

Alkermes plc.
Form 10-Q
April 26, 2018
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

OR

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

Commission File Number 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction of incorporation or organization)

98-1007018
(I.R.S. Employer Identification No.)

Connaught House

1 Burlington Road

Dublin 4, Ireland

(Address of principal executive offices)

+ 353-1-772-8000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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.

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes No

The number of the registrant's ordinary shares, \$0.01 par value, outstanding as of April 20, 2018 was 155,037,850 shares.

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ALKERMES PLC AND SUBSIDIARIES

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2018

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Cautionary Note Concerning Forward-Looking Statements

This document contains and incorporates by reference “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In some cases, these statements can be identified by the use of forward-looking terminology such as “may,” “will,” “could,” “should,” “would,” “expect,” “anticipate,” “continue,” “believe,” “plan,” “estimate” or other similar words. These statements discuss future expectations, and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Quarterly Report on Form 10-Q (“Form 10-Q”) include, without limitation, statements regarding:

our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;

our expectations regarding our products, including the development, regulatory (including expectations about regulatory filings, regulatory approvals and regulatory timelines), therapeutic and commercial scope and potential of such products and the costs and expenses related thereto;

our expectations regarding the initiation, timing and results of clinical trials of our products;

our expectations regarding the competitive landscape, and changes therein, related to our products, including competition from generic forms of our products, our development programs, and our industry generally;

our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;

our expectations regarding future amortization of intangible assets;

our expectations regarding our collaborations, licensing arrangements and other significant agreements with third parties relating to our products, including our development programs;

our expectations regarding the impact of new legislation and related regulations, including the Tax Cuts and Jobs Act of 2017, and the adoption of new accounting pronouncements;

our expectations regarding near term changes in the nature of our market risk exposures or in management’s objectives and strategies with respect to managing such exposures;

our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations;

our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements;

our expectations regarding the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents, other proprietary and intellectual property (“IP”) rights, and our products, including the commercialization of such products; and

other factors discussed elsewhere in this Form 10-Q.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to risks, assumptions and uncertainties. These risks, assumptions and uncertainties include, among others: the unfavorable outcome of litigation, including so-called “Paragraph IV” litigation and other patent litigation, related to any of our products, which may lead to competition from generic drug manufacturers; data from clinical trials may be interpreted by the United States (“U.S.”) Food and Drug Administration (“FDA”) in different ways than we interpret it; the FDA may not agree with our regulatory approval strategies or components of our filings for our products, including our clinical trial designs, conduct and methodologies and, for ALKS 5461, evidence of efficacy and adequacy of bridging to buprenorphine; clinical development activities may not be completed on time or at all; the results of our clinical development activities may not be positive, or predictive of real-world results or of results in subsequent clinical trials; regulatory submissions may not occur or be submitted in a timely manner; 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 governmental payers; the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding the company’s products; 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 December 31, 2017 (the “Annual Report”) and in subsequent filings made by the company with the U.S. Securities and Exchange Commission (“SEC”), which are

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available on the SEC's website at www.sec.gov. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Form 10-Q. All subsequent written and oral forward-looking statements concerning the matters addressed in this Form 10-Q and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

This Form 10-Q includes data that we obtained from industry publications and third-party research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. This Form 10-Q also includes data based on our own internal estimates and research. Our internal estimates and research have not been verified by any independent source, and, while we believe the industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Such third-party data and our internal estimates and research are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Item 1A—Risk Factors" in our Annual Report and in subsequent reports filed with the SEC. These and other factors could cause our results to differ materially from those expressed in the estimates included in this Form 10-Q.

Note Regarding Company and Product References

Alkermes plc (as used in this report, together with our subsidiaries, "Alkermes," the "Company," "us," "we" and "our") is a full integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of marketed drug products and a clinical pipeline of product candidates that address central nervous system ("CNS") disorders such as schizophrenia, depression, addiction and multiple sclerosis ("MS"). Except as otherwise suggested by the context, (a) references to "products" or "our products" in this Form 10-Q include our marketed products, marketed products using our proprietary technologies, our product candidates, product candidates using our proprietary technologies, development products and development products using our proprietary technologies, (b) references to the "biopharmaceutical industry" are intended to include reference to the "biotechnology industry" and/or the "pharmaceutical industry" and (c) references to "licensees" are used interchangeably with references to "partners."

Note Regarding Trademarks

We are the owner of various U.S. federal trademark registrations ("®") and other trademarks ("TM"), including ALKERMES®, ARISTADA®, LinkeRx®, NanoCrystal® and VIVITROL®.

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The following are trademarks of the respective companies listed: AMPYRA® and FAMPYRA®—Acorda Therapeutics, Inc. (“Acorda”); BYDUREON® —Amylin Pharmaceuticals, LLC; INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA®, XEPLION®, and RISPERDAL CONSTA®—Johnson & Johnson (or its affiliates); TECFIDERA®—Biogen MA Inc. (together with its affiliates, “Biogen”); and ZYPREXA®—Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-Q are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements:

ALKERMES PLC AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	March 31, 2018	December 31, 2017
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 186,505	\$ 191,296
Investments—short-term	218,057	242,208
Receivables, net	214,160	233,590
Contract assets	26,069	—
Inventory	84,884	93,275
Prepaid expenses and other current assets	46,463	48,475
Total current assets	776,138	808,844
PROPERTY, PLANT AND EQUIPMENT, NET	289,621	284,736
INTANGIBLE ASSETS, NET	240,099	256,168
INVESTMENTS—LONG-TERM	137,473	157,212
GOODWILL	92,873	92,873
CONTINGENT CONSIDERATION	82,900	84,800
DEFERRED TAX ASSETS	100,504	98,560
OTHER ASSETS	16,950	14,034
TOTAL ASSETS	\$ 1,736,558	\$ 1,797,227
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 268,166	\$ 286,166