

JAZZ PHARMACEUTICALS PLC  
PROXY STATEMENT & 2012 ANNUAL REPORT



Transformation

# Transformation



## OUR MISSION IS TO IMPROVE PATIENTS' LIVES

Keeping patients at the forefront of our mind inspires us to bring innovative and valuable resources to all aspects of our business for the ultimate benefit of the patients in need.

### Cover:

Hal – Living with Pain  
Kari – Corporate Compliance, Jazz Pharmaceuticals  
Lulu – Diagnosed with Acute Lymphoblastic Leukemia (ALL)  
Ronald – Medical Affairs, Jazz Pharmaceuticals  
Mary – Living with Narcolepsy  
Stanley – Oncology Sales, Jazz Pharmaceuticals  
LeAnn – Pain Sales, Jazz Pharmaceuticals  
Jed – Research and Pharmacology, Jazz Pharmaceuticals  
Julie – Oncology Sales, Jazz Pharmaceuticals

### Inside Cover:

Julia – Commercial Operations, Jazz Pharmaceuticals  
John – Pain Sales, Jazz Pharmaceuticals  
Trudy – Medical Affairs, Jazz Pharmaceuticals  
Fintan – Technical Operations, Jazz Pharmaceuticals

# SHAREHOLDER LETTER

June 12, 2013

Dear Shareholders,

**2012 was a transformational year for Jazz Pharmaceuticals.** We completed transactions with Azur Pharma and EUSA Pharma that broadened our product portfolio, enhanced the scale and capabilities of our company, and created an effective corporate platform for future growth, which enabled us to increase the number of patients benefiting from our therapies. Additionally, we aligned our commercial operations with our expanded product portfolio—all while delivering strong growth in revenues and earnings driven by our core products.

**In 2012 we demonstrated our ability to deliver strong growth, with:**

- Total revenues of \$586.0 million, an increase of 115% over the prior year
- Xyrem net sales of \$378.7 million, up 62% from the prior year
- Adjusted net income of \$290.4 million, or \$4.82 per diluted share, compared to 2011 adjusted net income of \$164.9 million, or \$3.52 per diluted share. 2012 GAAP income from continuing operations was \$261.1 million, or \$4.34 per diluted share, compared to \$125.0 million, or \$2.67 per diluted share, for 2011

**We remain committed to our strategy for sustainable growth of the top and bottom line by focusing on:**

- Unlocking the full potential of our product portfolio by applying our core expertise in commercializing specialty products to a targeted physician base with an emphasis on consultative clinical selling, sophisticated reimbursement and distribution support and providing healthcare provider education and direct-to-patient services
- Utilizing our strong balance sheet and cash flow to enhance shareholder value through additional acquisitions and targeted R&D investments with an emphasis on products that are in late-stage development or currently marketed
- Disciplined resource allocation

**And in the first quarter of 2013, we are continuing to execute on these strategies as demonstrated by:**

- Total revenues of \$196.2 million, an increase of 91% compared to total revenues of \$102.5 million in the first quarter of 2012, driven by record net sales of Xyrem and Erwinaze
- Adjusted net income of \$84.4 million, or \$1.37 per diluted share, compared to \$51.7 million, or \$0.89 per diluted share, for the first quarter of 2012. Both GAAP income from continuing operations and GAAP net income for the first quarter of 2013 were \$43.4 million, or \$0.71 per diluted share. GAAP income from continuing operations for the first quarter of 2012 was \$30.2 million, or \$0.52 per diluted share, and GAAP net income for the first quarter of 2012 was \$27.7 million, or \$0.48 per diluted share
- Cash and cash equivalents of \$450.5 million as of March 31, 2013

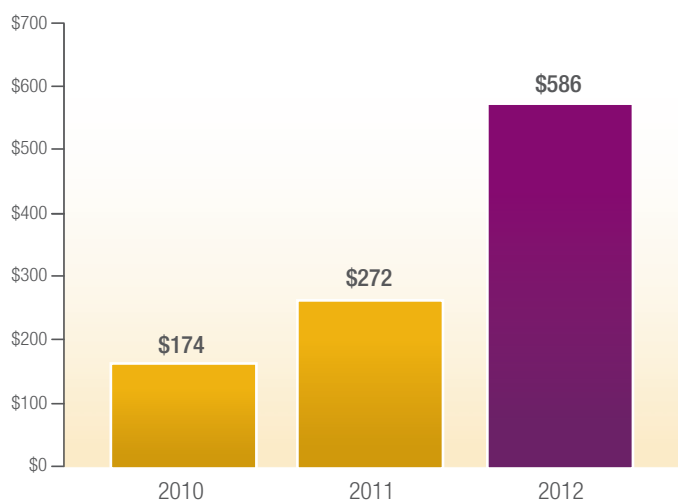
In May 2013, our Board of Directors authorized the use of up to \$200 million to repurchase the company's ordinary shares. We believe this presents an opportunity to increase shareholder value, while maintaining significant financial flexibility to finance future corporate development opportunities.

2013 is shaping up to be a notable year for Jazz Pharmaceuticals as we build on our success and momentum from 2012 to continue our mission of improving patients' lives. I want to thank our employees for their passion and dedication to delivering important therapies to patients through a period of rapid change. I want to thank you—our shareholders—for your continued support as we continue to help patients in need and pursue opportunities to generate significant shareholder value.

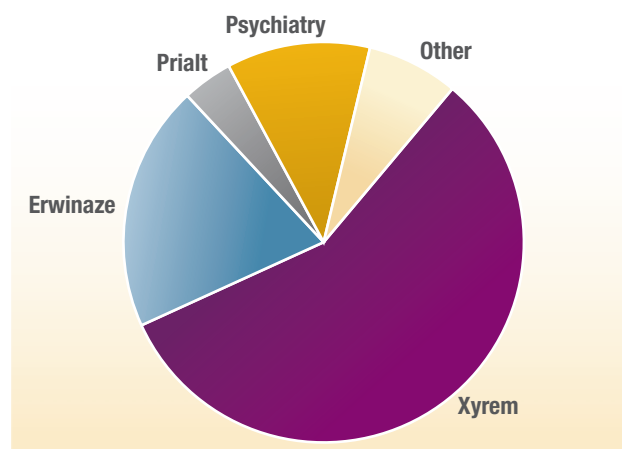


Bruce C. Cozadd  
Chairman and Chief Executive Officer

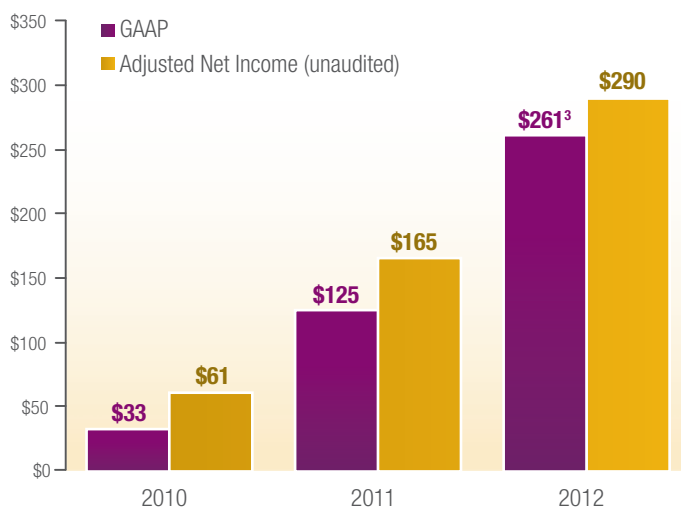
### Total Revenues in Millions



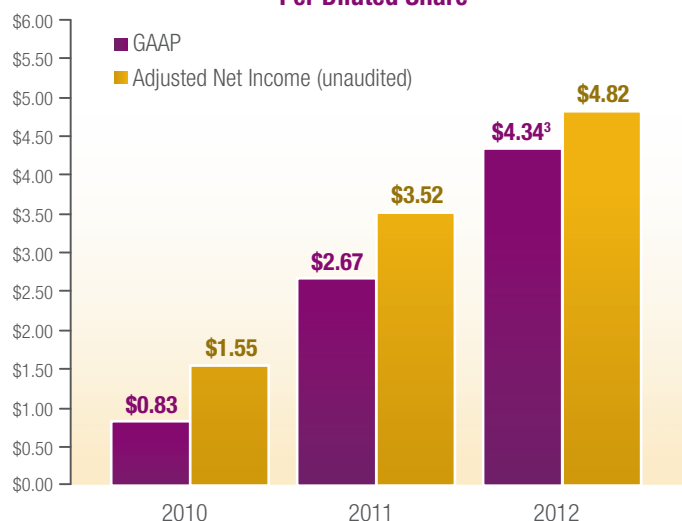
### Pro Forma 2012 Worldwide Net Sales Distribution by Product<sup>1</sup>



### Income From Continuing Operations in Millions<sup>2</sup>



### Income From Continuing Operations Per Diluted Share<sup>2</sup>



1. Pro forma worldwide net sales based on the combined revenues of Jazz Pharmaceuticals, Azur Pharma and EUSA Pharma as if the Azur Pharma merger and the EUSA Pharma acquisition had each been completed on January 1, 2012 (excluding the Women's Health business, which was accounted for as discontinued operations).

2. Represents GAAP income from continuing operations and adjusted net income for each period presented. GAAP income from continuing operations and adjusted net income for 2012 include Azur Pharma contribution from January 18, 2012 and EUSA Pharma contribution from June 12, 2012, and exclude the results of the Women's Health business, which was accounted for as discontinued operations. Reconciliations of GAAP income from continuing operations and adjusted net income for each period presented can be found under the heading "Non-GAAP Financial Measures" beginning on page 87 in the enclosed Annual Report on Form 10-K for the year ended December 31, 2012.

3. 2012 GAAP income from continuing operations includes a one-time tax benefit of \$104.2 million or \$1.73 per diluted share due to the reversal of the valuation allowance against substantially all of Jazz Pharmaceuticals' U.S. deferred tax assets.



**Jazz Pharmaceuticals®**

**JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY**

**Registered in Ireland – No. 399192**

**Fourth Floor, Connaught House**

**One Burlington Road**

**Dublin 4, Ireland**

**NOTICE OF 2013 ANNUAL GENERAL MEETING OF SHAREHOLDERS**

**TO BE HELD ON AUGUST 1, 2013**

Dear Shareholder:

You are cordially invited to attend the 2013 annual general meeting of shareholders (the “annual meeting”) of Jazz Pharmaceuticals plc, a public limited company formed under the laws of Ireland (the “company”). The annual meeting will be held on Thursday, August 1, 2013, at 10:30 a.m. local time at our corporate headquarters located at Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland, for the following purposes:

1. To elect the four nominees for director named in the accompanying proxy statement (the “proxy statement”) to hold office until the 2016 annual general meeting of shareholders.
2. To approve the appointment of KPMG as the independent auditors of the company for the fiscal year ending December 31, 2013 and to authorize the audit committee of the board of directors to determine the auditors’ remuneration.
3. To authorize the company and/or any subsidiary of the company to make market purchases of the company’s ordinary shares.
4. To approve, on an advisory basis, the compensation of the company’s named executive officers as disclosed in the accompanying proxy statement.
5. To conduct any other business properly brought before the annual meeting.

These items of business are more fully described in the proxy statement.

The company’s Irish statutory accounts for the fiscal year ended December 31, 2012, including the reports of the directors and auditors thereon, will be presented at the annual meeting. There is no requirement under Irish law that such statements be approved by the shareholders, and no such approval will be sought at the annual meeting. For the purposes of the company’s articles of association, Proposals 1 and 2 and the receipt and consideration of the Irish statutory accounts by the company at the annual meeting are deemed to be ordinary business, and Proposals 3 and 4 are deemed to be special business.

The record date for the annual meeting is June 4, 2013. Only shareholders of record at the close of business on that date may vote at the annual meeting or any adjournment or postponement thereof.

**Important Notice Regarding the Availability of Proxy Materials for the annual general meeting of shareholders to be held on August 1, 2013, at 10:30 a.m. local time at our corporate headquarters located at Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland.**

**The proxy statement and our annual report are available at <https://materials.proxyvote.com/G50871>.**

By order of the board of directors,

Shawn Mindus  
Secretary

Dublin, Ireland  
June 12, 2013

**You are cordially invited to attend the meeting in person. Whether or not you expect to attend the meeting, please vote as soon as possible. You may vote your shares over the telephone or via the internet. If you received a proxy card or voting instruction card by mail, you may submit your proxy card or voting instruction card by completing, signing, dating and mailing your proxy card or voting instruction card in the envelope provided. Even if you have voted by proxy, you may still vote in person if you attend the meeting. Please note, however, that if the record holder of your ordinary shares is a broker, bank or other nominee, and you wish to vote at the meeting, you must obtain a proxy issued in your name from that record holder.**

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## TABLE OF CONTENTS

	Page
INTRODUCTION .....	1
QUESTIONS AND ANSWERS ABOUT THESE PROXY MATERIALS AND VOTING .....	2
PROPOSAL 1—ELECTION OF DIRECTORS .....	8
CORPORATE GOVERNANCE AND BOARD MATTERS .....	12
PROPOSAL 2—APPROVAL OF APPOINTMENT OF INDEPENDENT AUDITORS AND AUTHORIZE THE AUDIT COMMITTEE TO DETERMINE THEIR REMUNERATION .....	21
PROPOSAL 3—AUTHORIZE THE COMPANY AND/OR ANY SUBSIDIARY OF THE COMPANY TO MAKE MARKET PURCHASES OF THE COMPANY’S ORDINARY SHARES .....	24
PROPOSAL 4—ADVISORY VOTE ON EXECUTIVE COMPENSATION .....	26
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT .....	28
SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE .....	31
EXECUTIVE OFFICERS .....	32
EXECUTIVE COMPENSATION .....	34
DIRECTOR COMPENSATION .....	66
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS .....	70
OTHER MATTERS .....	75

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**JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY**

**Registered in Ireland – No. 399192**

**Fourth Floor, Connaught House**

**One Burlington Road**

**Dublin 4, Ireland**

**PROXY STATEMENT  
FOR THE 2013 ANNUAL GENERAL MEETING OF SHAREHOLDERS  
TO BE HELD ON AUGUST 1, 2013**

**INTRODUCTION**

**General**

Our board of directors is soliciting proxies for use at our 2013 annual general meeting of shareholders, or the annual meeting. This proxy statement contains important information for you to consider when deciding how to vote on the matters brought before the annual meeting. Please read it carefully. Our proxy materials, which include this proxy statement, our annual letter to shareholders, and our annual report on Form 10-K for the year ended December 31, 2012 are first being mailed or made available to shareholders on or about June 12, 2013. Our proxy materials are also available online at <https://materials.proxyvote.com/G50871>.

This solicitation is made on behalf of our board of directors and we will pay for the entire cost of soliciting proxies. In addition to these proxy materials, our directors and employees may also solicit proxies in person, by telephone, or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. We may also reimburse brokerage firms, banks and other agents for the cost of forwarding proxy materials to beneficial owners.

Our board of directors has set the close of business on June 4, 2013 as the record date for the annual meeting. Shareholders of record who owned our ordinary shares on that date are entitled to vote at and attend the annual meeting. Each ordinary share is entitled to one vote. There were 58,627,032 of our ordinary shares outstanding and entitled to vote on the record date.

**Basis of Presentation**

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 (referred to throughout this proxy statement as 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. In addition, on June 12, 2012, Jazz Pharmaceuticals plc completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, referred to throughout this proxy statement as the EUSA Acquisition.

Unless otherwise indicated or the context otherwise requires, all references in this proxy statement to “Jazz Pharmaceuticals,” “the company,” “the registrant,” “we,” “us,” and “our” refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries, including its predecessor Jazz Pharmaceuticals, Inc., except that all such references

prior to the effective time of the Azur Merger on January 18, 2012 are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. 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. The disclosures in this proxy statement relating to the pre-Azur Merger business of Jazz Pharmaceuticals, as well as statements relating to pre-Azur Merger compensation, board of director and corporate governance matters, unless noted as relating to Azur Pharma prior to the Azur Merger, pertain only to Jazz Pharmaceuticals, Inc. prior to the Azur Merger. Accordingly, for purposes of the presentation of historical executive and director compensation information in this proxy statement, this compensation information consists of information with respect to Jazz Pharmaceuticals, Inc., our predecessor, for periods prior to January 18, 2012 and information with respect to Jazz Pharmaceuticals plc for the period January 18, 2012 through December 31, 2012. All references to “EUSA Pharma” in this proxy statement are references to EUSA Pharma Inc. and its consolidated subsidiaries prior to the effective time of the EUSA Acquisition. In addition, references in this proxy statement to “shares,” “stock” or “voting stock” refer to Jazz Pharmaceuticals, Inc.’s common stock, par value \$0.0001 per share, prior to the effective time of the Azur Merger and to our ordinary shares, nominal value \$0.0001 per share, from and since the effective time of the Azur Merger.

### **Purpose of the annual meeting**

The specific proposals to be considered and acted upon at the annual meeting are summarized in the accompanying Notice of 2013 Annual General Meeting of Shareholders. Each proposal is described in more detail in this proxy statement.

## **QUESTIONS AND ANSWERS ABOUT THESE PROXY MATERIALS AND VOTING**

### **Why am I receiving these materials?**

Our board of directors is soliciting your proxy to vote at the annual meeting, including at any adjournments or postponements of the annual meeting. This proxy statement contains important information regarding the annual meeting, the proposals on which you are being asked to vote, information you may find useful in determining how to vote and voting procedures.

### **Why did I receive a notice in the mail regarding the internet availability of proxy materials instead of a full set of proxy materials?**

We are pleased to take advantage of U.S. Securities and Exchange Commission, or SEC, rules that allow companies to furnish their proxy materials over the internet. In this regard, most of our shareholders holding their shares in “street name” will not receive paper copies of our proxy materials (unless requested), and will instead be sent a Notice of Internet Availability of Proxy Materials, or Notice, from the brokerage firms, banks or other agents holding their accounts. All “street name” holders receiving a Notice will have the ability to access the proxy materials on the website referred to in the Notice and to request a printed set of the proxy materials. Instructions on how to access the proxy materials via the internet or to request a printed set of the proxy materials may be found in the Notice.

### **Why did I receive a full set of proxy materials in the mail instead of a notice regarding the internet availability of proxy materials?**

We are providing shareholders of record who are holding shares in their own name and shareholders who have previously requested a printed set of our proxy materials with paper copies of our proxy materials instead of a Notice.

### **What is the annual report included in the proxy materials?**

Under applicable U.S. securities laws, we are required to send an annual report to security holders along with this proxy statement. We intend to satisfy this annual report requirement by sending our annual report on

Form 10-K for the year ended December 31, 2012 that we filed with the SEC on February 26, 2013 (referred to throughout this proxy statement as the 2012 10-K) together with this proxy statement.

### **How do I attend the annual meeting?**

You are invited to attend the annual meeting to vote on the proposals described in this proxy statement. The annual meeting will be held on Thursday, August 1, 2013, at 10:30 a.m. local time at our corporate headquarters located at Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland. For directions to attend the annual meeting in person, please contact our Investor Relations department at + 353 1 634 3211 (Ireland) or + 1 650 496 2800 (U.S.) or by email at [investorinfo@jazzpharma.com](mailto:investorinfo@jazzpharma.com). Information on how to vote in person at the annual meeting is discussed below. However, you do not need to attend the annual meeting to vote your ordinary shares.

### **Who can vote at the annual meeting?**

Only shareholders of record at the close of business on June 4, 2013 will be entitled to vote at the annual meeting.

#### ***Shareholders of Record: Shares registered in your name***

If on June 4, 2013 your shares were registered directly in your name with our transfer agent, Computershare Trust Company, N.A., then you are a shareholder of record. As a shareholder of record, you may vote in person at the annual meeting or vote by proxy. Whether or not you plan to attend the annual meeting, we urge you to vote by proxy over the telephone or via the internet as instructed below, or by filling out and returning a proxy card.

#### ***Beneficial Owners: Shares registered in the name of a broker, bank or other agent***

If on June 4, 2013 your shares were held not in your name, but rather in an account at a brokerage firm, bank or other agent, then you are the beneficial owner of shares held in “street name” and a Notice is being sent to you by that broker, bank or other agent. The broker, bank or other agent holding your account is considered to be the shareholder of record for purposes of voting at the annual meeting. As a beneficial owner, you have the right to direct your broker, bank or other agent regarding how to vote the shares in your account as set forth in the voting instructions in the Notice from your broker, bank or other agent. You are also invited to attend the annual meeting. However, since you are not the shareholder of record, you may not vote your shares in person at the annual meeting unless you request and obtain a valid proxy from your broker, bank or other agent.

### **What am I voting on?**

There are four matters scheduled for a vote at the annual meeting:

- Election of the four nominees for director named below to hold office until the 2016 annual general meeting of shareholders (Proposal 1).
- Approval of the appointment of KPMG as the independent auditors of the company for the fiscal year ending December 31, 2013 and to authorize the audit committee of the board of directors to determine the auditors’ remuneration (Proposal 2).
- Authorization of the company and/or any subsidiary of the company to make market purchases of the company’s ordinary shares (Proposal 3).
- Advisory approval of the compensation of our named executive officers as disclosed in this proxy statement (Proposal 4).

## **What are the board's voting recommendations?**

The board of directors recommends that you vote your shares:

- “For” each of the nominees named below for director to hold office until the 2016 annual general meeting of shareholders (Proposal 1).
- “For” the appointment of KPMG as the independent auditors of the company for the fiscal year ending December 31, 2013 and the authorization to the audit committee of the board of directors to determine the auditors’ remuneration (Proposal 2).
- “For” the authorization of the company and/or any subsidiary of the company to make market purchases of the company’s ordinary shares (Proposal 3).
- “For” approval, on an advisory basis, of the compensation of our named executive officers as disclosed in this proxy statement (Proposal 4).

## **What if another matter is properly brought before the annual meeting?**

The board of directors knows of no other matters that will be presented for consideration at the annual meeting. If any other matters are properly brought before the annual meeting, it is the intention of the persons named in the accompanying proxy to vote on those matters in accordance with their best judgment.

## **How do I vote?**

For the election of directors (Proposal 1), you may vote “For” or “Against” each nominee, or you may abstain from voting for all or any of the nominees. For each of the other proposals, you may vote “For” or “Against” or abstain from voting.

### ***Shareholders of Record: Shares registered in your name***

If you are a shareholder of record, you may vote in person at the annual meeting, you may vote by proxy using the enclosed proxy card, or you may vote by proxy over the telephone or via the internet as instructed below. Whether or not you plan to attend the annual meeting, we urge you to vote by proxy to ensure your vote is counted. You may still attend the annual meeting and vote in person even if you have already voted by proxy.

- To vote in person, come to the annual meeting and we will give you a ballot when you arrive.
- To vote using a proxy card, simply complete, sign and date the enclosed proxy card and return it promptly in the envelope provided. If you return your signed proxy card before the annual meeting, we will vote your shares as you direct.
- To vote by telephone, dial toll-free 1-800-652-VOTE (8683) within the United States, U.S. territories and Canada using a touch-tone phone and follow the recorded instructions. You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by 1:00 a.m., U.S. Central Time, on July 31, 2013 to be counted.
- To vote via the internet, go to [www.investorvote.com/JAZZ](http://www.investorvote.com/JAZZ) to complete an electronic proxy card. You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by 1:00 a.m., U.S. Central Time, on July 31, 2013 to be counted.

### ***Beneficial Owners: Shares registered in the name of a broker, bank or other agent***

If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, you should have received a Notice containing voting instructions from that broker, bank or other agent rather than from us. Simply follow the voting instructions in the Notice to ensure that your vote is counted. Alternatively,

you may vote by telephone or via the internet as instructed by your broker, bank or other agent. To vote in person at the annual meeting, you must request and obtain a valid proxy from your broker, bank, or other agent. Follow the voting instructions from your broker, bank or other agent included with the Notice, or contact your broker, bank or other agent to request a proxy form.

**We provide internet proxy voting to allow you to vote your shares online, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your internet access, such as usage charges from internet access providers and telephone companies.**

### **How many votes do I have?**

On each matter to be voted upon, you have one vote for each ordinary share you own as of June 4, 2013.

### **What if I return a proxy card or otherwise vote but do not make specific choices?**

#### ***Shareholders of Record: Shares registered in your name***

If you are a shareholder of record and you do not specify your vote on each proposal individually when voting via the internet or by telephone, or if you sign and return a proxy card without giving specific voting instructions, then the proxy holders will vote your shares in the manner recommended by the board of directors on all matters presented in this proxy statement and as the proxy holders may determine in their discretion with respect to any other matters properly presented for a vote at the annual meeting. The voting recommendations of the board of directors are set forth under “*What are the board’s voting recommendations?*” above.

#### ***Beneficial Owners: Shares registered in the name of a broker, bank or other agent***

If you are a beneficial owner of shares held in “street name” and you do not provide the broker, bank or other agent that holds your shares with specific instructions, under the rules of various national and regional securities exchanges, the broker, bank or other agent that holds your shares may generally vote on routine matters but cannot vote on non-routine matters. If the broker, bank or other agent that holds your shares does not receive instructions from you on how to vote your shares on a non-routine matter, the broker, bank or other agent that holds your shares will inform our inspector of elections that it does not have the authority to vote on that matter with respect to your shares. This is generally referred to as a “broker non-vote.” When our inspector of elections tabulates the votes for any particular matter, broker non-votes will be counted for purposes of determining whether a quorum is present, but will not be counted toward the vote total for any proposal. We encourage you to provide voting instructions to the broker, bank or other agent that holds your shares to ensure that your vote is counted on all four proposals.

### **Which proposals are considered “routine” or “non-routine”?**

The appointment of KPMG, Dublin, or KPMG, as the independent auditors of the company for the fiscal year ending December 31, 2013 and the authorization to the audit committee of the board of directors to determine the auditors’ remuneration (Proposal 2) is a matter considered routine under applicable rules. A broker or other nominee may generally vote on routine matters, and therefore no broker non-votes are expected on Proposal 2.

The election of directors (Proposal 1), the authorization of the company and/or any subsidiary of the company to make market purchases of the company’s ordinary shares (Proposal 3) and the advisory vote on the compensation of our named executive officers (Proposal 4) are matters considered non-routine under applicable rules. A broker or other nominee cannot vote without instructions on non-routine matters, and therefore we expect broker non-votes on Proposals 1, 3 and 4.

**What does it mean if I receive more than one set of proxy materials or more than one Notice, or combination thereof?**

If you receive more than one set of proxy materials or more than one Notice or a combination thereof, your shares may be registered in more than one name or are registered in different accounts. Please follow the voting instructions on **each** set of proxy materials or Notices to ensure that all of your shares are voted.

**Can I change my vote after submitting my proxy?**

Yes. You can revoke your proxy at any time before the final vote at the annual meeting. If you are the record holder of your shares, you may revoke your proxy in any one of the following ways:

- You may submit another properly completed proxy card with a later date.
- You may grant a subsequent proxy by telephone or via the internet.
- You may send a timely written notice that you are revoking your proxy to our Company Secretary at Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland.
- You may attend the annual meeting and vote in person. Simply attending the annual meeting will not, by itself, revoke your proxy.

Your most recent proxy card or telephone or internet proxy is the one that is counted.

If your shares are held by your broker, bank or other agent as a nominee or agent, you should follow the instructions provided by your broker, bank or other agent.

**Do I need a ticket to attend the annual meeting?**

Yes, you will need an admission ticket or proof of ownership of ordinary shares to enter the annual meeting. If you are a shareholder of record, your admission ticket is the bottom half of the proxy card sent to you. If you plan to attend the annual meeting, please so indicate when you vote and bring the ticket with you to the annual meeting. If your shares are held in the name of a bank, broker or other holder of record, your admission ticket is the left side of your voting information form. If you do not bring your admission ticket, you will need proof of ownership to be admitted to the annual meeting. A recent brokerage statement or letter from a bank or broker is an example of proof of ownership. If you arrive at the annual meeting without an admission ticket, we will admit you only if we are able to verify that you are a shareholder of our company. For directions to attend the annual meeting in person, please contact our Investor Relations department at + 353 1 634 3211 (Ireland) or + 1 650 496 2800 (U.S.) or by email at [investorinfo@jazzpharma.com](mailto:investorinfo@jazzpharma.com).

**How are votes counted?**

Votes will be counted by the inspector of elections appointed for the meeting, who will separately count, for each of the proposals, votes “For” and “Against” and abstentions, and, as applicable, broker non-votes. Abstentions and broker non-votes will be treated as shares present for the purpose of determining the presence of a quorum for the transaction of business at the annual meeting. Abstentions and broker non-votes will not, however, be considered votes cast at the annual meeting. Because the approval of all of the proposals is based on the votes cast at the annual meeting, abstentions and broker non-votes will not have any effect on the outcome of voting on the proposals.

**How many votes are needed to approve each proposal?**

Assuming that a quorum is present at the annual meeting, the following votes will be required for approval:

- Proposal 1: For the election of directors, each nominee named herein for election to the board of directors who receives the affirmative vote of a majority of the votes cast in person or by proxy at the annual meeting on his election will be elected to the board of directors.

- Proposal 2: The appointment of KPMG as the independent auditors of the company for the fiscal year ending December 31, 2013 and the authorization to the audit committee of the board of directors to determine the auditors' remuneration must receive the affirmative vote of a majority of the votes cast in person or by proxy at the annual meeting in order to be approved.
- Proposal 3: The authorization of the company and/or any subsidiary of the company to make market purchases of the company's ordinary shares must receive the affirmative vote of a majority of the votes cast in person or by proxy at the annual meeting in order to be approved.
- Proposal 4: The advisory approval of the compensation of our named executive officers must receive the affirmative vote of a majority of the votes cast in person or by proxy at the annual meeting in order to be approved, although such vote will not be binding on us.

### **What is the quorum requirement?**

A quorum of shareholders is necessary to hold a valid meeting. A quorum will be present if shareholders holding a majority of the issued and outstanding ordinary shares entitled to vote as of the record date are present at the annual meeting or represented by proxy. On the record date, there were 58,627,032 ordinary shares outstanding and entitled to vote.

Your shares will be counted towards the quorum only if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other nominee) or, provided that you are a shareholder of record, if you vote in person at the annual meeting. Abstentions and broker non-votes will be counted towards the quorum requirement. If there is no quorum within one hour of the time appointed for the annual meeting, the annual meeting will stand adjourned to August 3, 2013 at 10:30 a.m. local time at the same location, or such other time or place as the board of directors may determine.

### **How can I find out the results of the voting at the annual meeting?**

Preliminary voting results will be announced at the annual meeting. In addition, final voting results will be published in a current report on Form 8-K that we expect to file with the SEC within four business days after the annual meeting. If final voting results are not available to us in time to file a Form 8-K within four business days after the annual meeting, we intend to file a Form 8-K to publish preliminary results and, within four business days after the final results are known to us, file an additional Form 8-K to publish the final results.

### **What are the Irish statutory accounts?**

We are presenting our Irish statutory accounts, including the reports of the directors and the auditors thereon, at the annual meeting and we are mailing those accounts to shareholders of record. Since we are an Irish company, we are required to prepare Irish statutory accounts under applicable Irish company law and to deliver those accounts to shareholders of record in connection with our annual general meetings of shareholders. The Irish statutory accounts cover the results of operations and financial position of Jazz Pharmaceuticals plc for the year ended December 31, 2012. The Irish statutory accounts are prepared in accordance with the International Financial Reporting Standards as adopted by the European Union and as applied in accordance with the Irish Companies Acts of 1963 to 2012.

We will mail without charge, upon written request, a copy of the Irish statutory accounts to beneficial owners of our shares. Requests should be sent to: Jazz Pharmaceuticals plc, Attention: Company Secretary, Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland.

### **What proxy materials are available on the internet?**

This proxy statement, our letter to shareholders and the annual report are available at <https://materials.proxyvote.com/G50871>.

## **PROPOSAL 1 ELECTION OF DIRECTORS**

Our board of directors is divided into three classes, designated Class I, Class II and Class III. The term of the Class II directors will expire at the annual meeting; the term of the Class III directors will expire on the date of our 2014 annual general meeting of shareholders; and the term of the Class I directors will expire on the date of our 2015 annual general meeting of shareholders. At each annual general meeting of shareholders, successors to the class of directors whose term expires at that annual general meeting are elected for a three-year term. Vacancies on the board of directors, including a vacancy that results from an increase in the authorized number of directors, may be filled only by the affirmative vote of a majority of the directors then in office, provided that a quorum is present. A director elected by the board of directors to fill a vacancy in a class will serve for the remainder of the full term of that class and until the director's successor is elected and qualified.

The board of directors currently has eleven members and there are no vacancies on the board of directors. There are currently four directors in Class II, the class whose term of office expires at the annual meeting, all of whom are standing for election at the annual meeting. All four directors were nominated for election by the board of directors upon the recommendation of our nominating and corporate governance committee. Each of Messrs. Berns and Enright were previously elected to the Jazz Pharmaceuticals, Inc. board of directors by its stockholders and were elected to our board of directors effective upon the consummation of the Azur Merger. Mr. Mulligan was previously elected to Azur Pharma board of directors and remained as a member of our board of directors in connection with the Azur Merger. The board of directors elected Dr. Norbert Riedel to the board of directors in May 2013 upon recommendation of our nominating and corporate governance committee, based on its review of his experience and qualifications. Dr. Riedel was initially identified to this committee by our chief executive officer.

In order to be elected as a director, each nominee must receive the affirmative vote of a majority of the votes cast by the holders of ordinary shares represented at the annual meeting in person or by proxy. If any nominee becomes unavailable for election as a result of an unexpected occurrence, the proxy holders will vote your proxy for the election of any substitute nominee as may be proposed by the nominating and corporate governance committee. Each nominee has agreed to serve if elected, and we have no reason to believe that any nominee will be unable to serve. If elected at the annual meeting, each nominee would serve as a director until the 2016 annual general meeting of shareholders and until his successor has been elected and qualified, or, if sooner, until his death, resignation, retirement, disqualification or removal. It is our policy to invite directors and nominees for director to attend annual general meetings of shareholders. Seven directors attended our 2012 annual general meeting of shareholders.

The following includes a brief biography of each nominee for director and each of our other current directors, including their respective ages as of June 4, 2013. Each biography includes information regarding the specific experience, qualifications, attributes or skills that led the nominating and corporate governance committee and the board of directors to determine that the applicable nominee or other current director should serve as a member of the board of directors.

### **Class II Director Nominees for Election for a Three-year Term Expiring at the 2016 Annual General Meeting**

*Paul L. Berns*, age 46, has served as a member of our board of directors since the Azur Merger and was a director of Jazz Pharmaceuticals, Inc. from 2010 until the Azur Merger. Mr. Berns is a self-employed consultant to the pharmaceutical industry. From March 2006 to September 2012, he served as the President and Chief Executive Officer, and as a member of the board of directors, of Allos Therapeutics, Inc., a pharmaceutical company acquired by Spectrum Pharmaceuticals, Inc. From July 2005 to March 2006, Mr. Berns was a self-employed consultant to the pharmaceutical industry. From June 2002 to July 2005, Mr. Berns was President, Chief Executive Officer and a director of Bone Care International, Inc., a specialty pharmaceutical company that



was acquired by Genzyme Corporation in 2005. From 2001 to 2002, Mr. Berns served as Vice President and General Manager of the Immunology, Oncology and Pain Therapeutics business unit of Abbott Laboratories, a pharmaceutical company. From 2000 to 2001, he served as Vice President, Marketing of BASF Pharmaceuticals/Knoll, a pharmaceutical company, and from 1990 to 2000, Mr. Berns held various positions, including senior management roles, at Bristol-Myers Squibb Company, a pharmaceutical company. Mr. Berns joined the board of directors of Anacor Pharmaceuticals, Inc. in June 2012 and has been a director of Xenoport, Inc. since 2005. Mr. Berns received a B.S. in Economics from the University of Wisconsin. With his experience as Chief Executive Officer of Allos Therapeutics and Bone Care International, and his experience serving on the boards of directors for public companies, Mr. Berns provides significant management expertise and industry knowledge to our board of directors.

*Patrick G. Enright*, age 51, has served as a member of our board of directors since the Azur Merger and was a director of Jazz Pharmaceuticals, Inc. from 2009 until the Azur Merger. Since 2006, Mr. Enright has served as a Managing Director of Longitude Capital, a venture capital firm, of which he is a founder. From 2002 through 2006, Mr. Enright was a Managing Director of Pequot Ventures, a venture capital investment firm, where he co- led the life sciences investment practice. Mr. Enright also has significant life sciences operations experience, beginning his career more than 25 years ago at Sandoz (now Novartis), a pharmaceutical company. He currently serves on the boards of directors of Corcept Therapeutics Incorporated, a pharmaceutical company, and several privately held companies. In the past five years he also served as a director of Threshold Pharmaceuticals Inc. and Sequenom Inc. Mr. Enright received a B.S. from Stanford University and an M.B.A. from the Wharton School at the University of Pennsylvania. As a venture capital investor focused on life science companies and someone who has worked in the pharmaceutical industry, Mr. Enright brings to our board of directors both operating experience and financial expertise in the life sciences industry.

*Seamus Mulligan*, age 52, has served as a member of our board of directors since the Azur Merger and was a founder and principal investor of Azur Pharma. Since 2006, Mr. Mulligan has served as the Executive Chairman of Circ Pharma Limited and its subsidiaries, a pharmaceutical development stage group. Mr. Mulligan served as our Chief Business Officer, International Business Development from the Azur Merger until February 2013. Mr. Mulligan served as Azur Pharma's Chairman and Chief Executive Officer and as a member of its board of directors from 2005 until the Azur Merger. From 1984 until 2004, he held various positions with Elan Corporation, a pharmaceutical company, most recently as its Executive Vice President, Business and Corporate Development. Previously at Elan Corporation, he held the roles of President of Elan Pharmaceutical Technologies, the drug delivery division of Elan, Executive Vice President, Pharmaceutical Operations, Vice President, U.S. Operations and Vice President, Product Development. He served as a member of the board of directors of the U.S. National Pharmaceutical Council until 2004. Mr. Mulligan received a B.Sc (Pharm) and M.Sc from Trinity College, Dublin, Ireland. As a founder of Azur Pharma and a senior executive of Elan Corporation for 20 years, Mr. Mulligan brings his expertise in business development and deep knowledge of the pharmaceutical industry to our board of directors.

*Norbert G. Riedel, Ph.D.*, age 56, has served as a member of our board of directors since May 2013. Dr. Riedel is a retired executive of the pharmaceutical industry. From 2001 to January 2013, he served as Corporate Vice President and Chief Scientific Officer of Baxter International Inc., a diversified healthcare company, where from 1998 to 2001, he also served as President and General Manager of the recombinant therapeutic proteins business unit and Vice President of Research and Development of the bioscience business unit. From 1996 to 1998, Dr. Riedel served as head of worldwide biotechnology and worldwide core research functions at Hoechst-Marion Roussel, now Sanofi-Aventis, a global pharmaceutical company. Dr. Riedel is currently a member of the supervisory board of MediGene, AG, a biotechnology company, and serves on the board of directors of Ariad Pharmaceuticals, Inc., a biotechnology company focused on cancer, and the board of directors of the Illinois Biotechnology Industry Organization. Dr. Riedel is also a member of the Austrian Academy of Sciences, the advisory board of Northwestern University's Kellogg School of Management Center for Biotechnology, and the Illinois Innovation Council. Dr. Riedel is an Adjunct Professor at Boston University School of Medicine and an Adjunct Professor of Medicine at Northwestern University's Feinberg School of

Medicine. Dr. Riedel holds a Diploma in biochemistry from the University of Frankfurt and a Ph.D. in biochemistry from the University of Frankfurt. Dr. Riedel brings significant scientific, drug discovery and development, and commercial expertise to our board of directors with over 20 years of experience in the biotechnology and pharmaceutical industries.

*The board of directors recommends  
a vote “For” each nominee named above.*

### **Class III Directors Continuing in Office Until the 2014 Annual General Meeting**

*Bruce C. Cozadd*, age 49, has served as our Chairman and Chief Executive Officer since the Azur Merger. He was a co-founder and has served (and continues to serve) as Chairman and Chief Executive Officer of Jazz Pharmaceuticals, Inc. since April 2009. From 2003 until 2009, he served as Jazz Pharmaceuticals, Inc.’s Executive Chairman and as a member of its board of directors. From 1991 until 2001, he held various positions with ALZA Corporation, a pharmaceutical company acquired by Johnson & Johnson, most recently as its Executive Vice President and Chief Operating Officer, with responsibility for research and development, manufacturing and sales and marketing. Previously at ALZA Corporation he held the roles of Chief Financial Officer and Vice President, Corporate Planning and Analysis. He serves on the boards of Cerus Corporation, a biomedical products company, Threshold Pharmaceuticals, a clinical stage biopharmaceutical company, and The Nueva School and Stanford Hospital and Clinics, both non-profit organizations. He received a B.S. from Yale University and an M.B.A. from the Stanford Graduate School of Business. As our Chief Executive Officer, he brings to our board of directors a detailed knowledge of our business.

*Heather Ann McSharry*, age 51, has served as a member of our board of directors since May 2013. Ms. McSharry currently serves as a non-executive director on the boards of directors of several public and private companies, including Greencore Group plc, an international manufacturer of convenience foods, and CRH plc, an international building materials group. From 2006 to 2009, Ms. McSharry was Managing Director Ireland of Reckitt Benckiser, a multinational health, home and hygiene consumer products company. From 1989 to 2006, she held various positions at Boots Healthcare, a leading global consumer healthcare company, most recently as Managing Director of Boots Healthcare Ireland Limited. Ms. McSharry also serves on the board of directors of the Industrial Development Agency in Ireland, where she is Chair of the audit and finance committee. From 2007 to 2011, Ms. McSharry served on the board of directors of the Bank of Ireland, including serving on its audit committee from 2009 to 2011. Ms. McSharry holds a Bachelor of Commerce and a Master of Business Studies degree from University College Dublin. Ms. McSharry brings to our board of directors almost 30 years of experience in multiple international industries including healthcare, consumer goods, and financial services.

*James C. Momtazee*, age 41, has served as a member of our board of directors since the Azur Merger and was a director of Jazz Pharmaceuticals, Inc. from 2004 until the Azur Merger. He is a member of KKR Management LLC, the general partner of KKR & Co. L.P., and he has been employed by Kohlberg Kravis Roberts & Co. L.P., or KKR, a private equity investment firm, since 1996. Funds affiliated with KKR are collectively one of our largest shareholders. He serves on the boards of directors of HCA Inc., a healthcare services company, and Accellent Inc., a manufacturing and engineering services company. He received an A.B. from Stanford University and an M.B.A. from the Stanford Graduate School of Business. As a member of KKR and a board member of other healthcare companies, Mr. Momtazee brings to our board of directors significant expertise in financing and financial matters, including expertise and experience in structuring complex financial transactions and a broad understanding of the market related to those transactions.

*Rick E Winningham*, age 53, has served as a member of our board of directors since the Azur Merger and was a director of Jazz Pharmaceuticals, Inc. from 2010 until the Azur Merger. Since 2001, he has served as the Chief Executive Officer and since 2010, as Chairman of the board of directors of Theravance, Inc., a biopharmaceutical company. From 1986 to 2001, he held various positions with a pharmaceutical company,

Bristol-Myers Squibb and its predecessor Bristol-Myers, including serving as the President of Bristol-Myers Squibb Oncology/Immunology/Oncology Therapeutics Network and, from 2000 to 2001, as its President of Global Marketing. He is a member of the board of directors of the California Healthcare Institute (CHI) and is also a member of the external advisory board of directors for the College of Business and Administration and Business Hall of Fame at Southern Illinois University. Mr. Winningham holds an M.B.A. from Texas Christian University and a B.S. from Southern Illinois University. Mr. Winningham's experience in senior management positions in the pharmaceutical industry provides significant industry knowledge and operational and management expertise to our board of directors.

### **Class I Directors Continuing in Office Until the 2015 Annual General Meeting**

*Peter Gray*, age 58, has served as a member of our board of directors since May 2013. Mr. Gray currently serves as Chairman of the board of directors of United Drug plc, an international provider of healthcare services, and as a business consultant to the pharmaceutical industry. In 2011, Mr. Gray retired from his position as the Chief Executive Officer of ICON plc, a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries, which he held since November 2002. At ICON plc, Mr. Gray previously served as Group Chief Operating Officer from June 2001 to November 2002 and Chief Financial Officer from June 1997 to June 2001. Mr. Gray holds a degree in law from Trinity College Dublin and is a chartered accountant. Mr. Gray brings to our board of directors over 20 years of experience in the pharmaceutical industry.

