

**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): May 31, 2023

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction
of incorporation)

001-35299
(Commission
File Number)

98-1007018
(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 7.01 Regulation FD Disclosure.

On June 6, 2023, Alkermes plc (together with its subsidiaries, the “Company”) issued a press release related to the matter described in Item 8.01 below, a copy of which is furnished herewith as Exhibit 99.1 and is incorporated herein by reference. This Item 7.01 and Exhibit 99.1 furnished herewith shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and this Item 7.01 and Exhibit 99.1 shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On May 31, 2023, the Company received a final award (the “Final Award”) from the arbitral tribunal (the “Tribunal”) in the Company’s binding arbitration proceedings with Janssen Pharmaceutica N.V. (“Janssen”), a subsidiary of Johnson & Johnson, in respect of two license agreements. The Final Award reiterates the Tribunal’s findings from, and incorporates by reference, the First Interim Award and Second Interim Award issued by the Tribunal on December 21, 2022 and April 19, 2023, respectively. In connection with the Final Award, the Company raised its financial expectations for 2023 by approximately \$425 million, which includes back royalties of approximately \$194 million (inclusive of interest through March 15, 2023) related to 2022 U.S. net sales of INVEGA SUSTENNA[®], INVEGA TRINZA[®], INVEGA HAFYERA[®] and CABENUVA[®], and anticipated royalty revenues related to 2023 global net sales of these products. In addition, the Company is entitled to future royalty revenues from Janssen related to net sales of these products, as outlined in the Final Award.

This arbitration was conducted pursuant to the Institute for Conflict Prevention and Resolution (CPR) Rules for Non-Administered Arbitration before a panel of three arbitrators.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Alkermes plc on June 6, 2023.
104	Cover page interactive data file (embedded within the Inline XBRL document).

Note Regarding Forward-Looking Statements

Certain statements set forth or incorporated by reference in Item 8.01 above constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to, statements concerning the Company’s revised financial expectations for 2023 and expectations regarding future royalty revenues related to INVEGA SUSTENNA, INVEGA TRINZA, INVEGA HAFYERA and CABENUVA. 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, that the Final Award may be challenged by Janssen, 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 December 31, 2022 and in subsequent filings made by the Company with the U.S. Securities and Exchange Commission (“SEC”), which are available on the SEC’s website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in Item 8.01.

INVEGA SUSTENNA[®], INVEGA TRINZA[®], and INVEGA HAFYERA[®] are registered trademarks of Johnson & Johnson or its affiliated companies. CABENUVA[®] is a registered trademark of ViiV Healthcare UK (No.3) Limited.

Alkermes Contacts:

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

Alkermes Announces Final Award in Janssen Pharmaceutica Arbitration and Provides Updated Financial Expectations

— Company Raises 2023 Revenue and GAAP Net Income Expectations by Approximately \$425 Million —

— Conference Call Scheduled for Today at 8:00 a.m. ET —

DUBLIN, June 6, 2023 – Alkermes plc (Nasdaq: ALKS) today announced that on May 31, 2023 it received a final award (the Final Award) from the arbitral tribunal (the Tribunal) in its arbitration proceedings with Janssen Pharmaceutica N.V. (Janssen), a subsidiary of Johnson & Johnson, in respect of two license agreements. In connection with the Final Award, the company raised its financial expectations for 2023 by approximately \$425 million, which includes back royalties of approximately \$194 million (inclusive of interest through March 15, 2023) related to 2022 U.S. net sales of the long-acting INVEGA[®] products and CABENUVA[®] that the company has now received from Janssen, and anticipated royalty revenues related to 2023 global net sales of these products. In addition, the company is entitled to future royalty revenues from Janssen related to these products in 2024 and beyond as outlined in the Final Award and as summarized below.

“We are gratified to have final resolution in this arbitration. Alkermes’ technology and know-how enabled the development of the products covered by the license agreements — medicines that have benefited millions of patients around the world. From the outset, we believed strongly that Janssen was not entitled to cease paying royalties due to Alkermes on sales of these products,” said Richard Pops, Chief Executive Officer of Alkermes. “This outcome reestablishes significant cash flows to Alkermes, provides strategic capital to our balance sheet and strengthens our longer-term financial profile by clarifying the distinct royalty term for each product covered by the license agreements.”

The Final Award reiterates the Tribunal’s findings from, and incorporates by reference, the first and second Interim Awards (issued on Dec. 21, 2022 and April 19, 2023, respectively) that:

- While Janssen may terminate the license agreements, it may not continue to sell Products (as defined in the license agreements) developed during the term of the license agreements without paying royalties pursuant to the terms of the respective agreements;
 - Back royalties related to U.S. sales in 2022 of approximately \$194 million (inclusive of interest through March 15, 2023) are due to Alkermes from Janssen under the two agreements;
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- A separate Know-How Royalty (as defined in the applicable license agreement) term applies for each of INVEGA SUSTENNA[®], INVEGA TRINZA[®] and INVEGA HAFYERA[®], as follows:
 - o The term for INVEGA SUSTENNA ends on Aug. 20, 2024;
 - o The term for INVEGA TRINZA ends in the second quarter of 2030 (but no later than May 2030 when the applicable license agreement expires); and
 - o The term for INVEGA HAFYERA ends in May 2030 (when the applicable license agreement expires); and
- Royalties for CABENUVA[®] in the U.S. are owed until Dec. 31, 2036.

