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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2014
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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 ☒	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 Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $8,420,403,204 based upon the last sale price reported for the registrant's ordinary shares on such date on The NASDAQ Global Select Market. The calculation of the aggregate market value of voting and non-voting common equity excludes 2,311,701 ordinary shares of the registrant held by executive officers, directors and shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of February 18, 2015, a total of 60,657,182 ordinary shares, nominal value $0.0001 per share, of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2015 Annual General Meeting of Shareholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

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JAZZ PHARMACEUTICALS PLC
2014 ANNUAL REPORT ON FORM 10-K
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We own or have rights to various copyrights, trademarks, and trade names used in our business in the United States and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Xyrem Success Program®, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Erwinase®, Defitelio® (defibrotide), Prialt® (ziconotide) intrathecal infusion, FazaClo® (clozapine, USP), Versacloz® (clozapine) oral suspension, Leukotac™ (inolimomab) and ProstaScint® (capromab pendetide). This report also includes trademarks, service marks, and trade names of other companies. Service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "propose," "intend," "continue," "potential," "possible," "foreseeable," "likely," "unforeseen" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Risk Factors." Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update our forward-looking statements publicly, or to update the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

NOTE REGARDING COMPANY REFERENCE

In 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, except when the context makes clear that the time period being referenced is prior to January 18, 2012, in which case such terms are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. 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, in connection with which Azur Pharma was re-named Jazz Pharmaceuticals plc and we became the parent company of and successor to Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. becoming our wholly-owned subsidiary. Jazz Pharmaceuticals, Inc. was treated as the acquiring company in the Azur Merger for accounting purposes, and as a result, the historical consolidated financial statements of Jazz Pharmaceuticals, Inc. became our consolidated financial statements.

PART I

Item 1. Business

Overview

Jazz Pharmaceuticals plc is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying new growth opportunities;
- Acquiring additional differentiated products that are on the market or product candidates that are in late-stage development; and
- Pursuing focused development of a pipeline of post-discovery differentiated product candidates.

We have made substantial progress in the execution of our strategy. We have a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology.

Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the United States Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in patients with narcolepsy;
- **Erwinaze® (asparaginase *Erwinia chrysanthemi*)**, a treatment approved in the United States and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase; and
- **Defitelio® (defibrotide)**, a product approved in Europe for the treatment of severe hepatic veno-occlusive disease, or VOD, in adults and children undergoing hematopoietic stem cell transplantation, or HSCT, therapy.

Our research and development activities include clinical development of new product candidates, line extensions for existing products and the generation of additional clinical data for existing products. A summary of our development pipeline activities is provided below:

Project	Disease Area	Status
Sleep		
JZP-110	EDS in narcolepsy	Expect to initiate a Phase 3 clinical trial in the second quarter of 2015
	EDS in obstructive sleep apnea, or OSA	Expect to initiate two Phase 3 clinical trials in the second quarter of 2015
JZP-386	EDS in narcolepsy	Phase 1 clinical trial in progress; expect additional data in the second quarter of 2015
Xyrem	Cataplexy in narcolepsy in children and adolescents	Phase 3 clinical trial initiated in the fourth quarter of 2014
Hematology/Oncology		
Defibrotide	Severe VOD	Rolling new drug application, or NDA, submission initiated in the United States in December 2014; expect to complete the submission in mid-2015
Erwinaze	ALL in young adult population	Pharmacokinetic study in Phase 2 initiated in the second quarter of 2014
JZP-416	ALL	Phase 1 clinical trial in Europe completed; enrollment suspended in pivotal Phase 2 clinical trial in North America in first quarter of 2015
Leukotac™	Steroid refractory acute graft vs. host disease, or GvHD	Phase 3 clinical trial enrollment complete; expect preliminary data in mid-2015

Our Products

Xyrem® (sodium oxybate) oral solution

Xyrem is the only treatment approved by the FDA for both EDS and cataplexy in patients with narcolepsy. Sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a formulation of the sodium salt of gamma-hydroxybutyrate, an endogenous neurotransmitter and metabolite of gamma-aminobutyric acid. Xyrem was approved in the United States for the treatment of cataplexy in patients with narcolepsy in 2002 and was approved for EDS in patients with narcolepsy in 2005. The American Academy of Sleep Medicine recommended Xyrem as a standard of care for the treatment of both EDS and cataplexy associated with narcolepsy.

Narcolepsy is a chronic neurological disorder caused by a loss of neurons that produce the neurotransmitter hypocretin (also known as orexin), which is hypothesized to stabilize sleep-wake states. The primary symptoms of narcolepsy include EDS, cataplexy, sleep paralysis, hypnogogic hallucinations and disrupted nighttime sleep. EDS is an essential symptom of narcolepsy, is present in all narcolepsy patients and is characterized by chronic, pervasive sleepiness as well as sudden irresistible and overwhelming urges to sleep (inadvertent naps and sleep attacks). Cataplexy, the sudden loss of muscle tone, can be one of the most debilitating symptoms of narcolepsy. Cataplexy is present in approximately 70% of patients with narcolepsy. Cataplexy can range from slight weakness or a drooping of facial muscles to the complete loss of muscle tone resulting in postural collapse. It may also impair a patient's vision or speech. Cataplexy is often triggered by strong emotions such as laughter, anger or surprise. Cataplexy can severely impair a patient's quality of life and ability to function.