*Kenneth W. O'Keefe*, age 46, has served as a member of our board of directors since the Azur Merger and was a director of Jazz Pharmaceuticals, Inc. from 2004 until the Azur Merger. Since January 2011 he has been Managing Partner of, and from 1997 to January 2011, he was Managing Director of, Beecken Petty O'Keefe & Company, a private equity firm, which he co-founded. He serves on the boards of several privately held healthcare companies. He received a B.A. from Northwestern University and an M.B.A. from the University of Chicago. As a member of the private equity firm Beecken Petty O'Keefe, Mr. O'Keefe brings to our board of directors significant expertise in accounting and financial matters and in analyzing and evaluating financial statements, as well as substantial experience managing private equity investments. He serves or has served on the audit committee of several companies in the healthcare industry. As chairperson of our audit committee and the chairperson of the audit committee of Jazz Pharmaceuticals, Inc.'s board of directors for several years, Mr. O'Keefe has detailed knowledge of our financial position and financial statements.

*Catherine A. Sohn*, Pharm. D., age 60, has served as a member of our board of directors since her election at the July 2012 annual general meeting of shareholders. Dr. Sohn is the founder of Sohn Health Strategies, where since 2010 she has consulted to pharmaceutical, biotechnology, medical device, and consumer healthcare companies in the areas of business strategy, business development and strategic product development. She has served as a director of Landec Corporation, a material sciences company, since November 2012. From 1982 to 2010, she was with GlaxoSmithKline plc, a pharmaceutical company (and with SmithKline Beecham plc before its merger with GlaxoWellcome plc), where she served most recently as Senior Vice President, Worldwide Business Development and Strategic Alliances in the GSK Consumer Healthcare division, and before that, she held a series of positions in Medical Affairs, Pharmaceutical Business Development, U.S. Product Marketing, and global strategic product development in the pharmaceutical division. Dr. Sohn started her career as Assistant Professor of Clinical Pharmacy at the University of the Sciences in Philadelphia, where she currently holds the position of Dean's Professor. She received a Pharm.D. from the University of California, San Francisco, School of Pharmacy. She also received a Certificate of Professional Development from The Wharton School at the University of Pennsylvania. Dr. Sohn brings to our board of directors almost three decades of product development and business development experience in the pharmaceutical industry and a global perspective that is directly relevant to the company.

There are no family relationships among any of our executive officers and directors.

## **CORPORATE GOVERNANCE AND BOARD MATTERS**

### **Independence of the Board of Directors**

As required under the NASDAQ Stock Market LLC listing standards, or NASDAQ listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our board of directors consults with internal counsel to ensure that the board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in applicable NASDAQ listing standards, as in effect from time to time. Consistent with these considerations, after review of all relevant transactions or relationships between each director, or any of his or her family members, and our company, its senior management and its independent registered public accounting firm, the board of directors affirmatively determined that all of our current directors as well as those directors serving on the board of directors during any portion of 2012 are (or were in the case of former directors) independent directors within the meaning of the applicable NASDAQ listing standards, except that Mr. Cozadd, our Chairman and Chief Executive Officer, and Mr. Mulligan, our former Chief Business Officer, International Business Development, are not independent directors by virtue of their employment (or past employment) with our company. In addition, our board of directors has determined that each member of the audit committee, compensation committee and nominating and corporate governance committee meets the applicable NASDAQ and SEC rules and regulations regarding "independence" and that each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to Jazz Pharmaceuticals plc.

Prior to the Azur Merger, the board of directors of Jazz Pharmaceuticals, Inc. determined that each member of its board of directors that served during the period from January 1, 2012 until the consummation of the Azur Merger was an independent director within the meaning of the applicable NASDAQ listing standards, with the exception of Mr. Cozadd. The Jazz Pharmaceuticals, Inc. board of directors also determined that each member of its audit committee, compensation committee and nominating and corporate governance committee that served during the period from January 1, 2012 until the consummation of the Azur Merger met the applicable NASDAQ and SEC rules and regulations regarding "independence."

### **Board Leadership Structure and Risk Oversight**

Bruce Cozadd has served as our Chairman and Chief Executive Officer since the Azur Merger. Mr. Cozadd served (and continues to serve) as Chairman and Chief Executive Officer of Jazz Pharmaceuticals, Inc. since April 2009. Prior to that, he was the Executive Chairman since the founding of Jazz Pharmaceuticals in 2003. We believe that a combined Chairman/Chief Executive Officer role helps provide strong, unified leadership for our management team and optimizes communication with our board of directors.

The board of directors believes that the Chief Executive Officer is best suited to serve as our Chairman because he is the member of the board of directors who is most familiar with our business as a whole, and the most capable of identifying and bringing to the attention of the full board of directors the strategic priorities and key issues facing the company. As a person who has spent many years in executive management, and many years serving as a director of publicly-traded and privately-held companies and non-profit organizations, he brings both a strategic and operational perspective to the combined position.

Our board of directors is currently comprised of eleven directors, of whom nine are independent. When our independent directors meet without our Chief Executive Officer's participation, one of the independent directors takes the lead in communicating with and updating our Chief Executive Officer on such discussions. While there is no formal "lead" independent director, several directors have played this role on different issues, providing our Chief Executive Officer with their insight and expertise.

We believe that our directors provide effective oversight of risk management for our company, particularly as a result of the work of our committees, the ongoing dialogue between the full board and our Chairman and Chief Executive Officer and the active participation in important company matters by our independent directors.

Our audit committee is responsible for overseeing our financial reporting process on behalf of our board of directors and reviewing with management and our auditors, as appropriate, our major financial risk exposures and the steps taken by management to monitor and control these exposures. Our nominating and corporate governance committee oversees the company's risk management, other than with respect to risks related to the company's financial position or compensation policies, on behalf of our board of directors. Our compensation committee approves all material compensation plans for our company and reviews our compensation practices to ensure that they do not encourage excessive risk taking and are appropriate incentives for meeting both short-term and long-term objectives and increasing shareholder value over time. At its meetings, our full board of directors receives reports concerning the management of the relevant risks from each committee, in addition to reports concerning material risks and concerns or significant updates on such matters from our General Counsel and other executive officers, as necessary.

### Meetings of the Board

The Jazz Pharmaceuticals plc board of directors met four times during 2012 and did not act by written consent during the year. Prior to the Azur Merger, the Jazz Pharmaceuticals, Inc. board of directors did not meet during 2012 and acted by unanimous written consent three times during the year. All directors attended at least 75% of the aggregate number of meetings of the board of directors and of the committees on which they served which were held during the portion of 2012 for which they were directors or committee members, respectively.

As required under applicable NASDAQ listing standards, in fiscal 2012, the independent directors met at each regularly scheduled board meeting in regularly scheduled executive sessions at which only independent directors were present.

### Information About the Committees of the Board of Directors

The board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee. Each of these committees is comprised solely of independent directors and has a separate chairperson. Each committee has a written charter approved by the board of directors, which reflects the applicable standards and requirements adopted by the SEC and NASDAQ. A copy of each committee charter can be found on our website, [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com), in the section titled "About Us" under the subsection titled "Board Committees."

The following table provides membership information for 2012 for each of the audit committee, compensation committee and nominating and corporate governance committee:

<u>Name</u>	<u>Audit</u>	<u>Compensation</u>	<u>Nominating and Corporate Governance</u>
Paul L. Berns . . . . .	X	X*	X
Samuel D. Colella <sup>(1)</sup> . . . . .		X	X
Patrick G. Enright . . . . .	X	X	
Michael W. Michelson <sup>(1)</sup> . . . . .		X	
James C. Momtazee . . . . .			X*
Kenneth W. O'Keefe . . . . .	X*		
Alan M. Sebulsky <sup>(2)</sup> . . . . .	X		
Catherine A. Sohn, Pharm. D. . . . .		X	X
Rick E Winningham <sup>(3)</sup> . . . . .	X	X	

\* Committee Chairperson during 2012.

(1) On January 11, 2012, each of Messrs. Colella and Michelson resigned from the Jazz Pharmaceuticals, Inc. board of directors.

(2) Mr. Sebulsky resigned from our board of directors on July 20, 2012.

(3) Mr. Winningham served on the Jazz Pharmaceuticals, Inc. audit committee from January 1, 2012 until the closing of the Azur Merger.

The following table provides current membership information for our audit committee, compensation committee and nominating and corporate governance committee:

<u>Name</u>	<u>Audit</u>	<u>Compensation</u>	<u>Nominating and Corporate Governance</u>
Paul L. Berns . . . . .	X	X*	X
Patrick G. Enright . . . . .	X	X	
Peter Gray . . . . .	X		
Heather Ann McSharry . . . . .	X		
James C. Momtazee . . . . .			X*
Kenneth W. O’Keefe . . . . .	X*		
Norbert Riedel, Ph.D. . . . .		X	
Catherine A. Sohn, Pharm. D. . . . .		X	X
Rick E Winningham . . . . .		X	

\* Committee Chairperson.

### **Audit Committee**

The audit committee of the board of directors oversees our corporate accounting and financial reporting processes, our systems of internal control over financial reporting and audits of our financial statements, as well as the quality and integrity of our financial statements and reports and the qualifications, independence and performance of the auditors engaged as our independent registered public accounting firm for the purpose of preparing or issuing an audit report or performing audit services. Specific responsibilities of the audit committee include:

- evaluating the performance of and assessing the qualifications of the independent auditors;
- determining and approving the engagement and remuneration of the independent auditors;
- determining whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors;
- determining and approving the engagement of the independent auditors to perform any proposed permissible non-audit services;
- monitoring the rotation of partners of the independent auditors on our audit engagement team as required by applicable laws and rules;
- meeting to review our annual audited financial statements, our quarterly financial statements and our financial press releases with management and the independent auditor, including reviewing our disclosures under “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” included in our annual and quarterly reports filed with the SEC;
- reviewing, overseeing and approving transactions between Jazz Pharmaceuticals and any related persons;
- conferring with management and the independent auditors regarding the scope, adequacy and effectiveness of our internal control over financial reporting;
- reviewing with management and the independent auditors, as appropriate, major financial risk exposures and the steps taken by management to monitor and control these exposures; and
- establishing procedures, when and as required under applicable laws and rules, for the receipt, retention and treatment of complaints received by Jazz Pharmaceuticals (if any) regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters.

The audit committee is currently composed of five directors: Messrs. Berns, Enright, Gray and O’Keefe and Ms. McSharry. Our board of directors has determined that Messrs. Berns, Enright, Gray and O’Keefe and Ms. McSharry meet the independence requirements of Rule 10A-3 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and NASDAQ listing standards with respect to audit committee members. Our board of directors has also determined that each of Messrs. Enright, Gray and O’Keefe and Ms. McSharry is an “audit committee financial expert” as such term is defined in Item 407(d)(5) of Regulation S-K. In making this determination, our board of directors considered the overall knowledge, experience and familiarity of each of Messrs. Enright, Gray and O’Keefe and Ms. McSharry with accounting matters and in analyzing and evaluating financial statements. Mr. O’Keefe serves as chairperson of the audit committee.

The Jazz Pharmaceuticals plc audit committee met five times during 2012; prior to the Azur Merger, the Jazz Pharmaceuticals, Inc. audit committee did not meet in 2012.

### **Report of the Audit Committee of the Board of Directors<sup>(1)</sup>**

The audit committee has reviewed and discussed the company’s audited financial statements for the fiscal year ended December 31, 2012 with management of the company. The audit committee has discussed with KPMG, Dublin, the independent registered public accounting firm that audited the company’s financial statements for the fiscal year ended December 31, 2012, the matters required to be discussed by Accounting Standard No. 16 “Communications with Audit Committees,” as adopted by the Public Company Accounting Oversight Board, or the PCAOB, in Release No. 2012-004. The audit committee has also received the written disclosures and the letter from KPMG, Dublin required by applicable requirements of the PCAOB regarding the independent accountants’ communications with the audit committee concerning independence, and has discussed with KPMG, Dublin that firm’s independence. Based on the foregoing, the audit committee recommended to the board of directors that the audited financial statements be included in the company’s annual report on Form 10-K filed with the SEC for the fiscal year ended December 31, 2012.

Respectfully submitted,  
The Audit Committee of the Board of Directors\*

Mr. Kenneth W. O’Keefe (Chairperson)  
Mr. Paul L. Berns  
Mr. Patrick G. Enright

### **Compensation Committee**

The compensation committee oversees, reviews and approves our compensation policies, plans and programs, determines the compensation to be paid to our executive officers and directors, and prepares and reviews the compensation committee report included in our annual proxy statement. Specific responsibilities and authority of our compensation committee include:

- reviewing, modifying (as needed) and approving overall compensation strategy and policies;
- recommending to our board of directors for determination and approval the compensation and other terms of employment of our Chief Executive Officer and evaluating our Chief Executive Officer’s performance in light of relevant goals and objectives;

<sup>(1)</sup> The material in this report is not “soliciting material,” is not deemed “filed” with the SEC and is not to be incorporated by reference in any filing of the company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

\* The members of the audit committee who participated in the review, discussions and recommendation to the board of directors with respect to the company’s audited financial statements for the fiscal year ended December 31, 2012 included in the 2012 10-K were Messrs. Berns, Enright and O’Keefe. Mr. Gray and Ms. McSharry were appointed to the audit committee in May 2013.

- reviewing and approving the goals and objectives of our other executive officers and determining and approving the compensation and other terms of employment of these executive officers, as appropriate;
- reviewing and recommending to our board of directors the type and amount of compensation to be paid or awarded to the members of our board of directors;
- having the full power and authority of our board of directors regarding the adoption, amendment and termination of our compensation plans and programs and administering these plans and programs;
- having the authority, in its sole discretion, to retain or obtain, at the expense of the company, advice and assistance from compensation consultants and internal or external legal, accounting and other advisors;
- having direct responsibility for appointing, and providing compensation and oversight of the work of, any compensation consultants and other advisors retained by the compensation committee and considering the independence of each such advisor;
- periodically reviewing with our Chief Executive Officer the plans for succession to the offices of our executive officers and making recommendations to our board of directors with respect to the selection of appropriate individuals to succeed to these positions; and
- reviewing and discussing with management our disclosures contained under the caption “Compensation Discussion and Analysis.”

The compensation committee is currently composed of five directors: Messrs. Berns, Enright and Wunningham and Drs. Riedel and Sohn. Mr. Berns serves as the chairperson of the compensation committee. Each member of the compensation committee is independent (as independence is currently defined in Rule 5605(a)(2) of the NASDAQ listing standards).

The Jazz Pharmaceuticals plc compensation committee held four meetings during 2012 and did not act by written consent during the year. Prior to the Azur Merger, the Jazz Pharmaceuticals, Inc. compensation committee did not meet during 2012 and acted by unanimous written consent one time during 2012. The compensation committee also had a number of informal discussions and consultations with one another and with Mr. Cozadd, our Chairman and Chief Executive Officer.

### **Compensation Committee Processes and Procedures**

Typically, the compensation committee meets four times per year, generally on the same day as or near the time of regularly scheduled board meetings, and with greater frequency if necessary. The agenda for each compensation committee meeting is usually developed by the Senior Vice President, Human Resources and Chief Executive Officer, with input from the General Counsel, and is reviewed with the chairperson of the compensation committee. From time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the compensation committee to make presentations, provide financial or other background information or advice or otherwise participate in compensation committee meetings. Mr. Cozadd may not participate in, or be present during, any deliberations or determinations of the compensation committee regarding his compensation. The charter of the compensation committee grants the compensation committee full access to all books, records, facilities and personnel of the company, as well as authority to obtain, at our expense, advice and assistance from internal and external legal, accounting or other advisors and consultants and other external resources that the compensation committee considers necessary or appropriate in the performance of its duties. In particular, the compensation committee has the authority, in its sole discretion, to retain or obtain, at the expense of the company, compensation consultants to assist in its evaluation of executive compensation, and is directly responsible for the appointment, compensation and oversight of the work of its compensation consultants. In this regard, the compensation committee has retained Radford, an Aon Hewitt company, as its independent compensation consultant to provide the compensation committee with benchmark and industry compensation data and advice concerning setting executive officers’ compensation, including base salaries, performance-based bonuses and long-term equity compensation.



Under its charter, the compensation committee may form, and delegate authority to, subcommittees as appropriate, including, but not limited to, a subcommittee composed of one or more members of the board of directors, to grant stock awards under our equity compensation plans. The compensation committee has delegated authority to each of our Chief Executive Officer, Chief Financial Officer and General Counsel, while still also retaining authority for itself and for the board of directors, to approve discretionary equity grants under our 2011 Equity Incentive Plan, or the 2011 Plan, and our 2007 Equity Incentive Plan, or the 2007 Plan, as applicable, (i) to non-executive officer employees of our company or any of our subsidiaries as annual grants, new hire grants or promotion grants that are either (a) within the applicable ranges approved by the compensation committee depending on the level of the employee and the type of grant, or (b) in the aggregate with all annual grant, new hire and promotional grants do not exceed the maximum number approved by the compensation committee as subject to this delegated authority for any calendar year; (ii) to consultants that are within the ranges adopted by the compensation committee; (iii) to our President's Club participants that are within the guidelines or limits for the President's Club program adopted by the compensation committee with respect to the year as to which the equity incentives are being granted; and (iv) to employees of or consultants to the company or any of its subsidiaries for extraordinary reasons, other than those listed in clauses (i) through (iii) above, that in the aggregate with all grants listed in clause (i), do not exceed the maximum number approved by the compensation committee as subject to this delegated authority for any calendar year. The purpose of this authority is to enhance the flexibility of equity incentive administration within Jazz Pharmaceuticals and to facilitate the timely grant of stock awards to new non-executive officer employees of the company within the specified guidelines approved by the compensation committee. As part of its oversight function, the compensation committee reviews, at each regularly scheduled meeting of the compensation committee, a report of any equity incentives granted under this delegated authority since the last regularly scheduled meeting. The compensation committee does not delegate any of its functions to others in determining executive compensation.

For additional information regarding our processes and procedures for the consideration and determination of executive compensation, including the role of Radford in the determination of executive compensation, see the section of this proxy statement entitled "*Executive Compensation – Compensation Discussion and Analysis.*" With respect to director compensation matters, our compensation committee determines and sets non-employee director compensation. Our compensation arrangements for our non-employee directors are described under the section of this proxy statement entitled "*Director Compensation.*"

### **Compensation Committee Interlocks and Insider Participation**

In 2012, prior to the Azur Merger, Jazz Pharmaceuticals, Inc.'s compensation committee was composed of three directors: Messrs. Berns, Colella and Michelson. Each of Messrs. Colella and Michelson resigned prior to the Azur Merger. Following the Azur Merger, our compensation committee was composed of three directors: Messrs. Berns, Enright and Winningham, who were joined by Dr. Sohn, who was appointed to our compensation committee following her election to our board of directors at the 2012 annual general meeting of shareholders, and by Dr. Riedel, who was appointed to our compensation committee following his appointment to our board of directors in May 2013. Please refer to the section of this proxy statement entitled "*Certain Transactions With or Involving Related Persons*" for information concerning certain transactions with or involving Messrs. Berns and Enright.

No member of our compensation committee or of Jazz Pharmaceuticals, Inc.'s compensation committee during 2012 has at any time been an officer or employee of us or Jazz Pharmaceuticals, Inc. None of our executive officers serves, or in the past fiscal year has served, as a member of the board of directors or the compensation committee of any entity that has one or more of its executive officers serving on the board of directors or compensation committee of us or Jazz Pharmaceuticals, Inc.

## Compensation Committee Report<sup>(1)</sup>

The compensation committee has reviewed and discussed with management the Compensation Discussion and Analysis contained herein. Based on this review and discussion, the compensation committee has recommended to the board of directors that the Compensation Discussion and Analysis be included in our proxy statement for the 2013 annual general meeting of shareholders and be included in our annual report on Form 10-K that we filed with the SEC for the fiscal year ended December 31, 2012.

Respectfully submitted,  
The Compensation Committee of the Board of  
Directors\*

Mr. Paul L. Berns (Chairperson)  
Mr. Patrick G. Enright  
Dr. Catherine A. Sohn  
Mr. Rick E Winningham

## Nominating and Corporate Governance Committee

The nominating and corporate governance committee of our board of directors is responsible for, among other things:

- overseeing all aspects of our corporate governance functions on behalf of our board of directors;
- making recommendations to our board of directors regarding corporate governance issues;
- identifying, reviewing and evaluating candidates to serve on our board of directors, and reviewing and evaluating incumbent directors;
- reviewing, evaluating and considering the recommendation for nomination of incumbent members for reelection to our board of directors and monitoring the size of our board;
- recommending director candidates to our board of directors;
- overseeing on behalf of our board of directors the company's compliance with applicable laws and regulations, other than the financial compliance issues overseen by the audit committee;
- overseeing on behalf of our board of directors the company's risk management matters, other than with respect to risks related to the company's financial position or compensation policies overseen by the audit committee and compensation committee, respectively;
- evaluating director nominations and proposals by our shareholders and establishing policies, requirements, criteria and procedures in furtherance of the foregoing; and
- reviewing, discussing and assessing the performance of our board of directors, including committees of our board of directors, seeking input from senior management, our full board of directors and others.

The nominating and corporate governance committee believes that candidates for director should have certain minimum qualifications, including the ability to read and understand basic financial statements, being

<sup>1</sup> The material in this report is not "soliciting material," is not deemed "filed" with the Commission and is not to be incorporated by reference in any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

\* The members of the compensation committee who participated in the review, discussions and recommendation to the board of directors of the Compensation Discussion and Analysis contained herein were Messrs. Berns, Enright and Winningham and Dr. Sohn. Dr. Riedel was appointed to the compensation committee in May 2013.

over 21 years of age, and having the highest personal integrity and ethics. The nominating and corporate governance committee also intends to consider such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to our affairs, and demonstrated excellence in his or her field, having the ability to exercise sound business judgment and having the commitment to rigorously represent the long-term interests of our shareholders. However, the nominating and corporate governance committee retains the right to modify these qualifications from time to time. Members of the nominating and corporate governance committee obtain recommendations for potential directors from their and other board members' contacts in our industry, and may from time to time engage a search firm to assist in identifying potential directors.

Candidates for director nominees are reviewed in the context of the then current composition of the board of directors, the operating requirements of the company and the long-term interests of shareholders. While we do not have a formal policy on board diversity, the nominating and corporate governance committee takes into account a broad range of diversity considerations when assessing director candidates, including individual backgrounds and skill sets, professional experience and other factors, which include gender and residency in and outside of the United States and Ireland, that contribute to our board of directors having an appropriate range of expertise, talents, experiences and viewpoints, and considers those diversity considerations, in view of the needs of the board of directors as a whole, when making decisions on director nominations. In the case of incumbent directors whose terms of office are set to expire, the nominating and corporate governance committee reviews these directors' overall service to the company during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence, to determine whether to recommend them to the board of directors for nomination for a new term. In the case of new director candidates, the nominating and corporate governance committee also determines whether the nominee is "independent" based upon applicable NASDAQ listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The nominating and corporate governance committee conducts appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the board of directors. The nominating and corporate governance committee meets to discuss and consider the candidates' qualifications and then selects a nominee for recommendation to the board of directors.

In 2012, the company, at the direction of the nominating and corporate governance committee, engaged a search firm to conduct a search on our behalf for an audit committee financial expert with extensive Irish private limited company board experience and financial expertise gained as a chief financial officer of a public company, an audit partner at a major public accounting firm or a senior executive with responsibility for a division or corporation, in addition to experience in the healthcare or healthcare products industries. The company additionally charged the search firm with being mindful of the gender diversity of our board of directors in conducting this search. In 2013, the search firm identified and recommended Mr. Gray and Ms. McSharry as director candidates with extensive relevant experience. Dr. Riedel was initially identified to the nominating and corporate governance committee by our chief executive officer in response to interest, on the part of the board of directors, in adding an independent director with a strong scientific background and significant experience managing research and development. The nominating and corporate governance committee reviewed the background and qualifications of each of Mr. Gray, Ms. McSharry and Dr. Riedel and nominated them to our board of directors, which elected each of them to our board of directors in May 2013.

The nominating and corporate governance committee, to date, has not adopted a formal policy with regard to the consideration of director candidates recommended by shareholders and will consider director candidates recommended by shareholders on a case-by-case basis, as appropriate. Shareholders wishing to recommend individuals for consideration by the nominating and corporate governance committee may do so by delivering a written recommendation to our company secretary at Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland with the candidate's name, biographical data and qualifications and a document indicating the candidate's willingness to serve if elected. The nominating and corporate governance committee does not intend to alter the manner in which it evaluates candidates based on whether the candidate was recommended by a shareholder or not.

To date, the nominating and corporate governance committee has not received any such nominations nor has it rejected a director nominee from a shareholder or shareholders holding more than 5% of our voting stock.

The nominating and corporate governance committee is currently composed of three directors: Messrs. Berns and Momtazee and Dr. Sohn. Mr. Momtazee is chairperson of the nominating and corporate governance committee. Each member of the nominating and corporate governance committee is independent (as independence is currently defined in Rule 5605(a)(2) of the NASDAQ listing standards).

The Jazz Pharmaceuticals plc nominating and corporate governance committee met twice during 2012; prior to the Azur Merger, the Jazz Pharmaceuticals, Inc. nominating and corporate governance committee did not meet in 2012.

### **Shareholder Communications with the Board of Directors**

To date, we have not adopted a formal process related to shareholder communications with the board of directors. Nevertheless, every effort has been made to ensure that the views of shareholders are heard by the board of directors or individual directors, as applicable, and that appropriate responses are provided to shareholders in a timely manner. We believe that our responsiveness to shareholder communications to the board of directors has been excellent. As a result, the board of directors believes that there has not been a need to adopt a formal process for shareholder communications with the board.

### **Code of Conduct**

Our Code of Conduct applies to all of our employees, directors and officers, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and those of our subsidiaries. The Code of Conduct is available on our website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) under the section entitled "About Us" at "Corporate Responsibility." Shareholders may request a free copy of the Code of Conduct by submitting a written request to Jazz Pharmaceuticals plc, Attention: Investor Relations, c/o Jazz Pharmaceuticals, Inc., 3180 Porter Drive, Palo Alto, California 94304 U.S.A. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

**PROPOSAL 2**  
**APPROVAL OF APPOINTMENT OF INDEPENDENT AUDITORS**  
**AND AUTHORIZE THE AUDIT COMMITTEE TO DETERMINE THEIR REMUNERATION**

The audit committee of the board of directors is responsible for the appointment, remuneration and retention of our independent auditors. The audit committee has selected KPMG, a registered public accounting firm, as our independent auditors to audit our consolidated financial statements for the year ending December 31, 2013, and our shareholders are being asked to approve such appointment and to authorize the audit committee to determine KPMG's remuneration.

As described elsewhere in this proxy statement, 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 upon the consummation of the Azur Merger. Ernst & Young LLP was the independent registered public accounting firm that audited the financial statements of Jazz Pharmaceuticals, Inc. for the fiscal year ended December 31, 2011. Ernst & Young LLP had audited Jazz Pharmaceuticals, Inc.'s financial statements since its inception in 2003.

Since we are an Irish company, our statutory auditor is required under the Irish Companies Acts of 1963 to 2012, to be based in Ireland. In addition, we determined that our independent registered public accounting firm should be based in Ireland. In order to implement this decision, on January 13, 2012, in connection with but prior to consummation of the Azur Merger, the board of directors of Azur Pharma, in consultation with the audit committee of the board of directors of Jazz Pharmaceuticals, Inc., approved the engagement of KPMG as our independent registered public accounting firm to audit our consolidated financial statements for the fiscal year ended December 31, 2012, with such engagement effective upon consummation of the Azur Merger on January 18, 2012.

Ernst & Young LLP remained as the independent registered public accounting firm of Jazz Pharmaceuticals, Inc. during the period necessary to complete the audit for the year ended December 31, 2011. Our audit committee dismissed Ernst & Young LLP as the independent registered public accounting firm of Jazz Pharmaceuticals, Inc. upon the delivery by Ernst & Young LLP of its audit report for the Jazz Pharmaceuticals, Inc. financial statements for the year ended December 31, 2011, which delivery and dismissal were effective on February 28, 2012.

For the fiscal year ended December 31, 2011, no report by Ernst & Young LLP on the Jazz Pharmaceuticals, Inc. financial statements contained an adverse opinion or a disclaimer of opinion, or was qualified or modified as to uncertainty, audit scope or accounting principles. During the fiscal year ended December 31, 2011 and the subsequent interim period through February 28, 2012, (i) there were no disagreements with Ernst & Young LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Ernst & Young LLP's satisfaction, would have caused Ernst & Young LLP to make reference to the subject matter of the disagreement in connection with its report, and (ii) there were no reportable events of the type described in Item 304(a)(1)(v) of Regulation S-K.

We provided Ernst & Young LLP with copies of the above statements that we also filed with the SEC on January 18, 2012 and February 28, 2012, in each case on a Form 8-K, and in each case requested that Ernst & Young LLP furnish to us a letter addressed to the SEC stating whether or not it agrees with the above statements made by us in response to Item 304(a) of Regulation S-K. Copies of those letters, dated January 18, 2012 and February 28, 2012, are filed as Exhibit 16.1 to the applicable Form 8-K.

Prior to the Azur Merger, KPMG served as the statutory auditor and the independent registered public accounting firm of Azur Pharma. During the fiscal year ended December 31, 2011, and during the subsequent interim period through January 18, 2012, neither Jazz Pharmaceuticals, Inc. (as the accounting acquirer in the Azur Merger and our predecessor) nor anyone acting on its behalf consulted KPMG regarding either: (i) the

application of accounting principles to any transaction, either completed or proposed, or the type of audit opinion that might be rendered on its financial statements, and either a written report was provided or oral advice was provided that KPMG concluded was an important factor that Jazz Pharmaceuticals, Inc. considered in reaching a decision as to the accounting, auditing or financial reporting issue, or (ii) any other matter that was either the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K, or a reportable event of the type described in Item 304(a)(1)(v) of Regulation S-K.

Representatives of KPMG are expected to be present at the annual meeting, will have an opportunity to make a statement if they so desire, and will be available to respond to appropriate questions. Representatives of Ernst & Young LLP are not expected to be present at the annual meeting.

### **Independent Registered Public Accounting Firm Fees and Services**

In connection with the audit of our 2012 financial statements, we entered into an engagement agreement with KPMG which sets forth the terms by which KPMG performed audit and tax services for the company.

The following table represents aggregate fees billed to us for (i) the fiscal year ended December 31, 2012 by KPMG, our independent registered public accounting firm, and (ii) for the fiscal year ended December 31, 2011 by Ernst & Young LLP, Jazz Pharmaceuticals, Inc.'s independent registered public accounting firm for the fiscal year ended December 31, 2011:

	<b>Fiscal Year Ended</b>	
	<b>2012</b>	<b>2011</b>
	<b>(In thousands)</b>	
Audit Fees .....	\$1,706	\$ 803
Audit-Related Fees .....	70	410
Tax Fees .....	2,183	318
All Other Fees .....	<u>3</u>	<u>1</u>
Total Fees .....	<u>\$3,962</u>	<u>\$1,532</u>

*Audit Fees:* Consists of fees and expenses for professional services in respect of the audit of the company's consolidated financial statements, the review of quarterly consolidated financial statements, and statutory audits, including the review of internal controls over financial reporting.

*Audit-Related Fees:* Consists of fees for assurance and related services that are reasonably related to the performance of the audit and the review of the financial statements and which are not reported under "Audit Fees." During the fiscal year ended December 31, 2012, these services consisted of comfort letter procedures performed in connection with a March 2012 public offering by selling shareholders and accounting consultations in connection with our Irish restructuring. During the fiscal year ended December 31, 2011, these services primarily related to due diligence, accounting consultations and work performed in connection with SEC filings made in order to effectuate the Azur Merger.

*Tax Fees:* Consists of fees and expenses for professional services for tax compliance, tax advice and tax planning. During the fiscal year ended December 31, 2012, fees and expenses for professional services of approximately \$119,000 were billed in connection with tax compliance services and approximately \$2,064,000 were billed in connection with tax advice and planning services. The higher level of tax fees and expenses billed in 2012 compared to 2011 reflects additional tax compliance, tax advice and tax planning services provided in connection with significant transactions undertaken by the company in 2012, including the Azur Merger, the EUSA Acquisition and the disposition of the women's health business. During the fiscal year ended December 31, 2011, fees and expenses of approximately \$84,000 were billed in connection with tax compliance services and fees and expenses of approximately \$234,000 were billed in connection with tax advice and planning services.

*All Other Fees:* Consists of fees for products and services other than the services described above. For the fiscal years ended December 31, 2012 and 2011, these are fees paid in connection with access to the online accounting and tax research tools of KPMG and Ernst & Young, respectively.

All fees described above were approved by our or Jazz Pharmaceutical Inc.'s audit committee, as applicable, for the fiscal years ended December 31, 2012 and December 31, 2011, respectively.

### **Pre-Approval Policies and Procedures**

Our audit committee has a policy and procedures for the pre-approval of audit and non-audit services rendered by its independent registered public accounting firm, which is substantially similar to the policy and procedures maintained by Jazz Pharmaceuticals, Inc. prior to the Azur Merger. Our policy, as well as the policy maintained by Jazz Pharmaceuticals, Inc. prior to the Azur Merger, generally requires the pre-approval of specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the audit committee's approval of the scope of the engagement of the independent auditor or on an individual explicit case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the audit committee's members, but the decision must be reported to the full audit committee at its next scheduled meeting.

Our audit committee determined that the rendering of the services other than audit services by our independent registered public accounting firm is compatible with maintaining the principal accountant's independence.

### **Required Vote**

The appointment of KPMG as the independent auditors of the company for the fiscal year ending December 31, 2013 and the authorization to the audit committee to determine the auditors' remuneration must receive the affirmative vote of a majority of the votes cast in person or by proxy at the annual meeting in order to be approved.

*The board of directors recommends a vote "For" Proposal 2.*

**PROPOSAL 3**  
**AUTHORIZE THE COMPANY AND/OR ANY SUBSIDIARY OF THE COMPANY**  
**TO MAKE MARKET PURCHASES OF THE COMPANY'S ORDINARY SHARES**

On January 3, 2012, the historic shareholders of Azur Pharma authorized the company to make open-market purchases of its ordinary shares in an amount up to 20% of the ordinary shares outstanding as of January 18, 2012, giving effect to the Azur Merger. Under Irish law, this authority continued to apply to the company following the Azur Merger but expires on July 3, 2013. In 2012, the company made no repurchases of its ordinary shares, either pursuant to this authority or the redemption authority under its articles of association. In May 2013, the board of directors authorized the company to use up to \$200 million to repurchase its ordinary shares. The company may currently effect repurchases under this share repurchase program, either pursuant to the authority approved by the historic Azur Pharma shareholders in January 2012, or under the redemption authority in its articles of association. Whether or not this Proposal 3 is approved by our shareholders, the company will retain its ability to effect repurchases as redemptions pursuant to its articles of association, although after July 3, 2013, subsidiaries of the company will not be able to make market purchases of our ordinary shares.

In this proposal, shareholders are being asked to authorize the company and/or any of its subsidiaries to make open-market purchases of up to 11,602,815 ordinary shares, which is equal to 20% of the company's issued ordinary shares outstanding as of December 31, 2012, in accordance with the Irish Companies Act 1990, for 18 months from the date of such authorization. Accordingly, if this Proposal 3 is approved by our shareholders, the authority conferred thereby will expire on the close of business on January 31, 2015, unless re-approved prior to such date. Acquisitions of our ordinary shares under this authority would be made only at price levels that the directors consider to be in the best interests of the shareholders generally, after taking into account the company's overall financial position. In addition, this authority is being requested to make repurchases at a price not less than 80% or more than 120% of the then closing market price of those shares on the NASDAQ Global Select Market on the day preceding the day on which the relevant share is purchased.

In order for the company or any of its subsidiaries to make market purchases of the company's ordinary shares pursuant to the authority conferred under this Proposal 3, such shares must be purchased on a "recognized stock exchange." The NASDAQ Global Select Market, on which the company's ordinary shares are listed, is specified as a recognized stock exchange for this purpose by Irish law. This general authority, if approved by our shareholders, will become effective from the date of the annual meeting.

The board of directors is asking our shareholders to vote "For" the following resolution:

"RESOLVED, that the company and any subsidiary of the company is hereby generally authorized to make overseas market purchases of ordinary shares in the company ("shares") on such terms and conditions and in such manner as the board of directors (or a duly constituted committee thereof) of the company may determine from time to time but subject to the provisions of the Companies Act 1990 and to the following provisions:

- a) The maximum number of shares authorized to be acquired by the company and/or any subsidiary of the company pursuant to this resolution shall not exceed, in the aggregate, 20% of the company's issued ordinary shares outstanding as of December 31, 2012.
- b) The maximum price to be paid for any ordinary share shall be an amount equal to 120% of the closing price on the NASDAQ Global Select Market for the ordinary shares on the trading day preceding the day on which the relevant ordinary share is purchased by the company or by the relevant subsidiary of the company, and the minimum price to be paid for any ordinary share shall be an amount equal to 80% of the closing price on the NASDAQ Global Select Market for the ordinary shares on the trading day preceding the day on which the relevant ordinary share is purchased by the company or by the relevant subsidiary of the company.



- c) This general authority will be effective from the date of passing of this resolution and will expire eighteen months from the date of the passing of this resolution, unless previously varied, revoked or renewed by special resolution in accordance with the provisions of section 215 of the Irish Companies Act 1990. The company or any such subsidiary may, before such expiry, enter into a contract for the purchase of shares which would or might be executed wholly or partly after such expiry and may complete any such contract as if the authority conferred hereby had not expired.”

The proposal to authorize the company and/or any subsidiary of the company to make market purchases of the company’s ordinary shares must receive the affirmative vote of a majority of the votes cast in person or by proxy at the annual meeting in order to be approved.

***The board of directors recommends a vote “For” Proposal 3.***

## **PROPOSAL 4**

### **ADVISORY VOTE ON EXECUTIVE COMPENSATION**

Under the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and Section 14A of the Exchange Act, our shareholders are entitled to vote to approve, on an advisory (nonbinding) basis, the compensation of our named executive officers as disclosed in this proxy statement in accordance with the compensation disclosure rules of the SEC. This nonbinding advisory vote is commonly referred to as a “say-on-pay” vote.

At our 2012 annual general meeting of shareholders, the shareholders overwhelmingly approved, on an advisory basis, the compensation of the named executive officers as disclosed in the proxy statement for that meeting pursuant to the compensation disclosure rules of the SEC, with approximately 98% of the votes cast voting in favor of the proposal. The shareholders were also asked to indicate if we should hold a “say-on-pay” vote every year, every two years or every three years. The shareholders indicated by advisory vote their preference to hold a say-on-pay vote every year. After consideration of the voting results, the board of directors elected to hold a shareholder say-on-pay vote every year.

This vote is not intended to address any specific item of compensation, but rather the overall compensation of our named executive officers and the philosophy, policies and practices described in this proxy statement. The compensation of our named executive officers subject to the vote is disclosed in the Compensation Discussion and Analysis, the compensation tables and the related narrative disclosure contained in this proxy statement. As discussed in those disclosures, our compensation committee believes that our executive compensation program is appropriately designed and reasonable in light of the executive compensation programs of its peer group companies, as well as responsible in that it both encourages executive officers to work for meaningful shareholder returns and reflects a pay-for-performance philosophy. The goals of our executive compensation program are to align executive officers’ compensation with our corporate goals and objectives and the interests of our shareholders and to incentivize and reward executive officers for our success. Specifically, we have an executive compensation program that combines short- and long-term components, cash and equity, and fixed and contingent payments, in proportions that we believe are the most appropriate to incentivize and reward our executive officers for achieving our corporate goals while minimizing incentives for excessive risk taking. We place significant emphasis on pay-for-performance-based incentive compensation programs, so that targeted compensation can be achieved only if corporate goals and objectives are met and, in the case of our stock option awards, only if our share price appreciates over time. We also strive to ensure that our compensation program for our executive officers stays competitive to help attract, as needed, and retain talented individuals to manage and operate all aspects of our business. To execute this compensation philosophy, the compensation committee regularly assesses our individual and total compensation programs against comprehensive market data and utilizes an independent compensation consultant to engage in ongoing review of all aspects of our executive compensation programs. Our compensation committee believes that the compensation policies and elements described in this proxy statement provide the necessary incentives to properly align our company’s performance and the interests of our shareholders while maintaining equitable and competitive executive compensation practices that enable us to attract and retain the highest caliber of executives.

The board of directors is asking our shareholders to indicate their support for the compensation of our named executive officers as described in this proxy statement by casting a non-binding advisory vote “For” the following resolution:

“RESOLVED, that the compensation paid to Jazz Pharmaceuticals’ named executive officers, as disclosed pursuant to Item 402 of Regulation S-K, including the Compensation Discussion and Analysis, compensation tables and narrative discussion, is hereby APPROVED.”

Because the vote is advisory, it is not binding on the board of directors or the company. Nevertheless, the views expressed by our shareholders, whether through this vote or otherwise, are important to management and

the board of directors and, accordingly, the board of directors and the compensation committee intend to consider the results of this vote in making determinations in the future regarding executive compensation arrangements.

Unless our board of directors modifies its policy on the frequency of future advisory votes on the compensation of our named executive officers, the next advisory vote on the compensation of our named executive officers will be held at the 2014 annual general meeting of shareholders.

Advisory approval of the compensation of our named executive officers must receive the affirmative vote of a majority of the votes cast in person or by proxy at the annual meeting in order to be approved.

***The board of directors recommends a vote “For” Proposal 4.***

**SECURITY OWNERSHIP OF  
CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information regarding the ownership of our ordinary shares as of May 15, 2013 (except as noted) by: (i) each director and each nominee for director; (ii) each of the executive officers named in the Summary Compensation Table (referred to throughout this proxy statement as our “named executive officers”); (iii) all of our executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our ordinary shares.

<u>Name and Address of Beneficial Owner<sup>(1)</sup></u>	<u>Beneficial Ownership<sup>(2)</sup></u>	
	<u>Number of Shares</u>	<u>Percentage of Total</u>
<b>5% Shareholders:</b>		
Janus Capital Management LLC <sup>(3)</sup> . . . . . 151 Detroit Street Denver, CO 80206	5,662,470	9.6%
BlackRock, Inc. <sup>(4)</sup> . . . . . 40 East 52 <sup>nd</sup> Street New York, NY 10022	4,157,072	7.1%
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P. 9 West 57th Street, Suite 4200 New York, NY 10019		
KKR JP LLC <sup>(5)</sup> . . . . .	3,782,895	6.4%
KKR JP III LLC <sup>(5)</sup> . . . . .	7,888	*
Putnam Investment, LLC <sup>(6)</sup> . . . . . One Post Office Square Boston, MA 02109	3,531,824	6.0%
<b>Named Executive Officers and Directors:</b>		
Bruce C. Cozadd <sup>(7)</sup> . . . . .	513,546	*
Kathryn E. Falberg <sup>(8)</sup> . . . . .	102,952	*
Suzanne Sawochka Hooper . . . . .	—	*
Russell J. Cox <sup>(9)</sup> . . . . .	40,394	*
Jeffrey K. Tobias, M.D. . . . .	—	*
Paul L. Berns <sup>(10)</sup> . . . . .	8,816	*
Patrick G. Enright <sup>(11)</sup> . . . . .	1,746,013	2.9%
Peter Gray . . . . .	—	*
Heather Ann McSharry . . . . .	—	*
James C. Momtazee <sup>(12)</sup> . . . . .	35,517	*
Seamus Mulligan <sup>(13)</sup> . . . . .	2,002,555	3.4%
Kenneth W. O’Keefe <sup>(14)</sup> . . . . .	287,586	*
Norbert G. Riedel, Ph.D. . . . .	—	*
Catherine A. Sohn, Pharm.D. . . . .	—	*
Rick E Winningham <sup>(15)</sup> . . . . .	41,782	*
All directors and executive officers as a group (17 persons) <sup>(16)</sup> . . . . .	4,816,982	8.0%

\* Less than 1%.

(1) Unless otherwise provided in the table above or in the notes below, the address for each of the beneficial owners listed is c/o Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland.