“We are pleased to raise our financial expectations for 2023 based on the outcome of the arbitration proceedings with Janssen. Our revised 2023 expectations reflect the payment of back royalties and interest for 2022 and the reinstatement of royalties for 2023, which we expect will increase total revenues and GAAP net income by approximately \$425 million for the year,” stated Iain Brown, Chief Financial Officer of Alkermes. “We expect these royalty revenues to be incrementally accretive to Alkermes’ bottom line in 2023 and beyond as we continue to manage our business to drive profitability for the benefit of Alkermes’ shareholders.”

In accordance with the license agreements, the arbitration was conducted pursuant to the Institute for Conflict Prevention and Resolution (CPR) Rules for Non-Administered Arbitration before a panel of three arbitrators.

Updated Financial Expectations for 2023

The following financial expectations for 2023 reflect the company’s revised assumptions, based on the Final Award, that it will receive royalty payments from Janssen related to worldwide sales of the long-acting INVEGA products (INVEGA SUSTENNA, XEPLION[®], INVEGA TRINZA, TREVICTA[®], INVEGA HAFYERA and BYANNLI[®]) and CABENUVA for the full year. In May 2023, the company received payment from Janssen for back royalties related to 2022 of approximately \$194 million (inclusive of interest through March 15, 2023). This payment will be recorded in the second quarter of 2023 as “Royalty and Manufacturing Revenues” and will be excluded from the company’s non-GAAP net income measure due to the one-time and out-of-period nature of the revenue. These financial expectations continue to reflect Alkermes’ combined neuroscience and oncology business for the full year, as the company works toward the planned separation of its oncology business, which it continues to expect to complete in the second half of the year.

All line items set forth below are according to GAAP, except as otherwise noted.

In millions (except per share amounts)

Updated 2023 Expectations (Provided June 6, 2023)	Prior 2023 Expectations (Provided April 26, 2023)
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Total Revenue	\$1,550 – \$1,680	\$1,130 – \$1,250
VIVITROL [®] Net Sales	\$380 – \$410	\$380 – \$410
ARISTADA [®] Net Sales	\$315 – \$345	\$315 – \$345
LYBALVI [®] Net Sales	\$180 – \$205	\$180 – \$205
INVEGA Franchise Royalties related to 2023	\$265 – \$280	\$40 – \$45*
Royalties and interest related to 2022	~\$195	-
Other Revenues	\$215 – \$245	\$215 – \$245
Cost of Goods Sold	\$230 – \$250	\$230 – \$250
R&D Expenses	\$370 – \$400	\$370 – \$400
SG&A Expenses	\$695 – \$725	\$695 – \$725
Amortization of Intangible Assets	~\$35	~\$35
Interest Expense, Net	\$5 – \$10	\$5 – \$10
Income Tax Benefit	\$5 – \$10	\$5 – \$10
GAAP Net Income (Loss)	\$225 – \$265	(\$160) – (\$200)
GAAP Earnings (Loss) per Share (Diluted) ⁺	\$1.31 – \$1.54	(\$0.96) – (\$1.20)
Non-GAAP Net Income [†]	\$230 – \$270	\$0 – \$40
Non-GAAP Earnings Per Share (Diluted) ⁺	\$1.34 – \$1.57	\$0.00 – \$0.23
Capital Expenditures	\$35 – \$40	\$35 – \$40

*Previous expectations provided on April 26, 2023 reflected royalties related to sales of XEPLION/TREVICTA/BYANNLI outside of the U.S. through the end of July 2023.

⁺2023 per share expectations are calculated based on a weighted average basic share count of approximately 166.5 million shares outstanding and a weighted average diluted share count of approximately 171.5 million shares outstanding. Prior 2023 expectations for GAAP loss per share, presented above, were calculated using the weighted average basic share count.

[†]Non-GAAP Net Income excludes royalties and interest related to 2022 of approximately \$195 million due to the one-time and out-of-period nature of this revenue.

Janssen Royalties Expected to be Accretive to Profitability Targets

The company expects royalties related to the Janssen license agreements to be incrementally accretive to its profitability targets. The company today reiterated its profitability targets for FY 2024 and FY 2025, which will continue to exclude royalty revenues related to worldwide sales of products covered by the Janssen license agreements in order to highlight the strength and growth of the company's underlying neuroscience business. The company is not providing reconciliations of, or comparable GAAP measures for, the following non-GAAP profitability targets, as they are not determinable without unreasonable efforts.*

The company today reiterated its commitment to achieving:

- FY 2024 non-GAAP net income margin of 25%, and EBITDA margin of 20%, of the company's total revenues (excluding royalty revenues from Janssen).