Narcolepsy may affect many areas of life, including limiting a patient's education and employment opportunities and leading to driving or machinery accidents or difficulties at work resulting in disability or job dismissal. Patients with narcolepsy may also suffer from significant medical comorbidities, including social anxiety disorder, OSA, bipolar disorder, depression, hypercholesterolaemia, diseases of the digestive system, cardiovascular diseases, upper respiratory tract diseases and hypertension.

It is estimated that narcolepsy affects approximately 1 in 2,000 people in the United States, or approximately 160,000 people in 2014. Less than half of those people have been definitively diagnosed with narcolepsy. In the fourth quarter of 2014, the average number of patients in the United States receiving Xyrem treatment was approximately 12,250 patients, and we believe that there are significantly more patients with narcolepsy and cataplexy and/or EDS who might benefit from treatment with Xyrem. In an effort to reach more patients, we have implemented a number of initiatives including increased outreach to prescribers who treat narcolepsy and physician/healthcare provider disease education programs.

In 2014, net product sales of Xyrem were $778.6 million, which represented 67.0% of our total net product sales.

We promote Xyrem in the United States through a specialty sales force of approximately 100 sales professionals dedicated to Xyrem. Our marketing, sales and distribution of Xyrem are subject to a risk management and controlled distribution system, or Xyrem Risk Management Program, which was required in conjunction with Xyrem's approval by the

FDA to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. The Xyrem Risk Management Program includes a number of elements including patient and physician education, a database of information so that we may track and report certain information, and the use of a single central pharmacy to distribute Xyrem.

Under our current Xyrem Risk Management Program, all of the Xyrem sold in the United States must be dispensed and shipped directly to patients through a single central pharmacy, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or ESSDS. Xyrem may not be stocked in retail pharmacies. Physicians and patients must enroll in the Xyrem Success Program®, which is part of our Xyrem Risk Management Program, prior to fulfillment of Xyrem prescriptions. Each physician and patient receives materials concerning the risks and benefits of Xyrem before the physician can prescribe, or a patient can receive, the product. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and must speak with the patient before each prescription of Xyrem is filled and sent to the patient. The central pharmacy ships the product directly to the patient by a courier service, and the patient or his/her designee signs for the package. The initial shipment may only be for up to a one-month supply, and refill orders may only be for up to a three-month supply.

Pursuant to our agreement, ESSDS exclusively distributes Xyrem in the United States and provides customer support services related to the sales and marketing of Xyrem. For example, ESSDS provides reimbursement support to patients by coordinating insurance coverage for Xyrem, and as applicable, referring qualified patients to various patient savings or assistance programs. Our agreement with ESSDS, which has been in effect since July 2002, expires on June 30, 2015, subject to automatic two-year extensions unless either party provides notice to the other of its intent to terminate the agreement not less than 120 days before the end of the then current term. We do not intend to exercise our termination right, and ESSDS has informed us that it does not intend to exercise its termination right, in connection with the expiration of the current term. Under the agreement, we own all of the standard operating procedures, business rules and intellectual property, and the agreement provides for ESSDS to assist in the orderly transfer of the services that ESSDS provides to us and the related intellectual property, including intellectual property related to the patient database, to any new pharmacy that we may we engage.

Elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require a risk evaluation and mitigation strategy, or REMS, are deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The Xyrem Risk Management Program, however, is not in the form that is now required for REMS documents. The FDAAA requires that deemed REMS and related documents be updated to comply with the current requirements for REMS documents. We are engaged in ongoing communications with respect to our REMS documents for Xyrem, but have not reached agreement with the FDA on certain significant terms. In late 2013, the FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014, and the process is ongoing. See more discussion regarding this matter under "Business—Government Regulation—Approval of Pharmaceutical Products" in Part I, Item 1 of this Annual Report on Form 10-K.

Five companies have notified us that they have filed abbreviated new drug applications, or ANDAs, with the FDA seeking FDA approval to market a generic version of Xyrem. We initiated lawsuits against each of these companies, and the litigation proceedings are ongoing. In addition, certain of the ANDA filers have sought to challenge the validity of our patents covering the distribution system for Xyrem by filing petitions for covered business method, or CBM, post-grant patent review and/or inter partes review, or IPR, by the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO. The PTAB has issued decisions denying institution of CBM review for all of the CBM petitions and has not yet determined whether to institute proceedings with respect to the petitions for IPR. For a description of these matters, see "Legal Proceedings" in Part I, Item 3 of this Annual Report on Form 10-K.

We also expect to face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. In January 2014, the FDA held an initial meeting with us and the then-current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). The parties have had numerous interactions with respect to a single shared system REMS since the initial meeting, and we expect the interactions to continue. In addition, if we do not develop a single shared system REMS or license or share our REMS with a generic competitor within a time frame or on terms that the FDA considers acceptable, the FDA may assert that its waiver authority permits it to allow the generic competitor to market a generic drug with a REMS that does not include the same elements that are in our deemed REMS or, when Xyrem REMS documents are approved, with a separate REMS that includes different, but comparable, elements to assure safe use, or ETASU. Similarly, it is possible that, consistent with the position that the FDA articulated in its December 2012 response denying a Citizen Petition we filed in July 2012, the FDA could approve an ANDA with a risk management plan that is separate from our Xyrem deemed REMS, rather than with a final REMS or a shared REMS for both the generic and Xyrem. For a more detailed explanation and discussion regarding these matters, see "Business—Government Regulation—The Hatch Waxman Act" in Part I, Item 1 of this Annual Report on Form 10-K.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

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Sync your system to PACER to automate legal marketing.