(2) This table is based upon information supplied by officers, directors and principal shareholders and Schedules 13G or 13D filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the shareholders named in

this table has sole voting and investment power with respect to the ordinary shares indicated as beneficially owned. Applicable percentages are based on 58,884,120 ordinary shares outstanding on May 15, 2013, adjusted as required by rules promulgated by the SEC. The number of shares beneficially owned includes ordinary shares issuable pursuant to the exercise of stock options and warrants that are exercisable within 60 days of May 15, 2013, and shares credited to individual non-employee director phantom stock accounts as of May 15, 2013 under our amended and restated Directors Deferred Compensation Plan, which is referred in this proxy statement as the Directors Deferred Plan. Amounts credited to individual non-employee director phantom stock accounts under our Directors Deferred Plan are payable solely in our ordinary shares, but such shares do not have current voting or investment power. Shares issuable pursuant to the exercise of stock options and warrants that are exercisable within 60 days of May 15, 2013 and shares issuable pursuant to our Directors Deferred Plan are deemed to be outstanding and beneficially owned by the person to whom such shares are issuable for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

- (3) This information is based on a Schedule 13G filed by Janus Capital Management LLC (“Janus Capital”) with the SEC on February 14, 2013, which reported that Janus Capital has a direct 95.67% ownership stake in INTECH Investment Management (“INTECH”) and a direct 77.8% ownership stake in Perkins Investment Management LLC (“Perkins”) and, as a result of this ownership structure, holdings for Janus Capital, Perkins and INTECH are aggregated for purposes of reporting the holdings of Janus Capital. According to the Schedule 13G, Janus Capital, Perkins and INTECH are registered investment advisers, each furnishing investment advice to various investment companies registered under section 8 of the Investment Company Act of 1940 (“ICA”) and to individual and institutional clients (collectively referred to herein as “Managed Portfolios”). As a result of its role as investment adviser or sub-adviser to the Managed Portfolios, Janus Capital may be deemed to be the beneficial owner of 5,662,470 ordinary shares held by such Managed Portfolios as of December 31, 2012 and has sole voting power and sole dispositive power over all 5,662,470 ordinary shares reported. However, Janus Capital does not have the right to receive any dividends from, or the proceeds from the sale of, the securities held in the Managed Portfolios and disclaims any ownership associated with such rights. Janus Overseas Fund is an investment company registered under the ICA and is one of the Managed Portfolios to which Janus Capital provides investment advice. As of December 31, 2012, Janus Overseas Fund beneficially held 3,074,338 ordinary shares. The Schedule 13G filed by the reporting persons provides information only as of December 31, 2012, and, consequently, the beneficial ownership of the above-mentioned reporting persons may have changed between December 31, 2012 and May 15, 2013.
- (4) This information is based on a Schedule 13G filed by BlackRock, Inc. (“BlackRock”) with the SEC on January 30, 2013, which reported the beneficial ownership of our ordinary shares as of December 31, 2012 by the following subsidiaries of BlackRock: BlackRock Advisors, LLC, BlackRock Financial Management, Inc., BlackRock Investment Management, LLC, BlackRock Asset Management Australia Limited, BlackRock Asset Management Canada Limited, BlackRock Advisors (UK) Limited, BlackRock Fund Advisors, BlackRock International Limited, BlackRock Institutional Trust Company, N.A., BlackRock Japan Co. Ltd. and BlackRock Investment Management (UK) Limited. The Schedule 13G reported that BlackRock has sole voting power and sole dispositive power over all of the 4,157,072 ordinary shares reported. The Schedule 13G provides information only as of December 31, 2012, and, consequently, the beneficial ownership of the above-mentioned reporting person may have changed between December 31, 2012 and May 15, 2013.
- (5) KKR JP LLC (“KKR JP”) directly holds 3,185,058 of our ordinary shares and warrants to purchase 597,837 of our ordinary shares. KKR Millennium Fund L.P. (“KKR Millennium Fund”) is the sole member of KKR JP. KKR Associates Millennium L.P. (“KKR Associates Millennium”) is the sole general partner of KKR Millennium Fund. KKR Millennium GP LLC (“KKR Millennium GP”) is the sole general partner of KKR Associates Millennium. KKR Fund Holdings L.P. (“KKR Fund Holdings”) is the designated member of KKR Millennium GP. KKR Fund Holdings GP Limited (“KKR Fund Holdings GP”) is a general partner of KKR Fund Holdings. KKR Millennium Fund, KKR Associates Millennium, KKR Millennium GP, KKR Fund Holdings and KKR Fund Holdings GP disclaim beneficial ownership of the securities held by KKR JP.

KKR JP III LLC (“KKR JP III”) directly holds 7,888 of our ordinary shares. KKR Partners III, L.P. (“KKR Partners III”) is the sole member of KKR JP III. KKR III GP LLC (“KKR III GP”) is the sole general partner of KKR Partners III. KKR Partners III and KKR III GP disclaim beneficial ownership of the securities held by KKR JP III.

Each of KKR Group Holdings L.P. (“KKR Group Holdings”) (as the sole shareholder of KKR Fund Holdings GP and a general partner of KKR Fund Holdings L.P.); KKR Group Limited (“KKR Group”) (as the general partner of KKR Group Holdings); KKR & Co. L.P. (“KKR & Co.”) (as the sole shareholder of KKR Group); and KKR Management LLC (as the general partner of KKR & Co.) disclaim beneficial ownership of the securities held by KKR JP.

As the designated members of KKR Management LLC and the managing members of KKR III GP LLC, Messrs. Henry R. Kravis and George R. Roberts may be deemed to be the beneficial owner of the securities held by KKR JP and KKR JP III but disclaim beneficial ownership of such securities. Messrs. Kravis and Roberts have also been designated as managers of KKR Millennium GP by KKR Fund Holdings.

The entities named in this footnote (5) are sometimes referred to herein as the KKR Entities. The KKR Entities may be deemed to be a group with respect to our securities which they hold directly or indirectly. The KKR Entities disclaim such group membership.

James C. Momtazee is an executive of Kohlberg Kravis Roberts & Co. L.P. and/or one or more of its affiliates. Mr. Momtazee is a member of our board of directors. Mr. Momtazee disclaims beneficial ownership of any securities beneficially owned by the KKR Entities. The address of the KKR Entities and Mr. Kravis is c/o Kohlberg Kravis Roberts & Co. L.P., 9 West 57th Street, New York, NY 10019. The address of Messrs. Roberts and Momtazee is c/o Kohlberg Kravis Roberts & Co. L.P., 2800 Sand Hill Road, Suite 200, Menlo Park, CA 94025.

- (6) This information is based on a report on Form TR-1 and other information provided to us by Putnam Investments, LLC (“Putnam”) on May 17, 2013, which reported the holdings of Putnam as of May 15, 2013. According to the report, shares reflected as indirectly owned by Putnam consist of 3,445,345 ordinary shares owned by Putnam Investment Management, LLC (“PIM”), 38,517 ordinary shares owned by The Putnam Advisory Company, LLC (“PAC”), 17,362 ordinary shares owned by Putnam Fiduciary Trust Company (“PFTC”), 16,300 ordinary shares owned by Putnam Investments Inc. (“PII”) and 14,300 ordinary shares owned by Putnam Investments Limited (“PIL”). Each of PIM, PAC, PFTC, PII and PIL is a wholly owned subsidiary of Putnam. PIM is the investment advisor to the Putnam family of mutual funds and PAC is the investment advisor to Putnam’s institutional clients. Putnam holds all of these shares on behalf of either its mutual funds or its institutional clients for investment purposes only. As of May 15, 2013, Putnam held indirect voting rights over all 3,531,824 ordinary shares reported.
- (7) Includes 2,903 ordinary shares Mr. Cozadd has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013.
- (8) Includes 4,535 ordinary shares Ms. Falberg has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013.
- (9) Includes 30,375 ordinary shares Mr. Cox has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013.
- (10) Includes 4,691 ordinary shares issuable to Mr. Berns pursuant to our Directors Deferred Plan as of May 15, 2013 and 4,125 ordinary shares Mr. Berns has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013.
- (11) Includes 9,929 ordinary shares issuable to Mr. Enright pursuant to our Directors Deferred Plan as of May 15, 2013 and 4,125 ordinary shares Mr. Enright has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013. Also includes 768,670 ordinary shares and a warrant to acquire 929,243 of our ordinary shares held by Longitude Venture Partners, L.P. and 15,422 ordinary shares and a warrant to acquire 18,624 of our ordinary shares held by Longitude Capital Associates, L.P. The funds named in this footnote (11) are sometimes referred to herein as the Longitude Funds. Each of Mr. Enright and Juliet Tammenoms Bakker are managing members of Longitude Capital Partners, LLC, which is the general

partner of each of the Longitude Funds, and may be deemed to have shared voting and dispositive power with respect to the ordinary shares held by or issuable to the Longitude Funds. Each of Mr. Enright and Ms. Bakker disclaims beneficial ownership of all such ordinary shares except to the extent of such person's proportionate pecuniary interest therein.

- (12) Includes 17,507 ordinary shares issuable to Mr. Momtazee pursuant to our Directors Deferred Plan as of May 15, 2013 and 4,125 ordinary shares Mr. Momtazee has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013. Mr. Momtazee disclaims beneficial ownership of the shares described in footnote (5) above.
- (13) Includes 1,500 ordinary shares Mr. Mulligan has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013. Also includes 569,161 ordinary shares held by Deutsche Bank National Trust Company, or Deutsche Bank, as escrow agent, as security for the indemnification obligations of the historic Azur Pharma shareholders in connection with the Azur Merger pursuant to an escrow agreement among us, Jazz Pharmaceuticals, Inc., Seamus Mulligan, as representative of the indemnitors, and Deutsche Bank.
- (14) Includes 22,249 ordinary shares issuable to Mr. O'Keefe pursuant to our Directors Deferred Plan as of May 15, 2013 and 4,125 ordinary shares Mr. O'Keefe has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013. Also includes (i) 222,865 ordinary shares held by Beecken Petty O'Keefe Fund II L.P., Beecken Petty O'Keefe QP Fund II, L.P. and Beecken Petty O'Keefe Executive Fund II, L.P. as tenants in common (collectively, "BPO Fund II") and (ii) 38,347 ordinary shares held by Beecken Petty O'Keefe & Company II, L.P. Beecken Petty O'Keefe & Company II, L.P., is the general partner of BPO Fund II and Beecken Petty O'Keefe & Company, LLC is the general partner of Beecken Petty O'Keefe & Company II, L.P. Mr. O'Keefe, David K. Beecken and William G. Petty, Jr. are member managers of Beecken Petty O'Keefe & Company, LLC, and as such may be deemed to have shared voting and dispositive power with respect to the ordinary shares beneficially owned by BPO Fund II and Beecken Petty O'Keefe & Company II, L.P. Each of Messrs. O'Keefe, Beecken and Petty disclaims beneficial ownership of the ordinary shares beneficially owned by BPO Fund II and Beecken Petty O'Keefe & Company II, L.P., except to the extent of each of their pecuniary interest therein.
- (15) Includes 4,125 ordinary shares Mr. Winningham has the right to acquire pursuant to options exercisable within 60 days of May 15, 2013.
- (16) Includes 1,045,304 ordinary shares and warrants to purchase 947,867 ordinary shares held by entities affiliated with certain of our non-employee directors, 58,910 ordinary shares that our executive officers have the right to acquire pursuant to options exercisable within 60 days of May 15, 2013, 22,125 ordinary shares that our non-employee directors have the right to acquire pursuant to options exercisable within 60 days of May 15, 2013, and 54,376 ordinary shares issuable to non-employee directors pursuant to our Directors Deferred Plan as of May 15, 2013. See footnotes (7) through (15) above.

#### **SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the Securities and Exchange Commission, or SEC, initial reports of ownership and reports of changes in ownership of our ordinary shares and other equity securities. Officers, directors and greater than ten percent shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the fiscal year ended December 31, 2012, all Section 16(a) filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with, except that a Form 4 originally filed on January 13, 2012 by Bryan C. Cressey, a former director, incorrectly stated the number of shares of Jazz Pharmaceuticals, Inc. common stock indirectly held by Mr. Cressey. This error was carried over to a Form 4 filed by Mr. Cressey on January 18, 2012 to report the disposition of securities of Jazz Pharmaceuticals, Inc. in the Azur Merger, and a separate Form 4 filed by Mr. Cressey on January 18, 2012 to report the corresponding acquisition of our securities in the Azur Merger.

## EXECUTIVE OFFICERS

The following table sets forth certain information concerning our executive officers as of June 4, 2013:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Bruce C. Cozadd . . . . .	49	Chairman and Chief Executive Officer
Russell J. Cox . . . . .	50	Executive Vice President and Chief Commercial Officer
Kathryn E. Falberg . . . . .	52	Executive Vice President and Chief Financial Officer
Suzanne Sawochka Hooper . .	47	Executive Vice President and General Counsel
Fintan Keegan. . . . .	54	Executive Vice President, Technical Operations
Jeffrey K. Tobias, M.D. . . . .	58	Executive Vice President, Research and Development and Chief Medical Officer
Karen J. Wilson . . . . .	50	Senior Vice President, Finance and Principal Accounting Officer

*Bruce C. Cozadd.* Biographical information regarding Mr. Cozadd is set forth above under “*Proposal 1—Election of Directors—Class III Directors Continuing in Office Until the 2014 Annual General Meeting.*”

*Russell J. Cox* was appointed our Executive Vice President and Chief Commercial Officer as of March 2012 and served as our Senior Vice President, Sales and Marketing from the Azur Merger until March 2012. Prior to the Azur Merger, he served in a variety of senior management roles since joining Jazz Pharmaceuticals, Inc. in 2010. From January 2009 to January 2010, he was Senior Vice President and Chief Commercial Officer of Ipsen Group, and from 2007 until December 2008, he was Vice President of Marketing at Tercica, Inc. (acquired by Ipsen Group), a biotechnology company. From 2003 to 2007, he was with Scios Inc. (acquired by Johnson and Johnson later in 2003), where he also held the role of Vice President, Marketing. Prior to 2003, Mr. Cox was with Genentech, Inc. for 12 years, where he was a Product Team Leader (PTL) responsible for the Growth Hormone franchise and led numerous product launches as a Group Product Manager. Mr. Cox received a B.S. in Biomedical Science from Texas A&M University.

*Kathryn E. Falberg* was appointed our Executive Vice President and Chief Financial Officer as of March 2012 and served as our Senior Vice President and Chief Financial Officer from the Azur Merger until March 2012. Prior to the Azur Merger, she served as Jazz Pharmaceuticals, Inc.’s Senior Vice President and Chief Financial Officer since joining Jazz Pharmaceuticals, Inc. in December 2009. From 2003 to 2008, Ms. Falberg was President of Canyon Capital & Consulting, a private investment and consulting firm, where she worked with a number of smaller companies while also serving as a corporate director and audit committee chair for several companies, and from February to November 2009, she was Chief Financial Officer and Chief Operating Officer at ARCA biopharma, Inc., a biopharmaceutical company. From 1995 through 2001, Ms. Falberg was with Amgen, Inc., where she served as Senior Vice President Finance, Strategy and Chief Financial Officer, and before that as Vice President, Controller and Chief Accounting Officer, and Vice President, Treasurer. Ms. Falberg received an M.B.A. and B.A. in Economics from the University of California, Los Angeles and is a Certified Public Accountant (inactive). Ms. Falberg currently serves on the boards, and is chair of the audit committees, of the biopharmaceutical companies Halozyme Therapeutics, Inc. and Medivation, Inc.

*Suzanne Sawochka Hooper* was appointed our Executive Vice President and General Counsel as of March 2012. From 1999 through early 2012, she was a partner in the law firm Cooley LLP. Ms. Hooper served for several years as a member of Cooley’s Management Committee and as Vice Chair of the firm’s Business Department. While at Cooley, Ms. Hooper practiced corporate and securities law, primarily with companies and investors in the life sciences industry. Ms. Hooper received a J.D. from the University of California, Berkeley, Boalt Hall School of Law and a B.A. in Political Science from the University of California, Santa Barbara. Ms. Hooper is a member of the State Bar of California.

*Fintan Keegan* was appointed our Executive Vice President, Technical Operations in July 2012 and served as our Senior Vice President of Technical Operations from the Azur Merger until July 2012. Prior to the Azur



Merger, he was Senior Vice President and Chief Technical Officer of Azur Pharma from 2006 until the Azur Merger, where he was responsible for quality, regulatory, compliance, supply chain and development. Prior to his work with Azur Pharma, Mr. Keegan most recently served as Vice President of Quality and Regulatory for Elan Corporation, plc. He also held various positions with Wyeth Pharmaceuticals, Inc., Merck & Co., Inc. and at a clinical contract research organization. Mr. Keegan holds a B.Sc and a H. Dip in Pharmaceutical Manufacturing Technology from Trinity College Dublin and a M.Sc from the School of Chemistry, University of Bristol, in the United Kingdom.

*Jeffrey K. Tobias, M.D.*, was appointed our Executive Vice President, Research and Development and Chief Medical Officer as of March 2012 and served as our Senior Vice President, Research and Development and Chief Medical Officer from the Azur Merger until March 2012. Prior to the Azur Merger, he served as Jazz Pharmaceuticals, Inc.'s Senior Vice President, Research and Development and Chief Medical Officer since joining Jazz Pharmaceuticals, Inc. in October 2011. From January 2010 to October 2011, Dr. Tobias served as Executive Vice President, Research and Development at NeurogesX, Inc.; previously, he served as NeurogesX's Chief Medical Officer since November 2005. Dr. Tobias was founder and managing director of the Aquila Consulting Group, LLC, a biopharmaceutical consulting firm, from September 1996 to November 2005. Prior to these activities, Dr. Tobias was a Director, New Product Discovery at ALZA Corporation, Director, Clinical Development at Chiron Corporation and Director, Clinical Research at Xoma Corporation. Dr. Tobias received board certification in both Internal Medicine and Pulmonary Medicine and completed training in Critical Care Medicine at the University of California, Los Angeles. He received an M.D. with honors and a B.A. from the University of Illinois.

*Karen J. Wilson* has served as our Senior Vice President, Finance and Principal Accounting Officer since February 2013 and served as our Vice President, Finance and Principal Accounting Officer from the Azur Merger until February 2013. Prior to the Azur Merger, she served as Jazz Pharmaceuticals, Inc.'s Vice President, Finance since February 2011 and was appointed Principal Accounting Officer in March 2011. From 2009 to January 2011, Ms. Wilson served as Vice President of Finance and Principal Accounting Officer at PDL BioPharma, Inc. From 2005 to 2009, she served as a principal at the consulting firm Wilson Crisler LLC. Previously, from 2001 to 2004, she was Chief Financial Officer of ViroLogic, Inc. Prior to joining ViroLogic, Ms. Wilson served as Chief Financial Officer and Vice President of Operations for Novare Surgical Systems, Inc. from 1999 to 2001. Prior to 1999, Ms. Wilson worked for Deloitte & Touche LLP for ten years, serving clients in both the medical and technology fields. Ms. Wilson is a Certified Public Accountant (inactive) in the State of California and received a B.S. in Business from the University of California, Berkeley.

## EXECUTIVE COMPENSATION

### Compensation Discussion and Analysis

The following Compensation Discussion and Analysis describes the material elements of compensation for the individuals who served as our principal executive officer, principal financial officer and three other most highly compensated executive officers as of December 31, 2012, or the named executive officers: Bruce C. Cozadd, Chairman and Chief Executive Officer, Kathryn E. Falberg, Executive Vice President and Chief Financial Officer, Russell J. Cox, Executive Vice President and Chief Commercial Officer, Suzanne Sawochka Hooper, Executive Vice President and General Counsel and Jeffrey K. Tobias, M.D., Executive Vice President, Research and Development and Chief Medical Officer.

### Executive Summary

The compensation committee believes that our executive compensation program is appropriately designed and reasonable in light of the executive compensation programs of our peer group companies. The compensation committee also believes that our executive compensation program is responsible in that it both encourages executive officers to work for meaningful shareholder returns and reflects a pay-for-performance philosophy, without encouraging our executive officers to assume excessive risks.

2012 was an exceptional year for Jazz Pharmaceuticals. The highlights of our performance during the year included:

- The price of our ordinary shares increased 38%. As of December 31, 2012, our one-year and three-year annualized total shareholder returns were approximately 38% and 89%, respectively, and significantly outperformed the Global Industry Classification Standard Pharmaceuticals and Biotechnology median one-year and three-year total shareholder returns of approximately 18% and 8% for the same periods (as published by Institutional Shareholder Services).
- We achieved our third successive year of profitability, with significant increases in net income and operating cash flows, driven primarily by inclusion of revenues from the acquired Azur Pharma and EUSA Pharma businesses and increased net sales of Xyrem® (sodium oxybate) oral solution.
  - Total revenues were \$586.0 million, representing an increase of 115% over total revenues of \$272.3 million in 2011.
  - GAAP income from continuing operations for 2012 was \$261.1 million compared to \$125.0 million for 2011, representing a 108.9% increase.
  - Net sales of Xyrem increased from \$233.3 million in 2011 to \$378.7 million in 2012, representing a 62% increase.
  - For the full year, we reported GAAP net income per diluted share of \$4.79.
- The Azur Merger was announced in September 2011 and completed in January 2012.
- The EUSA Acquisition was announced in April and completed in June 2012.
  - Among other products, Erwinaze®/Erwinase® (asparaginase *Erwinia chrysanthemi*) was added to our global product portfolio and our 2012 net sales of Erwinaze/Erwinase since the EUSA Acquisition on June 12, 2012 were \$72.1 million.
- As a result of the Azur Merger and EUSA Acquisition, in 2012 we also:
  - gained an enhanced commercial platform and commercial infrastructure in the United States and Europe and an international distribution network;
  - moved our headquarters to Dublin, Ireland, gained multiple offices in the United States, the United Kingdom and other countries in Europe, and increased the number of our employees from approximately 260 in the United States at the end of 2011 to approximately 610 in 11 countries at the end of 2012; and

- made substantial progress towards our strategy to increase the number of products we market and, as a result, decreased our revenue concentration risk.
- Our efforts to improve patient support services and our deployment of a dedicated Xyrem sales force to increase physician knowledge about Xyrem and narcolepsy reaped tangible benefits in 2012, contributing to the year's increase in the average number of patients on Xyrem.
- Two additional patents for Xyrem issued in 2012, expanding intellectual property protection for our lead product.
- In October 2012, we completed the sale of our women's health business, which included six products acquired in the Azur Merger, to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl for net cash proceeds of \$93.9 million.

We believe our executive compensation program design provides a balanced approach between rewarding our executives for current and long-term performance. Our 2012 executive compensation policies included the following:

- The majority of our compensation is linked to performance: 7% of compensation is fixed and 93% of compensation is performance-based for our Chief Executive Officer, while for our other named executive officers, an average of 11% of compensation is fixed and 89% of compensation is performance-based.
- We generally target total cash compensation for employees (including both base salary and the annual target performance bonus) at the 50<sup>th</sup> percentile and equity compensation for employees at the 60<sup>th</sup> percentile, in each case, of market data compiled by our compensation consultant, and only provide above-market pay when warranted by performance.
- We align our executives' interests with our shareholders' interests by rewarding our executives for both current performance and longer-term performance, with performance measured both by milestones for financial performance and advancement of our long-term development programs and strategic initiatives.
- As a general practice, we do not maintain employment agreements with our executive officers in the United States. Our executive officers are employed at-will and are expected to demonstrate high-quality performance in order to continue serving as members of our executive team.
- We maintain an executive change in control and severance benefit plan, or change in control plan, that complies with corporate governance best practices:
  - the change in control plan is limited to "double-trigger" payments (requiring termination other than for cause or resignation for good reason in connection with a change in control to trigger payments); and
  - the change in control plan does not provide for any tax gross-ups.
- Our Chief Executive Officer's performance bonus is based 100% on our company's overall performance and achievement of our annual corporate objectives, which aligns our Chief Executive Officer's interests with our shareholders' interests.
- We do not provide any executive fringe benefits to our executives in the United States, such as car allowances, personal security, financial planning advice or club memberships.
- In 2013, our board of directors adopted minimum share ownership guidelines for our board of directors, Chief Executive Officer and certain other employees who serve on our executive committee, including the named executive officers, so that they have an even greater financial stake in our company, thereby further aligning the interests of our named executive officers and non-employee directors with those of our shareholders.

Our board of directors and/or compensation committee has also implemented a number of other corporate governance practices that were determined to be in the best interest of our shareholders:

- Our 2012 advisory say-on-pay vote was approved by approximately 98% of our shareholders who voted on this advisory proposal. Based on this positive feedback, the board of directors and the compensation committee decided to maintain our current approach to executive compensation for our Chief Executive Officer and named executive officers.
- Our compensation committee is derived solely of independent directors.
- Our compensation committee has engaged an independent compensation consultant that reports directly to the compensation committee, which has the sole authority to direct the work of the consultant.
- The compensation committee regularly meets in executive session without management present.
- The company's insider trading policy prohibits executives from engaging in speculative trading activities, including hedging or pledging their company securities as collateral.
- The compensation committee conducts an annual review of executive compensation to better align the company's compensation policies with the interests of the company's changing shareholder base.

## Overview

Our executive compensation program is designed to help attract talented individuals to manage and operate all aspects of our business, to reward those individuals fairly over time, and to retain those individuals who continue to meet our high expectations. The goals of our executive compensation program are to align executive officers' compensation with our business objectives and the interests of our shareholders and to incentivize and reward executive officers for our success. Specifically, we have an executive compensation program that combines short- and long-term components, cash and equity, and fixed and contingent payments, in the proportions that we believe are the most appropriate to incentivize and reward our executive officers for achieving our corporate goals while minimizing incentives for excessive risk taking. We place significant emphasis on pay-for-performance-based incentive compensation programs, so that targeted compensation can be achieved only if performance goals are met and, in the case of our stock option awards, only if our share price appreciates over time. We consider our annual performance bonus awards and equity incentive awards to be "at risk," or performance-based compensation, because our annual bonus awards are not earned unless pre-determined levels of performance are achieved against annual corporate objectives that are derived from our annual corporate goals and approved by our board of directors in advance, and our stock option awards will not provide realizable value and our restricted stock unit, or RSU, awards will not provide increased value unless there is an increase in the value of our stock. Our executive compensation program is intended to attract and retain key employees with relevant experience in the life sciences industry, where there is significant competition for talented employees, and to be fair to professionals within our organization. We believe that we must provide competitive compensation packages to attract and retain executive officers and to incentivize our executive management team to achieve success for us and our shareholders over the longer term.

As discussed in further detail below, our executive compensation program consists of the following three principal components:

- *Base Salary.* Our compensation committee reviews and determines base salary rates for our executive officers each year, which are then generally effective beginning by March 1. Base salary rates are determined, in consultation with the compensation committee's independent compensation consultant, based on each executive officer's responsibilities, individual performance, achievement of corporate and strategic goals and a review of competitive salary and total cash compensation data.
- *Performance Bonus Awards.* We have an annual performance-based incentive bonus plan, or the performance bonus plan, for our employees, including our executive officers, under which bonuses may be paid after the end of each year, at the discretion of the compensation committee (and our board

of directors in the case of the Chief Executive Officer), based on our performance in meeting designated corporate objectives for the prior year and each individual's performance and contribution in meeting such corporate objectives.

- *Equity Grants.* Our executive officers are eligible to receive equity grants which serve as long-term incentives to ensure that a portion of their total compensation is linked to our long-term success, thereby aligning their incentive compensation with the interests of our shareholders.

The compensation committee does not have any formal policies for allocating compensation among salary, annual target performance bonus awards and equity grants. Instead, the compensation committee uses its judgment to establish for each named executive officer a mix of current, short-term and long-term incentive compensation, and cash and non-cash compensation, that it believes appropriate to achieve the goals of our executive compensation program and our corporate objectives as described above. However, because we believe it is important to our success to aggressively pursue long-term corporate goals, to avoid excessive risk taking, and to preserve our cash resources, a significant portion of the named executive officers' total compensation is comprised of performance-based bonus opportunities and long-term equity awards, which align the executive officers' incentives with the interests of our shareholders. In keeping with our pay-for-performance philosophy, the compensation market data provided by our compensation committee's independent compensation consultant for each executive officer's position, and our continued success in achieving corporate goals and increasing total shareholder return, the compensation committee determined that a significant proportion of target compensation for 2011 and 2012 should consist of performance-based bonuses and long-term equity incentive compensation. In 2012, our compensation committee determined to further increase the proportion of total target compensation that consisted of performance-based bonuses and long-term equity incentive compensation in order to continue to implement our pay-for-performance philosophy.

#### **Role of the Compensation Committee and Executive Officers in Setting Executive Compensation**

The compensation committee reviews and oversees our compensation policies, plans and programs and reviews and determines the compensation to be paid to the named executive officers and other executive officers. In making its executive compensation determinations, the compensation committee considers recommendations from the Chief Executive Officer. In making his recommendations, the Chief Executive Officer receives input from our human resources department and has access to various third party compensation surveys and compensation data provided by the independent compensation consultant to the compensation committee, as described below. While the Chief Executive Officer discusses his recommendations with the compensation committee, he does not participate in the deliberations concerning, or the determination of, his own compensation. Our Senior Vice President, Human Resources and General Counsel also attend compensation committee meetings. The compensation committee discusses and makes determinations with respect to executive compensation matters without any named executive officers or other executive officers, other than the Chief Executive Officer as described above, present. From time to time, various other members of management and other employees as well as outside advisors or consultants may be invited by the compensation committee to make presentations, provide financial or other background information or advice or otherwise participate in the compensation committee meetings. The compensation committee does not delegate any of its functions to others in determining executive compensation.

The compensation committee generally engages an independent compensation consultant each year to provide a competitive compensation assessment with respect to the executive officers to assist the compensation committee in making annual compensation decisions. Since 2010, Radford, an Aon Hewitt Company, has been engaged by the compensation committee each year to provide benchmark and industry compensation data and provide the compensation committee with advice concerning setting executive officers' compensation, including base salaries, performance-based bonuses and long-term equity compensation. The compensation committee has also consulted with Radford to update the benchmarking information on an annual basis and as needed with respect to specific questions that arise, new compensation programs being considered and best practices for compensation committees. Specific examples of services provided by Radford include benchmarking executive

officers' compensation against our peer group in preparation for making annual salary decisions and for the preparation of equity award guidelines for executive officers and key personnel. Radford reports directly to the compensation committee, which maintains the authority to direct their work and engagement, and advises the compensation committee and our human resources department on ad hoc projects from time to time. Radford interacts with management to gain access to company information that is required to perform services and to understand the culture and policies of the organization. The compensation committee and Radford meet, as needed, in executive session, with no members of management present, to address various compensation matters.

The compensation committee has analyzed whether the work of Radford as a compensation consultant raised any conflict of interest, taking into consideration the following factors: (i) the provision of other services to our company by Radford; (ii) the amount of fees from our company paid to Radford as a percentage of the firm's total revenue; (iii) Radford's policies and procedures that are designed to prevent conflicts of interest; (iv) any business or personal relationship of Radford or the individual compensation advisors employed by it with an executive officer of our company; (v) any business or personal relationship of the individual compensation advisors with any member of the compensation committee; and (vi) any stock of our company owned by Radford or the individual compensation advisors employed by it. The compensation committee has determined, based on its analysis of the above factors, that the work of Radford and the individual compensation advisors employed by it as compensation consultants to our company has not created any conflict of interest.

The compensation committee is (and was at all times during 2012) composed entirely of independent directors, as defined by Rule 5605(a)(2) of the NASDAQ listing standards. Our compensation committee meets as often as it determines necessary to carry out its duties and responsibilities through regularly scheduled meetings and, if necessary, special meetings. Our compensation committee also has the authority to take certain actions by written consent of all members. The agenda for each compensation committee meeting is usually developed by the Senior Vice President, Human Resources and Chief Executive Officer, with input from the General Counsel, and is reviewed with the chairperson of the compensation committee.

The Jazz Pharmaceuticals plc compensation committee met four times and acted by unanimous written consent one time in 2012. As of the date of this proxy statement, in 2013 the Jazz Pharmaceuticals plc compensation committee met three times.

### **Benchmarking of Cash and Long-Term Compensation**

We aim to attract and retain the most highly qualified executives in an extremely competitive market. Accordingly, the compensation committee believes that it is important when making its compensation decisions to be informed as to the current practices of comparable public companies with which we compete for top talent. To this end, the compensation committee reviews market data for each executive's position, compiled by Radford, as described below, including information relating to the mix and levels of compensation for executives in the life sciences industry.

In late 2011, the compensation committee, consistent with its practice in previous years, engaged Radford to provide a comprehensive market review of executive compensation. At that time, Radford reexamined our company's compensation philosophy and peer group companies. Based on the increase in our share price, revenues, market capitalization, and the likely expansion of our geographic reach, product portfolio and headcount through the anticipated closing of the Azur Merger in early 2012, Radford recommended updates to the list of peer group companies that we used to benchmark our executive compensation. Specifically, Radford recommended that Alexion Pharmaceuticals, Inc., Amylin Pharmaceuticals, Inc., BioMarin Pharmaceutical Inc., Cubist Pharmaceuticals, Inc., Elan Corporation, plc, Endo Health Solutions Inc. (formerly Endo Pharmaceuticals Holdings Inc.), Impax Laboratories, Inc., Myriad Genetics, Inc., Regeneron Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., The Medicines Company and United Therapeutics Corporation be added to the peer group company list, and Depomed, Inc., Enzon Pharmaceuticals, Inc., Isis Pharmaceuticals, Inc., ISTA Pharmaceuticals, Inc., Nektar Therapeutics, Questcor Pharmaceuticals, Inc., Santarus, Inc. and Theravance, Inc. be removed from the peer company list.

In late 2011, when it was developing a proposed list of our peer group companies to be used in connection with making compensation decisions for 2012, Radford selected companies that were in the life sciences industries with a product on the market, had revenue of approximately one half to two times our then-projected revenue, giving effect to the Azur Merger which at the time had not yet been consummated (resulting in a range of generally \$200 million to \$1 billion in revenue), had market values of approximately one half to three times our market capitalization at the time (resulting in a range of between \$600 million to \$6 billion in market capitalization), and were located primarily in the United States or were headquartered in Europe.

Based on these parameters, Radford recommended and, after discussion, in late 2011 our compensation committee approved the following companies as our appropriate peer group for 2012: Acorda Therapeutics, Inc., Alexion Pharmaceuticals, Inc., Alkermes, Inc., Amylin Pharmaceuticals, Inc., Auxilium Pharmaceuticals, Inc., BioMarin Pharmaceutical Inc., Cubist Pharmaceuticals, Inc., Elan Corporation, plc, Endo Health Solutions Inc. (formerly Endo Pharmaceuticals Holdings Inc.), Impax Laboratories, Inc., InterMune, Inc., Myriad Genetics, Inc., Onyx Pharmaceuticals, Inc., Regeneron Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., The Medicines Company, United Therapeutics Corporation, and ViroPharma Incorporated. In determining executive compensation for 2012, the compensation committee reviewed data from this group of peer companies.

To better inform the compensation committee in making compensation decisions for our executive officers, Radford provided our compensation committee with market data regarding employee compensation at comparable public companies. This market data was compiled from multiple sources, including: (i) data from public biotechnology and pharmaceutical companies in the Radford Global Life Sciences Survey that had revenues between \$200 million and \$1 billion, or the general survey data, which includes survey data with respect to our selected 2012 peer group companies; (ii) data from the Radford Global Life Sciences Survey with respect to the 2012 selected peer group companies listed above, or the peer survey data; and (iii) the 2012 selected peer group companies' publicly disclosed information, or public peer data. The components of the market data used for benchmarking our executive officer compensation were based on the availability of sufficient comparative data for an executive's position. Generally, peer survey data and public peer data is used primarily in establishing benchmarks, and the general survey data is used when there is a lack of peer survey data and public peer data for an executive's position. The peer survey data, the general survey data, and the public peer data, collectively referred to throughout this proxy statement as market data, were used by the compensation committee, with the assistance of Radford, to set our executive officers' compensation.

The compensation committee generally benchmarks both cash compensation and equity compensation to the market data described above primarily to ensure that our executive compensation program as a whole is competitive to attract and retain the highest caliber executives. The compensation committee generally targets total cash compensation (including both base salary and the annual target performance bonus) at levels that the compensation committee considers to be competitive and appropriate for each named executive officer's position based on applicable benchmarking market data, as described above, taking into account the individual performance and qualifications of each named executive officer and our general philosophy of targeting cash compensation at the 50<sup>th</sup> percentile and equity compensation at the 60<sup>th</sup> percentile, in each case, of market data.

In determining annual compensation, the compensation committee benchmarks against the market data described above, and considers specific recommendations from Radford for each named executive officer's compensation, including salary, target bonus and equity grants. Our Chief Executive Officer assesses the performance for each named executive officer and presents his recommendations, which reflect his consideration of the benchmarked data and his extensive experience, to the compensation committee to determine specific recommendations for pay changes for the executive officers. In performing its duties, the compensation committee regularly meets with Radford, with senior members of the human resources and/or finance group present, but with no executive officers present. The compensation committee also meets in executive session, with no members of management, human resources and/or finance present, to consider compensation changes for the Chief Executive Officer, which are then presented to the board of directors for consideration and approval.

The compensation committee applies its professional experience and judgment when interpreting benchmarking data. An individual may receive compensation above or below the targeted percentiles based on performance, job criticality, experience and skill set.

In late 2012 in preparation for making executive compensation decisions for 2013, Radford reexamined our compensation philosophy and peer group and recommended updates to the list of peer companies to reflect our growth as a result of the Azur Merger and the completion of the EUSA Acquisition and the related increase in our revenues and market capitalization, the expansion of our geographic reach, product portfolio and headcount, and the consolidation in our industry. Accordingly, Radford recommended that Amylin Pharmaceuticals, Inc. and InterMune Inc. be removed from our peer company list and that Incyte Corporation, Medivation, Inc. and Seattle Genetics Inc. be added to our peer group company list for 2013 and, to better inform the compensation committee in setting executive compensation levels for 2013, provided the compensation committee updated survey data that included public companies in the life sciences industry with higher revenues and a greater number of employees, reflecting our increased revenues, market value and headcount.

### **Advisory Vote on Executive Compensation**

At our 2012 annual general meeting of shareholders, the shareholders approved, on an advisory basis, the compensation of the named executive officers, as disclosed in the proxy statement for that meeting pursuant to the compensation disclosure rules of the SEC. The compensation committee reviewed the final vote results for the proposal, and, given the significant level of shareholder support (approximately 98% of total votes cast with respect to the advisory proposal), concluded that our compensation program continues to provide a competitive pay-for-performance package that effectively incentivizes the named executive officers and encourages long-term retention. Accordingly, the compensation committee and, with respect to our Chief Executive Officer's compensation, our board of directors, determined not to make any significant changes to our executive compensation policies or decisions as a result of the vote. Our compensation committee and, with respect to our Chief Executive Officer's compensation, our board of directors, expects to continue to consider the outcome of our say-on-pay votes and our shareholder views when making future compensation decisions for the named executive officers.

### **Executive Compensation Program**

Our executive compensation program currently consists of three principal components: base salary, annual performance bonuses (if approved by the compensation committee) and long-term incentive compensation currently in the form of stock options and RSU awards, which are subject to time-based vesting. We also offer our executive officers certain severance benefits upon a change in control under our change in control plan. Finally, the named executive officers have the opportunity to participate in the Jazz Pharmaceuticals, Inc. 401(k) plan, or the 401(k) Plan, employee stock purchase plan and other benefits generally available to all employees. Each component of compensation is evaluated based on the factors discussed below.

#### ***Base Salary***

None of the named executive officers has a guaranteed base salary; base salary is set each year by the compensation committee. The compensation committee reviews and determines the appropriate level of base salary for the named executive officers generally effective beginning by March 1 of each year. We generally aim to ensure that the base salaries of our executive officers, including the named executive officers, are maintained at competitive levels. To this end, our policy is to target base salary at the 50<sup>th</sup> percentile of the market data.

As described above under the heading entitled "*Compensation Discussion and Analysis—Benchmarking of Cash and Long-Term Compensation*," our compensation committee generally targets base salary at the 50<sup>th</sup> percentile of the market data because competition for executive talent is intense in our industry and in our geographic areas. Our executives have many years of valuable experience in our industry, and their continued leadership is deemed critical to our short-term and long-term success. Because the compensation committee aims



to ensure that our executives' base salaries are competitive, the base salaries of individual executive officers may fall outside of the 50<sup>th</sup> percentile range, based on a particular individual's experience, overall qualifications and current and expected future contribution to our company's success. Although an individual's compensation may fall outside the target percentile, the compensation committee keeps the target percentile in mind when evaluating the total cash compensation of each executive officer.

### ***Performance Bonus Plan***

In accordance with the performance bonus plan, we maintain an annual bonus award program to reward the named executive officers (and other employees) for attaining our company's corporate objectives and for their individual contributions toward such achievements. Corporate objectives under the performance bonus plan are derived from our annual corporate goals and generally relate to our commercial efforts, financial measures (such as sales and adjusted net income targets), financing efforts, strategic transactions, progress of our clinical development programs, regulatory matters, as well as regulatory and sales and marketing compliance and effective employee engagement, alignment and professional development.

Before 2011, the bonus pool under the performance bonus plan and therefore the total amount available for bonus payouts was based primarily on our board of directors' determination of our company's success in achieving its corporate goals for the plan year. For 2011 and 2012, the compensation committee took a more formulaic approach in keeping with our pay-for-performance philosophy. The compensation committee assigned a specific weighting to each quantitative corporate objective and assigned a separate weighting to the qualitative corporate objectives taken as a whole. An algorithm was defined for calculating the achievement of the quantitative corporate objectives, with contributions to the bonus pool determined based on the specific level of achievement. The contribution to the bonus pool with respect to the achievement of the qualitative corporate objectives continued to be evaluated based on the compensation committee's determination of the company's success in achieving such objectives.

The compensation committee determines the portion of the bonus pool, if any, that will be allocated to the executive officers, including the named executive officers, as a group and the bonuses for each individual executive officer. Actual performance bonus awards to executive officers are determined to a large extent based on the compensation committee's (and in the case of Mr. Cozadd, our board of directors') subjective assessment of executive officers' contributions as a group to the achievement of our company's corporate objectives and, to a lesser extent, on each individual executive officer's contribution to the achievement of such corporate objectives. Mr. Cozadd provides input to the compensation committee with respect to bonuses for the executive officers other than himself.

The performance bonus plan, approved by the compensation committee, sets specific executive target bonus opportunities, expressed as a percentile of salary paid in the respective year. The compensation committee determines the appropriate annual target performance bonus based on each executive's level in light of the benchmarking provided by Radford and considering internal equity for positions of similar scope and impact. Generally, the targets are reviewed on an annual basis. Our policy is to generally target levels that would result in total annual cash compensation (consisting of both base salary and the annual target performance bonus) at the 50<sup>th</sup> percentile of the market data, for the reasons described above under the headings entitled "*Compensation Discussion and Analysis—Benchmarking of Cash and Long-Term Compensation*" and "*Compensation Discussion and Analysis—Executive Compensation Program—Base Salary*," although actual compensation may deviate from the target. Annual target performance bonuses are generally higher for those executives who have a greater opportunity to impact corporate performance.

At the end of each year, the compensation committee determines the funding of the total bonus pool under the performance bonus plan, as described above. The actual performance bonus awarded to each executive officer in any year, if any, may be more or less than the applicable target, depending primarily on the compensation committee's determination of our company's achievement of corporate objectives (and therefore the total bonus pool) and the executive's individual performance with respect to such objectives. Whether or not

a performance bonus is paid for any year is within the discretion of the compensation committee (or the board of directors in the case of Mr. Cozadd) based on such achievement.

We have not historically paid any guaranteed bonuses to the named executive officers. From time to time, we pay signing bonuses in connection with the commencement of employment of executive officers, contingent upon their continued service, such as the signing and retention bonuses paid to Ms. Falberg, Ms. Hooper and Dr. Tobias pursuant to each of their offer letters, described below under the heading entitled “*Description of Compensation Arrangements—Executive Employment Agreements.*”

As a public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws as a result of misconduct, the Chief Executive Officer and Chief Financial Officer may be legally required to reimburse our company for any bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of section 304 of the Sarbanes-Oxley Act of 2002. Additionally, we intend to implement a Dodd-Frank Wall Street Reform and Consumer Protection Act-compliant clawback policy as soon as, and to the extent that, the requirements of such clawbacks are more clearly defined by the SEC.

### ***Long-Term Equity Awards***

The compensation committee believes that long-term performance is achieved through an ownership culture that rewards executive officers through the use of equity incentives. Historically the compensation committee believed that long-term incentive compensation in the form of stock option grants provided our executive officers with meaningful compensation awards that align their incentives with global value creation for our shareholders.

In 2012, we began granting RSUs, in addition to stock options, in part because the compensation committee believes that long-term equity awards composed of a mix of stock options and RSUs may better align our executive officers’ interests with those of our shareholders by minimizing the incentive for inappropriate short-term risk taking at the expense of realizing long-term value. RSUs generally cover fewer shares than the stock options that we would otherwise grant to deliver a similar value to an executive officer. As a result, RSU awards enable the company to minimize dilution to shareholders. Both stock options and RSUs vest over time, thereby increasing retention value.

