Jazz Pharmaceuticals plc
Form 10-Q
May 07, 2013
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
ý Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2013
or
¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to
Commission File Number: 001-33500
JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Exact name of registrant as specified in its charter)

Ireland	98-1032470
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Fourth Floor, Connaught House,
One Burlington Road, Dublin 4, Ireland
011-353-1-634-7800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of each class	Name of each exchange on which registered
Ordinary shares, nominal value $0.0001 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

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 ý 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	ý	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

As of April 22, 2013, 58,850,434 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

Table of Contents

JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2013

INDEX

We own or have rights to various copyrights, trademarks, and trade names used in our business in the United States and/or non-U.S. countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Xyrem Success Program®, FazaClo® (clozapine, USP), Luvox CR® (fluvoxamine maleate) Extended-Release Capsules, Luvox® (fluvoxamine maleate), Versacloz™ (clozapine, USP) oral suspension, Prialt® (ziconotide) intrathecal infusion, Niravam® (orally disintegrating tablet presentation of alprazolam), Parcopa® (orally disintegrating tablet presentation of carbidopa/levodopa), Erwinaze® (asparaginase Erwinia chrysanthemi), Erwinase®, Asparec® (mPEG-r-crisantaspase), Leukotac® (inolimomab), ProstaScint® (capromab pendetide), Quadramet® (samarium sm 153 lexidronam injection), Caphosol® (supersaturated calcium phosphate rinse), Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole®, Kidrolase® (Escherichia coli L-asparaginase), Xenazine® (tetrabenazine), Custodiol® (solution HTK) and NAVIGATOR Reimbursement and Access Program™. This report also includes trademarks, service marks, and trade names of other companies.

2

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	March 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$450,511	$387,196
Accounts receivable, net	93,833	75,480
Inventories	22,830	26,525
Prepaid expenses	11,286	7,445
Deferred tax assets, net	47,517	35,813
Other current assets	21,395	19,113
Total current assets	647,372	551,572
Property and equipment, net	7,795	7,281
Intangible assets, net	835,003	869,952
Goodwill	436,355	442,600
Deferred tax assets, net, non-current	62,933	74,850
Deferred financing costs	15,686	16,576
Other long-term assets	4,546	3,662
Total assets	$2,009,690	$1,966,493
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$31,634	$15,887
Accrued liabilities	100,935	104,666
Current portion of long-term debt	32,656	29,688
Income taxes payable	37,803	39,884
Contingent consideration	39,300	—
Deferred tax liability, net	259	275
Deferred revenue	1,138	1,138
Total current liabilities	243,725	191,538
Deferred revenue, non-current	6,566	6,776
Long-term debt, less current portion	418,506	427,073
Contingent consideration, non-current	—	34,800
Deferred tax liability, net, non-current	169,176	178,393
Other non-current liabilities	9,817	6,621
Commitments and contingencies (Note 6)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	471	471
Additional paid-in capital	1,168,633	1,151,010
Accumulated other comprehensive income	10,606	31,046
Accumulated deficit	(17,871)	(61,296)

Total shareholders' equity	1,161,900	1,121,292
Total liabilities and shareholders' equity	$2,009,690	$1,966,493

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Revenues:		
Product sales, net	$194,652	$101,452
Royalties and contract revenues	1,585	1,078
Total revenues	196,237	102,530
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technologies)	27,220	7,744
Selling, general and administrative	70,528	44,356
Research and development	10,747	3,959
Intangible asset amortization	19,555	10,732
Total operating expenses	128,050	66,791
Income from operations	68,187	35,739
Interest income (expense), net	(7,399)	13
Foreign currency gain	271	—
Income from continuing operations before income tax provision	61,059	35,752
Income tax provision	17,634	5,517
Income from continuing operations	43,425	30,235
Loss from discontinued operations	—	(2,554)
Net income	$43,425	$27,681
Basic income (loss) per ordinary share:		
Income from continuing operations	$0.74	$0.56
Loss from discontinued operations	—	(0.05)
Net income	$0.74	$0.51
Diluted income (loss) per ordinary share:		
Income from continuing operations	$0.71	$0.52
Loss from discontinued operations	—	(0.04)
Net income	$0.71	$0.48
Weighted-average ordinary shares used in per share computations:		
Basic	58,358	53,923
Diluted	61,511	58,084