- FY 2025 non-GAAP net income margin of 30%, and EBITDA margin of 25%, of the company's total revenues (excluding royalty revenues from Janssen).

Conference Call

Alkermes will host a conference call and webcast presentation at 8:00 a.m. EDT (1:00 p.m. BST) today, June 6, 2023, to discuss the Final Award and provide an update on the company's financial expectations. The webcast may be accessed on the Investors section of Alkermes' website at www.alkermes.com. The conference call may be accessed by dialing +1 877 407 2988 for U.S. callers and +1 201 389 0923 for international callers. In addition, a replay of the conference call may be accessed by visiting Alkermes' website.

About Alkermes plc

Alkermes plc is a fully-integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurological disorders and cancer. Headquartered in Dublin, Ireland, Alkermes has a research and development center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Non-GAAP Financial Measures

This press release includes information about certain financial measures that are not prepared in accordance with GAAP, including non-GAAP net income and non-GAAP diluted earnings per share, non-GAAP net income margin (non-GAAP net income/total revenue) and EBITDA margin (EBITDA/total revenue). These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Non-GAAP net income adjusts for certain one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; change in the fair value of contingent consideration; certain other one-time or non-cash items; and the income tax effect of these reconciling items.

The company's management and board of directors utilize these non-GAAP financial measures to evaluate the company's performance. The company provides these non-GAAP financial measures of the company's performance to investors because management believes that these non-GAAP financial measures, when viewed with the company's results under GAAP and the accompanying reconciliations, are useful in identifying underlying

trends in ongoing operations. However, non-GAAP net income, non-GAAP diluted earnings per share, non-GAAP net income margin (non-GAAP net income/total revenue) and EBITDA margin (EBITDA/total revenue) 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, non-GAAP diluted earnings per share, non-GAAP net income margin (non-GAAP net income/total revenue) and EBITDA margin (EBITDA/total revenue) 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.

*The company has not provided full financial expectations for time periods after the year ending Dec. 31, 2023 and therefore is not providing reconciliations of, or comparable GAAP measures for, non-GAAP net income margins or EBITDA margins, for time periods after the year ending Dec. 31, 2023. Reconciliations of such forward-looking non-GAAP profitability measures to comparable GAAP measures are not determinable without unreasonable efforts due to the inherent difficulty in forecasting and quantifying certain future financial amounts necessary for such reconciliations, which amounts could have a significant impact on the company's future financial results, including such non-GAAP profitability measures and the comparable GAAP financial measures.

Important Additional Information and Where to Find It

The company has filed its definitive proxy statement, accompanying WHITE proxy card and other relevant documents with the U.S. Securities and Exchange Commission (the SEC) in connection with the solicitation of proxies for the company's 2023 Annual General Meeting of Shareholders. BEFORE MAKING ANY VOTING DECISION, SHAREHOLDERS OF THE COMPANY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING THE COMPANY'S DEFINITIVE PROXY STATEMENT AND ANY AMENDMENTS AND SUPPLEMENTS THERETO, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and shareholders will be able to obtain a copy of the definitive proxy statement and other documents filed by the company with the SEC free of charge from the SEC's website at www.sec.gov. In addition, copies will be available at no charge by visiting the "Investors" section of the company's website at www.alkermes.com, as soon as reasonably practicable after such materials are filed with, or furnished to, the SEC.

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 future financial and operating performance, business plans or prospects, including the company's

expectations regarding the payments due to the company under the license agreements with Janssen, the respective duration of the royalty term for each product under the license agreements, the company's profitability targets and its ability to drive profitability, and the company's revised financial expectations for 2023; and the company's plans to separate its neuroscience and oncology businesses, including expectations regarding the anticipated timing of the planned separation. 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, that the company may not ultimately separate its oncology business in 2023 or at all; unanticipated developments, costs or difficulties that may delay or otherwise negatively affect the planned separation; the company may not be able to achieve its profitability targets in a timely manner or at all; the terms of the Final Award may be challenged by Janssen; 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; 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, 2022 and in subsequent filings made by the company with the SEC, which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

VIVITROL[®] is a registered trademark of Alkermes, Inc.; ARISTADA[®] 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 or its affiliated companies. CABENUVA[®] is a registered trademark of ViiV Healthcare UK (No.3) Limited.

Alkermes plc and Subsidiaries
2023 Guidance — GAAP to Non-GAAP Adjustments

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

(In millions, except per share data)	Amount	Shares	Earnings Per Share
Projected Net Income — GAAP	\$ 245.0	171.5	\$ 1.43
Adjustments:			
Share-based compensation expense	97.5		
Depreciation expense	42.5		
Amortization expense	35.0		
Separation expense	21.0		
Income tax effect related to reconciling items	3.5		
Non-cash net interest expense	0.5		
Royalties and interest related to 2022*	(195.0)		
Projected Net Income — Non-GAAP	<u>\$ 250.0</u>	171.5	\$ 1.46

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

* Pursuant to final award related to arbitration proceedings with Janssen Pharmaceutica N.V.

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