Equity award grants may be made at varying times and in varying amounts in the discretion of the compensation committee, but are generally made to executive officers, including the named executive officers, once a year unless such executive officer is promoted, in which case a grant will normally be made at that time, or, in rare circumstances, for recognition of outstanding performance. Additionally, the compensation committee generally grants an equity award shortly after an executive officer commences employment. We do not time the granting of equity awards with any favorable or unfavorable news, and the proximity of the grant of any equity awards to an earnings announcement or other market events is coincidental. After the Azur Merger, our board of directors approved an equity incentive grant policy, which provides that equity grants to newly hired employees, to current employees, including our executive officers, who are promoted, or to members of our board of directors generally will be made on the third trading day of the calendar month following the month in which such employees are hired, promotions are effective or awards to our directors are approved, respectively. The exercise price of our stock options is equal to the fair market value (the closing price as reported on NASDAQ) of our shares on the date of grant. Stock option grants generally vest 25% upon the one year anniversary of the grant date and vest as to the remainder of the shares in 36 equal monthly installments thereafter, subject to the optionholder’s continued service with us. RSUs typically vest annually over four years from the grant date, also subject to the holder’s continued service with us. Stock options and RSUs are subject to potential vesting acceleration as described below under the heading entitled “*Potential Payments upon Termination or Change in Control.*”

For the reasons described above under the headings entitled “*Compensation Discussion and Analysis—Benchmarking of Cash and Long-Term Compensation*” and “*Compensation Discussion and Analysis—Executive Compensation Program—Base Salary,*” our policy is to generally target levels that would result in long-term

equity awards at the 60<sup>th</sup> percentile of the market data, and the vesting schedules are established to ensure a meaningful incentive to remain employed with our company and to work toward its success. Accordingly, an equity award will generally provide a return to the employee only if he or she remains in our company's service, and then, in the case of stock options, only if the market price of our stock appreciates over the equity award term. Our philosophy of generally targeting the 60<sup>th</sup> percentile for long-term incentives is designed to deliver total compensation that is competitive, reflect the long-term nature of our business and product cycles, and to create and continue an ownership culture. We target the 60<sup>th</sup> percentile for long-term equity awards, rather than the 50<sup>th</sup> percentile, because we believe that a greater emphasis should be placed on long-term compensation that aligns the interests of our executives with those of our shareholders and encourages them to work towards increasing value for our shareholders. Long-term equity awards to particular individuals may be above or below the 60<sup>th</sup> percentile target, based on experience, performance and other factors determined material by our compensation committee for a particular grant.

We currently grant equity awards, including stock options and RSUs to the named executive officers, under the 2011 Equity Incentive Plan, or the 2011 Plan. The 2011 Plan was adopted by Jazz Pharmaceuticals, Inc.'s board of directors and approved by Jazz Pharmaceuticals, Inc.'s stockholders in connection with their approval of the Azur Merger in December 2011 and was assumed by us upon the completion of the Azur Merger. The 2011 Plan replaces our 2007 Equity Incentive Plan, or the 2007 Plan, and affords the compensation committee the flexibility to utilize a broad array of equity incentives and performance cash incentives in order to secure and retain the services of employees of our company and its subsidiaries, and to provide long-term incentives that align the interests of employees with the interests of our shareholders. Before the 2011 Plan was adopted, we granted stock options under our 2007 Plan, which was adopted by Jazz Pharmaceuticals, Inc.'s board of directors and approved by Jazz Pharmaceuticals, Inc.'s stockholders in connection with Jazz Pharmaceuticals' initial public offering. Prior to the initial public offering, we granted stock awards under the 2003 Equity Incentive Plan, or the 2003 Plan, which was replaced by the 2007 Plan.

Additional long-term equity incentives are provided through the 2007 Employee Stock Purchase Plan, as amended and restated, or the ESPP, which we assumed upon the completion of the Azur Merger. Pursuant to the ESPP, all eligible employees, including the named executive officers, may allocate up to 15% of their base salary to purchase our stock at a 15% discount to the market price, subject to specified limits.

In February 2013, we adopted share ownership guidelines for the named executive officers, certain other executive officers and non-employee directors in order to better align their interests with those of our shareholders. The practice of implementing share ownership guidelines for executive officers is aligned with our ownership culture and is becoming more common in our industry. In addition, our board determined that establishing such a policy would no longer place us at a competitive disadvantage compared to other life sciences companies. A description of this policy is included below under the heading entitled "*Ownership Guidelines for Directors and Executive Officers.*"

#### ***Severance Benefits upon Change in Control***

All of the named executive officers, as well as the other employees at the vice president level or above, are eligible to participate in the change in control plan, or in the case of executive employees residing in Ireland, receive comparable severance benefits, during their employment with our company. We assumed the change in control plan in connection with the Azur Merger and the compensation committee approved certain modifications to the change in control plan in 2012 with respect to the benefits payable under the plan to our executive officers. A description of this plan is included below under the heading entitled "*Potential Payments upon Termination or Change in Control.*"

The change in control plan provides certain severance benefits to our executive officers, including the named executive officers, in connection with specified involuntary termination events, including termination without cause and constructive termination, following a change in control. The compensation committee believes these severance benefits are important from a retention perspective to provide some level of protection to our

executives who might be terminated following a change in control and the amounts are reasonable and maintain the competitiveness of our executive compensation and retention program. All severance compensation is structured as a “double-trigger” benefit, meaning that an executive officer receives benefits only if the executive officer has an involuntary termination within a specified period of time following a change in control transaction, but does not provide benefits solely as a result of a change in control. The compensation committee believes this structure serves to mitigate the distraction and loss of key executive officers that may occur in connection with rumored or actual fundamental corporate changes. Such payments protect the interests of our shareholders by enhancing executive focus during rumored or actual change in control activity, retaining executives despite the uncertainty that generally exists while a transaction is under consideration and encouraging the executives responsible for negotiating potential transactions to do so with independence and objectivity. Furthermore, this protection assists us in attracting and retaining highly valued executives. The compensation committee also believes that termination without cause and constructive termination are the appropriate involuntary termination events that should trigger benefits in a change in control transaction, because such terminations are generally considered to be beyond the control of a terminated employee and are terminations that, under different circumstances, would not have occurred. We do not provide any tax gross up payments on severance benefits. The Azur Merger did not constitute a change in control for purposes of the change in control plan or our equity compensation plans.

### ***Other Benefits***

Executive officers based in the United States are eligible to participate in all of our benefit plans such as the 401(k) Plan (see the section below entitled “*Description of Compensation Arrangements—401(k) Plan*”), medical, dental, vision, short-term disability, long-term disability, group life insurance and the ESPP, in each case generally on the same basis as other employees. We also have a section 125 flexible benefits healthcare plan and a flexible benefits childcare plan under which employees can set aside pre-tax funds to pay for qualified healthcare expenses and qualified childcare expenses not reimbursed by insurance. We do not currently offer pension or other retirement benefits in the United States but do offer pension or other retirement benefits in certain other countries.

### ***Ownership Guidelines for Directors and Executive Officers***

In February 2013, our board of directors adopted share ownership guidelines for the company’s non-employee directors, Chief Executive Officer and certain other employees who serve on our executive committee, including the named executive officers, or the covered individuals. Under the guidelines, these individuals are expected to own a number of the company’s ordinary shares with a value equal to: three times (3x) base salary, for the company’s Chief Executive Officer; one times (1x) base salary, for each other member of the company’s executive committee; and three times (3x) the director’s annual cash retainer, for each non-employee director of the company.

The guidelines provide that the individuals subject to the guidelines are expected to establish the minimum ownership levels within five years of the company’s adoption of the guidelines (or within five years of the date an officer or director first becomes subject to them).

The value of the company’s ordinary shares for purposes of determining the number of shares subject to these guidelines in a given year is determined as the product of (i) the number of ordinary shares credited as held by the individual and (ii) the greater of (a) the closing price of the company’s ordinary shares on the applicable date, or (b) the purchase or exercise price paid for such shares. Shares that count toward satisfaction of these guidelines include: shares owned outright by the individual (including RSUs that have vested but not yet settled, net of taxes); shares retained after an option exercise or issuance under another type of equity award granted under the company’s equity incentive plans; shares retained after purchase under the company’s ESPP; shares held in trust for the benefit of the individual; and, solely with respect to non-employee directors, shares held in a deferral account and issuable to such director pursuant to the Directors Deferred Plan.

The compensation committee has discretion to develop an alternative individual guideline or an alternative method of complying with the applicable individual guideline for a covered individual if compliance would place a significant hardship on such covered individual.

### **2012 Compensation Decisions for the Named Executive Officers**

We believe that 2012 was a transformational year for the company due in part to the Azur Merger and EUSA Acquisition and resulting expansion of our product portfolio and international footprint. As described above under the heading entitled “*Compensation Discussion and Analysis—Executive Summary*,” this transformational growth was reflected in our one-year and three-year annualized total shareholder returns, or TSRs, of approximately 38% and 89%, respectively.

#### ***Base Salary***

As described above under the heading entitled “*Compensation Discussion and Analysis—Executive Compensation Program—Base Salary*,” we generally target total cash compensation (including both base salary and the annual target performance bonus) at the 50<sup>th</sup> percentile of market data. Because there were significant changes to our peer group for 2012, Radford provided the compensation committee with an analysis of the year-over-year change in market cash compensation and ran regression and geographical analyses to determine the impact of the new peer group on chief executive officer compensation. These analyses revealed that Mr. Cozadd’s base salary rate was below the 25<sup>th</sup> percentile of the market data for his position. Upon recommendation from the compensation committee, which considered these analyses, the board of directors increased the 2012 base salary rate for Mr. Cozadd by 30% from the prior year both to address this gap and in recognition of Mr. Cozadd’s outstanding achievement and integral role in our company’s exceptional performance in 2011 and the completion of the Azur Merger in January 2012. After the increase, Mr. Cozadd’s 2012 base salary was between the 50<sup>th</sup> percentile and 60<sup>th</sup> percentile of the market data for his position.

Ms. Falberg’s 2012 base salary rate was increased by 21% from her 2011 base salary rate, based on her strong performance and reflecting her promotion to Executive Vice President. Following this increase, Ms. Falberg’s 2012 base salary rate was just below the 75<sup>th</sup> percentile of the market data for her position, reflecting the multiple functions she manages and the strength of the teams she has assembled.

Mr. Cox became an executive officer in January 2011. Mr. Cox’s 2012 base salary rate was increased 20%, which approximated the 75<sup>th</sup> percentile of the market data for his position, reflecting his promotion to Executive Vice President, the strong performance of the commercial organization and to advance internal pay equity within the senior management team, which the compensation committee determined was appropriate in this circumstance.

Ms. Hooper joined our company in February 2012, and her 2012 base salary rate was set above the 75<sup>th</sup> percentile of the market data for her position. The compensation committee felt it was necessary to set Ms. Hooper’s base salary above the 75<sup>th</sup> percentile to recruit her due to her superior qualifications, prior industry experience, familiarity with and prior representation of our company, and compensation history as a partner of a private law firm.

Dr. Tobias joined our company in October 2011. Dr. Tobias’ 2012 base salary rate was increased by 4% from his 2011 base salary rate, which had been established a few months earlier, to bring his salary closer to the 50<sup>th</sup> percentile of the market data for his position and reflect his promotion to Executive Vice President. After this increase, Dr. Tobias’ 2012 base salary rate was below, but closer to, the 50<sup>th</sup> percentile of the market data for his position.

The 2012 base salary rates and percentage increases from the 2011 base salary rates for the named executive officers are set forth in the table below.

<u>Name</u>	<u>2012 Base Salary (\$)<sup>(1)</sup></u>	<u>Increase over 2011 Base Salary (%)</u>
Bruce C. Cozadd . . . . .	750,000	30
Kathryn E. Falberg . . . . .	460,000	21
Russell J. Cox <sup>(2)</sup> . . . . .	390,000	20
Suzanne Sawochka Hooper <sup>(3)</sup> . . . . .	465,000	—
Jeffrey K. Tobias, M.D. <sup>(4)</sup> . . . . .	425,000	4

(1) Base salary rates beginning March 1, 2012, except that Ms. Hooper’s rate was effective from the date she joined our company in February 2012.

(2) Mr. Cox joined Jazz Pharmaceuticals, Inc. in July 2010 and became an executive officer in January 2011.

(3) Ms. Hooper joined our company in February 2012 and became an executive officer in March 2012.

(4) Dr. Tobias became an executive officer in October 2011.

In February 2013, the compensation committee and, with respect to Mr. Cozadd, the board of directors, approved the following 2013 base salaries for the named executive officers effective beginning by March 1, 2013: Mr. Cozadd, \$775,000; Ms. Falberg, \$475,000; Mr. Cox, \$425,000; Ms. Hooper, \$475,000; and Dr. Tobias, \$425,000. The 2013 base salaries for the named executive officers reflect merit increases, adjustments to advance internal pay equity among members of senior management of the company and adjustments to align with the market data for each position.

***Performance Bonus Awards***

In early 2012, the annual target performance bonuses for the named executive officers were established as follows: 100% of annual base salary earned for Mr. Cozadd and 50% of the applicable annual base salary earned for each of Ms. Falberg, Mr. Cox, Ms. Hooper and Dr. Tobias. We set these targets in order to provide financial incentives to the named executive officers to work to achieve our corporate objectives, derived from our annual corporate goals, and to assist the company in remaining competitive with the performance bonus practices of its peers. The board of directors sets the annual target performance bonus for the Chief Executive Officer at a higher percentage than the percentages for other executive officers to reflect that the Chief Executive Officer has ultimate responsibility for, and control over, our company’s performance.

Annual target performance bonuses for each named executive officer were set after review of the market data provided by Radford. The annual target performance bonus for Mr. Cozadd was increased by the board of directors from 65% for 2011 to 100% for 2012, because the board of directors believed that a greater emphasis should be placed on Mr. Cozadd’s potential performance-based compensation in order to further incentivize him to work to achieve critical corporate goals. In setting the Chief Executive Officer’s annual target performance bonus, the compensation committee considered his total cash compensation (including both base salary and this annual target performance bonus), which for 2012 was set between the 60<sup>th</sup> and 75<sup>th</sup> percentile of market data for his position, in recognition of Mr. Cozadd’s outstanding achievement and integral role in our company’s exceptional performance in 2011 and the completion of the Azur Merger in January 2012. The other named executive officers’ annual target performance bonuses were increased from 40% to 50% because the compensation committee determined that this level was appropriate for all Executive Vice Presidents, was consistent with market data, and was in accordance with our general team approach to provide consistent target incentive opportunities for executives with similar organizational responsibilities. In setting these annual target performance bonuses, the compensation committee considered the total cash compensation for each individual (including both base salary and this annual target performance bonus), which for the named executive officers other than Mr. Cozadd were: for Ms. Falberg, between the 60<sup>th</sup> and the 75<sup>th</sup> percentile of the market data for her position; for Mr. Cox, at the 75<sup>th</sup> percentile of the market data for his position; for Ms. Hooper, above the

75<sup>th</sup> percentile of the market data for her position; and for Dr. Tobias, between the 25<sup>th</sup> and the 50<sup>th</sup> percentile of the market data for his position.

For 2012, the quantitative and qualitative corporate objectives for purposes of the performance bonus plan approved by our board of directors and communicated to the named executive officers in early 2012 were as follows:

***Quantitative Objectives:***

- Achieve total revenue of \$485 million.
- Achieve Xyrem year-over-year revenue bottle growth of 8.1%.
- Achieve Prialt® (ziconotide) intrathecal infusion revenues of \$29 million.
- Achieve adjusted net income of \$248 million.<sup>1</sup>
- Acquire new product(s) with expected 2013 revenues of \$100 million.
- Advance our R&D pipeline, with performance multipliers of 50%, 100%, 150% and 200% upon achievement of: (i) board approval of one program, (ii) one program in clinical development, (iii) one program in clinical development and a board approval of a second program, and (iv) two programs in clinical development or one program in Phase III development, respectively.

***Qualitative Objectives:***

- Complete the integration with Azur to maximize benefits from the Azur Merger per the board-approved merger plan.
- Establish a broad risk management plan for our larger, more distributed company environment.
- Continue our corporate culture of compliance by achieving our corporate objectives while operating in a manner that is compliant with the laws and regulations that govern our industry.
- Continue to build our organization through effective communication, investment in talent, and providing opportunities for innovative learning and development.

For 2012, our board of directors determined that the bonus pool for the 2012 plan year should be based 80% on the level of achievement of quantitative objectives and 20% on the level of achievement of qualitative objectives collectively. The quantitative objectives related to total revenue, Xyrem revenue bottle growth and Prialt revenues were weighted at 20%, 15% and 5%, respectively. The quantitative objectives related to adjusted net income, acquiring new products and advancing the R&D pipeline were weighted at 15%, 15% and 10%, respectively.

For the quantitative objectives, the compensation committee defined a payout algorithm with respect to each performance target for calculating the actual percent of bonus pool funding attributable to each. If a specified minimum annual performance level is met, then a scaled performance multiplier ranging from 51% to 200% for each of the quantitative objectives is determined and used to calculate the applicable bonus pool funding percentage attributable to such quantitative objective. The performance multiplier would be 0 if performance is

<sup>1</sup> Adjusted net income as used in this proxy statement with respect to our corporate objectives is a non-GAAP financial measure that excludes certain items from continuing operations. For more information on our presentation and calculation of adjusted net income, see “*Item 7. Management’s Discuss and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures*” in the 2012 10-K.

below the minimum level, 50% if performance is at the minimum level, and then scaled for performance between 51% and 200%. For the quantitative objectives, the minimum and maximum performance levels for 2012 were:

<u>Quantitative Objective</u>	<u>Minimum Level</u>	<u>Maximum Level</u>
1. Total revenue . . . . .	96% of target	108% of target
2. Xyrem year-over-year revenue bottle growth . . . . .	62% of target	148% of target
3. Prialt revenues . . . . .	86% of target	128% of target
4. Adjusted net income . . . . .	96% of target	112% of target
5. Acquiring new product(s) . . . . .	(1)	(1)
6. Advancing R&D pipeline . . . . .	(2)	(2)

- (1) With respect to the quantitative objective of acquiring new product(s) with expected 2013 revenues of \$100 million, the minimum and maximum performance levels would be based on the compensation committee's assessment of the new product deal(s).
- (2) With respect to the quantitative objective of advancing our R&D pipeline, the minimum level of achievement would be met if one program was approved by our board of directors, and the maximum level of achievement would be met if two programs were in clinical development or one program was in Phase III development.

The table below summarizes the weights, targets, actual results, their corresponding multipliers and the resulting bonus pool funding percentage used for the quantitative objectives, with the actual results as adjusted by the compensation committee as reflected in the table below.

<u>Quantitative Objective</u>	<u>Weight</u>	<u>Target</u>	<u>Actual Result<sup>(1)</sup></u>	<u>Multiplier</u>	<u>Bonus Pool Funding %<sup>(2)</sup></u>
1. Total revenue . . . . .	20%	\$485.0 million	\$553.0 million	194%	39%
2. Xyrem year-over-year revenue bottle growth . . . . .	15%	8.1%	10.8%	170%	26%
3. Prialt revenues . . . . .	5%	\$ 29.0 million	\$ 26.4 million	67%	3%
4. Adjusted net income . . . . .	15%	\$248.0 million	\$284.0 million	200%	30%
5. Acquiring new product(s) . . . . .	15%	(3)	(3)	150%	22%
6. Advancing R&D pipeline . . . . .	10%	(4)	(4)	150%	15%
<b>Total Quantitative Objective Weight . . . . .</b>	<b>80%</b>			<b>169%</b>	<b>135%</b>

- (1) The dollar figures in this column represent the average of our actual results for the year ended December 31, 2012, and our results as adjusted to exclude the financial impact of the EUSA Acquisition and the sale of our women's health business, which transactions were not contemplated at the time the performance objectives were established. In this regard, our reported total revenues for 2012 were \$586.0 million, or \$553.0 million after giving effect to the foregoing adjustments. Likewise, our adjusted net income for 2012 was \$290.4 million (see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures" in the 2012 10-K), or \$284.0 million after giving effect to the foregoing adjustments. The actual results for the Xyrem year-over-year revenue bottle growth and Prialt revenue objectives were unaffected by the foregoing adjustments since those results were not impacted by either the EUSA Acquisition or the sale of our women's health business.
- (2) The percentages in this column represent, for each quantitative objective, the weight of the quantitative objective, multiplied by the performance multiplier that corresponds to the actual achievement of such quantitative objective.
- (3) With respect to the quantitative objective of acquiring new product(s) with expected 2013 revenues of \$100 million, the compensation committee determined the actual achievement by the company was above target, resulting in a performance multiplier of 150%, and therefore a 22% bonus pool funding percentage.
- (4) With respect to the quantitative objective of advancing our R&D pipeline, the compensation committee determined that the actual achievement by the company was above target, resulting in a performance multiplier of 150%, and therefore a 15% bonus pool funding percentage.



The other four qualitative corporate objectives approved by the board of directors are inherently less quantifiable than the quantitative objectives and accordingly were not assigned individual weightings. In evaluating the qualitative objectives, the compensation committee determined the following accomplishments were relevant: (i) the achievement of an Irish corporate structure, combined with the successful integration with Azur; (ii) progress towards the establishment of an appropriate risk management plan for our larger, international company; (iii) maintaining and strengthening our corporate culture of compliance; and (iv) significant efforts to build our organization through investment in talent, as well as work toward more effective internal communication and providing opportunities for innovative learning and development. After balancing the performance with respect to all of the qualitative objectives, the compensation committee determined that overall achievement resulted in a multiplier of 75%, and therefore a 15% bonus pool funding percentage for the 2012 qualitative objectives.

After adding together the bonus pool funding percentages for the quantitative and qualitative objectives, the compensation committee approved an overall bonus pool funding percentage of 150% for 2012, or the 2012 bonus percentage, which resulted in approval of an aggregate corporate bonus payout for the company's employees of 150% of the total target bonus pool.

The compensation committee did not set specific objectives for individual executive officers. Each of the executive officers is responsible for meeting the corporate objectives, and each objective was deemed important in determining the level of the company's performance during the year. Accordingly, the actual bonus amount paid under the performance bonus plan for each named executive officer (other than the Chief Executive Officer's) in 2012 was determined in part based on such officer's individual contributions towards achievement of the corporate objectives, as determined by the compensation committee based on its review and an assessment by our Chief Executive Officer. The compensation committee determined the actual 2012 bonus amount for each named executive officer based upon the 2012 bonus percentage, the named executive officer's (other than the Chief Executive Officer) individual contributions to achievement of the corporate objectives, the named executive officer's target bonus percentage and the actual salary the named executive officer earned during the year. All of the named executive officers contributed significantly to the achievement of our corporate objectives in 2012. However, certain of the named executive officers' responsibilities and contributions more directly related to achievement of key corporate objectives and therefore were given a greater weight in the compensation committee's determination of the bonus amount paid to each named executive officer.

The compensation committee (with approval from the board of directors with regard to Mr. Cozadd) determined that the company's overall 2012 bonus percentage of 150% was applicable for Mr. Cozadd, because as Chief Executive Officer, Mr. Cozadd is responsible for the company meeting all of its objectives. Ms. Falberg was awarded a bonus at a rate higher than the company's 2012 bonus percentage because of her leadership of the company's corporate development efforts, her strong leadership in championing and structuring the Azur Merger and the EUSA Acquisition, the financing of the EUSA Acquisition and the sale of our women's health business, her strong management of the company's balance sheet and financial planning and analysis and her continued development of the company's strategic plan. Mr. Cox was awarded a bonus at a rate higher than the company's 2012 bonus percentage because of his leadership of the commercial organization in its strong performance. Ms. Hooper was awarded a bonus at a rate higher than the company's 2012 bonus percentage because she was responsible for the legal aspects that relate to all of the corporate objectives, including her efforts to complete the EUSA Acquisition and her strategic leadership in strengthening and defending our intellectual property. In her first year, she also assembled a talented legal team appropriate for the company's increased scope, while managing the complexities of operating as an Irish public limited company listed on NASDAQ. Dr. Tobias was awarded a bonus at a rate lower than the company's 2012 bonus percentage based on the compensation committee's determination that other executives had more significantly contributed to the achievement of the company's corporate objectives for the year, as well as consideration that the company continues to face regulatory issues that were not yet fully resolved in 2012.

In February 2013, the compensation committee and, with respect to Mr. Cozadd, the board of directors, approved the following performance cash bonus award payments for 2012 under the performance bonus plan: Mr. Cozadd, \$1,081,600; Ms. Falberg, \$390,000; Mr. Cox, \$300,000; Ms. Hooper, \$350,000; and Dr. Tobias, \$250,000.

### ***Stock Option and RSU Awards***

*Reduction in long-term equity incentives resulting from the Azur Merger.* In connection with the Azur Merger and pursuant to the Internal Revenue Code of 1986, as amended, or the Code, an excise tax on nonstatutory stock options, or NSOs, would have applied to NSOs held by certain officers of Jazz Pharmaceuticals, Inc., even if the NSOs were unvested and even if the NSOs were “underwater” (that is, if the exercise price was greater than the fair market value of Jazz Pharmaceuticals, Inc.’s common stock on the date of closing of the Azur Merger). However, to the extent the NSOs were exercised before the closing of the Azur Merger, then the excise tax would not apply to the exercised NSOs. In October 2011, our board of directors decided that NSOs held by executive officers serving at that time (including, among the 2012 named executive officers, Messrs. Cozadd and Cox and Ms. Falberg) who were subject to the excise tax would become fully vested and exercisable, to be effective upon the approval of the Azur Merger by Jazz Pharmaceuticals, Inc.’s stockholders.

In December 2011, at a special meeting of the stockholders of Jazz Pharmaceuticals, Inc., the company’s stockholders approved, on an advisory basis, the acceleration of vesting of the NSOs. As a result, on December 13, 2011, all of the then-unvested NSOs held by our executive officers who were serving at that time and were subject to the excise tax (including, among the 2012 named executive officers, Messrs. Cozadd and Cox and Ms. Falberg), became fully vested and exercisable.

In January 2012, the affected executive officers (including Messrs. Cozadd and Cox and Ms. Falberg) exercised all of their outstanding NSOs by a cashless exercise in which the company withheld shares to cover the exercise price of the NSOs and, for the executives, any applicable withholding tax obligations. As a result of these exercises, each of the executive officers serving at that time (including Messrs. Cozadd and Cox and Ms. Falberg) significantly increased his or her holdings in the company’s shares.

As a result of this acceleration and exercise of the NSOs, the equity grants held by Messrs. Cozadd and Cox and Ms. Falberg, the 2012 named executive officers who were executive officers in 2011 and were subject to the excise tax, were significantly reduced in January 2012, thus reducing the retention and incentive value of such grants. The excise tax described above applied to equity awards for a period of approximately six months following the Azur Merger. As a result, our board of directors and the compensation committee determined not to make any equity grants during this period, including annual and new hire grants, to the executive officers, including the 2012 named executive officers.

*2012 Stock Option and RSU Awards.* In July 2012, the compensation committee engaged Radford to provide benchmarking data and recommendations regarding long-term equity incentive awards to our then-current executive officers. After review of the market data provided by Radford, the compensation committee determined that due to the factors described above, some of the executive officers no longer held long-term equity incentives in amounts similar to those held by other executives in our peer group and that, in order to promote retention, the long-term equity incentives held by our executive officers should more closely approximate those of recently hired executive officers in our peer group. The compensation committee reviewed market data for annual grants and grants to recently hired executive officers to determine the appropriate level of awards to grant and determined that awards to newly hired executives at our peer companies and other companies with whom we compete were generally two times the value of annual awards at the 60<sup>th</sup> percentile of the market data granted to those executives. The compensation committee, and with respect to our Chief Executive Officer, the board of directors, therefore determined that the value of the 2012 equity awards to the named executive officers would be made at two times the value of annual grants to executives at the 60<sup>th</sup> percentile of the market data.

As a result, in July 2012, the compensation committee and, with respect to Mr. Cozadd, the board of directors, approved the grant of stock options under the 2011 Plan for 200,000 shares to Mr. Cozadd and for 70,000 shares to each of Ms. Falberg, Mr. Cox, Ms. Hooper and Dr. Tobias, and the grant of RSUs under the 2011 Plan for 100,000 shares to Mr. Cozadd and for 35,000 shares to each of Ms. Falberg, Mr. Cox, Ms. Hooper and Dr. Tobias. Together, the stock option and RSU awards were granted at approximately two times an amount

that was, for Mr. Cozadd, at the 60<sup>th</sup> percentile, and for the named executive officers other than Mr. Cozadd, between the 60<sup>th</sup> and the 75<sup>th</sup> percentile, in each case of the market data for annual equity grants. For the stock options grants, the long-term incentive value was calculated using the Black-Scholes methodology as of the date of grant and as a percentage of outstanding shares. The compensation committee and the board of directors determined that these equity grants should be structured to consist of 50% stock options and 50% RSUs using a 2:1 ratio of stock option grants to RSUs to control dilution and to reflect the increased value of receiving shares at full value without the payment of an exercise price.

The compensation committee believes that equity award grants to the named executive officers in 2012, taken together with the named executive officers' prior equity positions, as applicable, were consistent with providing each named executive officer with an ongoing equity position in the company that is competitive with similarly situated executive officers at companies included in the market data and fosters an ownership culture focused on the company's long-term performance. In further support of fostering an ownership culture, in February 2013, we adopted share ownership guidelines for the named executive officers, certain other executive officers and non-employee directors in order to better align their interests with those of our shareholders. A description of this policy is included above under the heading entitled "*Ownership Guidelines for Directors and Executive Officers.*"

In February 2013, the compensation committee and, with respect to Mr. Cozadd, the board of directors, approved annual equity grants under our 2011 Plan to the named executive officers. Mr. Cozadd received 125,000 options and 50,000 RSUs. Each of Ms. Falberg and Ms. Hooper was awarded 32,000 options and 16,000 RSUs. Mr. Cox received 27,500 options and 13,750 RSUs, and Dr. Tobias was awarded 25,000 options and 12,500 RSUs. These equity grants vest over four years, with 25% of the shares subject to the option awards vesting on the one-year anniversary of the grant date and the remainder vesting in equal monthly installments thereafter over the remaining 36 months, and 25% of the RSUs vesting on the first through fourth anniversaries of the grant date. The 2013 annual equity grants to the named executive officers reflect the compensation committee's review of market data for annual grants to executive officers in similar positions, based on industry and responsibility level.

### ***Change in Control Plan***

In February 2012, the compensation committee reviewed the benefits offered under the change in control plan in light of the consummation of the Azur Merger after reviewing a market data analysis for severance benefits prepared by Radford. The compensation committee also considered increased consolidation activity in our industry and recent advancements in the company's commercial operations, both of which were determined to contribute to the increased retention value of a change in control plan. The compensation committee approved certain modifications to increase the level of benefits offered under the change in control plan. Specifically, such modifications included (i) increasing the applicable percentages (as defined in the change in control plan) from 150% to 200% for the Chief Executive Officer, Executive Chairman or President, and from 125% to 150% for Senior Vice Presidents and above (including Executive Vice Presidents); (ii) increasing the applicable COBRA payments from 18 months to 24 months for the Chief Executive Officer, Executive Chairman or President and from 15 months to 18 months for Senior Vice Presidents and above (including Executive Vice Presidents); and (iii) amending the applicable bonus percentage to mean the greater of (a) any annual bonus, as a percentage of annual base salary paid in the year of determination, paid to the executive in respect of either of the last two calendar years prior to the date of termination or (b) the executive's target bonus, expressed as a percentage of annual base salary, for the calendar year in which the termination occurs (subject to an alternative calculation as well as a reduction for executives who have not been employed for the entire calendar year prior to the date of termination). The terms of the change in control plan are described below under the heading entitled "*Potential Payments upon Termination or Change in Control—Amended and Restated Executive Change in Control and Severance Benefit Plan.*" The compensation committee believes that the benefits we provide under the change in control plan are representative of market practice, both in terms of design and cost, and are sufficient to retain our current executive team and to recruit talented executives in the future.

## **Accounting and Tax Considerations**

Under Financial Accounting Standard Board ASC Topic 718, or ASC 718, the company is required to estimate and record an expense for each award of equity compensation (including stock options and RSUs) over the vesting period of the award. We record stock-based compensation expense on an ongoing basis according to ASC 718. The compensation committee has considered, and may in the future consider, the grant of restricted stock or other stock awards to executive officers in lieu of or in addition to stock option and RSU grants in light of the accounting impact of ASC 718 with respect to stock option and RSU grants and other considerations. Accounting rules also require the company to record cash compensation as an expense at the time the obligation is incurred.

Section 162(m) of the Code limits companies to a deduction for federal income tax purposes of not more than \$1 million of compensation paid to certain executive officers in a calendar year. Compensation above \$1 million may be deducted if it is “performance-based compensation.” To maintain flexibility in compensating executive officers in a manner designed to promote the company’s goals, the compensation committee has not yet established a policy for determining which forms of incentive compensation awarded to executive officers shall be designed to qualify as “performance-based compensation,” for purposes of section 162(m) or that requires all compensation to be deductible. However, the compensation committee intends to evaluate the effects of the compensation limits of section 162(m) on any compensation it proposes to grant, and the compensation committee intends to provide future compensation in a manner consistent with the best interests of the company and its shareholders.

## **Risk Assessment Concerning Compensation Practices and Policies**

In April 2012 and February 2013, the compensation committee reviewed all of the company’s compensation policies and practices to assess whether they encourage employees to take inappropriate risks. After review of each of the company’s compensation plans, and the provisions, checks and balances and oversight of each plan, the compensation committee determined that any risks arising from our compensation policies and practices for our employees are not reasonably likely to have a material adverse effect on our company as a whole. In addition, the compensation committee believes that the mix and design of the elements of executive compensation do not encourage management to assume excessive risks and, as described under the heading above entitled “*Compensation Discussion and Analysis*,” significant compensation decisions, and decisions concerning the compensation of the company’s executives, include subjective considerations by the compensation committee or the full board of directors, which restrain the influence of formulae or objective factors on excessive risk taking. Finally, the mix of short-term compensation (in the form of salary and annual bonus, if any), and long-term compensation (in the form of stock options and other equity awards, if any) also prevents undue focus on short-term results and helps align the interests of the company’s executives with the interests of our shareholders.

## **Conclusion**

It is the opinion of the compensation committee that the compensation policies and elements described above provide the necessary incentives to properly align our executive officers’ performance and the interests of our shareholders while maintaining equitable and competitive executive compensation practices that enable us to attract and retain the highest caliber of executives.

## SUMMARY COMPENSATION TABLE

### Summary of Compensation

The following table sets forth certain summary information for the years indicated with respect to the compensation earned by the named executive officers for fiscal years 2012, 2011 and 2010, as applicable. The compensation information presented below consists of information with respect to Jazz Pharmaceuticals, Inc., our predecessor, for periods prior to January 18, 2012 and information with respect to Jazz Pharmaceuticals plc for the period January 18, 2012 through December 31, 2012. See “Introduction—Basis of Presentation” beginning on page 1 of this proxy statement.

Name and Principal Position	Year	Salary (\$) <sup>(1)</sup>	Bonus (\$) <sup>(2)</sup>	Stock Awards (\$) <sup>(3)</sup>	Option Awards (\$) <sup>(4)</sup>	Non-Equity Incentive Plan Compensation (\$) <sup>(6)</sup>	All Other Compensation (\$) <sup>(7)</sup>	Total (\$)
Bruce C. Cozadd Chairman and Chief Executive Officer	2012	722,158	—	4,682,990	4,627,340	1,081,600	1,710	11,115,798
	2011	563,173	—	—	2,474,780 <sup>(5)</sup>	552,000	1,710	3,591,663
	2010	496,877	—	—	1,163,414	267,300	1,437	1,929,028
Kathryn E. Falberg Executive Vice President and Chief Financial Officer	2012	446,769	—	1,639,047	1,619,569	390,000	2,622	4,098,007
	2011	377,635	—	—	707,080 <sup>(5)</sup>	300,000	2,312	1,387,027
	2010	366,404	30,000	—	498,606	150,000	1,100	1,046,110
Russell J. Cox <sup>(8)</sup> Executive Vice President and Chief Commercial Officer	2012	379,250	—	1,639,047	1,619,569	300,000	1,629	3,939,495
	2011	322,576	—	—	707,080 <sup>(5)</sup>	225,000	1,067	1,255,723
Suzanne Sawochka Hooper <sup>(9)</sup> Executive Vice President and General Counsel	2012	420,289	187,500	1,639,047	1,619,569	350,000	1,453	4,217,858
Jeffrey K. Tobias, M.D. <sup>(10)</sup> Executive Vice President, Research and Development and Chief Medical Officer	2012	422,023	125,000	1,639,047	1,619,569	250,000	4,527	4,060,166

- (1) The dollar amounts in this column represent base salary earned during the indicated fiscal year. For more information regarding salaries in 2012, see “Compensation Discussion and Analysis—2012 Compensation Decisions for the Named Executive Officers—Base Salary” above.
- (2) The dollar amounts in this column represent cash signing and or retention bonuses paid during the indicated fiscal year to each of Ms. Falberg, Ms. Hooper and Dr. Tobias. See “—Description of Compensation Arrangements—Executive Employment Agreements” below.
- (3) The dollar amounts in this column reflect the aggregate grant date fair value of all RSU awards granted in 2012 computed in accordance with ASC 718. The grant date fair value of each RSU award is measured based on the closing price of our ordinary shares on the date of grant. These amounts do not necessarily correspond to the actual value recognized or that may be recognized by the named executive officers.
- (4) The dollar amounts in this column reflect the aggregate grant date fair value of all stock option awards granted during the indicated fiscal year. These amounts have been calculated in accordance with ASC 718, using the Black-Scholes option-pricing model and excluding the effect of estimated forfeitures. Assumptions used in the calculation of these amounts are included in the notes to our audited consolidated financial statements included in the 2012 10-K. These amounts do not necessarily correspond to the actual value recognized or that may be recognized by the named executive officers.
- (5) There was no incremental fair value, as determined in accordance with ASC 718, associated with the modification of nonstatutory stock options held by Messrs. Cozadd and Cox and Ms. Falberg in 2011 to provide for the full acceleration of vesting in connection with the Azur Merger, which vesting acceleration is described under “—Options Exercises and Stock Vested” below. The intrinsic value of the foregoing vesting acceleration, or the value of the accelerated vesting of unvested NSOs held by the applicable named executive officer, calculated as the difference between (a) the closing price of Jazz Pharmaceuticals, Inc.

common stock as reported on NASDAQ on the date of the vesting acceleration and (b) the exercise price of each of the unvested NSOs subject to accelerated vesting, was \$3,075,998 for Mr. Cozadd, \$1,701,368 for Ms. Falberg and \$500,441 for Mr. Cox.

- (6) The dollar amounts in this column represent the cash bonus awarded under the performance bonus plan for the indicated fiscal year. For more information, see “*Compensation Discussion and Analysis—2012 Compensation Decisions for the Named Executive Officers—Performance Bonus Awards*” above.
- (7) The dollar amounts in this column represent group term life insurance premiums paid during the indicated fiscal year.
- (8) Mr. Cox joined us in July 2010 and became an executive officer in January 2011.
- (9) Ms. Hooper joined us in February 2012 and became an executive officer in March 2012.
- (10) Dr. Tobias joined us in October 2011 as an executive officer.

### Grants of Plan-Based Awards

The following table shows, for the fiscal year ended December 31, 2012, certain information regarding grants of plan-based awards to the named executive officers.

#### GRANTS OF PLAN-BASED AWARDS IN FISCAL 2012

Name	Award Type	Grant Date	Approval Date	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards Target (\$) <sup>(1)</sup>	All Other Stock Awards: Number of Shares of Stock or Units (#) <sup>(2)</sup>	All Other Option Awards: Number of Securities Underlying Options (#) <sup>(2)</sup>	Exercise or Base Price of Option Awards (\$/Sh) <sup>(3)</sup>	Grant Date Fair Value of Stock and Option Awards (\$) <sup>(4)</sup>
Bruce C. Cozadd	Annual Cash	—	—	722,158	—	—	—	—
	Annual Option	8/9/2012	7/27/2012	—	—	200,000	46.83	4,627,340
Kathryn E. Falberg	Annual RSU	8/9/2012	7/27/2012	—	100,000	—	—	4,682,990
	Annual Cash	—	—	223,385	—	—	—	—
Russell J. Cox	Annual Option	8/9/2012	7/27/2012	—	—	70,000	46.83	1,619,569
	Annual RSU	8/9/2012	7/27/2012	—	35,000	—	—	1,639,047
Suzanne Sawochka Hooper	Annual Cash	—	—	189,625	—	—	—	—
	Annual Option	8/9/2012	7/27/2012	—	—	70,000	46.83	1,619,569
Jeffrey K. Tobias, M.D.	Annual RSU	8/9/2012	7/27/2012	—	35,000	—	—	1,639,047
	Annual Cash	—	—	211,012	—	—	—	—
	Annual Option	8/9/2012	7/27/2012	—	—	70,000	46.83	1,619,569
	Annual RSU	8/9/2012	7/27/2012	—	35,000	—	—	1,639,047

(1) This column sets forth the target bonus amount for each named executive officer for the year ended December 31, 2012 under the performance bonus plan. There are no thresholds or maximum bonus amounts for each individual officer established under the performance bonus plan. Target bonuses were set as a percentage of each named executive officer’s base salary earned for the fiscal year ended December 31, 2012 and were 100% for Mr. Cozadd and 50% for each of Ms. Falberg, Mr. Cox, Ms. Hooper and Dr. Tobias. The dollar value of the actual bonus award earned for the year ended December 31, 2012 for each named executive officer is set forth in the Summary Compensation Table above. As such, the amounts set forth in this column do not represent additional compensation earned by the named executive officers for the year ended December 31, 2012. For a description of the performance bonus plan, please see “*Compensation Discussion and Analysis—Executive Compensation Program—Performance Bonus Plan*” and “*Compensation Discussion and Analysis—2012 Compensation Decisions for the Named Executive Officers—Performance Bonus Awards*” above.

(2) Annual stock options and RSU awards were granted under the 2011 Plan. Each of the stock option awards listed in the table above vests as to 25% of the ordinary shares underlying the stock options upon the one

year anniversary of the grant date and vest as to the remainder of the shares in 36 equal monthly installments thereafter. Each of the RSU awards vest in four equal annual installments on the anniversary of the grant date. As a general matter, the vested portion of stock options granted to the named executive officers will expire three months after each named executive officer's last day of service, subject to extension upon certain termination situations such as death or disability, and RSUs will cease vesting upon each named executive officer's last day of service. Stock option and RSU awards are subject to potential vesting acceleration as described below under the headings entitled "*Description of Compensation Arrangements—Equity Compensation Arrangements—2011 Equity Incentive Plan*" and "*Potential Payments upon Termination or Change in Control—Amended and Restated Executive Change in Control Plan and Severance Benefit Plan*" below. See also the discussion under "*Description of Compensation Arrangements—Equity Compensation Arrangements—2011 Equity Incentive Plan*" below for a general description of the material terms of the 2011 Plan.

- (3) Stock options were granted with an exercise price equal to 100% of the fair market value on the date of grant, \$46.83 per share, which was the closing price of our ordinary shares on the grant date.
- (4) The dollar amounts in this column represent the grant date fair value of each stock option and RSU award, as applicable, granted to the named executive officers in 2012. These amounts have been calculated in accordance with ASC 718. The grant date fair value of each stock option is calculated using the Black-Scholes option-pricing model and excluding the effect of estimated forfeitures. The grant date fair value of each RSU award is measured based on the closing price of our ordinary shares on the date of grant. Assumptions used in the calculation of these amounts are included in the notes to our audited consolidated financial statements included in the 2012 10-K.

## **Description of Compensation Arrangements**

### **Executive Employment Agreements**

We do not have employment agreements currently in effect with any of our named executive officers. Like other employees, executives are eligible for annual salary increases, participation in the performance bonus plan and discretionary equity grants.

From time to time, we have provided an offer letter in connection with an executive officer's commencement of employment, which describes such executive officer's initial terms of employment. For example, in November 2009, we provided Ms. Falberg with an offer letter that included an initial base salary and a hiring bonus of \$30,000. In September 2011 and January 2012, we provided offer letters to Dr. Tobias and Ms. Hooper, respectively. These offer letters included an initial base salary and a hiring bonus of \$125,000, payable in connection with commencement of employment, in 2011 for Dr. Tobias and in 2012 for Ms. Hooper, and a retention bonus of \$62,500, payable on each of the six and twelve months following their respective commencement dates of employment. However, each of Ms. Falberg, Dr. Tobias and Ms. Hooper's employment is at-will and not governed by the terms of their respective offer letters.

