland expected to remain with Alkermes
Closing Conditions	• Final approval by Alkermes Board of Directors • Customary closing conditions

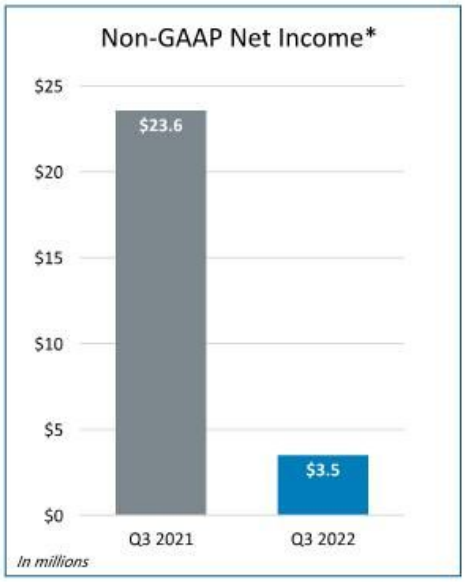
‡ Assuming separation is effected through a spin-off of the oncology business into an independent, publicly-traded company

Q3 Financial and Operational Performance

Q3 2022 Financial Results Summary







* Reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure can be found in the Appendix of this presentation.

Third Quarter 2022 Revenue Summary

In millions, except %	Q3'22	Q3'21	Δ Q3'22 vs. Q3'21
Total Proprietary Net Sales	$199.4	$157.7	26%
VIVITROL®	$96.5	$88.8	9%
ARISTADA®*	$75.7	$68.9	10%
LYBALVI®	$27.1	-	NA
Manufacturing & Royalty Revenue**†	$52.9	$136.3	(61%)
Research & Development Revenue	$0.0	$0.1	NA
Total Revenue	$252.4	$294.1	(14%)

Amounts in the table above may not sum due to rounding.

*Inclusive of ARISTADA INITIO®

**In Q3'22, 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 in Q3'21. This decrease was driven by Janssen's partial termination of the license agreement related to sales of the long-acting INVEGA products in the U.S., effective Feb. 2, 2022. In April 2022, Alkermes commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of the license agreement and Janssen's royalty and other obligations under the agreement.

† In Q3'22, the Company recorded a one-time reversal of royalty revenue of approximately $21.5 million 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.

Alkermes: 2022 Financial Expectations*

(in millions, except per share amounts)	**Current Financial Expectations for Year Ending Dec. 31, 2022** *(Provided 11/2/22)*	Previous Financial Expectations for Year Ending Dec. 31, 2022 *(Provided 7/27/22)*
Revenues	$1,070 – $1,120	$1,050 – $1,120
COGS	$220 – $230	$215 – $225
R&D Expense	$385 – $400	$380 – $400
SG&A Expense	$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 (Basic and Diluted)‡	$0.15 – $0.33	$0.09 – $0.27

- Expected net sales of proprietary products:
  - VIVITROL® net sales of $370M – $380M
  - ARISTADA® net sales of $300M – $310M
  - LYBALVI® net sales of $88M – $95M
- Assumes $115M – $120M of royalties related to sales of INVEGA SUSTENNA®, INVEGA TRINZA® and INVEGA HAFYERA® in the U.S. through January 2022 and sales of XEPLION®, TREVICTA® and BYANNLI® outside the U.S. through December 2022

*These expectations are provided by the Company on Nov. 2, 2022 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm these expectations.
‡Reconciliation of these non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the Appendix of this presentation.

VIVITROL® Performance and Expectations

- Q3'22 year-over-year net sales increased 9% to $96.5M
  - Gross-to-net deductions: 51.2% in Q3'22, compared to 52.3% in Q3'21
- FY'22 net sales expected to range from $370M – $380M*
  - Expect gross-to-net deductions of ~51% in FY'22