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Net income	$43,425	$27,681
Other comprehensive income (loss):		
Foreign currency translation adjustments	(20,440)	—
Available-for-sale securities:		
Net unrealized gain on available-for-sale securities, net of income taxes	—	34
Other comprehensive income (loss)	(20,440)	34
Total comprehensive income	$22,985	$27,715
Total comprehensive income arises from:		
Continuing operations	$22,985	$30,269
Discontinued operations	—	(2,554)
Total comprehensive income	$22,985	$27,715

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Operating activities		
Net income	$43,425	$27,681
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization of intangible assets	19,555	13,513
Depreciation	575	186
Loss on disposal of property and equipment	40	—
Share-based compensation	8,757	3,281
Excess tax benefit from share-based compensation	(889)	(1,914)
Acquisition accounting inventory fair value step-up	1,545	2,369
Change in fair value of contingent consideration	4,500	—
Deferred income taxes	(3,874)	—
Provision for losses on accounts receivable and inventory	142	43
Other non-cash transactions	1,975	42
Changes in assets and liabilities:		
Accounts receivable	(18,911)	(8,794)
Inventories	1,231	(101)
Prepaid expenses and other current assets	(6,272)	(2,217)
Other long-term assets	(999)	(298)
Accounts payable	16,158	4,649
Accrued liabilities	(2,660)	(6,539)
Income taxes payable	(1,397)	—
Deferred revenue	(207)	(285)
Other non-current liabilities	3,196	(1)
Liability under government settlement	—	(7,320)
Net cash provided by operating activities	65,890	24,295
Investing activities		
Cash acquired from merger with Azur Pharma	—	81,751
Purchases of marketable securities	—	(30,628)
Proceeds from sale of marketable securities	—	15,082
Proceeds from maturities of marketable securities	—	17,838
Purchases of intangible assets	(1,300)	—
Purchases of property and equipment	(1,143)	(285)
Purchase of product rights	—	(1,250)
Net cash provided by (used in) investing activities	(2,443)	82,508
Financing activities		
Proceeds from exercise of share options and warrants	9,609	5,160
Payment of employee withholding taxes related to share-based awards	(1,427)	(25,299)
Excess tax benefit from share-based compensation	889	1,914
Repayment of long-term debt	(5,938)	—
Net cash provided by (used in) financing activities	3,133	(18,225)
Effect of exchange rates on cash and cash equivalents	(3,265)	—

Net increase in cash and cash equivalents	63,315	88,578
Cash and cash equivalents, at beginning of period	387,196	82,076
Cash and cash equivalents, at end of period	$450,511	$170,654

The condensed consolidated statements of cash flows include the activities of discontinued operations.
The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

JAZZ PHARMACEUTICALS PLC
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. The Company and Summary of Significant Accounting Policies

Jazz Pharmaceuticals plc, a public limited company formed under the laws of Ireland, is a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing innovative products that address unmet medical needs. Our strategy is to continue to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying new growth opportunities;
- Acquiring additional marketed specialty products or products close to regulatory approval to leverage our existing expertise and infrastructure; and
- Pursuing targeted development of a pipeline of post-discovery specialty product candidates.

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, or the Azur Merger, accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with Jazz Pharmaceuticals, Inc. treated as the acquiring company for accounting purposes. As part of the Azur Merger, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as a wholly-owned subsidiary of Jazz Pharmaceuticals plc. Prior to the Azur Merger, Azur Pharma changed its name to Jazz Pharmaceuticals plc.

On June 12, 2012, we completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, which we refer to as the EUSA Acquisition.

Throughout this report, unless otherwise indicated or the context otherwise requires, all references to "Jazz Pharmaceuticals," "the registrant," "we," "us," and "our" refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries, including its predecessor Jazz Pharmaceuticals, Inc. All references to "Azur Pharma" are references to Jazz Pharmaceuticals plc (f/k/a Azur Pharma Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Azur Merger on January 18, 2012. All references to "EUSA Pharma" are references to EUSA Pharma Inc. and its consolidated subsidiaries prior to the effective time of the EUSA Acquisition on June 12, 2012.