### **Amended and Restated Executive Change in Control and Severance Benefit Plan**

Each of the named executive officers is a participant in the change in control plan, a description of which is included below under the heading entitled "*Potential Payments upon Termination or Change in Control.*"

### **Equity Compensation Arrangements**

Since the Azur Merger, we have granted stock options and RSU awards to employees, including the named executive officers, under the 2011 Plan. From the initial public offering of Jazz Pharmaceuticals, Inc. until the Azur Merger, we granted stock options to our employees, including some of the named executive officers, under the 2007 Plan. From 2003 until the initial public offering of Jazz Pharmaceuticals, Inc., we granted stock options to employees, including Mr. Cozadd, under the 2003 Plan. For more information on our current equity compensation program and decisions regarding the grants of equity awards in 2012 for our named executive

officers, see “*Compensation Discussion and Analysis—Executive Compensation Program—Long-Term Equity Awards*” and “*Compensation Discussion and Analysis—2012 Compensation Decisions for the Named Executive Officers—Stock Option and RSU Awards*.” The following is a brief summary of the material terms of each of our equity compensation plans.

### ***2011 Equity Incentive Plan***

In connection with the Azur Merger, Jazz Pharmaceuticals, Inc.’s board of directors adopted the 2011 Plan in October 2011, and its stockholders approved the 2011 Plan at the special meeting of the stockholders held in December 2011. The 2011 Plan became effective immediately before the consummation of the Azur Merger and was assumed and adopted by us upon the consummation of the Azur Merger. The following is a brief summary of the material terms of the 2011 Plan.

*Administration.* The board of directors has delegated its authority to administer the 2011 Plan to the compensation committee. Subject to the terms of the 2011 Plan, the board of directors or a committee authorized by the board determines recipients, dates of grant, the numbers and types of stock awards to be granted, and the terms and conditions of the stock awards, including the period of their exercisability and vesting. The compensation committee has the authority to delegate its administrative powers under the 2011 Plan to a subcommittee consisting of members of the compensation committee and may, at any time, revert in itself some or all of the power previously delegated to the subcommittee. Our board of directors may also delegate to one or more of our officers the authority to designate employees who are not officers to be recipients of certain stock awards and the number of shares subject to such stock awards, provided that our board of directors must specify the total number of shares that may be subject to the stock awards granted by such officer and such officer may not grant a stock award to himself or herself.

*Types of Awards.* The 2011 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, RSU awards, other stock awards, and performance awards that may be settled in cash, shares, or other property, which may be granted to employees, including officers.

*Corporate Transactions.* In the event of certain significant Corporate Transactions, our board of directors will have the discretion to take one or more of the following actions with respect to outstanding stock awards (contingent upon the closing or completion of such Corporate Transaction), unless otherwise provided in the stock award agreement or other written agreement with the participant or unless otherwise provided by our board of directors at the time of grant:

- arrange for assumption, continuation, or substitution of a stock award by a surviving or acquiring corporation (or its parent company);
- accelerate the vesting and exercisability of a stock award and provide for its termination prior to the effective time of the Corporate Transaction;
- arrange for the assignment or the lapse of any reacquisition or repurchase rights held by us or any of our affiliates with respect to the stock award;
- cancel or arrange for the cancellation of a stock award, to the extent not vested or exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the board of directors may consider appropriate; or
- make a payment equal to the excess, if any, of (a) the value of the property that the participant would have received upon the exercise of the stock award over (b) any exercise price payable in connection with such exercise.

Our board of directors need not take the same action for each stock award or with regard to all participants.

For purposes of the 2011 Plan, a “Corporate Transaction” generally means (i) a sale or disposition of all or substantially all of our assets or a sale or disposition of at least 90% of our outstanding securities; (ii) a merger,



consolidation or similar transaction after which we are not the surviving corporation; or (iii) a merger, consolidation or similar transaction after which we are the surviving corporation but our shares are converted into other property.

*Change in Control.* The board of directors has the discretion to provide additional acceleration of vesting and exercisability upon or after a Change in Control (as defined in the 2011 Plan and described below) as may be provided in a stock award agreement or any other written agreement between us or any of our affiliates and a participant. The forms of stock option agreement and RSU award agreement adopted by the board of directors under the 2011 Plan provide that in the event a participant's service relationship with us or a successor entity is terminated due to an Involuntary Termination Without Cause (as defined in the stock award agreement and as described below) within 12 months following, or one month prior to, the effective date of a Change in Control, the vesting (and in the case of stock options, exercisability) of the stock award will accelerate in full.

For purposes of the 2011 Plan and the forms of stock option agreement and RSU award agreement issued thereunder, a "Change in Control" generally means (i) a person or group acquires ownership of more than 50% of the combined voting power of our outstanding securities (other than in connection with a financing, or a repurchase program); (ii) a merger, consolidation or similar transaction involving our company, after which our shareholders do not own more than 50% of the combined voting power of the surviving entity or its parent in substantially the same proportion as their ownership of our outstanding voting securities immediately before the transaction; (iii) our shareholders or our board of directors approves a complete dissolution or liquidation of our company, or a complete dissolution or liquidation of our company otherwise occurs (except for a liquidation into a parent company); (iv) a sale, lease, license or other disposition of substantially all of our assets; or (v) individuals who are members of our board of directors on the date of adoption of the 2011 Plan (or members of our board of directors approved or recommended by a majority vote of such members still in office) cease to constitute a majority of our board of directors.

An "Involuntary Termination Without Cause" generally means that a participant's service relationship with us is terminated for any reason other than for the following reasons (and not upon a participant's death or disability): (i) participant's commission of any felony or crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) participant's attempted commission of or participation in a fraud or act of dishonesty against us; (iii) participant's intentional, material violation of any contract or agreement with us or of any statutory duty owed to us; (iv) participant's unauthorized use or disclosure of our confidential information or trade secrets; or (v) participant's gross misconduct.

### ***2007 Equity Incentive Plan***

The 2007 Plan, which was initially adopted by the Jazz Pharmaceuticals, Inc. board of directors and approved by the Jazz Pharmaceuticals, Inc. stockholders in connection with its initial public offering, was continued and assumed by us upon consummation of the Azur Merger. The following is a brief summary of the material terms of the 2007 Plan.

*Administration.* The board of directors has delegated its authority to administer the 2007 Plan to the compensation committee. Subject to the terms of the 2007 Plan, the board of directors or a committee authorized by the board determines recipients, dates of grant, the numbers and types of stock awards to be granted, and the terms and conditions of the stock awards, including the period of their exercisability and vesting.

*Awards.* The 2007 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, RSU awards, stock appreciation rights, performance stock awards and other forms of equity compensation, which may be granted to employees, including officers, non-employee directors, and consultants. Incentive stock options may be granted only to employees, including executive officers.

*Corporate Transaction.* Pursuant to the 2007 Plan, in the event of a Corporate Transaction (as defined in the 2007 Plan and described below), the board of directors has the discretion to take one or more of the following actions with respect to outstanding stock awards, unless otherwise provided in the stock award agreement or other written agreement with the participant or unless otherwise provided by our board of directors at the time of grant:

- arrange for the assumption, continuation, or substitution of a stock award by the surviving or acquiring entity (or its parent company);
- arrange for the assignment of any reacquisition or repurchase rights applicable to any shares issued pursuant to a stock award to the surviving or acquiring corporation (or its parent company);
- accelerate the vesting and exercisability of a stock award prior to the effective time of the Corporate Transaction followed by the termination of such stock award if it is not exercised at or prior to the Corporate Transaction;
- arrange for the lapse of any reacquisition or repurchase rights applicable to any shares issued pursuant to a stock award;
- cancel or arrange for the cancellation of a stock award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for cash consideration as the board of directors considers appropriate; and
- arrange for the surrender of a stock award in exchange for a payment equal to the excess of (a) the value of the property the holder of the stock award would have received upon the exercise of the stock award, over (b) any exercise price payable by such holder in connection with such exercise.

The board of directors need not take the same action for each stock award. For purposes of the 2007 Plan, a “Corporate Transaction” generally means (i) a sale or disposition of all of our assets or a sale or disposition of at least 90% of our outstanding securities; (ii) a merger, consolidation or similar transaction after which we are not the surviving corporation; or (iii) a merger, consolidation or similar transaction after which we are the surviving corporation but our shares are converted into other property.

*Change in Control.* The board of directors has the discretion to provide additional acceleration of vesting and exercisability upon or after a Change in Control (as defined in the 2007 Plan and described below) as may be provided in a stock award agreement or any other written agreement between us or any of our affiliates and a participant. The forms of stock option agreement and RSU award agreement adopted by the board of directors under the 2007 Plan provide that in the event a participant’s service relationship with us or a successor entity is terminated due to an Involuntary Termination Without Cause (as defined in the stock award agreement and as described below) within 12 months following, or one month prior to, the effective date of a Change in Control, the vesting (and in the case of stock options, exercisability) of the stock award will accelerate in full. For purposes of the 2007 Plan and the forms of stock option agreement and RSU award agreement issued thereunder, a “Change in Control” has a similar meaning as under the change in control plan, as described below under the heading entitled “*Potential Payments upon Termination or Change in Control—Amended and Restated Executive Change in Control and Severance Benefit Plan,*” except that it also means a change in which the members of the incumbent board of directors (or persons elected by a majority of the incumbent board of directors) cease to constitute a majority of the board of directors.

The term “Involuntary Termination Without Cause” has a similar meaning as under the 2011 Plan, as described above.

### ***2003 Equity Incentive Plan***

The 2003 Plan, which was initially adopted by the Jazz Pharmaceuticals, Inc. board of directors and approved by the Jazz Pharmaceuticals, Inc. stockholders, was continued and assumed by us upon consummation of the Azur Merger. The material terms of the 2003 Plan are summarized below.

*Administration.* The board of directors has the authority to administer the 2003 Plan and the awards granted under it. The 2007 Plan is the successor to and continuation of the 2003 Plan and, upon adoption of the 2007

Plan, no additional awards were permitted to be granted under the 2003 Plan. All then outstanding awards under the 2003 Plan continued to be governed by their existing terms.

*Fundamental Transactions.* Pursuant to the 2003 Plan, in the event of certain Fundamental Transactions (as described below), the Jazz Pharmaceuticals board of directors has the discretion to take one or more of the following actions:

- arrange for the assumption or substitution of outstanding awards;
- accelerate the vesting and termination of outstanding awards in whole or in part;
- cancel or arrange for the cancellation of awards in exchange for cash payments; and
- arrange for any repurchase rights applicable to award shares to apply to any substituted securities issued in the transaction or be terminated.

The board of directors need not take the same action for each award.

Under the form of stock option agreement under the 2003 Plan, as amended, the vesting and exercisability of stock options granted under the 2003 Plan will accelerate in full if, within 12 months following, or one month prior to, the effective date of a Change in Control (as defined in the 2007 Plan), the participant's continuous service with us or a successor entity is terminated due to an Involuntary Termination Without Cause. For purposes of the stock options granted under the 2003 Plan, an "Involuntary Termination Without Cause" generally means that a participant's service relationship with us is terminated by any reason other than for the following reasons (and not upon a participant's death or disability): (i) participant's intentional act or act of gross negligence that materially injured the business of our company; (ii) participant's intentional refusal or failure to follow lawful and reasonable directions of the board of directors or the appropriate individual to whom participant reports; (iii) participant's willful and habitual neglect of duties for our company; or (iv) participant's conviction of a felony involving moral turpitude that is likely to inflict or has inflicted material injury on the business of our company.

For purposes of the 2003 Plan, a "Fundamental Transaction" includes a merger of our company with another entity in which our company is not the surviving entity or any other transaction or event where other securities are substituted for our shares or our shares may no longer be outstanding. Additionally, the board of directors can specify that other transactions will constitute a Fundamental Transaction, such as (i) a merger transaction after which our shareholders cease to own 50% of the voting power of the company; (ii) a person or group acquires 30% or more of our total combined voting power; or (iii) members of our board of directors cease to constitute a majority of our board of directors due to a contested election. The term "Involuntary Termination Without Cause" has a similar meaning as described above with respect to the 2007 Plan.

In connection with the Azur Merger, each stock option under the 2007 Plan and the 2003 Plan outstanding immediately prior to the Azur Merger was converted into an option to acquire, on substantially the same terms and conditions as were applicable under such option before the effective time of the Azur Merger, the number of our ordinary shares equal to the number of shares of Jazz Pharmaceuticals, Inc. common stock subject to such option immediately prior to the effective time of the Azur Merger, at an exercise price per ordinary share equal to the exercise price per share of Jazz Pharmaceuticals, Inc. common stock otherwise purchasable pursuant to such option. Prior to the Azur Merger, no stock options were outstanding under the 2011 Plan. The Azur Merger did not constitute a Change in Control or Fundamental Transaction for purposes of either the 2007 Plan or the 2003 Plan.

#### ***2007 Employee Stock Purchase Plan***

Additional long-term equity incentives are provided through the ESPP, which was amended and restated by Jazz Pharmaceuticals, Inc.'s board of directors in October 2011 and approved by its stockholders in December 2011, to be effective immediately prior to the Azur Merger, and, in October 2012, amended and restated by our

compensation committee. The ESPP was assumed by us upon the consummation of the Azur Merger. The ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of section 423 of the Code. Under the ESPP, all of our regular employees and employees of any of our parent or subsidiary companies if the board of directors designates such company as eligible to participate (including the named executive officers), may participate and may contribute, normally through payroll deductions, up to 15% of their earnings up to a total of \$15,000 per purchase period for the purchase of our ordinary shares under the ESPP. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with a duration of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which our ordinary shares will be purchased for employees participating in the offering. Unless otherwise determined by the board of directors, ordinary shares are purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of an ordinary share on the first date of an offering or (b) 85% of the fair market value of an ordinary share on the date of purchase.

### **Performance Bonus Plan**

We maintain a performance bonus plan to reward executive officers and other employees for successful achievement of company-wide and individual performance objectives on an annual basis. More information regarding the performance bonus plan is provided above under the headings entitled “*Compensation Discussion and Analysis—Executive Compensation Program—Performance Bonus Plan*” and “*Compensation Discussion and Analysis—2012 Compensation Decisions for the Named Executive Officers—Performance Bonus Awards.*”

### **401(k) Plan**

Our U.S.-based employees are eligible to participate in the 401(k) Plan. The 401(k) Plan is intended to qualify as a tax-qualified plan under section 401 of the Code. The 401(k) Plan provides that each participant may contribute a portion of his or her pretax compensation, up to a statutory limit, which for most employees was \$17,500 in 2012 (with a larger “catch up” limit for older employees). Employee contributions are held and invested by the plan’s trustee. The 401(k) Plan also permits us to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. Through 2012, we had not made any such discretionary or matching contributions to the plan. In 2013, we began making discretionary matching contributions subject to an annual limit of \$1,000 per employee.

### **Additional Benefits**

The named executive officers are eligible to participate in our benefit plans generally available to all employees, as described in “*Compensation Discussion and Analysis—Executive Compensation Program—Other Benefits.*”

### **Pension Benefits**

Other than with respect to defined contribution plans, the named executive officers do not participate in any plan that provides for retirement payments and benefits, or payments and benefits that will be provided primarily following retirement.

### **Nonqualified Deferred Compensation**

During the year ended December 31, 2012, the named executive officers did not contribute to, or earn any amounts with respect to, any defined contribution or other plan sponsored by us that provides for the deferral of compensation on a basis that is not tax-qualified.

### **Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth, for the fiscal year ended December 31, 2012, certain information regarding outstanding equity awards at fiscal year-end for the named executive officers.

## OUTSTANDING EQUITY AWARDS AT 2012 FISCAL YEAR-END TABLE

Name	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#) <sup>(1)</sup>	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested(#)	Market Value of Shares or Units of Stock That Have Not Vested(\$) <sup>(2)</sup>
	Exercisable	Unexercisable				
Bruce C. Cozadd . . . . .	—	200,000 <sup>(3)</sup>	46.83	08/08/2022	100,000	5,325,000
	—	17,420 <sup>(4)</sup>	11.48	03/07/2020		
	182	—	1.25	01/20/2019		
	7,040	—	7.96	05/15/2018		
	12,583	—	19.37	02/26/2017		
	15,902	—	15.09	02/17/2014		
	5,299	—	30.18	02/17/2014		
Kathryn E. Falberg . . . . .	—	70,000 <sup>(3)</sup>	46.83	08/08/2022	35,000	1,863,750
	—	3,750 <sup>(5)</sup>	11.48	03/07/2020		
	40,815	13,605 <sup>(6)</sup>	7.35	12/06/2019		
Russell J. Cox . . . . .	—	70,000 <sup>(3)</sup>	46.83	08/08/2022	35,000	1,863,750
	24,300	20,900 <sup>(7)</sup>	8.23	08/24/2020		
Suzanne Sawochka Hooper . . . . .	—	70,000 <sup>(3)</sup>	46.83	08/08/2022	35,000	1,863,750
Jeffrey K. Tobias, M.D. . . . .	—	70,000 <sup>(3)</sup>	46.83	08/08/2022	35,000	1,863,750

- (1) In addition to the specific vesting schedule for each stock option award, each unvested stock option is subject to the general terms of the 2011 Plan, 2007 Plan and 2003 Plan, as applicable, including the potential for future vesting acceleration described above in this section under the heading entitled “*Description of Compensation Arrangements—Equity Compensation Arrangements.*”
- (2) The market values of the RSU awards that have not vested are calculated by multiplying the number of RSU awards shown in the table by the closing share price of our ordinary shares on December 31, 2012, which was \$53.25.
- (3) The unexercisable shares subject to this stock option award as of December 31, 2012 will vest with respect to 25% of the shares underlying the stock option on August 9, 2013 and the remainder will vest monthly from September 8, 2013 to August 9, 2016.
- (4) The unexercisable shares subject to this stock option award as of December 31, 2012 will vest with respect to 8,710 shares monthly from January 8, 2013 to December 8, 2013 and the remainder will vest monthly from January 8, 2014 to March 8, 2014.
- (5) The unexercisable shares subject to this stock option award as of December 31, 2012 will vest monthly from January 8, 2013 to March 8, 2014.
- (6) The unexercisable shares subject to this stock option award as of December 31, 2012 will vest monthly from January 1, 2013 to December 1, 2013.
- (7) The unexercisable shares subject to this stock option award as of December 31, 2012 will vest with respect to 12,150 shares monthly from January 21, 2013 to December 21, 2013 and the remainder will vest monthly from January 21, 2014 to July 21, 2014.

### Option Exercises and Stock Vested

In December 2011, in connection with the Azur Merger, the Jazz Pharmaceuticals, Inc. stockholders, on an advisory basis, approved the acceleration of vesting of the NSOs held by certain of Jazz Pharmaceuticals, Inc.’s

executive officers and non-employee directors in order to avoid imposition of an excise tax on NSOs held at any time during the six months before and six months after the closing of the Azur Merger. On December 13, 2011, all of the then-unvested NSOs held by our executive officers and non-employee directors who were serving at that time and were subject to the excise tax (including, among the 2012 named executive officers, Messrs. Cozadd and Cox and Ms. Falberg) became fully vested and exercisable.

In January 2012, the affected executive officers (including Messrs. Cozadd and Cox and Ms. Falberg) exercised all of their outstanding NSOs by a cashless exercise in which the company withheld shares to cover the exercise price of the NSOs and, for the executives, any applicable withholding tax obligations.

The table below presents all option exercises by the named executive officers in the year ended December 31, 2012, which consisted only of options exercises in connection with the acceleration and vesting of NSOs described above. No RSU awards held by the named executive officers vested in 2012.

Name	Option Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$) <sup>(1)</sup>
Bruce C. Cozadd	836,971	27,875,365
Kathryn E. Falberg	141,830	4,813,775
Russell J. Cox	54,800	1,443,076
Suzanne Sawochka Hooper	—	—
Jeffrey K. Tobias, M.D.	—	—

<sup>(1)</sup> The value realized on exercise is based on the difference between the closing price of Jazz Pharmaceuticals, Inc. common stock as reported on NASDAQ on the date of exercise and the applicable exercise price of those options, and does not represent actual amounts received by the named executive officers as a result of the option exercises.

## Potential Payments upon Termination or Change in Control

### Amended and Restated Executive Change in Control and Severance Benefit Plan

Under Jazz Pharmaceuticals, Inc.'s executive change in control plan, which we assumed upon the consummation of the Azur Merger, as amended through April 2012, or the change in control plan, in the event that an executive's employment terminates due to an Involuntary Termination without Cause or a Constructive Termination, within 12 months following a Change in Control (as such capitalized terms are defined in the change in control plan and described generally below), and assuming all of the other conditions of the change in control plan are met, then each executive who is a participant in the change in control plan would be entitled to the following benefits under the change in control plan:

- a single lump sum cash severance payment equal to the sum of: (1) the executive's base salary in effect during the last regularly scheduled payroll period immediately preceding the termination (without, as a general matter, giving effect to any voluntary pay reduction taken by the executive during the 12 months preceding the date of termination), which is referred to as the applicable base salary, multiplied by the applicable percentage set forth below; *plus* (2) the product of (i) the applicable base salary and (ii) the applicable bonus percentage described below, and (iii) the applicable percentage set forth below; *plus* (3) the product of (A) the executive's applicable base salary and (B) the executive's applicable bonus percentage and (C) the quotient obtained by dividing the number of full months that an executive is employed in the year of the termination by 12.
- The "applicable percentage" as of December 31, 2012 was 200% for the Chief Executive Officer, Executive Chairman or President (currently only Mr. Cozadd), 150% for Senior Vice Presidents and above (which includes our Executive Vice Presidents) and 100% for Vice Presidents.

- The “applicable bonus percentage” is the greater of (a) any annual bonus, as a percentage of annual base salary paid in the year of determination, paid to the executive in respect of either of the last two calendar years prior to the date of termination or (b) the executive’s target bonus, expressed as a percentage of annual base salary, for the calendar year in which the termination occurs (subject to an alternative calculation as well as a reduction for executives who have not been employed for the entire calendar year prior to the date of termination);
- full payment of all of the applicable COBRA premiums for any health, dental or vision plan sponsored by us. As of December 31, 2012, the applicable COBRA payments were for a period of up to (i) 24 months for the Chief Executive Officer, Executive Chairman or President, (ii) 18 months for Senior Vice Presidents and above (which includes our Executive Vice Presidents), and (iii) 12 months for Vice Presidents, provided that the executive timely elects continued coverage; and
- acceleration in full of the vesting and exercisability, and termination of any of our repurchase rights, with respect to outstanding stock options and other equity awards held by the executives.

The following key terms are defined in the change in control plan:

- A “Change in Control” generally means the consummation of any of the following events: (i) a person or group acquires ownership of more than 50% of our outstanding securities (other than in connection with a private financing, recapitalization or conversion or restructuring of our indebtedness); (ii) a merger transaction involving us, after which our shareholders do not own more than 50% of the combined voting power of the surviving entity; (iii) our complete dissolution or liquidation; or (iv) a sale, lease, license or other disposition of substantially all of our assets.
- An “Involuntary Termination without Cause” generally means an executive’s employment relationship is terminated by any reason other than for the following reasons (and not upon an executive’s death or disability): (i) executive’s unauthorized use or disclosure of confidential information or trade secrets which causes material harm to us; (ii) executive’s material breach of any agreement with us after an opportunity to cure; (iii) executive’s material failure to comply with our written policies or rules after an opportunity to cure; (iv) executive’s conviction or plea of guilty or no contest to any crime involving fraud, dishonesty or moral turpitude; (v) executive’s gross misconduct; (vi) executive’s continued failure to perform his or her assigned duties after notification; or (vii) executive’s failure to cooperate in good faith with any governmental or internal investigation of us or our directors, officers or employees.
- A “Constructive Termination” generally means an executive resigns employment after any of the following actions or events: (i) a reduction in executive’s base salary by more than ten percent (other than a company-wide or executive-level general reduction); (ii) a relocation of executive’s place of employment by more than 35 miles without executive’s consent; (iii) a substantial reduction in the executive’s duties or responsibilities prior to a Change in Control; (iv) a reduction in executive’s title; or (v) a substantial increase in executive’s required business travel without executive’s consent.

We benefit by requiring our executive officers to execute an effective general waiver and release of claims in order to be eligible to receive benefits under the change in control plan. All other benefits (such as life insurance, disability coverage and 401(k) Plan coverage) will terminate as of the executive’s termination date.

The change in control plan does not provide for the gross up of any excise taxes imposed by section 4999 of the Code. If any of the severance benefits payable under the change in control plan would constitute a “parachute payment” within the meaning of section 280G of the Code, subject to the excise tax imposed by section 4999 of the Code, the change in control plan provides for a best after-tax analysis with respect to such payments, under which the executive will receive whichever of the following two alternative forms of payment would result in executive’s receipt, on an after-tax basis, of the greater amount of the transaction payment notwithstanding that all or some portion of the transaction payment may be subject to the excise tax: (i) payment in full of the entire

amount of the transaction payment, or (ii) payment of only a part of the transaction payment so that the executive receives the largest payment possible without the imposition of the excise tax.

No executive would receive benefits under the change in control plan if (i) the executive has entered into an individually negotiated employment agreement that provides for severance or change in control benefits, (ii) the executive is entitled to receive benefits under another change in control plan maintained by us that provides benefits in connection with an Involuntary Termination without Cause or a Constructive Termination, in each case within 12 months following a Change in Control, (iii) the executive voluntarily terminates employment with us to accept employment with another entity that is controlled, directly or indirectly, by us or is otherwise affiliated with us, or (iv) the executive does not confirm in writing that he or she is subject to agreements with us relating to proprietary and confidential information. In addition, benefits would be terminated under the change in control plan if the executive willfully breaches his or her agreements with us relating to proprietary and confidential information or engages in certain solicitation or business interference activities.

The structure and amount of benefits provided under the change in control plan are intended to balance our goals of attracting and retaining highly qualified individuals, providing the appropriate incentive for such individuals to perform in the best interests of our shareholders and maintaining responsible pay practices. In 2008 and early 2011, our compensation committee reviewed the publicly disclosed severance and change in control benefits offered by pharmaceutical companies with whom Jazz Pharmaceuticals, Inc. competed to gain a general understanding of the benefits offered by its competitors. In February 2012, our compensation committee again reviewed the benefits offered under the change in control plan in light of the consummation of the Azur Merger after examining a market data analysis for severance benefits prepared by Radford. See “*Compensation Discussion and Analysis—Executive Compensation Program—Benchmarking of Cash and Long-Term Compensation*” for a discussion of how we determine market data. As a result, certain modifications to the change in control plan were approved in April 2012.

### **Equity Compensation Plans**

The 2011 Plan, 2007 Plan and 2003 Plan and award agreements thereunder provide for potential vesting acceleration upon an executive’s termination in connection with a change in control and, at the discretion of the board of directors, upon certain change in control events, as further described above under the heading entitled “*Description of Compensation Arrangements—Equity Compensation Arrangements.*”

### **Potential Payments upon Termination or Change in Control Table**

The following table estimates the potential severance payments and benefits under the change in control plan to which the named executive officers would be entitled in connection with specified termination events, calculated as if the named executive officers’ employment had terminated as of December 31, 2012. In addition, the table sets forth the amounts to which the named executive officers would be entitled under the 2011 Plan and 2007 Plan if, upon a corporate transaction or change in control transaction, the board of directors exercised its discretion to accelerate the vesting and exercisability of stock options and the vesting of RSU awards, and such event occurred on December 31, 2012. No options granted under the 2003 Plan remain unvested.

There are no other agreements, arrangements or plans that entitle any named executive officers to severance, perquisites or other benefits upon termination of employment or a change in control. For purposes of the table below, we have assumed that none of the potential severance benefits payable under the change in control plan would be subject to the excise tax imposed by section 4999 of the Code and therefore would not be reduced in accordance with the terms of the change in control plan.



**POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL AS OF  
DECEMBER 31, 2012**

<u>Name</u>	<u>Benefit</u>	<u>Involuntary Termination Without Cause or Constructive Termination in Connection with a Change of Control (\$)<sup>(1)</sup></u>	<u>2011 Plan and 2007 Plan—Certain Corporate Transactions (\$)<sup>(2)</sup></u>
Bruce C. Cozadd . . . . .	Lump Sum Cash Severance Payment	3,750,000	
	COBRA Payments	53,182	
	Vesting Acceleration <sup>(3)</sup>	7,336,633	7,336,633
	<b>Benefit Total</b>	<b>11,139,815</b>	<b>7,336,633</b>
Kathryn E. Falberg . . . . .	Lump Sum Cash Severance Payment	1,603,581	
	COBRA Payments	37,650	
	Vesting Acceleration <sup>(3)</sup>	3,094,257	3,094,257
	<b>Benefit Total</b>	<b>4,735,488</b>	<b>3,094,257</b>
Russell J. Cox . . . . .	Lump Sum Cash Severance Payment	1,265,072	
	COBRA Payments	39,887	
	Vesting Acceleration <sup>(3)</sup>	3,254,068	3,254,068
	<b>Benefit Total</b>	<b>4,559,027</b>	<b>3,254,068</b>
Suzanne Sawochka Hooper . . .	Lump Sum Cash Severance Payment	1,517,521	
	COBRA Payments	25,878	
	Vesting Acceleration <sup>(3)</sup>	2,313,150	2,313,150
	<b>Benefit Total</b>	<b>3,856,549</b>	<b>2,313,150</b>
Jeffrey K. Tobias, M.D. . . . .	Lump Sum Cash Severance Payment	1,412,826	
	COBRA Payments	25,878	
	Vesting Acceleration <sup>(3)</sup>	2,313,150	2,313,150
	<b>Benefit Total</b>	<b>3,751,854</b>	<b>2,313,150</b>

- <sup>(1)</sup> These benefits would be payable under the change in control plan if the Involuntary Termination without Cause or Constructive Termination occurred within 12 months following a Change in Control and assuming such termination took place on December 31, 2012. The forms of stock option agreements under the 2011 Plan and the 2007 Plan provide for the same vesting acceleration benefit as shown here under the change in control plan, therefore no separate vesting acceleration benefit is listed. The Azur Merger did not constitute a change in control or similar event under the change in control plan or the 2007 Plan.
- <sup>(2)</sup> These benefits would be payable under the 2011 Plan and the 2007 Plan if, upon a corporate transaction event the board of directors exercised its discretion to accelerate the vesting and exercisability of outstanding stock options and RSU awards, assuming the vesting acceleration took place on December 31, 2012. For a description of the potential vesting acceleration provisions in the 2011 Plan and the 2007 Plan, see “*Description of Compensation Arrangements—Equity Compensation Arrangements*” above.
- <sup>(3)</sup> The value of stock option and RSU award vesting acceleration is based on the closing stock price of \$53.25 per share for our ordinary shares as reported on NASDAQ on December 31, 2012, minus, in the case of stock options, the exercise price of the unvested stock option shares subject to acceleration.

Proxy

## DIRECTOR COMPENSATION

### Cash Compensation Arrangements

Pursuant to our compensation program for non-employee directors in effect for 2012, each non-employee director was entitled to receive the following cash compensation for board services, as applicable:

- a \$55,000 annual retainer for service as a member of our board of directors (paid quarterly);
- a supplemental annual retainer for the chairs of the board committees in the following amounts: \$25,000 for the chairperson of the audit committee, \$22,500 for the chairperson of the compensation committee and \$20,000 for the chairperson of the nominating and corporate governance committee (each paid quarterly); and
- a supplemental annual retainer for each member of the following committees other than the chairs, in the following amounts: \$15,000 for service as a member of the audit committee, \$12,500 for service as a member of the compensation committee and \$10,000 for service as a member of the nominating and corporate governance committee (each paid quarterly).

In May 2013, our board of directors approved a Non-Employee Director Compensation Policy, or the Director Compensation Policy. Under the Director Compensation Policy, each of our non-employee directors is entitled to receive the same cash compensation for board services as described above for the non-employee director compensation program in effect during 2012.

In addition, in February 2013, in furtherance of our ongoing commitment to the continuing education of our directors, our nominating and corporate governance committee adopted a policy for the reimbursement of director continuing education. Under this policy, we will pay or reimburse each director for enrollment fees and reasonable expenses incurred in connection with attending one continuing education program sponsored by an outside provider each year. Our non-employee directors are also reimbursed for travel and other reasonable expenses incurred in attending board or committee meetings, as are our employees who serve as directors.

### Directors Deferred Plan

In May 2007, the Jazz Pharmaceuticals, Inc. board of directors adopted the Directors Deferred Plan. We continued and assumed the Directors Deferred Plan in connection with the Azur Merger. The Directors Deferred Plan allows each non-employee director to elect to defer receipt of all or a portion of his or her annual retainer fees to a future date or dates. Amounts deferred under the Directors Deferred Plan are credited as our ordinary shares to a phantom stock account, and the number of shares credited is based on the amount of the retainer fees deferred divided by the market value of our ordinary shares on the first trading day of the first open window period following the date the retainer fees were deemed earned. On the 10<sup>th</sup> business day following the day of separation from the board of directors or the occurrence of a change in control, or as soon thereafter as practical once the non-employee director has provided the necessary information for electronic deposit of the deferred shares, each non-employee director will receive (or commence receiving, depending upon whether the director has elected to receive distributions from his or her phantom stock account in a lump sum or in installments over time) a distribution from his or her phantom stock account in our ordinary shares. The Directors Deferred Plan may be amended or terminated at any time by the board of directors. The Directors Deferred Plan in form and operation is intended to be compliant with section 409A of the Code.

Although we continue to maintain the Directors Deferred Plan, since the closing of the Azur Merger we have not permitted and will not permit our non-employee directors to defer any annual retainer fees under the Directors Deferred Plan.

### Ownership Guidelines for Directors and Executive Officers

In February 2013, our board of directors adopted share ownership guidelines for the company's non-employee directors, Chief Executive Officer and certain other employees who serve on our executive committee,

including the named executive officers. Under the guidelines, these individuals are expected to own the company's ordinary shares with a value equal to: three times (3x) base salary, for our Chief Executive Officer; one times (1x) base salary, for each other member of the company's executive committee; and three times (3x) the director's annual cash retainer, for each non-employee director. A description of this policy is included above under the heading entitled "*Compensation Discussion and Analysis—Executive Compensation Program—Ownership Guidelines for Directors and Executive Officers.*"

## Equity Compensation Arrangements

The Amended and Restated 2007 Non-Employee Directors Stock Option Plan, or the 2007 Directors Plan, which was initially adopted by the Jazz Pharmaceuticals, Inc. board of directors and approved by the Jazz Pharmaceuticals, Inc. stockholders in connection with its initial public offering, was continued and assumed by us upon the consummation of the Azur Merger.

Pursuant to the terms of the 2007 Directors Plan, until October 2011, any individual who first became a non-employee director was automatically granted an option to purchase 30,000 shares of Jazz Pharmaceuticals, Inc. common stock. Each initial option vested with respect to 33% of the shares on the first anniversary of the date of grant, and the balance in a series of 24 successive equal monthly installments thereafter. In addition, until October 2011, each individual who was serving as a non-employee director on the first trading day on or after August 15 of each year was automatically granted an option to purchase 12,500 shares of Jazz Pharmaceuticals, Inc. common stock on such date. The shares subject to each such annual option vested in a series of 12 successive equal monthly installments measured from the date of grant. All stock options granted under the 2007 Directors Plan have a maximum term of ten years, and the exercise price of each option granted under the 2007 Directors Plan was equal to 100% of the fair market value of Jazz Pharmaceuticals, Inc. common stock on the date of grant.

On October 24, 2011, the board of directors amended the 2007 Directors Plan to eliminate all future initial and annual automatic grants so that future automatic grants would not be made that would be subject to the excise tax imposed by section 4985 of the Code in connection with the Azur Merger. Accordingly, from October 24, 2011 until the current Director Compensation Policy was adopted on May 2, 2013, stock option grants under the 2007 Directors Plan were made in the discretion of the board of directors.

In July 2012, the board of directors approved annual and initial equity grants to our non-employee directors under the 2007 Plan, pursuant to which the following grants were made on August 9, 2012, the first trading day of the first open window period following the 2012 annual general meeting of shareholders: Dr. Sohn, who was first elected to our board of directors at the 2012 annual general meeting of shareholders, was granted (a) an option to purchase 8,000 ordinary shares that vests with respect to 33% of the shares on the first anniversary of the date of grant, and the balance in a series of 24 successive equal monthly installments thereafter and (b) an RSU award covering 4,000 ordinary shares that vests in equal annual installments over three years from the date of grant. Additionally, each director who continued serving as a non-employee director or who was re-elected as a non-employee director at the 2012 annual general meeting of shareholders was granted (i) an option to purchase 4,500 ordinary shares that vests in a series of 12 successive equal monthly installments measured from the date of grant and (ii) an RSU award covering 2,250 ordinary shares that vests in full on the first anniversary of the date of grant.

In addition, in connection with the Azur Merger, all of the unvested shares subject to options granted under the 2007 Directors Plan and held on December 13, 2012 by members of our board of directors who were subject to the excise tax described above became fully vested and exercisable. Accordingly, on January 11, 2012, each of such non-employee directors exercised all of their outstanding NSOs by a cashless exercise in which the company withheld shares to cover the exercise price of the NSOs. Additional information regarding this vesting acceleration benefit is provided above under the heading entitled "*Executive Compensation—Option Exercises and Stock Vested.*"

With respect to options granted under the 2007 Directors Plan and 2007 Plan, if a non-employee director's service relationship with us or any of our affiliates, whether as a non-employee director or subsequently as our employee, director or consultant or that of any of our affiliates, ceases for any reason other than disability or death, or, with respect to options granted under the 2007 Directors Plan only, after any 12-month period following a change in control, the optionee may exercise any vested options for a period of three months following the cessation of service. If such optionee's service relationship with us, or any of our affiliates, ceases due to disability or death (or an optionee dies within a certain period following cessation of service), the optionee or a beneficiary may exercise the option for a period of 12 months in the event of disability, and 18 months in the event of death. With respect to options granted under the 2007 Directors Plan, if such optionee's service terminates within 12 months following a specified change in control transaction, the optionee may exercise any vested portion of the option for a period of 12 months following the effective date of such a transaction. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term.

With respect to RSU awards granted under the 2007 Plan, if a non-employee director's service relationship with us or any of our affiliates, whether as a non-employee director or subsequently as our employee, director or consultant or that of any of our affiliates, ceases for any reason, any RSU awards that were unvested as of the date of such termination will be forfeited.

In the event of certain significant corporate transactions (which generally have a similar meaning as a "Corporate Transaction" under the 2007 Plan), all outstanding options under the 2007 Directors Plan may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such options, then (a) with respect to any such options that are held by optionees then performing services for us or our affiliates, the vesting and exercisability of such options will be accelerated in full and such options will be terminated if not exercised prior to the effective date of the corporate transaction and (b) all other outstanding options will terminate if not exercised prior to the effective date of the corporate transaction. The board of directors may also provide that the holder of an outstanding option not assumed in the corporate transaction will surrender such option in exchange for a payment equal to the excess of (i) the value of the property that the optionee would have received upon exercise of the option, over (ii) the exercise price otherwise payable in connection with the option. In addition, the vesting and exercisability of options under the 2007 Directors Plan held by non-employee directors who are either required to resign their position in connection with a specified change in control transaction (which generally has a similar meaning as a "Change in Control" under the 2007 Plan) or are removed from their position in connection with such a change in control will be accelerated in full.

The treatment of outstanding options and RSU awards under the 2007 Plan in the event of certain significant corporate transactions or a specified change in control transaction is described above under the heading entitled "*Executive Compensation—Description of Compensation Arrangements—Equity Compensation Arrangements—2007 Equity Incentive Plan.*"

Under the current Director Compensation Policy, adopted on May 2, 2013, each non-employee director will receive automatic grants of stock options to purchase our ordinary shares under the 2007 Directors Plan (unless the board of directors determines that such stock options will be granted under the 2007 Plan) and RSU awards under the 2007 Plan. Specifically, in connection with each non-employee director's initial election or appointment to the board of directors, each such new director will receive (i) an initial nonstatutory stock option to purchase 8,000 ordinary shares that vests with respect to 1/3<sup>rd</sup> of the shares on the first anniversary of the date of election or appointment, and the balance in a series of 24 successive equal monthly installments thereafter and (ii) an initial RSU award covering 4,000 ordinary shares that generally vests in equal annual installments over three years from the date of election or appointment. In addition, each director who continues serving as a non-employee director on the date of each annual general meeting of our shareholders will be granted (i) a nonstatutory stock option to purchase 4,500 ordinary shares that vests in a series of 12 successive equal monthly installments measured from the date of the annual general meeting and (ii) an RSU award covering 2,250 ordinary shares that generally vests in full

on the first anniversary of the date of the annual general meeting. If a person is elected or appointed as a non-employee director for the first time other than at an annual general meeting of our shareholders, the director will receive a continuing grant at the next occurring annual general meeting, unless such annual general meeting is less than four calendar months following the director's initial election or appointment. If a person is elected or appointed as a non-employee director for the first time at an annual general meeting of our shareholders, the director will not receive a continuing grant at such annual general meeting.

### Director Compensation Table

The following table sets forth certain information with respect to the compensation of each person who served as a non-employee director during the fiscal year ended December 31, 2012.

Mr. Cozadd, our Chairman and Chief Executive Officer, is not listed in the following table because he is our employee. Mr. Cozadd's compensation is described under "*Executive Compensation*." Mr. Mulligan is also not listed in the following table because he was our employee in 2012 in the capacity of Chief Business Officer, International Business Development. A description of Mr. Mulligan's compensatory arrangements in 2012 in his capacity as an employee is described under "*Certain Relationships and Related Transactions, and Director Independence—Certain Transactions With or Involving Related Persons—Transactions with Seamus Mulligan—Seamus Mulligan Employment Agreement and Compensation*." Neither Mr. Cozadd nor Mr. Mulligan received any additional compensation for serving on our board of directors or its committees in 2012.

#### DIRECTOR COMPENSATION FOR FISCAL 2012

Name	Fees Earned or Paid in Cash (\$) <sup>(1)</sup>	Stock Awards (\$) <sup>(2)</sup>	Option Awards (\$) <sup>(3)(4)</sup>	Total (\$)
Paul L. Berns	93,940	105,367	104,115	303,422
Samuel D. Colella <sup>(5)</sup>	—	—	—	—
Bryan C. Cressey <sup>(5)</sup>	41,250	—	—	41,250
Patrick G. Enright	82,500	105,367	104,115	291,982
Michael W. Michelson <sup>(5)</sup>	—	—	—	—
James C. Momtazee	75,000	105,367	104,115	284,482
Kenneth W. O'Keefe	80,000	105,367	104,115	289,482
Alan M. Sebulsky <sup>(5)</sup>	52,500	—	—	52,500
Catherine A. Sohn <sup>(6)</sup>	33,274	187,320	185,094	405,688
Rick E Winningham	67,500	105,367	104,115	276,982

(1) The dollar amounts in this column represent each non-employee director's actual annual cash retainer for board services, which is equal to the aggregate of his or her annual retainer of \$55,000 plus his or her annual retainers for service on one or more board committees, in each case for 2012. Each non-employee director's total fees were earned and payable in four quarterly installments subject to the non-employee director's continuous service at the beginning of each quarter. Following the Azur Merger, the board did not permit cash retainer fees to be deferred by our non-employee directors pursuant to the Directors Deferred Plan. The total number of shares previously credited to each individual non-employee director's phantom stock account under the Directors Deferred Plan as of December 31, 2012 were as follows: 4,691 shares for Mr. Berns; 9,929 shares for Mr. Enright; 17,507 shares for Mr. Momtazee; 22,249 shares for Mr. O'Keefe; and no shares for each of Dr. Sohn and Messrs. Colella, Cressey, Michelson, Sebulsky and Winningham.

(2) The dollar amounts in this column reflect the aggregate grant date fair value of RSU awards computed in accordance with ASC 718. The grant date fair value of each RSU award is measured based on the closing price of our ordinary shares on the date of grant. These amounts do not necessarily correspond to the actual value recognized or that may be recognized by the non-employee directors.

(3) The dollar amounts in this column represent the aggregate grant date fair value of each stock option award granted to our non-employee directors in 2012. These amounts have been calculated in accordance with

ASC 718, using the Black-Scholes option-pricing model and excluding the effect of estimated forfeitures. Assumptions used in the calculation of these amounts are included in the notes to our audited consolidated financial statements included in the 2012 10-K. These amounts do not necessarily correspond to the actual value recognized or that may be recognized by the non-employee directors.