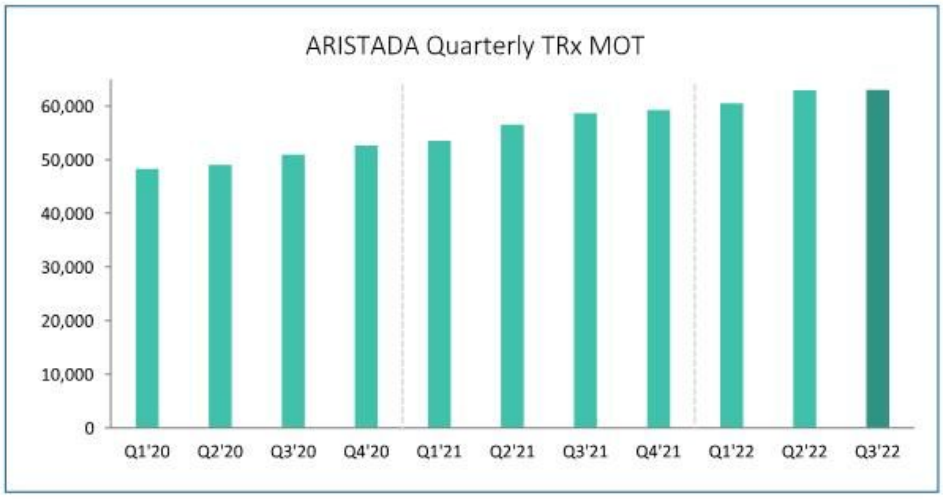
* These expectations are provided by the Company on Nov. 2, 2022 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

ARISTADA® Performance and Expectations

- Q3'22 year-over-year net sales increased 10% to $75.7M
  - Gross-to-net deductions: 54.6% in Q3'22, compared to 54.8% in Q3'21
- FY'22 net sales expected to range from $300M - $310M†*
  - Expect gross-to-net deductions of ~54% in FY'22

*Inclusive of ARISTADA INITIO®
† These expectations are provided by the Company on Nov. 2, 2022 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

ARISTADA® Prescription Growth Trends



- Q3'22 year-over-year growth of 7% on TRx months of therapy (MOT) basis
- Market share:
  - TRx MOT: 10% of atypical LAI market prescriptions in Q3'22

Source: IQVIA NPA

LYBALVI® Performance and Expectations

- Q3'22 net sales of $27.1M reflect 35% sequential growth compared to Q2'22
  - Q3'22 gross-to-net deductions: ~26%, reflecting continued less restrictive initial commercial payer coverage than anticipated, which reduced the cost associated with patient copay assistance program
- FY'22 net sales expected to range from $88M - $95M†
  - Expect gross-to-net deductions of ~27% in FY'22

† These expectations are provided by the Company on Nov. 2, 2022 and are effective only as of such date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

LYBALVI® Prescription Growth Trends

- Q3'22 total TRx: ~23,000 reflecting 35% sequential growth compared to Q2'22
- ~6,000 prescribers had written a prescription for LYBALVI since launch reflecting 41% increase since Q2'22

*Source: IQVIA NPA Weekly

Appendix

Appendix: Financial Results GAAP to Non-GAAP Adjustments

(In millions)	Quarter Ended September 30, 2022	Quarter Ended September 30, 2021
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
Change in the fair value of contingent consideration	5,835	5,195
Non-GAAP Net Income	$ 3,513	$ 23,557

Appendix: 2022 Guidance GAAP to Non-GAAP Adjustments

(In millions, except per share data)	Year Ended December 31, 2022	Shares	(Loss) Earnings Per Share
Projected Net Loss — GAAP	$ (170.0)	164	$ (1.04)
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	$ 0.24

Projected GAAP and non-GAAP measures reflect the mid-points within our financial expectations ranges.

www.alkermes.com

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Alkermes plc Announces Intent to Separate Oncology Business

— Alkermes to Focus on Profitable Growth of Pure-Play, Commercial-Stage Neuroscience Business —

— Separation Expected to Unlock Value Through Sharpened Strategic Focus, Simplified Capital Allocation Decision-Making, and Distinct Investment Profiles —

— Company to Host Webcast Today at 8 a.m. ET —

DUBLIN, Nov. 2, 2022 — Alkermes plc (Nasdaq: ALKS) today announced approval by its Board of Directors (the Board) to explore separating 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 (Oncology Co.) as part of an ongoing review of strategic alternatives for the oncology business.
Alkermes believes separation of the oncology business into Oncology Co. would:

- Drive a sharp strategic focus for each business;
- Establish separate and distinct management teams with relevant therapeutic expertise based on each business' unique strategic priorities and opportunities;
- Simplify capital allocation decision-making and increase flexibility to pursue growth and investment strategies more directly aligned with each business' respective goals; and
- Enable the capital markets to better assess each business' value, performance and potential, and attract a long-term shareholder base suited to each business.

"Alkermes will continue to build on our heritage of innovation and excellence in neuroscience. With a strong topline driven by the growth of our proprietary products, a specialized commercial infrastructure in neuropsychiatry and addiction, and proven drug development capabilities, the standalone neuroscience business represents a compelling opportunity to capture operating leverage, drive growth and profitability, and advance new potential medicines for neurological disorders," said Richard Pops, Chief Executive Officer of Alkermes. "With nemvaleukin now in two potential registrational studies, the oncology business has a compelling standalone investment thesis anchored by the potential medical and economic value of this potential first-in-class cancer therapy. We believe separating the oncology business at this time will best support and position nemvaleukin for success, create value for shareholders, and enable efficient advancement of our preclinical pipeline of engineered cytokines."