Basis of Presentation

These unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or GAAP, can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the annual consolidated financial statements and accompanying notes of Jazz Pharmaceuticals plc included in its Annual Report on Form 10-K for the year ended December 31, 2012. The results of operations of the acquired Azur Pharma and EUSA Pharma businesses, along with the estimated fair values of the assets acquired and liabilities assumed in each transaction, have been included in our condensed consolidated financial statements since the effective dates of the Azur Merger and the EUSA Acquisition, respectively.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. The results for the three months ended March 31, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013, for any other interim period or for any future period.

These condensed consolidated financial statements include the accounts of Jazz Pharmaceuticals plc and our wholly-owned subsidiaries and intercompany transactions and balances have been eliminated.

Significant Risks and Uncertainties

Our financial results are significantly influenced by sales of Xyrem® (sodium oxybate) oral solution. Maintaining or increasing sales of Xyrem in its approved indications is subject to a number of risks and uncertainties, including the potential introduction of generic competition, changed or increased regulatory restrictions, and continued acceptance

of Xyrem as safe and effective by physicians and patients. Two abbreviated new drug applications, or ANDAs, have been filed with the United States Food and Drug Administration, or FDA, by third parties seeking to market generic versions of Xyrem. We have sued

Table of Contents

both third parties for infringement of our patents, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, we are continuing our work on various regulatory matters, including our work with the FDA on updated documents that we have submitted to the FDA on our risk management and controlled distribution system for Xyrem, which we refer to as the Xyrem Risk Management Program. The updated documents are intended to conform to current formatting requirements for risk evaluation and mitigation strategies, or REMS, required by law, as well as to make other updates to the program and its documentation. While we cannot predict the timing of finalization, or the final terms, of approved REMS documents for Xyrem, we expect that the FDA will require final REMS documents that will result in, or permit, modifications to aspects of the Xyrem Risk Management Program, which may include the ability to distribute Xyrem through more than one pharmacy. We also expect that the final REMS documents will include requirements that are not currently implemented in the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors to enter the market and/or negatively affect sales of Xyrem.

In addition to risks related specifically to Xyrem, we are subject to risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including: the challenges of protecting our intellectual property rights; delays or problems in the supply or manufacture of our products, particularly because we maintain limited inventories of certain products, including products for which our supply demands are growing, and we are dependent on single source suppliers to continue to meet our ongoing commercial needs; the need to obtain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to health care cost containment and other austerity measures in the United States and worldwide; the ongoing regulation and oversight by the FDA, the U.S. Drug Enforcement Administration, or DEA, and non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, adverse event reporting and product recalls or withdrawals; the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors; and the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval.

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash equivalents and marketable securities. Our investment policy permits investments in U.S. federal government and federal agency securities, corporate bonds or commercial paper issued by U.S. corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, and tax-exempt obligations of U.S. states, agencies and municipalities and places restrictions on credit ratings, maturities, and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and marketable securities and issuers of investments to the extent recorded on the balance sheet.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to hospitals, pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the United States, and to other international distributors. Customer creditworthiness is monitored and collateral is not required. We monitor deteriorating economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on our financial position, liquidity or results of operations. As of March 31, 2013, five customers accounted for 81% of gross accounts receivable including Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, which accounted for 60% of gross accounts receivable, and Accredo Health Group, Inc., or Accredo, which accounted for 9% of gross accounts receivable. As of December 31, 2012, five

customers accounted for 78% of gross accounts receivable, including Express Scripts which accounted for 51% of gross accounts receivable and Accredo which accounted for 11% of gross accounts receivable.

We rely on single source suppliers for drug substance and single source manufacturing partners for each of our marketed products and product candidates.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the condensed consolidated financial statements and

Table of Contents

accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Net Income per Ordinary Share

Basic net income per ordinary share is based on the weighted-average number of ordinary shares outstanding. Diluted net income per ordinary share is based on the weighted-average number of ordinary shares outstanding and potentially dilutive ordinary shares outstanding. Basic and diluted net income per ordinary share were computed as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2013	2012
Numerator:		
Income from continuing operations	$43,425	$30,235
Loss from discontinued operations	—	(2,554)
Net income		