- (4) The aggregate number of shares subject to outstanding stock options and RSU awards held by the non-employee directors listed in the table above as of December 31, 2012 was as follows: 4,500 shares subject to outstanding stock options and 2,250 RSUs for each of Messrs. Berns, Enright, Momtazee, O’Keefe and Winningham; 8,000 shares subject to outstanding stock options and 4,000 RSUs for Dr. Sohn; and no shares subject to outstanding stock options or RSU awards for each of Messrs. Colella, Cressey, Michelson, and Sebulsky.
- (5) Messrs. Colella and Michelson resigned from Jazz Pharmaceuticals, Inc.’s board of directors in January 2012, shortly before the consummation of the Azur Merger. Mr. Sebulsky resigned from our board of directors on July 20, 2012. Mr. Cressey’s term of office expired at our 2012 annual general meeting of shareholders. The outstanding shares then credited to each of Messrs. Colella, Michelson and Sebulsky’s non-employee director phantom stock accounts were distributed to them in connection with their respective resignations or expiration of term of office, as applicable, in accordance with the terms of the Directors Deferred Plan.
- (6) Dr. Sohn was elected to our board of directors at our 2012 annual general meeting of shareholders.

In February 2013, Mr. Mulligan ceased being our employee but continued his service with the company as a non-employee director. In connection with Mr. Mulligan’s transition to non-employee director status in February 2013, he was granted (i) under the 2007 Directors Plan, an option to purchase 4,500 ordinary shares that vests in a series of 12 successive equal monthly installments measured from the date of grant and (ii) under the 2007 Plan, an RSU award covering 2,250 ordinary shares that vests in full on the first anniversary of the date of grant. These equity grants were consistent with the annual grants in August 2012 to our continuing non-employee directors, as summarized above.

## **CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

### **Policy and Procedures for Review of Related Party Transactions**

We have adopted a Related Party Transaction Policy that sets forth our procedures for the identification, review, consideration and approval or ratification of “related-person transactions.” For purposes of our policy only, a “related-person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related person” are, were or will be participants and in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A “related person” is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related-person transaction (including any transaction that was not a related-person transaction when originally consummated or any transaction that was not initially identified as a related-person transaction prior to consummation), our management must present information regarding the related-person transaction to our audit committee (or, if audit committee approval would be inappropriate, to another independent body of our board of directors) for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will, on an annual basis, collect information that our General Counsel deems reasonably necessary from each director, executive officer and (to the extent feasible) significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors have

an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest to our General Counsel, or, if the employee is an executive officer, to our board of directors. In considering related-person transactions, our audit committee (or other independent body of our board of directors) will take into account the relevant available facts and circumstances including, but not limited to, the risks, costs and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products and, if applicable, the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated.

The policy requires that, in determining whether to approve, ratify or reject a related-person transaction, our audit committee (or other independent body of our board of directors) must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee (or other independent body of our board of directors) determines in the good faith exercise of its discretion.

### **Certain Transactions With or Involving Related Persons**

Set forth below is information with respect to certain transactions with or involving related persons and to which we, Jazz Pharmaceuticals, Inc. or Azur Pharma was or is to be a participant.

#### **Secondary Offerings**

*March 2012 Offering.* In March 2012, we entered into an underwriting agreement with Barclays Capital Inc. and Citigroup Global Markets Inc. and certain selling shareholders, pursuant to which the selling shareholders sold to the underwriters an aggregate of 7,883,366 of our ordinary shares at a purchase price of \$49.56 per ordinary share, resulting in aggregate gross proceeds to the selling shareholders of approximately \$390.7 million. The offering closed on March 9, 2012. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the offering. The names of the selling shareholders and number of shares sold to the underwriters in the offering are included in a table below. Consistent with our obligations under the registration rights agreements described below, we were obligated to pay our total expenses in connection with this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, as well fees of special counsel to the selling shareholders of up to \$50,000, which expenses totaled approximately \$0.4 million. Prior to the offering, our board of directors formed a special financing committee consisting of two independent directors to review and approve our participation in the offering. The financing committee was aware of the relationship between the selling shareholders and our company when it approved our participation in the transaction, and functioned as the independent review and oversight body under our Related Party Transaction Policy.

<u>Selling Shareholder</u>	<u>Number of Shares Sold</u>
<b>Principal Shareholder or Affiliated Entities:<sup>(1)</sup></b>	
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P. ....	3,000,000
Entities affiliated with Longitude Capital Partners, LLC ....	1,100,015
Entities affiliated with Thoma Cressey Equity Partners ....	950,000
Entities affiliated with Beecken Petty O'Keefe & Company, LLC ....	600,000
<b>Directors and Executive Officers:</b>	
Paul L. Berns ....	39,200
Patrick G. Enright ....	49,985
Seamus Mulligan ....	2,000,000
Alan M. Sebulsky <sup>(2)</sup> ....	31,166
Russell J. Cox ....	5,000
Bruce C. Cozadd ....	50,000
Carol A. Gamble <sup>(3)</sup> ....	50,000
Karen J. Wilson ....	8,000

- (1) Certain of our current and former directors are affiliated or associated with the entities listed in the table as indicated below:

<u>Director</u>	<u>Entities</u>
James C. Momtazee . . . . .	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
Patrick G. Enright . . . . .	Entities affiliated with Longitude Capital Partners, LLC
Bryan C. Cressey . . . . . (former director)	Entities affiliated with Thoma Cressey Equity Partners
Kenneth W. O’Keefe . . . . .	Entities affiliated with Beecken Petty O’Keefe & Company, LLC

- (2) Mr. Sebulsy resigned from our board of directors on July 20, 2012.  
(3) Ms. Gamble retired from the company in March 2012.

*March 2013 Offering.* In March 2013, we entered into an underwriting agreement with Barclays Capital Inc. and certain selling shareholders, pursuant to which the selling shareholders sold to the underwriter an aggregate of 5,375,000 of our ordinary shares at a purchase price of \$58.28 per ordinary share, resulting in aggregate gross proceeds to the selling shareholders of approximately \$314.4 million, before deducting underwriting discounts and commissions and other offering expenses. The offering closed on March 8, 2013. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the offering. The names of the selling shareholders and number of shares sold to the underwriters in the offering are included in a table below. Consistent with our obligations under the registration rights agreements described below, we are obligated to pay our total expenses in connection with this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, as well fees of special counsel to the selling shareholders of up to \$50,000, which total offering expenses are estimated to be approximately \$0.5 million. Our participation in this offering did not require approval under our Related Party Transaction Policy because our actions with respect to the offering were undertaken in accordance with our pre-existing obligations under the registration rights agreements described below. Our nominating and corporate governance committee, which served as the independent review and oversight body, was advised of the relationship between the selling shareholders and our company prior to the transaction.

<u>Selling Shareholder</u>	<u>Number of Shares Sold</u>
<b>Principal Shareholder or Affiliated Entities:<sup>(1)</sup></b>	
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P. . . . .	3,750,000
Entities affiliated with Longitude Capital Partners, LLC . . . . .	800,000
Entities affiliated with Beecken Petty O’Keefe & Company, LLC . . . . .	400,000
<b>Director:</b>	
Seamus Mulligan . . . . .	425,000

- (1) Certain of our directors are affiliated or associated with the entities listed in the table as indicated below:

<u>Director</u>	<u>Entities</u>
James C. Momtazee . . . . .	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
Patrick G. Enright . . . . .	Entities affiliated with Longitude Capital Partners, LLC
Kenneth W. O’Keefe . . . . .	Entities affiliated with Beecken Petty O’Keefe & Company, LLC

**Registration Rights**

*2007 Investor Rights Agreement.* Pursuant to the terms of a third amended and restated investor rights agreement dated June 6, 2007, as amended, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein, or the 2007 Investor Rights Agreement, which 2007 Investor Rights Agreement was assumed by us in the Azur Merger, the holders of up to approximately 2.7 million ordinary shares as of March 31, 2013 or their transferees are entitled to certain rights with respect to the registration of such shares under the Securities



Act of 1933, as amended, or the Securities Act. In addition, Mr. Cozadd is entitled to rights with respect to registration of our ordinary shares he has or may acquire upon exercise of stock options or vesting of RSU awards. If we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the holders of these shares are entitled to notice of the registration and are entitled to include, at our expense, their ordinary shares in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of ordinary shares to be included in the registration. In addition, the holders of these ordinary shares may require us, at our expense and subject to certain limitations, to file one or more registration statements under the Securities Act with respect to their ordinary shares. Each of the entities referred to in the tables above under “Secondary Offerings” (other than the entities affiliated with Longitude Capital Partners, LLC) as well as Mr. Cozadd are parties to or otherwise are or were entitled to registration rights under the 2007 Investor Rights Agreement.

*2009 Investor Rights Agreement.* Pursuant to the terms of an investor rights agreement dated July 7, 2009, as amended, or the 2009 Investor Rights Agreement, by and between Jazz Pharmaceuticals, Inc. and entities affiliated with Longitude Capital Partners, LLC, or the Longitude Funds, which 2009 Investor Rights Agreement was assumed by us in the Azur Merger, we agreed to file a registration statement under the Securities Act registering (or to otherwise effect the registration of) the resale of all of our ordinary shares originally purchased by the Longitude Funds in the July 7, 2009 private placement relating to the 2009 Investor Rights Agreement, including approximately 0.9 million of our ordinary shares underlying the warrants purchased by the Longitude Funds, and to keep such registration continuously effective. In addition, if we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the Longitude Funds are entitled to notice of the registration and are entitled to include, at our expense, their ordinary shares in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration.

*Registration Rights Agreement.* In connection with the Azur Merger, Azur Pharma entered into a registration rights agreement on January 13, 2012 with the holders of Azur Pharma’s ordinary shares as of that date, including Seamus Mulligan and Davycrest Nominees, a significant investor in Azur Pharma, which holders are referred to herein as the Azur Pharma rights parties. Pursuant to the registration rights agreement, Azur Pharma agreed to register for resale under the Securities Act 12,020,616 ordinary shares held by the Azur Pharma rights parties (or their permitted transferees) on the date of the closing of the Azur Merger (immediately after giving effect to such closing), which shares are referred to herein as the Azur Resale Shares. We registered for resale all of the Azur Resale Shares on January 19, 2012 and we are obligated under the registration rights agreement to keep such registration statement continuously effective under the Securities Act until the earlier of such time as all of the Azur Resale Shares are publicly resold or the registration rights of the Azur Pharma rights parties expire under the registration rights agreement. Under the registration rights agreement, holders of Azur Resale Shares are entitled to sell Azur Resale Shares in underwritten public offerings provided that the aggregate amount of Azur Resale Shares to be offered and sold in any underwritten public offering represent not less than 5% of our ordinary shares outstanding at such time or are reasonably expected to result in aggregate gross proceeds of not less than \$50 million, subject to our ability to defer effecting such an underwritten public offering under certain circumstances.

The assumption of or the entering into of the foregoing investor or registration rights agreements were negotiated as part of the Azur Merger.

## **Transactions with Seamus Mulligan**

### *Seamus Mulligan Employment Agreement and Compensation*

In connection with the Azur Merger, Azur Pharma and Mr. Mulligan entered into an employment agreement in September 2011, as amended in February 2012, that became effective on the Azur Merger closing date and that superseded all prior employment-related agreements between Mr. Mulligan and Azur Pharma. Pursuant to the employment agreement, following the closing date, Mr. Mulligan continued his employment with us on a

part-time basis on the terms and conditions set forth in the employment agreement as Chief Business Officer, International Business Development until February 2013. Mr. Mulligan's initial base salary was €300,000 per year based on a 75% time commitment during the 12-month period following the closing date. Mr. Mulligan was also eligible to receive annual cash bonuses under our company's performance bonus plan, with a target bonus equal to 40% of base salary. Mr. Mulligan terminated his employment with us in February 2013.

In connection with his employment as a non-executive employee for the year ended December 31, 2012, Mr. Mulligan received a base salary of \$391,236, paid in Euro. The conversion to U.S. dollars was calculated based on the average exchange rate for each month. Mr. Mulligan received no bonus related to his employment in 2012. Also in connection with his employment, in August 2012, Mr. Mulligan received equity awards under the 2011 Plan consisting of an option to purchase 35,000 ordinary shares and an RSU award covering 17,500 ordinary shares. The stock option award was scheduled to vest as to 25% of the ordinary shares underlying the stock option upon the one year anniversary of the grant date with the remainder of the shares in 36 equal monthly installments thereafter. The RSU award was scheduled to vest in four equal annual installments on the anniversary of the grant date. These equity awards were unvested when Mr. Mulligan terminated his employment in February 2013 and have been cancelled.

In addition, in connection with the Azur Merger, stock options held by all of Azur Pharma's option holders, including Mr. Mulligan, were accelerated and became exercisable prior to the Azur Merger. The value Mr. Mulligan received in connection with this acceleration and exercisability was \$341,977. For this purpose, this value was calculated as the number of ordinary shares subject to each option, adjusted as described below, multiplied by the difference between (a) \$46.64, which was the closing price of Jazz Pharmaceuticals, Inc. common stock as reported on NASDAQ on the date prior to the closing of the Azur Merger and (b) the exercise price of each of the share options subject to acceleration, adjusted as described below. For purposes of this calculation, (x) the number of shares subject to each share option was multiplied by 0.2883, which represents the ratio of an ordinary share of Azur Pharma for each whole ordinary share of Azur Pharma by which the outstanding ordinary shares of Azur Pharma held by the historic Azur Pharma shareholders were reduced immediately prior to and in connection with the Azur Merger, (y) the exercise price of each share option was converted from Euro to U.S. dollars using an exchange rate of 1.2736, which was the ending exchange rate for January 17, 2012, and (z) the exercise price of each share option was divided by 0.2883.

#### ***Lease, Sublease and Lease Termination***

On October 20, 2008, Azur Pharma entered into a lease agreement with Mr. Mulligan, pursuant to which Mr. Mulligan, as landlord, leased to Azur Pharma, as tenant, an aggregate of 4,128 square feet of office space located at 45 Fitzwilliam Square, Dublin 2, Ireland. The term of the lease was 21 years from October 20, 2008. The annual rent due under the lease was €206,760. A total of \$0.3 million in rent payments were made under the lease agreement in 2012. Since Azur Pharma entered into the lease agreement with Mr. Mulligan prior to the Azur Merger, our Related Party Transaction Policy did not require that we seek approval or ratification from the audit committee in connection with our rental payments under the lease. However, under the charter of the audit committee and applicable NASDAQ rules, our audit committee provided oversight of the lease arrangement. In November 2012, we entered into an agreement with Mr. Mulligan pursuant to which we terminated this lease in exchange for \$1.2 million that we paid to Mr. Mulligan. Our audit committee reviewed and approved the terms of the lease termination agreement pursuant to our Related Party Transaction Policy.

#### ***License Option***

On May 30, 2011, Azur Pharma entered into a Development Agreement with Circ Pharma Limited and Circ Pharma Research and Development Limited, or the development agreement, providing for the purchase of an option to license certain rights and assets in relation to a chronotherapeutic formulation of Tramadol for \$250,000, together with the sum of \$50,000 as a contribution to the patent expenses incurred by Circ Pharma prior to the effective date of the option. Mr. Mulligan is Chairman and owner of the Circ Pharma Group. On

January 9, 2012, Azur Pharma entered into an amendment to the development agreement, which provides for an extension to consider and evaluate the program contemplated by the option for a period of six months from the closing of the Azur Merger. No amounts were paid under this agreement in 2012. We did not exercise the option and in 2012 terminated the agreement pursuant to its terms. Since Azur Pharma entered into the development agreement prior to the Azur Merger, our Related Party Transaction Policy did not require that we seek approval or ratification from the audit committee. However, under the charter of the audit committee and applicable NASDAQ rules, our audit committee provided oversight of this transaction.

### **Fintan Keegan Employment Agreement and Compensation**

In connection with the Azur Merger, Azur Pharma and Mr. Keegan entered into an employment agreement in September 2011, as amended in February 2012, that became effective on the Azur Merger closing date and that superseded all prior employment-related agreements between Mr. Keegan and Azur Pharma. Pursuant to the employment agreement, following the closing date, Mr. Keegan has continued his employment with us on the terms and conditions set forth in the employment agreement. In March 2012, in connection with his employment and prior to his promotion in July 2012 to Executive Vice President, Technical Operations, Mr. Keegan received equity awards under the 2011 Plan consisting of an option to purchase 46,000 ordinary shares and an RSU award covering 23,000 ordinary shares. The stock option award vests as to 25% of the ordinary shares underlying the stock option upon the one year anniversary of the grant date and vest as to the remainder of the shares in 36 equal monthly installments thereafter. The RSU award vests in four equal annual installments on the anniversary of the grant date.

In addition, in connection with the Azur Merger, stock options held by all of Azur Pharma's option holders, including Mr. Keegan, were accelerated and became exercisable prior to the Azur Merger. The value, calculated as described above under "*Transactions with Seamus Mulligan – Seamus Mulligan Employment Agreement and Compensation*," that Mr. Keegan received in connection with this vesting acceleration was \$3,202,399.

### **Indemnification Agreements**

On or after the effective time of the Azur Merger, we entered into indemnification agreements with our directors, executive officers and certain other of our officers and employees, or the indemnification agreements. The indemnification agreements require us, under the circumstances and to the extent provided for therein, to indemnify such persons to the fullest extent permitted by applicable law against certain expenses and other amounts incurred by any such person as a result of such person being made a party to certain actions, suits, proceedings and other actions by reason of the fact that such person is or was a director, officer, employee, consultant, agent or fiduciary of our company or any of our subsidiaries or other affiliated enterprises. The rights of each person who is a party to an indemnification agreement are in addition to any other rights such person may have under our memorandum and articles of association, the Irish Companies Acts 1963 to 2012, any other agreement, a vote of the shareholders of our company, a resolution of directors of our company or otherwise. We believe that these agreements are necessary to attract and retain qualified persons as our officers and directors. We also maintain directors' and officers' liability insurance.

## **OTHER MATTERS**

### **Presentation of Irish statutory accounts**

Our Irish statutory accounts for the fiscal year ended December 31, 2012, including the reports of the directors and auditors thereon, will be presented at the annual meeting in accordance with the requirements of the Irish Companies Acts of 1963 to 2012. Our Irish statutory accounts will be approved by the board of directors. There is no requirement under Irish law that such statements be approved by shareholders, and no such approval will be sought at the annual meeting.

## **Registered and Principal Executive Offices**

The registered and principal executive offices of Jazz Pharmaceuticals plc are located at Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland. Our telephone number there is +353 1 634 7800.

## **Shareholder Proposals and Director Nominations for the 2014 Annual General Meeting**

Shareholders of Jazz Pharmaceuticals may submit proposals on matters appropriate for shareholder action at meetings of its shareholders in accordance with Rule 14a-8 promulgated under the Exchange Act. For such proposals to be included in our proxy materials relating to our 2014 annual general meeting of shareholders, all applicable requirements of Rule 14a-8 must be satisfied and, pursuant to Rule 14a-8, such proposals must be received by us no later than February 12, 2014. However, if our 2014 annual general meeting of shareholders is not held between July 2, 2014 and August 31, 2014, then the deadline will be a reasonable time prior to the time that we begin to print and mail our proxy materials. Such proposals should be delivered to Jazz Pharmaceuticals plc, Attention: Company Secretary, Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland.

Our memorandum and articles of association provide that shareholder nominations of persons to be elected to the board of directors at an annual general meeting must be made following written notice to our Company Secretary which is executed by a shareholder and accompanied by certain background and other information specified in our memorandum and articles of association. Such written notice and information must be received by our Company Secretary not later than the close of business on March 14, 2014 nor earlier than January 13, 2014; provided, however, that in the event our 2014 annual general meeting of shareholders is not held between July 2, 2014 and August 31, 2014, notice must be delivered no earlier than 150 days prior to nor later than 90 days prior to the date of the 2014 annual general meeting or the 10th day following the day on which public announcement of the date of such meeting is first made. Our memorandum and articles of association provide that other proposals may only be proposed at an annual general meeting if either (i) it is proposed by or at the direction of our board of directors; (ii) it is proposed at the direction of the Irish High Court; or (iii) the chairman of the meeting decides, in his or her absolute discretion, that the proposal may properly be regarded as within the scope of the relevant meeting. In addition, the proxy solicited by our board of directors for the 2014 annual general meeting of shareholders will confer discretionary voting authority with respect to (i) any proposal presented by a shareholder at that meeting for which we have not been provided with notice by April 28, 2014 and (ii) if we have received notice of such proposal by April 28, 2014, if the 2014 proxy statement briefly describes the matter and how management's proxy holders intend to vote on it, if the shareholder does not comply with the requirements of Rule 14a-4(c)(2) promulgated under the Exchange Act.

## **Householding of Proxy Materials**

The SEC has adopted rules that permit companies and intermediaries (such as brokers) to satisfy the delivery requirements for Notices and proxy materials with respect to two or more shareholders sharing the same address by delivering a single Notice or a single set of proxy materials, as applicable, addressed to those shareholders. This process, which is commonly referred to as "householding," potentially means extra convenience for shareholders and cost savings for companies.

A number of brokers with account holders who are Jazz Pharmaceuticals shareholders will be "householding" Notices and our proxy materials. A single Notice or a single set of proxy materials, as applicable, may be delivered to multiple shareholders sharing an address unless contrary instructions have been received from the affected shareholders. Once you have received notice from your broker that it will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate Notice or set of proxy materials, as applicable, in the future you may: (1) notify your broker, (2) direct your written request to Jazz Pharmaceuticals plc, Attention: Investor Relations, Investor Relations, c/o Jazz Pharmaceuticals, Inc., 3180 Porter Drive, Palo Alto, California 94304 U.S.A. or (3) contact our Investor

Relations department at + 353 1 634 3211 (Ireland) or + 1 650 496 2800 (U.S.) or by email at investorinfo@jazzpharma.com. Shareholders who currently receive multiple copies of Notices or proxy materials at their address and would like to request “householding” of their communications should contact their broker. In addition, we will promptly deliver, upon written or oral request to the address or telephone number above, a separate copy of a Notice or set of proxy materials to a shareholder at a shared address to which a single Notice or set of proxy materials, as applicable, was delivered.

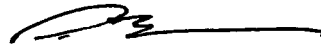
### **Annual Report on Form 10-K**

**We will mail without charge, upon written request, a copy of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, including the consolidated financial statements, schedules and list of exhibits, and any particular exhibit specifically requested. Requests should be sent to: Jazz Pharmaceuticals plc, Attention: Company Secretary, Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland.**

### **General**

Your proxy is solicited on behalf of our board of directors. Unless otherwise directed, proxies will be voted at the annual meeting (or an adjournment or postponement thereof), “For” all of the nominees listed in Proposal 1 and “For” Proposals 2, 3 and 4. If any matter other than those described in this proxy statement properly comes before the annual meeting, or with respect to any adjournment or postponement thereof, it is the intention of the persons named in the accompanying proxy to vote on such matters in accordance with their best judgment.

By order of the board of directors,



Shawn Mindus  
Secretary

June 12, 2013

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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, 2012

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

(State or other jurisdiction of incorporation or organization)

98-1032470

(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:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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  Smaller reporting company   
(Do not check if a 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 29, 2012, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$1,948,413,000 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 14,246,377 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 20, 2013, a total of 58,037,532 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 2013 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**  
**2012 ANNUAL REPORT ON FORM 10-K**

**TABLE OF CONTENTS**

	<u>Page</u>
<b>PART I</b>	
Item 1. Business .....	2
Item 1A. Risk Factors .....	31
Item 1B. Unresolved Staff Comments .....	70
Item 2. Properties .....	70
Item 3. Legal Proceedings .....	70
Item 4. Mine Safety Disclosures .....	72
<b>PART II</b>	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities .....	73
Item 6. Selected Financial Data .....	77
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations .....	80
Item 7A. Quantitative and Qualitative Disclosures About Market Risk .....	98
Item 8. Financial Statements and Supplementary Data .....	99
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure .....	100
Item 9A. Controls and Procedures .....	100
Item 9B. Other Information .....	103
<b>PART III</b>	
Item 10. Directors, Executive Officers and Corporate Governance .....	103
Item 11. Executive Compensation .....	103
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .....	103
Item 13. Certain Relationships and Related Transactions, and Director Independence .....	104
Item 14. Principal Accountant Fees and Services .....	104
<b>PART IV</b>	
Item 15. Exhibits and Financial Statement Schedules .....	104
Signatures .....	112

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

Form 10-K

chrysanthemi), Erwinase<sup>®</sup>, Asparec<sup>®</sup> (mPEG-r-crisantaspase), Leukotac<sup>®</sup> (inolimomab), ProstaScint<sup>®</sup> (capromab pendetide), Quadramet<sup>®</sup> (samarium sm 153 lexidronam injection), Caphosol<sup>®</sup> (supersaturated calcium phosphate rinse), Collatamp<sup>®</sup> (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole<sup>®</sup>, Kidrolase<sup>®</sup> (Escherichia coli L-asparaginase), Xenazine<sup>®</sup> (tetrabenazine), Custodiol<sup>®</sup> (solution HTK) and NAVIGATOR Reimbursement and Access Program<sup>™</sup>. This report also includes trademarks, service marks, and trade names of other companies.

## 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,” “intend,” “potential” 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 these 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.*

## PRESENTATION OF FINANCIAL AND OTHER INFORMATION

*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. Accordingly, the operating results of Jazz Pharmaceuticals, Inc. are included in our consolidated financial statements for all periods being presented, whereas the operating results of Azur Pharma are included only since January 18, 2012. In addition, on June 12, 2012, Jazz Pharmaceuticals plc completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, referred to as the EUSA Acquisition.*

*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, including its predecessor Jazz Pharmaceuticals, Inc., except that all such references prior to the effective time of the Azur Merger on January 18, 2012 are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. 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. The disclosures in this report relating to the pre-Azur Merger business of Jazz Pharmaceuticals, unless noted as being the business of Azur Pharma prior to the Azur Merger, pertain to the business of Jazz Pharmaceuticals, Inc. prior to the Azur Merger. All references to “EUSA Pharma” in this report are references to EUSA Pharma Inc. and its consolidated subsidiaries prior to the effective time of the EUSA Acquisition.*

## PART I

### Item 1. Business

#### Overview

We are a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing products that address unmet medical needs. Our marketed products address medical needs in the following therapeutic areas and include the following products:

**Narcolepsy:** 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 in patients with narcolepsy;

**Oncology:** Erwinaze® (asparaginase *Erwinia chrysanthemi*), called Erwinase® in markets outside of the United States, a treatment for patients with acute lymphoblastic leukemia, or ALL, who have developed sensitivity to *E. coli*-derived asparaginase, and other products, including products for oncology supportive care;

**Pain:** Prialt® (ziconotide) intrathecal infusion, the only non-opioid intrathecal analgesic indicated for the management of severe chronic pain for patients who are intolerant of or refractory to other treatments; and

**Psychiatry & Other:** A portfolio of products, including FazaClo® (clozapine, USP) LD and FazaClo HD, orally disintegrating clozapine tablets indicated for treatment-resistant schizophrenia, and Luvox CR® (fluvoxamine maleate) Extended-Release Capsules marketed for the treatment of obsessive compulsive disorder. In addition, in February 2013 the FDA approved a new drug application for Versacloz™ (clozapine, USP) oral suspension for treatment-resistant schizophrenia, which we have exclusive rights to market in the United States.

Our international division, based in Europe, commercializes Erwinase as well as a portfolio of other products outside of the United States. These products are primarily in the oncology, critical care and oncology supportive care therapeutic areas and include Caphosol® (supersaturated calcium phosphate rinse), Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole®, Kidrolase® (*Escherichia coli* L-asparaginase) and Xenazine® (tetrabenazine).

Our development pipeline projects currently include line extensions for existing products, the generation of additional clinical data for existing products and clinical development of new product candidates. These projects include two clinical trials involving Erwinaze, as well as the development of two product candidates: Asparec® (mPEG-r-crisantaspase), a pegylated recombinant *Erwinia* asparaginase for the treatment of patients with ALL with *E. coli* asparaginase hypersensitivity, and Leukotac® (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease.

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.

#### Significant Business Transactions in 2012

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc., our predecessor company, and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, the Azur Merger, which was 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, Azur Pharma changed its name to Jazz Pharmaceuticals plc, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as our wholly-owned subsidiary, and all outstanding shares of Jazz Pharmaceuticals, Inc.'s common stock were canceled and converted into the right to receive, on a one-for-one basis, our ordinary shares. The total acquisition consideration of \$576.5 million was determined based on the market value of our ordinary shares that were held by the historic Azur Pharma shareholders immediately following the closing of the Azur Merger. Immediately after giving effect to the issuance of our ordinary shares in the Azur Merger, approximately 78% of our ordinary shares were held by the former Jazz Pharmaceuticals, Inc. stockholders and approximately 22% were held by the persons who acquired Azur Pharma ordinary shares prior to the Azur Merger. Prior to the Azur Merger, Jazz Pharmaceuticals, Inc. marketed its two products, Xyrem and Luvox CR, through its experienced specialty sales force. Prior to the Azur Merger, Azur Pharma was a specialty pharmaceutical company engaged in the acquisition, development and commercialization of therapeutic products for the central nervous system and women's health areas. Azur Pharma's lead marketed products were FazaClo LD, FazaClo HD and Prialt. Azur Pharma also marketed a portfolio of women's health and other products. As a result of the Azur Merger, we transitioned from being a standalone public Delaware corporation to being a public limited company organized in, and a tax resident of, Ireland, and the ultimate parent company of the Jazz Pharmaceuticals group of companies.

On June 12, 2012, we completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, referred to as the EUSA Acquisition. At the closing of the EUSA Acquisition, we paid \$678.4 million in cash, and agreed to make an additional contingent payment of \$50.0 million in cash if Erwinaze, which we acquired in the EUSA Acquisition, achieves U.S. net sales of \$124.5 million or more in 2013. As part of the EUSA Acquisition, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as our indirect wholly-owned subsidiary. In connection with the EUSA Acquisition, we entered into a \$575.0 million credit agreement consisting of a \$475.0 million term loan and a \$100.0 million revolving credit facility. We used all of the proceeds of the term loan, together with cash on hand, to finance the EUSA Acquisition. Prior to the EUSA Acquisition, EUSA Pharma was a specialty pharmaceutical company with a portfolio of marketed products in therapeutic areas that included oncology, critical care and oncology supportive care products. EUSA Pharma's lead marketed product was Erwinaze, marketed directly in the United States and Europe and via distributors in other countries.

On October 15, 2012, we completed the sale of our women's health business, including six products, to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl for \$95.0 million, plus \$2.6 million for certain inventory transferred upon the closing of the sale.

With the completion of the EUSA Acquisition and the Azur Merger in 2012, we gained not only an expanded portfolio of specialty pharmaceutical products and product candidates, but also an enhanced commercial platform and a strengthened management team, adding EUSA Pharma's specialty commercial infrastructure in the United States and Europe and its international distribution network to our existing U.S. specialty product platform. Our international footprint now includes headquarters in Dublin, Ireland and multiple offices in the United States, the United Kingdom and other countries in Europe, with approximately 610 employees in 11 countries. We intend that our operations will function as an efficient platform for further growth, leveraging our commercial, medical and scientific experience to seek to maximize the potential of our existing products and expand our product portfolio through a combination of internal development, acquisition and in-licensing.

## Marketed Products

### *Xyrem® (sodium oxybate) oral solution*

Xyrem is the only treatment approved by the FDA for both excessive daytime sleepiness 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 for the treatment of cataplexy in patients with narcolepsy in 2002, and was approved for its second indication, excessive daytime sleepiness in patients with narcolepsy, in 2005. The American Academy of Sleep Medicine recommends Xyrem as a standard of care for the treatment of both excessive daytime sleepiness and cataplexy associated with narcolepsy.

Narcolepsy is a chronic neurologic disorder caused by targeted 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 excessive daytime sleepiness, cataplexy, sleep paralysis, hypnagogic hallucinations and disrupted nighttime sleep. Excessive daytime sleepiness is the most common symptom of narcolepsy and is present in all narcolepsy patients. Excessive daytime sleepiness 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 the face 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, with patients experiencing marked impairment of activities, such as limitations on education and employment opportunities, 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, obstructive sleep apnea, obesity, 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 157,000 people. Less than half of those people have been definitively diagnosed with narcolepsy. Xyrem is currently being used to treat more than 10,000 patients in the United States, and we believe that there are significantly more patients with narcolepsy and cataplexy and/or excessive daytime sleepiness who might benefit from treatment with Xyrem. In an effort to reach more patients, we are seeking to expand the base of physicians who prescribe Xyrem through a number of initiatives, including increased outreach to prescribers who treat narcolepsy, enhanced physician education and the launch of web-based pilot programs.

In 2012, net product sales of Xyrem were \$378.7 million, which represented 65.2% of total net product sales.

We promote Xyrem in the United States through a specialty sales force of approximately 80 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, that 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 is not in the form that is now required for a risk evaluation and mitigation strategy, or REMS. We have submitted updated REMS documents to the FDA, which are intended to conform the relevant elements of the Xyrem Risk Management Program to the current REMS formatting requirements, as well as to make other updates to the program and its documentation. We have had communications with the FDA with respect to our submitted REMS documents. These communications are ongoing, and we cannot predict the timing of finalization, or the final terms, of our updated REMS documents.

Under our current Xyrem Risk Management Program, all of the Xyrem sold in the United States must be shipped directly to patients through a single central pharmacy, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or ESSDS, through which Xyrem is distributed exclusively. Xyrem may not be stocked in retail pharmacies. Physicians and patients must enroll in the Xyrem Success Program<sup>®</sup>, 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 the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and must speak with the patient before each shipment of Xyrem is 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 up to a three-month supply for refills. ESSDS also provides reimbursement support to patients by coordinating insurance coverage for Xyrem, and as applicable, referring qualified patients to various patient savings or assistance programs.

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 in the United States. Our agreement, 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. 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.

Xyrem is a controlled substance in the United States, and therefore its manufacturing and distribution are highly restricted. The finished product and active pharmaceutical ingredient for Xyrem are each manufactured for us by a single source contract manufacturer.

Outside of the United States, we have licensed to UCB Pharma Limited, or UCB, the exclusive right to market Xyrem for the treatment of narcolepsy in 54 countries in exchange for milestone and royalty payments to us. UCB currently markets the product in 18 countries in Europe. We have licensed to Valeant Canada Limited, or Valeant, the Canadian marketing rights to Xyrem for the treatment of narcolepsy. We supply Xyrem to UCB and Valeant.

We have eleven U.S. patents covering Xyrem, which expire at various times from December 2019 to June 2024. Our issued patents relate to Xyrem's stable and microbially resistant formulation, its manufacturing process and its method of use, including its restricted distribution system. Two 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 are currently involved in litigation with both companies. For a description of these matters, please see Item 3. "Legal Proceedings."

#### ***Erwinaze® (asparaginase *Erwinia chrysanthemi*)***

Erwinaze, a biologic product, is used in conjunction with chemotherapy to treat patients with ALL who have developed hypersensitivity to *E. coli*-derived asparaginase. Erwinaze is an asparaginase, a type of enzyme that can deprive leukemic cells of an amino acid essential for their growth. It is derived from a rare bacterium (*Erwinia chrysanthemi*) and is therefore immunologically distinct from *E. coli*-derived asparaginase and suitable for patients with hypersensitivity to *E. coli*-derived treatments. For ALL patients with hypersensitivity to *E. coli*-derived asparaginase, Erwinaze is a crucial component of their therapeutic regimen. Erwinaze is currently delivered via intramuscular injection in conjunction with chemotherapy. Erwinaze was originally discovered by the U.K. Health Protection Agency, or the HPA, a non-departmental public body. Erwinaze was approved by the FDA under a biological license application, or BLA, in November 2011.

ALL is the most common childhood cancer. According to the U.S. National Cancer Institute, approximately 60% of ALL patients were diagnosed under age 20. The American Cancer Society estimated that approximately 6,000 new cases of ALL were diagnosed in the United States in 2012, of which approximately 3,600 were pediatric. Data reported in two papers published in *Pediatric Blood & Cancer* and *Journal of Clinical Oncology* suggest that approximately 20% of ALL patients develop hypersensitivity to *E. coli*-derived asparaginase. Current treatment guidelines and protocols recommend switching a patient receiving *E. coli*-derived asparaginase

to treatment with Erwinaze if the patient's hypersensitivity reaction to the *E. coli*-derived asparaginase is Grade 2-4, indicating that the hypersensitivity reaction has resulted in an intervention or interruption in infusion occurring in the patient's treatment regimen. While pediatric treatment protocols commonly include asparaginase, adult protocols do not. A retrospective comparison to determine whether the outcome for adolescent and young adult ALL patients differed depending on their enrollment in pediatric compared with adult cooperative group trials showed that the seven-year overall survival rate among the adolescent and young adult ALL patients treated on pediatric protocols was 67% compared to 46% for those patients treated on adult protocols. As more adolescent and young adult patients are treated with asparaginase-based regimens, we expect to see increased use of Erwinaze in this population. In addition, we believe that Erwinaze could be used in patients with silent hypersensitivity, a situation in which *E. coli*-derived asparaginase may induce antibodies that can neutralize the enzyme or increase its clearance, thereby depriving patients of its therapeutic benefits, without manifesting the clinical symptoms of hypersensitivity. In February 2013, a third party introduced an assay to determine the enzyme activity of asparaginase in patients who have been treated with any *E. coli*-derived asparaginase or Erwinaze. With this new assay, physicians will be able to monitor asparaginase levels to identify patients with silent hypersensitivity and maintain asparaginase activity by switching asparaginase preparations.

Erwinaze was launched in the U.S. market in November 2011. We promote Erwinaze in the United States through a specialty sales force of approximately 20 sales professionals. We provide reimbursement support through our Community Access Patient Program, a dedicated Erwinaze call center. Our field-based and internal reimbursement team provides additional reimbursement support, dealing specifically with the more complex needs of physicians and payors.

Outside of the United States, Erwinaze is sold under the name Erwinase pursuant to marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere. Our international division employs approximately 30 sales professionals to promote Erwinase in a number of European countries where Erwinase is fully registered. In addition, our medical science liaison managers provide information consistent with local treatment protocols to healthcare professionals and/or respond to medical information requests.

Erwinaze is exclusively licensed to us for worldwide marketing, sales and distribution, and is manufactured for us, by the HPA. The HPA is our sole supplier for Erwinaze. We are obligated to make tiered royalty payments to the HPA based on worldwide net sales of Erwinaze and Erwinase.

Although Erwinaze is not covered by any patents, Erwinaze has orphan drug marketing exclusivity through 2018 (seven years from its FDA approval in the United States), and we expect to receive data exclusivity for Erwinaze in the United States through 2023 under the U.S. Biologics Price Competition and Innovation Act, or BPCIA.

#### ***Prialt® (ziconotide) intrathecal infusion***

Prialt is an intrathecally administered infusion of ziconotide, approved by the FDA in December 2004 for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or intrathecal morphine. Intrathecal therapy is the delivery of the drug into the intrathecal space in the spine through an infusion system comprised of a programmable infusion pump and catheter. Ziconotide is a synthetic neuroactive peptide known as conotoxin and is the synthetic equivalent of a naturally-occurring conopeptide found in the piscivorous marine snail, *Conus Magus*. Ziconotide is thought to inhibit pain signals transmitted via N-type calcium channels, most densely located in the dorsal horn of the spinal cord, although the precise mechanism of action in humans is unknown. For most patients who achieve good pain relief and tolerability with Prialt, pain relief can be maintained over time without dose increases or cumulative toxicity. Prialt is the only FDA-approved non-opioid intrathecal analgesic. Treatment with Prialt can be interrupted or discontinued without evidence of withdrawal effects. Prialt is approved for use with Medtronic Inc.'s SynchroMed® II programmable implantable pumps.



Azur Pharma acquired the rights to Prialt from Elan Pharmaceuticals, Inc., or Elan, in May 2010. Pursuant to an asset purchase agreement executed between Azur Pharma and Elan in April 2010, Azur Pharma acquired worldwide rights to Prialt excluding those territories licensed by Elan to Eisai Co. Limited, or Eisai, which consist of 34 countries outside of the United States, mainly in Europe. We supply Prialt to Eisai. Azur Pharma paid Elan \$5 million on the closing of the transaction, with an additional \$12 million in deferred payments, which we paid to Elan in 2012. We are also obligated to pay up to a maximum aggregate amount of \$120 million in tiered contingent payments, with the first such payment becoming due if net sales of at least \$75 million are achieved in a calendar year, as well as a tiered royalty payment in the teens based on net sales.

We promote Prialt through a specialty sales force of approximately 30 sales professionals. In the fourth quarter of 2012, we began the roll-out of a new centralized distribution system for Prialt, the NAVIGATOR Reimbursement and Access Program™. Through this new distribution system, we provide a simplified single point of access to Prialt, offering reimbursement and insurance support that is intended to reduce the burden on physicians and patients and providing information and support through a dedicated Prialt call center outsourced to a third party vendor. Our field-based reimbursement team provides additional support, dealing specifically with the more complex needs of physicians and payors.

We have four U.S. patents covering Prialt, the last to expire of which expires in December 2016, and six U.S. patents on a formulation containing Prialt and other active ingredients and methods for their use, which will expire in October 2024. The finished product and active pharmaceutical ingredient are each manufactured for us by a single source contract manufacturer.

### *Psychiatry Products*

#### **FazaClo® LD (clozapine, USP) Orally Disintegrating Tablet, FazaClo® HD (clozapine, USP) Orally Disintegrating Tablet and Versacloz™ (clozapine, USP) oral suspension**

We market FazaClo LD and FazaClo HD, each of which is an orally disintegrating tablet formulation of clozapine that is indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia and for reduction in the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behavior, based on history and recent clinical state. FazaClo LD, comprising the original three lower dosage strength presentations, was approved by the FDA in February 2004 with respect to the 25mg and 100mg tablets and in May 2007 for the 12.5mg tablets. FazaClo HD received FDA approval in July 2010. Azur Pharma acquired the rights to FazaClo LD from Avaniir Pharmaceuticals, Inc., or Avaniir, in August 2007.

In February 2013, the FDA approved a new drug application, or NDA, for Versacloz for treatment-resistant schizophrenia. Versacloz is an oral suspension formulation of clozapine currently approved and marketed by other companies in Europe and in other territories outside of the United States. In February 2010, Azur Pharma entered into a license and supply agreement with Douglas Pharmaceuticals America Limited, or Douglas Pharmaceuticals, and obtained an exclusive license to market, distribute and sell Versacloz in the United States and Mexico from Douglas Pharmaceuticals. The initial term of the license and supply agreement expires 10 years after the first commercial sale of Versacloz in the United States, subject to automatic extension for additional five-year terms unless terminated by either party subject to certain conditions. We expect to commence marketing Versacloz in 2013.

According to IMS Health Inc., or IMS, the U.S. clozapine market is dominated by generics, which accounted for approximately 92.6% of clozapine prescription volumes in 2012. Our FazaClo LD and FazaClo HD products accounted for approximately 4.9% and 2.6%, respectively, of clozapine prescription volumes in 2012. An authorized generic version of FazaClo LD launched in August 2012. Other generics are referenced to Clozaril, a standard immediate release tablet formulation of clozapine from Novartis. FazaClo LD and FazaClo HD incorporate the DuraSolv® orally disintegrating tablet technology that we license from CIMA Labs

Inc., or CIMA, now a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, which enables the products to dissolve without the need to chew or to swallow with water. FazaClo LD (including its authorized generic version) and FazaClo HD are currently the only orally disintegrating tablet formulations of clozapine available in the United States. Versacloz is currently the only oral suspension formulation of clozapine approved by the FDA.

FazaClo LD and FazaClo HD are sold under a risk management plan in the United States. The program is not in the form that is now required for a REMS. In 2012, the FDA notified us, along with other holders of applications for products containing clozapine, including FazaClo LD, FazaClo HD and Versacloz, that a single shared system should be used to implement the REMS for all members of this class of products. We are working with other manufacturers of clozapine products to address the FDA's requirements.

One element of the risk management plan for FazaClo LD and FazaClo HD is the patient registry. The FDA requires that patients being prescribed any clozapine product must be enrolled in an FDA-approved patient registry, a database monitoring patients' white blood cell counts and absolute neutrophil counts to permit early detection of clozapine-induced leucopenia or agranulocytosis. The authorized generic form of FazaClo LD is part of the FazaClo LD and FazaClo HD patient registry. Similarly, as part of the risk management plan for Versacloz, patients who will be prescribed Versacloz are required to be enrolled in the Versacloz patient registry.