Expected Business Profiles:

Alkermes: Profitable, Pure-Play Commercial-Stage Neuroscience Company

Alkermes will retain its focus on significant unmet needs within neuroscience and on driving growth of its proprietary commercial products: LYBALVI®, ARISTADA®/ARISTADA INITIO® and VIVITROL®. The company will also focus on advancing the development of pipeline programs focused on neurological disorders, including ALKS 2680, an orexin 2 receptor agonist for the treatment of narcolepsy. Alkermes expects to retain manufacturing and royalty revenues related to its licensed products and third-party products using the company's proprietary technologies under license. Alkermes would expect to benefit from enhanced profitability and continued balance sheet strength following a separation of the oncology business. Richard Pops will continue as Chief Executive Officer and Chairman of Alkermes.

Oncology Co.: Pure-Play Development-Stage Oncology Company

The oncology business would continue to focus on the discovery and development of cancer therapies, including the continued development of nemvaleukin alfa (nemvaleukin), a novel, investigational, engineered interleukin-2 (IL-2) variant immunotherapy. Nemvaleukin is currently in potential registration enabling studies in two difficult-to-treat tumor types: platinum-resistant ovarian cancer and mucosal melanoma. By selectively targeting the IL-2 pathway, nemvaleukin has broad potential clinical utility in a variety of tumor types and offers the potential for significant value creation as the development program advances. The assets subject to a separation are also expected to include a portfolio of novel, preclinical, engineered cytokines, including tumor-targeted split interleukin-12 (IL-12) and interleukin-18 (IL-18).

“The potential separation of the oncology business from Alkermes’ neuroscience business would offer a platform to enhance the performance of both businesses and unlock shareholder value. With the early traction of the LYBALVI launch and progress in the nemvaleukin development program, the value propositions for each of the neuroscience and oncology businesses have come more clearly into focus. As we look ahead, the Board unanimously agrees that the unique needs of each business would be best served by simplified resource and capital allocation decision making, tailored operating structures, and distinct leadership teams, each with a clearly defined strategic focus,” said Nancy Wysenski, Lead Independent Director of Alkermes’ Board.

Process & Strategic Rationale

In 2020, the Board, working closely with management and external financial and legal advisors, commenced an evaluation of a broad range of potential strategic options for the company’s non-core assets, including an evaluation of strategic partnerships and other opportunities for its oncology business. With the advancement of nemvaleukin into potential registration enabling studies and recent developments in the healthcare industry generally, the Board and leadership believe that separating the oncology business at this time is in the best interests of patients, shareholders and other key stakeholders.

Financial Implications

In preparation for a potential separation, Alkermes will continue to carefully manage the cost structure of each business. The company would expect to incur transactional and separation expenses as part of a process to separate and transition the two businesses. Alkermes expects to provide additional financial details at a later date.

Transition and Timing

Additional details regarding a separation, including the name of the contemplated Oncology Co., its executive management team and its board of directors, as well as financial details for the two contemplated companies, would be provided at a later date. The separation, if consummated, is expected to be completed in the second half of 2023. Alkermes anticipates Oncology Co. would be located within the company’s existing Waltham, Mass. campus. The facilities and research and manufacturing operations in Wilmington, Ohio and Athlone, Ireland will remain with Alkermes.

Separation of the two businesses would be subject to customary closing conditions and final approval by Alkermes’ Board of Directors. There can be no assurance regarding the ultimate timing or structure of a contemplated separation or that the separation will ultimately occur.

Morgan Stanley and BofA Securities are serving as financial advisers to Alkermes, and Goodwin Procter LLP and Arthur Cox are serving as its legal counsel.

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.

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 intent to explore separating its neuroscience and oncology businesses, including the anticipated timing, structure, benefits and costs of a potential separation; the company's expectations concerning the business profiles and future financial and operating performance, business plans or prospects of the two businesses if separated, including its assumptions regarding growth and profitability, its commitment and plans to drive shareholder value, and the ability of the businesses to execute on their respective strategic priorities and advance their development programs; 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 may not ultimately separate the oncology business during 2023 or at all; unanticipated developments, costs or difficulties that may delay or otherwise negatively affect a potential separation; disruption to the company's operations resulting from a 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; a potential separation or announcement thereof may adversely impact the company's ability to attract or retain key personnel; 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 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; 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.

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