We promote FazaClo LD and FazaClo HD in the United States through a specialty sales force, with the support of our in-house registry team and a team of clinical compliance liaisons, who provide patient registry support services for FazaClo LD and FazaClo HD. This specialty sales force will promote Versacloz in the United States as well.

The two formulation patents covering FazaClo LD and FazaClo HD, which we license from CIMA, are under re-examination by the U.S. Patent and Trademark Office, or the USPTO, and both of the re-examination proceedings have proceeded to appeal at the USPTO. It is currently not possible to predict whether these re-examination proceedings will result in one or both of the patents being fully or partly invalidated and, if so, whether any appeal will be successful. Versacloz is covered by a U.S. formulation patent and a pending U.S. patent application that we license from Douglas Pharmaceuticals. The patent expires in May 2028.

Three generic manufacturers have filed ANDAs requesting approval to market generic versions of FazaClo LD, and one of them, Teva, has also submitted an ANDA requesting approval to market a generic version of FazaClo HD. Azur Pharma brought lawsuits against each of them and settled the lawsuit with Teva in 2011. In the settlement agreement, Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicenses for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product in August 2012.

### **Luvox CR® (fluvoxamine maleate) Extended-Release Capsules**

We market Luvox CR for the treatment of obsessive compulsive disorder. Luvox CR received FDA approval in 2008. Luvox CR incorporates the SODAS® drug delivery technology, developed by Elan Pharma International Limited, which subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes. The product is designed to minimize peak-to-trough plasma fluctuations over a 24-hour period and enable once-a-day dosing.

Obsessive compulsive disorder is a chronic anxiety disorder characterized by persistent, unwanted thoughts, or obsessions, and repetitive behaviors or rituals, or compulsions. According to the National Institute of Mental Health, obsessive compulsive disorder affects approximately 2.2 million adults in the United States. According to an article published in the *International Journal of Clinical Practice*, it is estimated that 60% of patients with

obsessive compulsive disorder worldwide receive no treatment for their disorder. Patients with obsessive compulsive disorder often use rituals to help control anxiety related to their obsessive thoughts, and these rituals can become disruptive to their daily lives.

We acquired the rights to market Luvox CR in the United States from Solvay Pharmaceuticals, Inc., or Solvay, which was subsequently acquired by Abbott Laboratories. Solvay assigned to us its rights and obligations under its license and supply agreement with Alkermes, and we sublicensed back to Solvay the rights under that agreement outside of the United States. Luvox CR is not currently marketed outside of the United States.

Three companies have filed ANDAs requesting FDA approval to market a generic version of Luvox CR, and we brought lawsuits against each of them. In August 2010, we and Alkermes settled the lawsuit against one of the companies, Anchen Pharmaceuticals, Inc. (now owned by Par Pharmaceutical Companies, Inc.), or Anchen, and granted a sublicense to Anchen of our rights to have manufactured, market and sell a generic version of Luvox CR, which sublicense commenced in February 2013. As of a result of this settlement, a generic version of Luvox CR could be introduced as soon as Anchen obtains FDA approval of its ANDA. In April 2012, we and Alkermes entered into settlement agreements with the other two companies, Actavis Elizabeth, LLC, or Actavis, and Torrent Pharma Limited, or Torrent, respectively, and granted a sublicense to each of Actavis and Torrent of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicenses will commence on April 15, 2014, or earlier if a generic version of Luvox CR receives FDA approval.

## Other Products

The other products that we sell in the United States include:

- Caphosol<sup>®</sup> (supersaturated calcium phosphate rinse), indicated for the treatment of oral mucositis, a common and debilitating side-effect of radiation therapy and high dose chemotherapy;
- Quadramet<sup>®</sup> (samarium sm 153 lexidronam injection), indicated for the treatment of pain in patients whose cancer has spread to the bones;
- ProstaScint<sup>®</sup> (capromab pendetide), indicated for imaging the extent and spread of prostate cancer;
- Niravam<sup>®</sup> (alprazolam orally disintegrating tablets), indicated for the treatment of generalized anxiety disorder and also indicated for the treatment of panic disorder, with or without agoraphobia; and
- Parcopa<sup>®</sup> (carbidopa and levodopa orally disintegrating tablets), indicated for the treatment of symptoms associated with idiopathic Parkinson's disease.

In addition, our international division commercializes a portfolio of other products in oncology, critical care and oncology supportive care outside of the United States, including:

Caphosol;

- Collatamp<sup>®</sup> (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), a surgical implant impregnated with the antibiotic gentamicin;
- Fomepizole<sup>®</sup> (fomepizole), indicated for the treatment of ethylene glycol poisoning;
- Kidrolase<sup>®</sup> (Escherichia coli L-asparaginase), indicated in the treatment of ALL, Leukaemic meningitis and Non-Hodgkin's lymphoma;
- Xenazine<sup>®</sup> (tetrabenazine), indicated for the treatment of movement disorders associated with Huntington's chorea and hemiballismus; and
- Custodiol<sup>®</sup> (solution HTK), a ready to use solution used in organ transplantation for rinsing and hypothermic storage for preservation of organs (heart, kidney, liver and pancreas) since their removal from the donor to the graft in the recipient.

## Research and Development Projects

Our development pipeline projects currently include line extensions for existing products, the generation of additional clinical data for existing products, and clinical development of new product candidates. These projects include two clinical trials involving Erwinaze: an ongoing pharmacokinetic clinical trial of the intravenous administration of Erwinaze in North America; and a planned clinical trial including pharmacokinetic efficacy measures to evaluate Erwinaze in adolescents and young adults with ALL who are hypersensitive to *E. coli*-derived asparaginase, which is expected to begin in the second half of 2013. In addition, we are developing two product candidates, including a Phase I clinical trial in Europe of Asparec® (mPEG-r-crisantaspase), a pegylated recombinant *Erwinia* asparaginase for the treatment of patients with ALL with *E. coli* asparaginase hypersensitivity; and a Phase III clinical trial in Europe of Leukotac® (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease. Worldwide rights to develop and commercialize Asparec were licensed by EUSA Pharma from Alizé Pharma II, or Alizé, in 2009. Under our license agreement with Alizé, we are subject to contractual obligations to meet certain development milestones within certain timeframes. We submitted an investigational new drug application, or IND, to conduct studies relating to Asparec to the FDA in November 2012, and we received FDA confirmation in December 2012 that we may proceed with the studies. EUSA Pharma acquired the rights for Leukotac from Biotest AG in 2003.

## Sales and Marketing

As of February 20, 2013, our commercial activities in the United States were dedicated to our marketed products Xyrem, Erwinaze, Prialt and our psychiatry products (FazaClo LD, FazaClo HD and Luvox CR), as well as preparing for the launch of Versacloz and providing support for sales of certain of our other products. We have approximately 170 trained, experienced sales professionals who detail our marketed products to physicians in specialties appropriate for each marketed product in the United States. In addition, our international division employs approximately 30 sales professionals to promote Erwinaze in a number of European countries where Erwinaze is fully registered. Our international division also sells products in oncology, oncology supportive care and critical care outside of the United States through a network of local distributors and wholesalers in more than 80 countries.

Our commercial activities include marketing and related services and commercial support services such as commercial operations, managed markets and commercial analytics. We also employ third party vendors, such as advertising agencies, market research firms and suppliers of marketing and other sales support related services, to assist with our commercial activities.

We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. We believe that the size of our sales force is appropriate to effectively reach our target audience for our marketed products in the specialty markets in which we currently operate. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization in the United States and internationally, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization.

## Competition

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies as well as specialty pharmaceutical companies that market neurology, oncology, pain, psychology and other products. Many of these companies, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. They can spend more on, and have more expertise in, research and development, regulatory, manufacturing, distribution and sales activities. As a result, our competitors may obtain FDA or other regulatory approvals for their product candidates

more rapidly than we may and may market their products more effectively than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our ability to continue to grow requires that we compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. Some of these competitors include Valeant, Shire Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., Forest Laboratories, Inc., Sigma-Tau Pharmaceuticals Inc. and Teva. These established companies may have a competitive advantage over us due to their size and financial resources.

We also face competition from manufacturers of generic drugs. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available.

Our products and product candidates may also compete in the future with new products currently under development by others. Any products that we develop are likely to be in a highly competitive market, and many of our competitors may succeed in developing products that may render our products obsolete or noncompetitive. In particular, our marketed products and product candidates face competition as described below:

- *Xyrem® (sodium oxybate) oral solution*. Xyrem is the only product approved for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. No product other than Xyrem is approved for the treatment of cataplexy. The only other products approved by the FDA for the treatment of excessive daytime sleepiness in patients with narcolepsy are Provigil® (modafinil) and Nuvigil® (armodafinil), which are marketed by Teva, and the generic versions of Provigil. Provigil, its generic equivalents and Nuvigil are also approved for the treatment of excessive daytime sleepiness in patients with obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder. Xyrem is often used in conjunction with stimulants and wakefulness promoting drugs, which are administered during the day.

As alternatives to Xyrem, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors, or SSRIs, or selective norepinephrine reuptake inhibitors, or SNRIs, although these products are not approved by the FDA for the treatment of cataplexy. Tricyclic antidepressants are a class of antidepressant drugs first used in the 1950s. The use of these drugs can often result in somnolence, which exacerbates the excessive daytime sleepiness already experienced by all patients with narcolepsy. SSRIs and SNRIs are compounds typically used for the treatment of clinical depression. Somnolence and insomnia are commonly reported side effects with SSRIs while loss of sleep is a commonly reported side effect with SNRIs. These side effects may be problematic for patients with narcolepsy.

- *Erwinaze® (asparaginase Erwinia chrysanthemi)*. Erwinaze is a biologic product used in conjunction with chemotherapy and is indicated for patients with ALL who have developed hypersensitivity to *E. coli*-derived asparaginase. While there is currently no direct competition to Erwinaze to treat ALL patients with hypersensitivity to *E. coli*-derived asparaginase, other companies are developing new treatments for ALL, including new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL and new treatment protocols for ALL that may not include asparaginase-containing regimens. Any of these potential new treatments could compete with, or reduce the market for, Erwinaze. As a biologic product, Erwinaze also faces potential competition from biosimilar products.
- *Prialt® (ziconotide) intrathecal infusion*. Prialt is the only FDA-approved non-opioid intrathecal analgesic. It competes with intrathecally administered morphine, which is the only other product approved by the FDA for the intrathecal treatment of severe chronic pain. Other drugs are also used intrathecally by physicians, including hydromorphone, clonidine, baclofen and sufentanil.

- *FazaClo*<sup>®</sup> LD (clozapine, USP) Orally Disintegrating Tablet, *FazaClo*<sup>®</sup> HD (clozapine, USP) Orally Disintegrating Tablet and *Versacloz*<sup>™</sup> (clozapine, USP) oral suspension. *FazaClo* LD, the authorized generic version of *FazaClo* LD launched in 2012 and *FazaClo* HD are the only orally disintegrating tablet formulations of clozapine available. *FazaClo* LD competes against the authorized generic. The bulk of prescriptions for clozapine are generic tablets, which compete with both *FazaClo* LD and *FazaClo* HD. In addition, prior to prescribing clozapine, most physicians choose other branded products as treatment options, including *Seroquel*<sup>®</sup>, marketed by AstraZeneca, *Risperdal*<sup>®</sup>, marketed by Janssen, and *Zyprexa*<sup>®</sup>, marketed by Eli Lilly. *Versacloz* is currently the only oral suspension formulation of clozapine approved by the FDA.
- *Luvox CR*<sup>®</sup> (fluvoxamine maleate) Extended-Release Capsules. The market for drugs to treat obsessive compulsive disorder is very fragmented. We believe that, in addition to *Luvox CR*, a large number of branded and generic drugs are used for the treatment of this disorder. Seven branded products, including *Luvox CR*, and generic equivalents of many of these, have been approved by the FDA for the treatment of obsessive compulsive disorder, and we believe that other products are regularly used to treat this disorder. A generic version of *Luvox CR* could be introduced as soon as the FDA approves Anchen's ANDA.

With respect to all of our products and product candidates, we believe that our ability to successfully compete will depend on, among other things:

- the existence of competing or alternative products in the marketplace, including generic competition, and the relative price of those products;
- the efficacy, safety and reliability of our products and product candidates compared to competing or alternative products;
- product acceptance by physicians, other health care providers and patients;
- protection of our proprietary rights;
- obtaining reimbursement for our products in approved indications;
- our ability to complete clinical development and obtain regulatory approvals for our product candidates, and the timing and scope of regulatory approvals;
- our ability to supply commercial quantities of a product to the market; and
- our ability to recruit and retain skilled employees.

### **Customers and Information About Geographic Areas**

In the United States, *Xyrem* is sold to one specialty pharmacy, ESSDS, which ships *Xyrem* directly to patients. *Erwinaze* is sold through an exclusive wholesaler and distributor, Accredo Health Group, Inc., to hospitals in the United States. The other products that we sell in the United States are sold primarily to distributors who distribute the product to pharmacies and hospitals. In 2012, the principal distributors for our products in the United States were Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation and its subsidiary, Integrated Commercialization Solutions Inc. We have standard industry agreements made in the ordinary course of business with these distributors, which include prompt payment discounts and various standard fee or rebate arrangements. Purchases are made on a purchase order basis.

Outside of the United States, UCB has rights to market *Xyrem* in 54 countries, and Valeant has rights for Canada. *Xyrem* is currently sold in 18 countries by UCB and in Canada by Valeant. Our international division distributes *Erwinaze* through Durbin PLC, a U.K.-based wholesaler and distributor, to hospitals and local wholesalers in Europe where it markets *Erwinaze* directly and, in markets where it does not market *Erwinaze* directly, to local distributors and wholesalers in Europe and elsewhere in the world. Our international division

also sells other products both directly and through local distributors and wholesalers in Europe and elsewhere in the world in accordance with local regulatory approval status. We do not have rights outside of the United States to our psychiatry products. Eisai has rights to market Prialt in 34 countries outside of the United States. While we retain the rights to Prialt in the rest of the non-U.S. territories, we are not currently selling the product outside of the United States.

Information on our total revenues attributed to U.S. and non-U.S. sources and customers who represented at least 10% of total revenues in each of 2012, 2011 and 2010, as well as the location of our long-lived assets, is included in Note 15 to our consolidated financial statements.

With the completion of the EUSA Acquisition and the Azur Merger in 2012, our international footprint now includes headquarters in Dublin, Ireland and multiple offices in the United States, the United Kingdom and other countries in Europe, with approximately 610 employees in 11 countries. For a discussion of risks related to our non-U.S. operations, see “Risk Factors—Risks Related to Our Business,” “—Risks Related to Our Industry” and “—Risks Relating to Our Financial Condition” in Item 1A, “Government Regulation—Ex-U.S. Regulations” in this Item 1, and “Quantitative and Qualitative Disclosure about Market Risk” in Item 7A.

## **Manufacturing**

We do not have our own manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. We have engaged third parties for these activities. Currently, we have a single source of supply for each of our marketed products and for the active pharmaceutical ingredients used in these products. Our ability to develop and deliver products in a timely and competitive manner depends on our third party suppliers and manufacturers being able to continue to meet our ongoing commercial needs. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state and non-U.S. regulations. These difficulties can be heightened when a supplier or manufacturer is required to scale up to produce increased quantities to meet growing demand.

In April 2010, we entered into an agreement with Siegfried (USA) Inc., or Siegfried, for the supply of sodium oxybate, the active pharmaceutical ingredient of Xyrem. Siegfried was approved by the FDA as our supplier in November 2011. Although Siegfried became our only supplier of sodium oxybate in 2012, we have the right to purchase a portion of our worldwide requirements of sodium oxybate from other suppliers. Under the agreement, we provide periodic rolling forecasts to Siegfried, and a portion of each rolling forecast constitutes a firm purchase order. The agreement with Siegfried expires in April 2015, subject to automatic three-year extensions until either party provides notice to the other of its intent to terminate the agreement at least 18 months before the end of the then-current term. Either party has the right to terminate the agreement in the event of the other party’s uncured material breach or insolvency. During the term of the agreement and, under certain circumstances for 18 months after the agreement terminates, Siegfried is not permitted to manufacture sodium oxybate for any other company.

We have an exclusive agreement with Patheon Pharmaceuticals, or Patheon, which became effective in 2008, under which we have agreed to purchase exclusively from Patheon (except in very limited circumstances), and Patheon has agreed to manufacture, supply and package, our worldwide supply of Xyrem. The current term of the agreement with Patheon, which is our sole supplier of Xyrem, extends until July 2014 and may be extended, at our option, for additional two-year terms with written notice at least twelve months before the end of the then current term. Either party has the right to terminate the agreement in the event of the other party’s uncured material breach or insolvency.

Quotas from the U.S. Drug Enforcement Administration, or DEA, are required in order to manufacture and package sodium oxybate and Xyrem. DEA quotas are required for Siegfried to supply us with sodium oxybate

and for Patheon to supply us with Xyrem. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for a quota request, obtaining a sufficient DEA quota can be a difficult and time consuming process. The need for quota has prevented us in the past, and may prevent us in the future, from building significant inventories. For information related to this quota requirement by the DEA, see “Government Regulation—U.S. Regulations-Other Regulatory Requirements” in this Item 1.

We have an agreement with the HPA under which Erwinaze is exclusively licensed to us for worldwide marketing, sales and distribution, and is manufactured for us, by the HPA. The HPA is our sole supplier for Erwinaze. The agreement with the HPA expires in December 2020, subject to automatic extension for additional five-year periods unless terminated by either party in writing at least a fixed period before the end of the then-current term. Either party has the right to terminate the agreement in the event of the other party’s uncured material breach or insolvency. We provide periodic rolling forecasts to the HPA, and a portion of each rolling forecast constitutes a firm purchase order. We are obligated to make tiered royalty payments to the HPA based on worldwide net sales of Erwinaze and Erwinase. During the review and approval process by the FDA of the BLA for Erwinaze, EUSA Pharma agreed to a number of post-marketing commitments related to the manufacture of Erwinaze by the HPA. In the past, there has been a disruption of supply of Erwinase in the European market due to manufacturing challenges. We have limited inventory of Erwinaze. If the HPA experiences a disruption in supply or capacity constraints as a result of increased demand, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach by the HPA or the cessation of HPA’s business. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming and would increase the likelihood of a delay or interruption in manufacturing or a shortage of supply of Erwinaze.

We are in the process of changing our supplier for ziconotide, the active ingredient in Prialt, and have commenced the transfer to the new supplier. We believe that we have sufficient supply of ziconotide to meet our commercial requirements for finished product for a number of years, which we expect to be sufficient time to complete the transfer to the new supplier. We are also in the process of changing our finished product manufacturer for Prialt. We believe that we have sufficient supply to meet commercial requirements for Prialt through the end of 2013. Our new manufacturer of finished product was approved by the FDA in December 2012 but has not yet needed to manufacture commercial supplies of Prialt for us.

For FazaClo LD, FazaClo HD and Luvox CR, we have single sources of supply for both the active pharmaceutical ingredient and finished product, and should it become necessary to change suppliers, the process could take two years or longer. Pursuant to our agreement, Douglas Pharmaceuticals has agreed to supply Versacloz finished product to us.

Our active pharmaceutical ingredient and finished product manufacturers may not be able to continue to meet our requirements for quality, quantity and timeliness. In addition, our manufacturers and suppliers are subject to the FDA’s current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and other rules and regulations prescribed by non-U.S. regulatory authorities. We depend on our third party suppliers and manufacturers for continued compliance with these requirements, and they may not be able to do so.

## **Government Regulation**

The research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of pharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities, and regulations differ from country to country. In the United States, the FDA, under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, regulates the review, approval, manufacturing and marketing of pharmaceutical products. We are not permitted to market medicines in the United States or countries in Europe until we receive approval from the FDA or the competent European authorities, respectively, generally of an NDA or a BLA, or their non-U.S.



equivalent. The application must contain information on the proposed product, including data from preclinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability.

Xyrem is also regulated as a controlled substance and is subject to additional regulation by the DEA under the Controlled Substances Act, or CSA, and its implementing regulations.

Failure of us or any of our third party partners to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to approve a product candidate, withdrawal of product approval, notices of violation, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall or seizure, total or partial suspension of production or distribution, interruption of manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, civil penalties and/or criminal prosecution.

## ***U.S. Regulations***

### **Drug and Biologic Approval Process**

To obtain FDA approval of a product candidate, an applicant, also called a sponsor, must, among other things, submit the results of the preclinical and clinical trials with data supporting safety and efficacy, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling. The submission is in the form of an NDA or BLA, as applicable, and includes payment of a user fee.

The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The steps required before a drug or biologic product may be approved for marketing in the United States generally include: preclinical laboratory tests and animal tests; submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials commence; adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug product for each indication; the submission to the FDA of a marketing application; satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made, analyzed and stored to assess compliance with cGMP; potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the application; and FDA review and approval of the application.

The FDA reviews all applications submitted before it accepts them for filing and may request additional information rather than, or before, accepting an NDA or BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has twelve months in which to complete its initial review of a standard application and respond to the applicant, and eight months for a priority application. The FDA does not always meet its PDUFA goal dates, and in certain circumstances the PDUFA goal date may be extended. The FDA may not act quickly or favorably in reviewing applications, and we may encounter significant difficulties or costs in any efforts to obtain FDA approvals, which could delay or preclude us from marketing our product candidates.

If the FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks, a sponsor may be required to include, as part of the application or after approval, a proposed REMS, which may include a patient package insert or a medication guide to provide information to consumers about the product's risks and benefits, a plan for communication to healthcare providers, and restrictions on the product's distribution referred to as "elements to assure safe use," or ETASU. For example, Xyrem is required to have a REMS. While elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS, are deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act of 2007, or FDAAA, the program is not in the form that is now required for REMS. FDAAA, which amended

FDCA, requires that certain products' risk management programs and related documents that existed prior to the adoption of FDAAA, including the Xyrem Risk Management Program, be updated to comply with the current requirements for REMS documents. We have submitted updated REMS documents to the FDA, which are intended to conform the relevant elements of the Xyrem Risk Management Program to the current REMS formatting requirements, as well as to make other updates to the program and its documentation. We have had communications with the FDA with respect to our submitted REMS documents. These communications are ongoing, and we cannot predict the timing of finalization, or the final terms, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem. See the discussion below regarding REMS in the context of potential generic competition under "The Hatch-Waxman Act" and in the risk factor in Item 1A entitled "*The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.*"

We also have a risk management plan for FazaClo LD and FazaClo HD that is deemed to be an approved REMS, but, as with Xyrem, the program is not in the form that is now required for REMS. In 2012, the FDA notified us, along with other holders of applications for products containing clozapine, including FazaClo LD, FazaClo HD and Versacloz, that a single shared system should be used to implement the REMS for all members of this class of products. We are working with other manufacturers of clozapine products to address the FDA's requirements.

After the FDA evaluates a marketing application, including a REMS program when applicable, it also evaluates any manufacturing facilities for the proposed product. When the FDA's evaluation is complete, it issues an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA will issue an approval letter. The FDA may also refer an application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has and has used various programs, including fast track, priority review, breakthrough therapy and accelerated approval (Subpart H and E), that are intended to expedite or simplify the process for reviewing certain applications, and/or provide for approval on the basis of surrogate endpoints or restricted distribution. Generally, drugs and biologics may be eligible for one or more of these programs if they are intended for serious or life-threatening diseases or conditions, have potential to address unmet medical needs, or may provide meaningful benefit over existing treatments. We cannot be sure that any of our product candidates will qualify for any of these programs, or that, if a product candidate does qualify, that the review time will be shorter than a standard review.

### **Post-Approval Regulation**

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted.

Often, even after a drug or biologic has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies and trials. If such post-approval conditions are not satisfied, the FDA may impose civil money penalties, declare the product

misbranded or prohibit the introduction of the drug in interstate commerce. In addition, holders of an approved NDA or BLA are required to: report certain adverse reactions to the FDA; comply with certain requirements concerning advertising and promotional labeling for their products; submit drug safety or adverse event reports; and continue to have quality control and manufacturing procedures conform to cGMP after approval. For example, during the review and approval process by the FDA of the BLA for Erwinaze, EUSA Pharma agreed to a number of post-marketing commitments related to the manufacture of Erwinaze by the HPA.

We monitor adverse events resulting from the use of our commercial products, as do the regulatory authorities, and we file periodic reports with the authorities concerning adverse events. The authorities review these events and reports, and if they determine that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing and/or require or conduct other actions. From time to time, the FDA issues drug safety communications on its adverse event reporting system based on its review of reported adverse events. In December 2012, the FDA issued a drug safety communication reminding physicians and patients that the use of Xyrem with alcohol or central nervous system depressants can impair consciousness and lead to severe breathing problems. Also in December 2012, we agreed with the FDA on a change to our label that included a new contraindication for the use of alcohol with Xyrem. See also the risk factor in Item 1A entitled *“The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.”*

The FDA also periodically inspects the sponsor’s records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved product, including withdrawal of the product from the market.

The FDA and other governmental authorities also actively enforce regulations prohibiting off-label promotion, and the government has levied large civil and criminal fines against companies for alleged improper promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies.

### **The Hatch-Waxman Act**

The approval process described above is premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove the safety and effectiveness of a drug product. This type of marketing application, sometimes referred to as a “full” or “stand-alone” NDA, is governed by Section 505(b)(1) of the FDCA. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information.

Alternatively, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which updated certain sections of the FDCA, establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of products already covered by an approved NDA. The first path, under Section 505(b)(2), is for the approval of a product that is similar, but not identical, to a previously-approved product. Under this path, the applicant is permitted to rely to some degree on the FDA’s finding that the referenced drug is safe and effective, and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. The FDA may then approve the new drug product for all or some of the label indications for which the referenced product has been approved, or for a new indication sought by the Section 505(b)(2) applicant.

The second path established under the Hatch-Waxman Act is for the approval of generic drugs. Section 505(j) of the FDCA permits the submission of an abbreviated new drug application, or ANDA, for a generic version of an approved, brand-name drug. Generally, an ANDA must contain data and information showing that the proposed generic product and the approved, brand-name drug, which is referred to as the “referenced drug,” (1) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. This data and information are provided instead of independently demonstrating the proposed generic product’s safety and effectiveness, which are inferred from the fact that the generic product is the same as the referenced drug, which the FDA previously found to be safe and effective. On October 18, 2010, we received notice from Roxane Laboratories, Inc., or Roxane, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem, and, on December 10, 2012, we received notice from Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an ANDA to the FDA seeking regulatory approval to market a generic version of Xyrem. ANDAs have been filed in the past seeking approval to market generic versions of certain of our other products, and additional ANDAs may be filed in the future seeking approval to market generic forms of Xyrem and/or other products.

To the extent that an ANDA or a Section 505(b)(2) NDA applicant is relying on the FDA’s findings for an already-approved product, the applicant is required to certify that there are no patents listed for that product in the FDA’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” or Orange Book, or that for each Orange-Book-listed patent the listed patent has expired, or will expire on a particular date and approval is sought after patent expiration, or the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product. A certification that the new product will not infringe the referenced product’s Orange-Book-listed patents or that such patents are invalid is called a Paragraph IV Certification. If the applicant does not challenge the listed patents, the ANDA or the Section 505(b)(2) NDA will not be approved until all the listed patents claiming the referenced product have expired, as well as any additional period of exclusivity that might be obtained for completing pediatric studies pursuant to the FDA’s written request. The ANDA or the Section 505(b)(2) NDA may also be subject to delay in review or approval based on applicable non-patent exclusivities, such as exclusivity that results from obtaining approval of a new chemical entity or of a new use of a previously approved active ingredient.

If the applicant has provided a Paragraph IV Certification to the FDA, the applicant must also send notice of the Paragraph IV Certification to the holder of the NDA and the relevant patent holders once the ANDA or the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the proposed generic product for infringing the patent. The filing of a patent infringement lawsuit within 45 days of receipt of a Paragraph IV Certification automatically prevents the FDA from approving the ANDA or the Section 505(b)(2) NDA until the earliest of 30 months after the NDA holder’s receipt of the notice of the Paragraph IV Certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA sponsor. The 30-month stay period may also be shortened or lengthened upon order of the court in the infringement lawsuit. For drugs with five-year exclusivity, if an action for patent infringement is initiated after year four of that exclusivity period, then the 30-month stay period is extended by such amount of time so that 7.5 years has elapsed since the approval of the reference drug NDA. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant will not be subject to the 30-month stay. The FDA may issue tentative approval of an ANDA if the generic applicant meets all conditions for approval but cannot receive effective approval because the 30-month stay or a period of statutory exclusivity has not expired.

We intend to submit for Orange Book listing all relevant patents for our products and product candidates, and to vigorously defend any patents for our approved products, including Orange Book-listed patents. In November 2010, we filed a lawsuit against Roxane in response to Roxane’s Paragraph IV Certification relating to Xyrem in connection with Roxane’s ANDA filing. In January 2013, we filed a lawsuit against Amneal in response to Amneal’s Paragraph IV Certification relating to Xyrem in connection with Amneal’s ANDA filing.

For a description of these matters, please see Item 3. “Legal Proceedings.” If an ANDA is approved after the 30-month stay and before conclusion of any relevant patent litigation at the district, and potentially appellate, court, a generic manufacturer could nonetheless choose to commercialize the generic product. In the event of such commercialization, the generic manufacturer generally would be liable to the NDA holder for damages in the event the NDA holder ultimately prevails in the patent litigation.

Section 505-1(i)(1) of the FDCA provides that (i) an ANDA with a referenced drug subject to the REMS requirements is required to have a REMS with the same or comparable elements as the referenced drug, such as a medication guide, a patient package insert and other ETASU, and (ii) the ANDA drug and the referenced drug shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and permit the ANDA holder to submit a separate but comparable REMS if the FDA determines that the burden of creating such a system outweighs its benefit or if the ANDA applicant certifies that it has been unable to obtain a license to any aspects of the REMS for the referenced drug product that are covered by a patent or a trade secret entitled to protection. The FDCA provides that the FDA may seek to negotiate a license between the ANDA sponsor and the sponsor of the listed product before granting a waiver. The FDCA further states that a REMS shall not be used by an NDA holder to block or delay generic drugs from entering the market. Accordingly, from time to time we may face pressure to license or share our Xyrem Risk Management Program, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that may be taken by a third party to seek to license or share our REMS program. Furthermore, if we do not share our REMS with a generic competitor, the FDA may grant the generic competitor a waiver and allow the generic competitor to market a generic drug with a comparable REMS.

On July 10, 2012, we submitted a Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, which did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. In the FDA’s response, the FDA stated that when the NDA holder has a deemed REMS, the FDA directs the ANDA applicant to work with the NDA holder to create a single shared system to implement the ETASU that will be approved as a final REMS. We cannot predict the outcome or impact on our business of any discussions with any ANDA applicant with respect to the potential creation of a single shared system. See the risk factor in Item 1A entitled “*We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products.*”

It is also possible that the FDA may take the position that a potential generic competitor does not need to share or license aspects of our deemed REMS program in order to obtain approval of its ANDA. In the December 13, 2012 denial of our Citizen Petition described above, the FDA stated that if the FDA determines that an ANDA may be ready for approval before final approval of the REMS of a sponsor holding a deemed REMS, the FDA will direct the ANDA applicant to submit a proposed risk management plan with ETASU that are comparable to the ETASU that are approved for the referenced drug to have adequate risk management elements in place for the ANDA until the final REMS is approved. Thus, it is possible that the FDA may rely on this position as a basis to grant approval or tentative approval of an ANDA without a final REMS.

Under the Hatch-Waxman Act, newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act prohibits the FDA accepting for review an ANDA or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, as explained above, submission of an ANDA or Section 505(b)(2) NDA containing a

Paragraph IV Certification is permitted after four years, which may trigger litigation leading to a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA that could extend to 7.5 years after approval of the referenced drug. Protection under the Hatch-Waxman Act will not prevent the submission or approval of another “full” NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application.

The Hatch-Waxman Act also permits a patent term extension of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years after the FDA approves a marketing application. The patent term extension period is generally equal to the sum of one-half the time between the effective date of an IND and the submission date of an NDA, and all of the time between the submission date of an NDA and the approval of that application, up to a total of five years. Only one patent applicable to a regulatory review period, that represents the first commercial marketing of that drug, is eligible for the extension, and it must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, or the USPTO, in consultation with the FDA, reviews and approves the application for patent term extension. We will consider applying for a patent term extension for some of our patents to add patent life beyond the expiration date, if we meet the legal requirements permitting an extension and depending on the expected length of clinical trials and other factors involved in the submission of an NDA.

#### **Orphan Drug and Other Exclusivities**

Some jurisdictions, including the United States and Europe, may designate drugs or biologics for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product. In the United States, in order to obtain orphan drug designation, this designation must be requested before submitting an application for marketing approval. An orphan drug designation does not shorten the duration of the regulatory review and approval process. If a product that has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years from the time of FDA approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity.

The FDA designated and approved Xyrem as an orphan drug for treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. The period of orphan drug exclusivity for cataplexy in patients with narcolepsy expired in July 2009, and the period of orphan drug exclusivity for excessive daytime sleepiness in patients with narcolepsy expired in November 2012. In addition, Erwinaze has orphan drug exclusivity until November 2018, seven years from its FDA approval. Our product candidate Asparec was also granted orphan drug designation by the FDA, subject to certain conditions.

Separately, Erwinaze, as a biologic product approved under a BLA, is subject to the BPCIA. The BPCIA establishes a period of twelve years of data exclusivity for reference products in order to preserve incentives for future innovation, protecting data included by the applicant in a BLA by prohibiting others from gaining FDA approval based in part on reliance on, or reference to, the data in the BLA during a twelve-year period. The FDA is in the process of implementing the BPCIA and has not established final guidelines for administering the review and approval of applications for data exclusivity. We expect that Erwinaze would receive data exclusivity in the United States through 2023 under the BPCIA.

## **United States Healthcare Reform**

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, together the Healthcare Reform Act, was adopted in the United States. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. The Healthcare Reform Act also makes changes to the Medicaid Drug Rebate Program, discussed in more detail below, including increasing the minimum rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products.

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014 and thereafter, and their details will be shaped significantly by implementing regulations that have yet to be finalized. In 2012, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, the Supreme Court struck down a provision in the Healthcare Reform Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014 than anticipated when Congress passed the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall, which could impact our sales, business and financial condition.

## **Other Regulatory Requirements**

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, or FTC, the U.S. Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those non-U.S. countries in which we commercialize our products. In addition to the FDCA, other federal, state and non-U.S. statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government healthcare programs. Our partners, including our suppliers, manufacturers and distributors and the central pharmacy for Xyrem, are subject to many of the same requirements.

These requirements include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. In addition to quota requirements, the DEA imposes various registration, recordkeeping and reporting requirements, labeling and packaging requirements, importing, exporting, security controls and a

restriction on prescription refills on certain pharmaceutical products under the CSA. The states also impose similar requirements for handling controlled substances. A principal factor in determining the particular requirements, if any, applicable to a product is the actual or potential abuse profile. Sodium oxybate, in the form of an active pharmaceutical ingredient, is regulated by the DEA as a Schedule I controlled substance, a category reserved for products believed to present the highest risk of substance abuse and with no approved medicinal use. When contained in Xyrem, sodium oxybate is regulated as a Schedule III controlled substance. Controlled substances are subject to DEA and state regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA regulates the amount of the scheduled substance that would be available for clinical trials and commercial distribution. As a Schedule III drug, Xyrem is subject to limitations on prescription refills. Sodium oxybate, as a Schedule I substance, is subject to additional controls, including quotas that limit the amount of product that can be manufactured each year. The DEA publishes an annual aggregate quota for the active pharmaceutical ingredient of Xyrem, and our supplier is required to request and justify allocation of sufficient annual manufacturing quota, as well as additional manufacturing quota if needed throughout the year. Until 2011, our active pharmaceutical ingredient supplier obtained substantially all of the published annual aggregate quota for use in the manufacture of Xyrem. However, for each of 2012 and 2013, our supplier has been allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. As a result, a generic manufacturer may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In addition, our supplier has been allocated only a portion of the requested quota for 2013 to make the active pharmaceutical ingredient of Xyrem. Our finished product manufacturer for Xyrem was similarly allocated only a portion of the requested quota to make finished product. As a result, we anticipate that both our active pharmaceutical ingredient supplier and our finished product manufacturer will need to obtain increased quotas from the DEA for 2013.

The third parties who perform our clinical and commercial manufacturing, distribution, dispensing and clinical studies for Xyrem are required to maintain necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA or relevant state authorities could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, and could have an adverse effect on our business and financial condition.

In addition, pursuant to the Export Administration Regulations, we are required to obtain a license from the U.S. Department of Commerce prior to the exportation of certain materials and technical information related to Prialt, a synthesized conotoxin, which is a designated controlled biological toxin.

### **Iran Related Disclosures**

Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 added a new subsection (r) to Section 13 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that requires a public company to disclose in its annual or quarterly reports whether it or any of its affiliates have knowingly engaged in specified activities or transactions relating to Iran, including activities not prohibited by U.S. law and conducted outside the U.S. by non-U.S. affiliates in compliance with local law. The following disclosure is made pursuant to Section 13(r) of the Exchange Act.

On June 12, 2012, we completed the EUSA Acquisition. Prior to the completion of the EUSA Acquisition, a French subsidiary of EUSA Pharma entered into a contract to sell Kidrolase (Escherichia coli L-asparaginase), a life-saving cancer drug produced outside of the United States, to Medical Equipment and Pharmaceutical Holding Co., or MEPH, which we understand is an affiliate of the Iranian Ministry of Health. Following the completion of the EUSA Acquisition, the French subsidiary of EUSA Pharma shipped Kidrolase to MEPH pursuant to the pre-existing contract. The Kidrolase contract was entered into prior to our acquisition of EUSA Pharma, was performed entirely by the French subsidiary, and we believe that the post-acquisition shipment of Kidrolase was not prohibited by or sanctionable under applicable law at the time. Our anticipated gross revenue from this shipment of Kidrolase was approximately 92,000 Euros. The French subsidiary of EUSA Pharma,



which is now our wholly-owned subsidiary, has sought payment from MEPH for this shipment. To date, no such payment has been received. No additional sales or shipments of Kidrolase to MEPH were made following the June 2012 shipment.

Our mission is to improve patients' lives by identifying, developing and commercializing products that address unmet medical needs. As part of fulfilling our mission, we intend to provide access to important and life-saving pharmaceutical products to patients wherever they may be located, including in Iran, to the extent permitted by applicable U.S. and non-U.S. laws and regulations. For that reason, we expect that we may make future sales of Kidrolase to MEPH in accordance with applicable law.

### *Ex-U.S. Regulations*

We are also subject to a variety of regulations and oversight in countries outside of the United States governing medicinal products and medical devices, including with respect to pre- and post-authorization clinical studies, product manufacturing, advertising and promotion, distribution, and safety reporting. Outside of the United States, our ability to market a product generally depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will generally be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. In addition, many countries have adopted specific legal frameworks and procedures to enable the supply of unauthorized medicinal products in the context of named patient or compassionate use programs. These programs are subject to different requirements and subject to different rules in the countries where we operate.

Most of the countries where we market our products have product authorization and post-authorization regulatory processes. In the European Union, or the EU, marketing authorization for medicinal products can be obtained through several different procedures. The centralized procedure allows a company to submit a single application to the European Medicines Agency, or EMA, which approves the application if it meets certain quality, safety, and efficacy requirements. A centralized marketing authorization is valid in all EU member states. The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products and advanced therapy medicinal products, and optional for certain other products. Unlike the centralized procedure, the national procedure requires a separate application to, and leads to separate approval by, each EU member state. The decentralized procedure allows applicants to file identical applications to several EU member states and receive simultaneous national approvals based on the recognition by EU member states of an assessment by a reference member state, and the mutual recognition procedure similarly is based on the acceptance by EU member states of the assessment and/or authorization of a medicinal product by a reference member state. The making available or placing on the EU market of unauthorized medicinal products is generally prohibited, but EU Member States may exceptionally and temporarily allow the making available of such products to individual patients or a group of patients. Clinical studies must be conducted in accordance with the requirements of the EU Clinical Trial Directive and applicable good clinical practice standards. The time needed to secure approval for medicinal products may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above.

Irrespective of the different marketing authorization tracks, various additional requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the EU Medicinal Products Directive, as amended by the EU Falsified Medicines Directive aimed at preventing falsified medicines from entering into the legal supply chain. These requirements include compliance with EU equivalent cGMP standards when manufacturing active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.

The holder of an EU marketing authorization for a medicinal product must also comply with the EU's revised pharmacovigilance legislation adopted in 2010, which entered into force in mid-2012 and entails many new and revised requirements for conducting pharmacovigilance, as well as the codification of various existing requirements previously set out in guidance. EU regulators now can, for example, require post-authorization efficacy studies at the time of approval of a medicinal product or afterwards, and require additional monitoring of products placed on the EU market. Compliance with the pharmacovigilance requirements, as well as the requirements of the EU Paediatric Regulation, is subject to the EU Penalties Regulation, which enables the European Commission to impose financial penalties on central marketing authorization holders for violation of specific pharmacovigilance and paediatric requirements. National marketing authorization holders may be subject to civil, criminal or administrative sanctions in case of non-compliance with the EU requirements applicable to the manufacturing and marketing of medicinal products.

The United States is a party to the Convention on Psychotropic Substances (1971), the 1971 Convention. In October 2012, the World Health Organization, or WHO, sent a recommendation to the United Nations Commission on Narcotic Drugs, or CND, to reschedule gamma-hydroxybutyrate, or GHB, under the 1971 Convention from its current Schedule IV status to Schedule II status. While the DEA imposes its own scheduling requirements in the United States under the CSA, the United States is obligated as a signatory to the 1971 Convention to ensure that drug scheduling in the United States is consistent with its obligations under the international treaties. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, if GHB is rescheduled internationally, Xyrem and/or sodium oxybate may be subject to more restrictive registration, recordkeeping, reporting, importing, exporting and other requirements. In the United States, under DEA regulations, the Xyrem finished product is currently classified as a Schedule III controlled substance, with sodium oxybate, classified as a Schedule I controlled substance. Although sodium oxybate and Xyrem are already subject to more restrictive regulations in the United States than required under the 1971 Convention, a decision by the CND to reschedule GHB would result in sodium oxybate and Xyrem being subject to more restrictive registration, recordkeeping, importing, exporting, reporting and other requirements in Europe and certain other countries than are currently in place given GHB's Schedule IV status under the 1971 Convention. The CND is expected to review the WHO recommendation at its annual meeting in March 2013. If GHB is rescheduled as a Schedule II substance under the 1971 Convention, we will likely be subject to additional regulatory requirements outside of the United States and may be subject to additional regulatory requirements in the United States.

Our international business activities face a variety of additional legal and compliance requirements. For example, our interactions with health care professionals are subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We are also subject to applicable anti-bribery laws in the countries in which we operate, such as the U.K. Bribery Act of 2010, or the UK Bribery Act, which became effective on July 1, 2011. The UK Bribery Act prohibits companies which do business with the United Kingdom and their employees and representatives from giving, offering, or promising bribes to any person, including non-UK government officials, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies may be held liable for failing to prevent employees and persons associated with the company from violating the Act. Other countries in which we operate have enacted similar laws. We have ongoing efforts that are designed to ensure our compliance with these laws, including training, policies, procedures, and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third party agents, although we may be liable for their actions. Any violation of these laws may result in civil and criminal penalties, and could have a material adverse impact on our business.

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration and, if adopted, could lead to additional and stricter requirements and penalties in the event of non-compliance.

Additional requirements and restrictions regarding, among other things, the export and importation of products, intellectual property rights, the environment, taxation and work safety apply in individual countries, and non-compliance with such requirements may result in civil, criminal or administrative sanctions.

### **Pharmaceutical Pricing and Reimbursement**

In both U.S. and non-U.S. markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than other products, and third party payors may not provide coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include: controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs, controls on healthcare providers; challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost effectiveness research, which may be used by government and private third party payors to make coverage and payment decisions.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and the Centers for Medicare and Medicare Services, or CMS, the federal agency that administers the Medicaid Drug Rebate program, has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. We also participate in and have certain price reporting obligations to several state Medicaid supplemental rebate programs and other governmental pricing programs, and we have obligations to report ASP for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the CMS. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

Federal law also requires that a company that participates in the Medicaid rebate program report ASP information to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS as to what should or should not be considered in computing ASP. An ASP for each National Drug Code for a product that is subject to the ASP reporting requirement must be submitted to CMS no later than 30 days after the end of each calendar quarter. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Changes affecting the calculation of ASP could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies, we participate in the Department of Veterans Affairs Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make our product available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense, Public Health Service and Coast Guard, that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the Department of Veterans Affairs on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, established by Section 703 of the National Defense Authorization Act for FY 2008 and related regulations, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between Annual Non-FAMP and FCP.

Outside of the United States, political, economic and regulatory developments are also subjecting the healthcare industry to fundamental changes and challenges. Pressure by governments and other stakeholders on prices and reimbursement levels continue to exist. In various European countries we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. In the EU, our products are marketed through various channels and within different legal frameworks. In certain EU Member States, reimbursement is provided for unauthorized products provided through national named patient or compassionate use programs.

Such reimbursement may no longer be available if authorization for named patient or compassionate use programs expire or are terminated. In other EU Member States, authorization and reimbursement policies may also delay commercialization of our products, or may adversely affect our ability to sell our products on a profitable basis.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted, could have a material adverse effect on our ability to operate profitably in the EU.

## Patents and Proprietary Rights

We actively seek to patent, or to obtain licenses to or to acquire third party patents, to protect our products, inventions and improvements that we consider important to our business. We own a portfolio of U.S. and non-U.S. patents and patent applications and have licensed rights to a number of issued patents and patent applications. Our owned and licensed patents and patent applications cover formulations of our products and product candidates, uses of our products and product candidates to treat particular conditions, drug delivery technologies and delivery profiles relating to our products and product candidates and methods for producing our products and product candidates. Patents extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. The patents and patent applications that relate to our products and product candidates include the following:

- *Xyrem*<sup>®</sup> (*sodium oxybate*) *oral solution*. Xyrem is covered by eleven U.S. patents that expire at various times from December 2019 to June 2024. These patents relate to Xyrem's stable and microbially resistant formulation, its manufacturing process, and its method of use, including its restricted distribution system. Nine of these eleven patents are listed in the Orange Book. Of the patents listed in the Orange Book, two are formulation patents expiring in July 2020; four are method of use patents covering the distribution of Xyrem, three of which expire in June 2024 and one of which expires in December 2022; two are method of use patents covering Xyrem's use in narcolepsy, both of which expire in December 2019; and one is formulation and method of use patent expiring in December 2019. A process patent and a distribution system patent not listed in the Orange Book also cover the product and expire in December 2019 and June 2024, respectively. A Xyrem formulation patent has issued in 19 other countries and will expire in December 2019. This formulation patent is currently pending in two additional countries. In addition to our issued patents, we have patent applications relating to Xyrem pending in the United States. The patent laws of non-U.S. countries differ from those in United States, and the degree of protection afforded by non-U.S. patents may be different from the protection offered by U.S. patents. Two companies have notified us that they have filed ANDAs with the FDA seeking FDA approval to market a generic version of Xyrem. We initiated lawsuits against each of these companies and are currently involved in litigation with both companies.
- *Prialt*<sup>®</sup> (*ziconotide*) *intrathecal infusion*. Prialt is covered by a portfolio of four U.S. patents for a formulation and methods of use. Two of these patents are listed in the Orange Book. These patents will expire from June 2015 to December 2016. Also, there are four non-U.S. patents that will expire in June 2016. There are also six additional U.S. patents issued on a formulation containing Prialt and other active ingredients and methods for their use. These U.S. patents will expire in October 2024. We also have equivalent non-U.S. applications to these additional patents pending in Canada and Japan that, if issued, would expire in October 2024.
- *FazaClo*<sup>®</sup> *LD (clozapine, USP) Orally Disintegrating Tablet and FazaClo*<sup>®</sup> *HD (clozapine, USP) Orally Disintegrating Tablet*. FazaClo LD and FazaClo HD are covered by three U.S. formulation

patents. All are licensed by us, one from Ethypharm, expiring in December 2017, and the other two from CIMA, expiring April 2018. The three patents are listed in the Orange Book. The two patents licensed from CIMA are subject to ongoing re-examination proceedings at the USPTO, as described in “Marketed Products” in this Item 1. As part of its settlement with Teva in 2011, Azur Pharma granted a sublicense to an affiliate of Teva of its rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD. The sublicenses for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events.

- *Versacloz™ (clozapine, USP) oral suspension.* Versacloz is covered by a U.S. formulation patent and a pending U.S. patent application that we license from Douglas Pharmaceuticals. The patent expires in May 2028.
- *Luvox CR® (fluvoxamine maleate) Extended-Release Capsules.* Luvox CR is covered by a U.S. formulation patent owned by Alkermes that is listed in the Orange Book and will expire in 2020. A continuation application is pending in the United States. Pursuant to our settlement agreements with three companies, we granted a sublicense to each of these companies of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The first of such sublicenses commenced in February 2013, and a generic version of Luvox CR could be introduced as soon as the FDA approves the generic company’s ANDA. The other two sublicenses will commence in April 2014, or earlier if a generic version of Luvox CR receives FDA approval.
- *Product candidate.* Asparec® (mPEG-r-crisantaspase) is not yet covered by any issued patents. We have rights to patent applications for Asparec pending in the United States and many other countries that, if issued, would expire in July 2030.

Erwinaze® (asparaginase *Erwinia chrysanthemi*) has no patent protection, and we therefore rely on trade secrets and other unpatented proprietary information to protect our commercial position, which we may be unable to do.

We cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents. Changes in patent laws could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, because the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions, the patents we own and license, or any additional patents we may own or license, may not prevent other companies from developing similar or therapeutically equivalent products. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful.

As reflected above, generic manufacturers have challenged our patents covering Xyrem, FazaClo LD, FazaClo HD and Luvox CR. Azur Pharma settled a suit against Teva relating to FazaClo LD and FazaClo HD, and we settled three suits against Anchen, Actavis and Torrent, relating to Luvox CR. Other suits are ongoing. See Item 3. “Legal Proceedings.” We cannot assure you that our patents will not be further challenged by third parties or that we will be successful in any defense we undertake. Failure to successfully defend a patent challenge could materially and adversely affect our business.

We cannot ensure that others will not be issued patents that may prevent the sale of our products or require licensing and the payment of significant fees or royalties. Furthermore, to the extent that any of our future products or methods is not patentable or infringes the patents of third parties, or in the event that our patents or future patents fail to give us an exclusive position in the subject matter claimed by those patents, our business could be adversely affected. We may be unable to avoid infringement of third party patents and may have to obtain a license, defend an infringement action, or challenge the validity of the patents in court. A license may be unavailable on terms and conditions acceptable to us, if at all. Patent litigation is costly and time consuming, and

we may be unable to prevail in any such patent litigation or devote sufficient resources to even pursue such litigation. If we do not obtain a license under necessary patents, are found liable for infringement, or are not able to have such patents declared invalid, we may be liable for significant money damages, encounter significant delays in bringing products to market, or be precluded from participating in the manufacture, use or sale of products or methods of treatment requiring such licenses.

We have also applied for a number of trademarks and service marks to further protect the proprietary position of our products. We have approximately 80 registered trademarks and service marks in the United States and approximately 390 registered trademarks and service marks in other jurisdictions. We also have pending trademark and service mark applications in the United States. We also rely on our trade secrets and those of our licensors, as well as other unpatented proprietary information, to protect our products. To the extent that our products have a competitive edge as a result of our reliance on trade secrets and unpatented know-how, our competitive position may be compromised if others independently develop products using the same or similar technologies or trade secrets.

We seek to protect our trade secrets and proprietary knowledge in part through confidentiality agreements with our employees, consultants, advisors and collaboration partners. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of our confidential information. In addition, if our employees, consultants, advisors or collaboration partners develop inventions or processes independently or jointly with us that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those third parties or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain patent and trade secret protection, for any reason, could have a material adverse effect on our business.

## **Employees**

As of February 20, 2013, we had approximately 610 employees. We consider our employee relations to be good.

## **About Jazz Pharmaceuticals plc**

Jazz Pharmaceuticals plc is a public limited company formed under the laws of Ireland (registered number 399192) and is the ultimate parent company to the Jazz Pharmaceuticals group of companies. The Jazz Pharmaceuticals plc corporate entity was originally formed as a private limited liability company in March 2005 under the name Azur Pharma Limited, and was subsequently re-registered as a public limited company under the name Azur Pharma Public Limited Company in October 2011. On January 18, 2012, the business of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in 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. Jazz Pharmaceuticals, Inc. was treated as the acquiring company in the Azur Merger for accounting purposes and the transaction was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. Our predecessor, Jazz Pharmaceuticals, Inc., was originally incorporated in California in March 2003 and was reincorporated in Delaware in January 2004. In the Azur Merger, all outstanding shares of Jazz Pharmaceuticals, Inc.'s common stock were canceled and converted into the right to receive, on a one-for-one basis, our ordinary shares. Our ordinary shares trade on the same exchange, The NASDAQ Global Select Market, and under the same trading symbol, "JAZZ," as the Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger.

Our principal offices are located at One Burlington Road, Dublin, 4 Ireland, and our telephone number is 353-1-634-7800. Our U.S. operations are located in Palo Alto, California and Philadelphia and Langhorne, Pennsylvania. Our international division is headquartered in Oxford, United Kingdom, with offices in Lyon,

France and elsewhere in Europe. Our website address is [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com). Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K. Service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

### **Available Information**

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, electronically with the U.S. Securities and Exchange Commission, or SEC. We make available on our website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com), free of charge, copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further copies of these reports are located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at [www.sec.gov](http://www.sec.gov).



## Item 1A. Risk Factors

*We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our ordinary shares could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should refer to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes.*

### **Risks Relating to Xyrem and the Significant Impact of Xyrem Sales**

***Xyrem is our largest selling product, and our inability to maintain or increase sales of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

Xyrem<sup>®</sup> is our largest selling product and our financial results are significantly influenced by sales of Xyrem, which accounted for 65% of our net product sales for the year ended December 31, 2012 and 88% of our net product sales for the year ended December 31, 2011, and our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2010 to 2011 and from 2011 to 2012, we cannot assure you that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in February 2013, and we cannot assure you that price adjustments we have taken or may take in the future have not already negatively affected, or will not in the future negatively affect, Xyrem sales volumes.

In addition to other risks described herein, our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, the most important of which are discussed below, including those related to:

- the potential introduction of a generic version of Xyrem;
- changed or increased regulatory restrictions, including changes to our risk management program, and the terms of the final REMS documents, for Xyrem, or regulatory actions by the FDA as a result of, or related to the matters raised in, the warning letter we received from the FDA in October 2011 or the Form FDA 483 we received in May 2012, as discussed in more detail in the risk factors below;
- our manufacturing partners' ability to obtain sufficient quota from the DEA to satisfy our needs for Xyrem;
- any supply, manufacturing or distribution problems arising with any of our manufacturing and distribution partners, all of whom are sole source providers for us;
- the availability of reimbursement from third party payors;
- changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement and coverage by federal healthcare programs;
- continued acceptance of Xyrem as safe and effective by physicians and patients, even in the face of negative publicity that surfaces from time to time; and
- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem.

These and the other risks described below related to Xyrem product sales and protection of our proprietary rights could have a material adverse effect on our ability to maintain or increase sales of Xyrem.

If sales of Xyrem were to decline significantly, we might need to reduce our operating expenses or to seek to raise additional funds, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects, or we might not be able to acquire, in-license or develop new products in the future to grow our business.

***If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.***

Although Xyrem is covered by patents covering its formulation, distribution system and method of use, two third parties have filed ANDAs seeking FDA approval of generic versions of Xyrem, and additional third parties may also seek to introduce generic versions of Xyrem. If one or more companies receive FDA approval of an ANDA, it is possible that such company or companies could introduce generic versions of Xyrem before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable.

On October 18, 2010, we received notice from Roxane that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem before expiration of the Orange-Book-listed patents relating to Xyrem. On December 10, 2012, we received notice from Amneal that Amneal has submitted an ANDA to the FDA seeking regulatory approval to market a generic version of Xyrem before expiration of the Orange-Book-listed patents relating to Xyrem. We have sued both Roxane and Amneal seeking to prevent them from introducing a generic version of Xyrem that would infringe our patents, but we cannot assure you that any of the lawsuits will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. Additional ANDAs could also be filed requesting approval to market generic forms of Xyrem. If an ANDA is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA is stayed until the earlier of (i) April 18, 2013 or (ii) a District Court decision finding that the patents that are the subject of our litigation with Roxane are invalid, unenforceable or not infringed. Our lawsuits with Roxane are ongoing. Although no trial date has been established, we do not expect a trial date or any decision by the District Court until after April 18, 2013. We do not know the status of Roxane's ANDA and cannot predict what actions the FDA or Roxane may take with respect to Roxane's ANDA. If Roxane's ANDA is approved before or at any time after the stay provided for under the Hatch-Waxman Act is lifted, Roxane may seek to launch a generic version of Xyrem prior to a District Court, or potential appellate court, decision in our ongoing patent litigation. While, in the event of such commercialization, Roxane would be liable to us for damages in the event we ultimately prevail in the patent litigation, we expect that the introduction of generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

On May 18, 2012, we submitted a Citizen Petition to the FDA that addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem. Among other actions requested of the FDA, this petition requested that the FDA (i) not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs and (ii) require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On November 13, 2012, the FDA denied this Citizen Petition. On July 10, 2012, we submitted a second Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, which did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition.

We are evaluating the FDA's responses to both Citizen Petitions and potential further actions that we may take with respect to the issues raised in, and the FDA's denials of, the Citizen Petitions. The FDA's denial of the Citizen Petitions does not have a direct impact on the merits of our ongoing lawsuits with Roxane and Amneal. However, we cannot predict the effect of the denial of either of our Citizen Petitions, or the FDA's

stated positions in its responses to the Citizen Petitions, on the timing of the potential introduction of a generic version of Xyrem. See the next risk factor in this Item 1A entitled *“The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.”*

A generic manufacturer would need to obtain quota from the DEA in order to manufacture both the active pharmaceutical ingredient and the finished product for a generic version of Xyrem. The DEA publishes an annual aggregate quota for the active pharmaceutical ingredient of Xyrem, and our supplier is required to request and justify allocation of sufficient annual manufacturing quota as well as additional manufacturing quota if needed throughout the year. Until 2011, our active pharmaceutical ingredient supplier obtained substantially all of the published annual aggregate quota for use in the manufacture of Xyrem. However, for each of 2012 and 2013, our supplier has been allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. As a result, a generic manufacturer may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In addition, our supplier has been allocated only a portion of the requested quota for 2013 to make the active pharmaceutical ingredient of Xyrem. Our finished product manufacturer for Xyrem was similarly allocated only a portion of the requested quota to make finished product. As a result, we anticipate that both our active pharmaceutical ingredient supplier and our finished product manufacturer will need to obtain increased quotas from the DEA for 2013.

After any introduction of a generic competitor, a significant percentage of the prescriptions written for Xyrem may be filled with the generic version, resulting in a loss in sales of Xyrem. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available. We expect that generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.***

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management and controlled distribution system that was implemented at the time Xyrem was approved, which includes parts of the Xyrem Success Program, to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. Our Xyrem Risk Management Program includes patient and physician education, a database of information so that we may track and report certain information and other elements. It also includes unique features that provide information about adverse events, including deaths, which is generally not available for other products that are not subject to similar risk management programs. As required by the FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to the FDA and could result in the FDA requiring changes to the Xyrem label or taking or requiring us to take other actions that could have an adverse effect on Xyrem’s commercial success.

While elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS, are deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act of 2007, or the FDAAA, the program is not in the form that is now required for REMS. FDAAA requires that certain products’ risk management programs and related documents that existed prior to the adoption of FDAAA, including the Xyrem Risk Management Program, be updated to comply with the current requirements for REMS documents. We have submitted updated REMS documents to the FDA, which are intended to conform the relevant elements of the Xyrem Risk Management Program to the current REMS formatting requirements, as well as to make other updates to the program and its documents. We have had

communications with the FDA with respect to our submitted REMS documents. These communications are ongoing, and we cannot predict the timing of finalization, or the final terms of, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

In addition, Section 505-1(i)(1) of the FDCA provides that (i) an ANDA with a referenced drug subject to the REMS requirements is required to have a REMS with the same or comparable elements as the referenced drug, such as a medication guide, a patient package insert and other “elements to assure safe use,” or ETASU, and (ii) the ANDA drug and the referenced drug shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and permit the ANDA holder to submit a separate but comparable REMS if the FDA determines that the burden of creating such a system outweighs its benefit or if the ANDA applicant certifies that it has been unable to obtain a license to any aspects of the REMS for the referenced drug product that are covered by a patent or a trade secret entitled to protection. The FDCA provides that the FDA may seek to negotiate a license between the ANDA sponsor and the sponsor of the listed product before granting a waiver. The FDCA further states that a REMS shall not be used by an NDA holder to block or delay generic drugs from entering the market. Accordingly, from time to time we may be face pressure to license or share our Xyrem Risk Management Program, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that may be taken by a third party to seek to license or share our REMS program. Furthermore, if we do not share our REMS with a generic competitor, the FDA may grant the generic competitor a waiver and allow the generic competitor to market a generic drug with a comparable REMS. In addition, the FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner.

On July 10, 2012, we submitted a Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, which did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. In the FDA’s response, the FDA stated that when the NDA holder has a deemed REMS, the FDA directs the ANDA applicant to work with the NDA holder to create a single shared system to implement the ETASU that will be approved as a final REMS. We cannot predict the outcome or impact on our business of any discussions with any ANDA applicant with respect to the potential creation of a single shared system. See the risk factor in this Item 1A entitled “*We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products.*”

It is also possible that the FDA may take the position that a potential generic competitor does not need to share or license aspects of our deemed REMS program in order to obtain approval of its ANDA. In the December 13, 2012 denial of our Citizen Petition described above, the FDA stated that if the FDA determines that an ANDA may be ready for approval before final approval of the REMS of a sponsor holding a deemed REMS, the FDA will direct the ANDA applicant to submit a proposed risk management plan with ETASU that are comparable to the ETASU that are approved for the referenced drug to have adequate risk management elements in place for the ANDA until the final REMS is approved. Thus, it is possible that the FDA may rely on this position as a basis to grant approval or tentative approval of an ANDA without a final REMS. We expect that the approval or tentative approval of an ANDA resulting 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.

Currently, our Xyrem Risk Management Program requires that all of the Xyrem sold in the United States must be shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under our program is cumbersome. While we have an exclusive agreement with the central pharmacy for Xyrem, ESSDS, through June 2015, if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem and our sales would be adversely affected. If we change our central pharmacy new contracts might be required with government and other insurers who pay for Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under our Xyrem Risk Management Program or any REMS that we are subject to in the future. Transitioning to a new central pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the United States, result in additional costs and expenses for us, and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA by us, as required. We reported these cases to the FDA when we discovered them, investigated the related data from ESSDS, as well as additional data we gathered, and submitted an analysis of the data to the FDA. In July 2012, we held a telephonic meeting with the FDA with respect to our analysis. Based in part on this meeting and our agreement with the FDA on a revised Xyrem label in December 2012, we believe that the FDA will not require any further data or analysis with respect to mortality during the historical period that was covered by our investigation and evaluation, and that no further action is required by us. However, there can be no assurance that the FDA will agree with our assessment, and the FDA may ultimately take, or require us to take, actions that may be costly or time consuming and/or that negatively affect the commercial success of Xyrem.

In October 2011, we received a warning letter from the FDA following a 2011 Form FDA 483 covering certain aspects of our adverse event reporting system for Xyrem and drug safety procedures related to the unreported deaths uncovered in April 2011. In May 2012, we received a Form FDA 483 at the conclusion of an FDA inspection conducted in May 2012, which noted the FDA investigators' observations with respect to our incomplete review of information from ESSDS related to potential Xyrem-related adverse events prior to 2011 and determination of whether there are additional adverse events that are required to be reported to the FDA based on such review; our investigation of serious unexpected adverse drug experiences, including insufficient documentation to demonstrate the past investigation; and our lack of a written procedure relating to one administrative aspect of our current drug safety monitoring procedures. We have completed the actions that we believe are required to address the observations in the May 2012 Form FDA 483, and we believe that we have submitted all data and completed all actions that are necessary to fully address the matters raised in the warning letter. We have submitted a request to the FDA to close out the warning letter, but we do not know whether the FDA will require further information or actions. In any event, we expect that the FDA will conduct a re-inspection before closing out the warning letter. We cannot predict either the timing or the final outcome of the FDA's regulatory compliance review. We do not know whether the FDA will take further action, or require us to take further action, with respect to our adverse event reporting, or whether the FDA will ultimately conclude we have not taken all appropriate corrective actions with respect to the May 2012 Form FDA 483 or the warning letter.

Regulatory authorities in other countries where Xyrem is sold may take similar actions. Any failure to demonstrate our substantial compliance with applicable regulatory requirements to the FDA's or any other regulatory authority's satisfaction could have a material and adverse effect on Xyrem sales and therefore on our business, financial condition, results of operations and growth prospects.

The FDA has required that Xyrem's label include a boxed warning regarding the risk of abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also

means, among other things, that the product cannot be advertised through reminder ads, or ads that mention the pharmaceutical brand name but not the indication or medical condition it treats. In addition, Xyrem's FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. We cannot predict whether the FDA will require additional warnings, including boxed warnings, to be included on Xyrem's label. For example, in December 2012, we updated our Xyrem label in conjunction with the FDA to include a new contraindication for the use of alcohol with Xyrem. Warnings in the Xyrem label and any limitations on our ability to advertise and promote Xyrem may have affected, and could in the future negatively affect, Xyrem sales and therefore our business, financial condition, results of operations and growth prospects.

### **Risks Relating to Our Business**

***While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other marketed products, and our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

In addition to Xyrem®, we have a portfolio of marketed products, including Erwinaze® (called Erwinase® in ex-U.S. markets) and Prialt®. Erwinaze, a biologic product, is used in conjunction with chemotherapy to treat patients with ALL with hypersensitivity to *E. coli*-derived asparaginase. Erwinaze is exclusively licensed to us, and manufactured for us, by the HPA and was approved by the FDA under a BLA, in November 2011 and launched in the U.S. market in the same month. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere.

Erwinaze represents an important part of our strategy to grow sales of our existing products. However, our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of challenges, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that population. Another challenge to growth is our need to assure sufficient supply of product on a timely basis as well as to apply for and receive marketing authorizations, through a mutual recognition process or otherwise, in certain additional countries so we can launch promotional efforts in those countries. We also face numerous risks that may impact Erwinaze sales, including manufacturing risks, regulatory risks, the development of new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL, the development of new treatment protocols for ALL that may not include asparaginase-containing regimens, difficulties with obtaining and maintaining profitable pricing and reimbursement arrangements and potential competition from biosimilar products. In addition, if we fail to comply with our obligations under our agreement with the HPA and lose exclusive rights to Erwinaze, or otherwise fail to maintain and grow sales of Erwinaze, our growth prospects could be negatively affected.

Prialt, an intrathecally administered infusion of ziconotide, was approved by the FDA in December 2004 for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or intrathecal morphine. We face many challenges in maintaining and growing sales of Prialt, including acceptance of intrathecal administration by patients and physicians and challenges for physicians with timely reimbursement for use of Prialt. In addition, the FDA has required that Prialt's label include a boxed warning regarding the risk of psychiatric symptoms and neurological impairment. We cannot predict whether the FDA will require additional warnings, or place any additional limitations on our ability to advertise and promote Prialt, which could negatively impact Prialt sales. In the fourth quarter of 2012, we began the roll-out of the NAVIGATOR Reimbursement and Access Program™, a new centralized distribution system for Prialt. In connection with the implementation of the new distribution system, we could experience disruptions that could negatively affect product sales.

Failure to maintain or increase prescriptions and revenue from sales of our marketed products other than Xyrem, including Erwinaze and Prialt, could have a material adverse effect on our business, financial condition,

results of operations and growth prospects. We may choose to increase the price of our marketed products, and we cannot assure you that price adjustments will not negatively affect our sales volumes. In addition, sales of Erwinaze may fluctuate significantly from quarter to quarter, depending on the number of patients receiving treatment, the dosing requirements of treated patients and other factors, and it may be difficult for us or investors to estimate Erwinaze revenue until we have more experience selling the product. The market price of our ordinary shares may decline if the sales of our products do not continue or grow at the rates anticipated by financial analysts or investors.

In addition, if we fail to obtain approvals for certain of our existing products in new indications or formulations, we will be unable to commercialize our products in new indications or formulations, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***We depend on single source suppliers and manufacturers for each of our products, product candidates and their active pharmaceutical ingredients. The loss of any of these suppliers or manufacturers, or delays or problems in the supply or manufacture of our products for commercial sale or our product candidates for use in our clinical trials, could materially and adversely affect our business, financial condition, results of operations and growth prospects.***

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredient and the finished product in sufficient quantities that meet detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state and non-U.S. regulations. If we or any of our third party suppliers or manufacturers encounter these or any other manufacturing, quality or compliance difficulties with respect to any of our products, we may be unable to meet the commercial demand for such products, which could adversely affect our business, financial condition, results of operations and growth prospects.

We do not have our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. The availability of our products for commercial sale depends upon our ability to procure the ingredients, raw materials, packaging materials and finished products we need from third parties. In part due to the limited market size for our products and product candidates, we have entered into supply and manufacturing agreements with suppliers and manufacturers, each of which is currently our single source for each of our marketed products and for the active pharmaceutical ingredients used in some of these products.

We maintain very limited inventories of certain of our products, including Xyrem and Erwinaze, as well as the ingredients or raw materials used to make our products. Our limited inventory puts us at significant risk of not being able to meet product demand. If our suppliers and manufacturers, including any new suppliers without a track record of meeting our supply needs, for any reason do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, if one of our suppliers or manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or manufacturers could require us to obtain regulatory clearance in the form of a “prior approval supplement” and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take up to two years, or longer in certain

cases, to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a finished product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA or similar international regulatory body approval of a new supplier or manufacturer.

The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem, sodium oxybate, is a Schedule I controlled substance, our supplier of sodium oxybate, as well as our finished product manufacturer, must each obtain separate DEA quotas in order to supply us with sodium oxybate and Xyrem. Since the DEA typically grants quotas on an annual basis, our sodium oxybate supplier and Xyrem manufacturer are required to request and justify allocation of sufficient annual DEA quotas as well as additional DEA quotas if our commercial or clinical requirements exceed the allocated quotas throughout the year. In the past, we have had to engage in lengthy legal and other efforts to obtain the needed quotas after the original annual quotas had first been allocated. For 2013, our supplier has been allocated only a portion of the requested quota to make the active pharmaceutical ingredient of Xyrem. Our finished product manufacturer for Xyrem was similarly allocated only a portion of the requested quota to make finished product. As a result, we anticipate that both our active pharmaceutical ingredient supplier and our finished product manufacturer will need to obtain increased quotas from the DEA for 2013. We cannot assure you sufficient quotas will be received from the DEA to meet our needs, and if we and our supplier and manufacturer cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

In addition, the FDA and similar international regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. If there are delays in qualifying new manufacturers or facilities or a new manufacturer is unable to obtain a sufficient quota from the DEA, if required, or to otherwise meet FDA or similar international regulatory body's requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, particularly since we do not have secondary sources for supply and manufacture of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates.

Our current supplier of sodium oxybate, Siegfried, was approved by the FDA in late 2011 and became our sole supplier in 2012. While we expect Siegfried will continue to be our sole supplier of sodium oxybate for the foreseeable future, we cannot assure you that Siegfried can or will continue to supply on a timely basis, or at all, sufficient quantities of active pharmaceutical ingredient to enable the manufacture of the quantities of Xyrem that we need.

Erwinaze is licensed to us, and manufactured for us, by the HPA, which is our sole supplier for Erwinaze. During the review and approval process by the FDA of the BLA for Erwinaze, EUSA Pharma agreed to a number of post-marketing commitments related to the manufacture of Erwinaze by the HPA. In the past, there has been a disruption of supply of Erwinaze in the European market due to manufacturing challenges. Failure by the HPA to comply with regulatory requirements, including post-marketing commitments, could adversely affect its ability to supply Erwinaze to us and could result in FDA approval being revoked or product recalls, either of which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. We cannot assure you that the HPA will be able to continue to supply our ongoing commercial needs of Erwinaze in a timely manner, or at all, especially if our demand for product continues to increase. We have limited inventory of Erwinaze. If the HPA experiences a disruption in supply or capacity constraints as a result of increased demand, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach by the HPA or the cessation of the HPA's business. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process



to the backup or alternative supplier would be difficult, costly and time-consuming and would increase the likelihood of a delay or interruption in manufacturing or a shortage of supply of Erwinaze. Any failure of the HPA to supply necessary quantities of Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, if the FDA or any non-U.S. regulatory authority mandates any changes to the specifications for Erwinaze, we may face challenges having product produced to meet such specifications, and the HPA may charge us more to supply Erwinaze meeting such specifications, which may result in additional costs to us and may decrease any profit we would otherwise achieve with Erwinaze.

We are in the process of changing our supplier for ziconotide, the active ingredient in Prialt, and have commenced the transfer to the new supplier. We are also in the process of changing our finished product manufacturer for Prialt. There can be no assurance that the new supplier of ziconotide will be approved by the FDA or non-U.S. regulatory authorities or that the new manufacturer of Prialt will be approved by non-U.S. regulatory authorities, or that our commercial supplies of such products will be sufficient until such approvals have been obtained. Any failure to obtain and maintain sufficient commercial supplies could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

For FazaClo LD, FazaClo HD and Luvox CR, we have single sources of supply for both the active pharmaceutical ingredient and finished product, and should it become necessary to change suppliers, the process could take two years or longer. Pursuant to our agreement, Douglas Pharmaceuticals has agreed to supply Versacloz finished product to us.

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products or ingredients to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with the FDA's current cGMP requirements. In complying with cGMP requirements, our suppliers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. DEA regulations also govern facilities where controlled substances such as sodium oxybate are manufactured. Manufacturing facilities are subject to periodic unannounced inspection by the FDA, the DEA and other regulatory authorities, including state authorities and similar authorities in non-U.S. jurisdictions. Failure to comply with applicable legal requirements subjects the suppliers to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with the ingredients or finished products we need.

Our ability to develop and deliver products in a timely and competitive manner depends on our third party suppliers and manufacturers being able to continue to meet our ongoing commercial needs. Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products, or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects.

***We may not be able to successfully identify and acquire, in-license or develop additional products or product candidates to grow our business, and, even if we are able to do so, we may not be able to successfully manage the risks associated with integrating any products or product candidates we may acquire in the future into our product portfolio or we may otherwise fail to realize the anticipated benefits of these acquisitions.***

We intend to grow our business over the long term by acquiring or in-licensing and developing additional products and product candidates that we believe have significant commercial potential. Future growth through acquisition or in-licensing will depend upon the availability of suitable products and product candidates for acquisition or in-licensing on acceptable prices, terms and conditions. Any growth through development will depend upon our identifying and obtaining product candidates, our ability to develop those product candidates and the availability of funding to complete the development of, obtain regulatory approval for and commercialize

these product candidates. Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities.

We cannot assure you that we will be able to successfully manage these risks or other anticipated and unanticipated problems in connection with an acquisition or in-licensing. We may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including the possibility that a product candidate proves not to be safe or effective in later clinical trials, a product fails to reach its forecasted commercial potential or the integration of a product or product candidate gives rise to unforeseen difficulties and expenditures. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business.

***We may not realize the anticipated financial and strategic benefits from the Azur Merger and/or the EUSA Acquisition or be able to successfully integrate the acquired businesses.***

The Azur Merger, which was completed in January 2012, and the EUSA Acquisition, which was completed in June 2012, created numerous uncertainties and risks, and have required, and will continue to require, significant efforts and expenditures, including with respect to integrating the acquired businesses with our historical business. We may encounter unexpected difficulties, or incur unexpected costs, in connection with our transition activities and integration efforts, which include:

- the risk that our lack of experience in new markets, including the oncology market, will not allow us to achieve growth in, or maintain current levels of, sales of our products in such markets;
- the strain on, and need to expand, our existing operational, technical, financial and administrative infrastructure, including our financial controls and reporting systems and procedures and disaster recovery procedures, in connection with integrating three different businesses and operations;
- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisitions, including professional fees to comply with corporate and tax laws and financial reporting requirements in a number of countries in Europe, costs and expenses incurred in connection with travel, and additional costs we may incur going forward as a result of our corporate structure that includes an increased number of subsidiaries in multiple additional countries;
- the diversion of our management's attention to integration of operations; and
- any unanticipated liabilities for activities of or related to Azur Pharma or EUSA Pharma or any of their operations, products or product candidates that occurred prior to the closing of the respective acquisitions or before adequate risk mitigation could be accomplished.

If any of these factors impairs our ability to integrate the acquired businesses successfully or on a timely basis, we may not be able to realize the anticipated financial and strategic benefits from combining the businesses. In addition, we may be required to spend additional time or money on integration activities that otherwise would be spent on the development and expansion of our business. If we fail to integrate or otherwise manage the acquired businesses successfully and in a timely manner, resulting operating inefficiencies could increase costs and expenses more than we planned, could negatively impact the market price of our ordinary shares and otherwise distract us from execution of our strategy. Failure to maintain effective financial controls and reporting systems and procedures could also impact our ability to produce timely and accurate financial statements.

As a result of these transactions, we have grown rapidly, and our business and corporate structure has become substantially more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage the increased complexity of the combined business and our failure to

successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, as a result of these transactions, our financial statements and results of operations in prior years may not provide meaningful guidance to form an assessment of the prospects or potential success of our future business operations.

***We have substantially expanded our international footprint and operations, and we may expand further in the future, but we do not have substantial experience in international markets and may not achieve the results that we or our shareholders expect.***

We are headquartered in Dublin, Ireland and have multiple offices in the United States, the United Kingdom, and other countries in Europe. Our headcount has grown from approximately 260 employees at the end of 2011 to approximately 610 in February 2013. This includes employees in ten countries in Europe, a European commercial presence, and a complex distribution network for products in Europe and additional territories. In addition, we may expand our international operations into other countries in the future, either organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, because we are conducting a larger portion of our business outside of the United States, we are now subject to a variety of risks and complexities that may materially and adversely affect our business, results of operations and financial condition, including, among other things:

- the increased complexity and costs inherent in managing international operations;
- diverse regulatory, financial and legal requirements, and any changes to such requirements in one or more countries where we are located or do business;
- country-specific tax laws and regulations;
- complying with applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions and any changes to them;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
- changes in non-U.S. currency rates; and
- regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

Failure to effectively manage these risks could have a material adverse effect on our business.

In recent years, the global economy has been impacted by the effects of an ongoing global financial crisis, including the European sovereign debt crisis, which has caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in Europe, could adversely affect our revenues, financial condition or results of operations, if, for example, our customers in Europe fail to pay or delay payments owed to us for our products.

***The commercial success of our products depends upon their market acceptance by physicians, patients, third party payors and the medical community.***

Physicians may not prescribe our products, in which case we would not generate the revenues we anticipate from product sales. Market acceptance of any of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved, including any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry or labeling restrictions;

- the prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and
- the availability of adequate reimbursement by third parties.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects. For example, from time to time, there is negative publicity about illicit GHB, and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Patients, physicians and regulators may therefore view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of its connection to GHB. Xyrem's label includes information about adverse events from GHB.

***We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have.***

The commercial opportunities of our products or potential future products may be reduced or eliminated if our competitors develop or acquire and commercialize generic or branded products that are safer or more effective, have fewer side effects, are easier to administer or are less expensive than our products. Many of our competitors, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. They can spend more on, and have more expertise in, research and development, regulatory, manufacturing, distribution and sales activities. As a result, our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may and may market their products more effectively than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

In addition, many of our competitors are able to deploy more personnel to market and sell their products than we do. We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization internationally, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization. We may not be able to achieve any necessary growth in a timely or cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect sales of our products. If our specialty sales forces and sales organization is not appropriately sized to adequately promote any current or potential future products, the commercial opportunity for our current or potential future products may be diminished.

In 2012 we added Erwinaze, as well as other smaller products in the oncology supportive care market, to our product portfolio. We compete with a significant number of pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in the oncology and oncology supportive care markets, and our failure to compete effectively in this area could negatively affect our sales of Erwinaze and other products.

***Conducting clinical trials is costly and time consuming, and the outcomes are uncertain. A failure to prove that our product candidates are safe and effective in clinical trials would require us to discontinue their development, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.***

We expect to increase our research and development organization to pursue targeted development activities in 2013. We have several development pipeline projects, including the development of two product candidates: Asparec<sup>®</sup>, which is in a Phase I clinical trial in Europe, and Leukotac<sup>®</sup>, which is in a Phase III clinical trial also in Europe. We also intend to pursue clinical development of other product candidates that we may acquire or in-license in the future. Significant clinical, development and financial resources will be required to progress these product candidates to obtain necessary regulatory approvals and to develop them into commercially viable products. We have not been successful in developing any product candidates that received FDA approval in the past. If a product candidate fails at any stage of development, it will not receive regulatory approval, we will not be able to commercialize it, or potentially even to continue to receive modest revenue being generated as a result of sales under a named patient program, such as in the case of Leukotac, and we will not receive any return on our investment from that product candidate.

As a condition to regulatory approval, each drug product candidate must undergo extensive and expensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. Clinical testing can take many years to complete and failure can occur any time during the clinical trial process. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Clinical trials can be delayed or halted for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- delays in recruiting patients to participate in a clinical trial;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA's Good Clinical Practices;
- unforeseen safety issues, including negative results from ongoing preclinical studies and adverse events associated with product candidates;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- failure of our third-party clinical trial managers to satisfy their contractual duties, comply with regulations or meet expected deadlines; or
- insufficient funds to complete the trials.

The results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. In that case, the FDA or the equivalent in jurisdictions outside of the United States may determine our data is not sufficiently compelling to warrant marketing approval, may require we engage in additional clinical trials, or provide further analysis which may be costly and time-consuming. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials.

We are currently undertaking a Phase 1 clinical trial of Asparec. Under our license agreement with Alizé under which we obtained rights to develop and commercialize Asparec, we are subject to contractual obligations to meet certain development milestones within certain timeframes. Our ability to meet each of these milestones is uncertain, and depends upon a number of factors, including our ability to obtain clinical material and to develop a clinical program meeting the development requirements of both the FDA and European regulatory authorities in a timely fashion. If our development activities are delayed for any reason and we fail to meet our licensing obligations to Alizé, we may lose our rights to develop and commercialize Asparec.

Our development pipeline projects include not only new product candidates, but also projects involving line extensions for existing products and the generation of additional clinical data for existing products. For example, we are conducting a pharmacokinetic clinical trial of the intravenous administration of Erwinaze in the North America, to generate support for approval for the intravenous administration of Erwinaze, which is intended to provide more convenient dosing for patients. We also plan to conduct a clinical trial including pharmacokinetic efficacy measures to evaluate Erwinaze in adolescents and young adults with ALL who are hypersensitive to *E. coli*-derived asparaginase, which is expected to begin in the second half of 2013. These development efforts may not be successful, and any adverse events or other information generated during the course of our studies related to existing products could result in action by the FDA or any non-U.S. regulatory agency, which may restrict our ability to sell, or sales of, currently marketed products, or such events or other information could otherwise have a material adverse effect on a related commercial product. Any failure or delay in completing clinical trials for line extensions or the generation of additional clinical data could materially and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

***We rely on third parties to conduct our clinical trials, and if they do not properly and successfully perform their legal and regulatory obligations, as well as their contractual obligations to us, we may not be able to obtain regulatory approvals for our product candidates.***

We rely on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as FDA's and non-U.S. regulatory agencies' requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and non-U.S. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's

cGMP regulations and similar regulations outside of the United States. Our failure, or the failure of our product manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

***If we fail to attract, retain and motivate key personnel or to retain the members of our executive management team, our operations and our future growth may be adversely affected.***

Our success and our ability to grow depend in part on our continued ability to attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team and other critical personnel, all of whom work on many complex matters that are essential to our success. We do not carry “key person” insurance. The loss of services of one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities. Any employee may terminate his or her employment at any time without notice or with only a few months’ notice and without cause or good reason. Since the completion of the Azur Pharma and EUSA Pharma transactions, several members of the former management teams of those entities, as well as other employees, have left our company to pursue other opportunities. The resulting loss of institutional knowledge may negatively impact our achievement of the anticipated benefits of those transactions.

In addition, to grow our company we will need additional personnel. Competition for qualified personnel in the pharmaceutical industry is very intense. If we lose key personnel or are unable to attract, retain and motivate quality individuals, our business, financial condition, results of operations and growth prospects could be adversely affected.

We also depend on the unique abilities, industry experience and institutional knowledge of the members of our board of directors to efficiently set company strategy and effectively guide our executive management team. We cannot be certain that future board turnover will not negatively affect our business in the future.

### **Risks Related to Our Intellectual Property**

***It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.***

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our products and product candidates and their use and the methods used to manufacture and distribute them, as well as successfully defending these patents against third party challenges, and successfully protecting our trade secrets. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importation by third parties depends on the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. Although Xyrem® is covered by patents covering its formulation, distribution system and method

of use, including a new formulation and method of use patent issued by the USPTO in September 2012 and a new patent for the treatment of narcolepsy issued by the USPTO in December 2012, third parties are seeking to introduce a generic equivalent of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem. If one or more companies receive FDA approval of an ANDA, it is possible that such company or companies could introduce generic versions of Xyrem before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable.

On December 10, 2012, we received a Paragraph IV Certification from Amneal Pharmaceuticals, LLC, or Amneal, that it filed an ANDA with the FDA requesting approval to market a generic version of Xyrem before the expiration of the Orange-Book-listed patents relating to Xyrem. Previously, on October 18, 2010, we received notice that Roxane filed an ANDA with the FDA requesting approval to market a generic version of Xyrem before the expiration of the Orange-Book-listed patents relating to Xyrem. If either of these applications is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Additional ANDAs could also be filed requesting approval to market generic forms of Xyrem; if those applications for generics were approved and the generics were launched, sales of Xyrem would decrease. We have sued both Roxane and Amneal to prevent either from introducing a generic version of Xyrem that would infringe our patents, but we cannot assure you that the lawsuit will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. See the risk factor in this Item 1A entitled *“If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.”*

Azur Pharma received Paragraph IV certifications from three generic manufacturers, two in 2008 and one in 2010, relating to generic versions of FazaClo<sup>®</sup> LD. Azur Pharma and CIMA, our licensor and whose drug-delivery technology is incorporated into FazaClo LD, filed lawsuits in response to each certification. In July 2011, Azur Pharma, CIMA, Barr Laboratories (one of the three generic manufacturers) and Teva, which had acquired Barr Laboratories, entered into an agreement settling the patent litigation and granting a license of our rights to have manufactured, market and sell a generic version of FazaClo LD and FazaClo HD. The sublicenses for FazaClo LD commenced in July 2012; the sublicense for FazaClo HD will commence in May 2015 or earlier upon the occurrence of certain events. In August 2011, Azur Pharma received a Paragraph IV certification notice from Teva advising that Teva had filed an ANDA with the FDA seeking approval to market a generic version of FazaClo HD. As noted above, FazaClo HD was covered under the July 2011 settlement agreement with Teva. In the July 2011 settlement agreement, Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma’s rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product at the end of August 2012, which is having a negative impact on our sales of FazaClo LD and may have a negative impact on our sales of FazaClo HD in future periods.

The two formulation patents covering FazaClo LD and FazaClo HD that we license from CIMA are under re-examination by the USPTO and both of the re-examination proceedings have proceeded to appeal at the USPTO. It is currently not possible to predict whether these re-examination proceedings will result in one or both of the patents being fully or partly invalidated. Any decision on the part of the USPTO that results in one or both of the patents being fully or partly invalidated could accelerate the entry of additional generic competitors for FazaClo LD and FazaClo HD.

The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.



On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has issued some and is developing additional regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until March 2013. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;
- our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- our issued patents and the issued patents of our licensors or partners may be vulnerable to legal challenges as a result of changes in applicable law;
- we may not develop additional proprietary products that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets and other unpatented proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Certain of the products we sell have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. For example, Erwinaze<sup>®</sup> has no patent protection, and we therefore must rely on trade secrets and other unpatented proprietary information in order to obtain a competitive advantage, which we may be unable to do. Erwinaze, as a biologic product approved under a BLA, is subject to

the BPCIA. The BPCIA establishes a period of twelve years of data exclusivity for reference products in order to preserve incentives for future innovation, protecting data included by the applicant in a BLA by prohibiting others from gaining FDA approval based in part on reliance on, or reference to, the data in the BLA during a twelve-year period. The FDA is in the process of implementing the BPCIA and has not established final guidelines for administering the review and approval of applications for data exclusivity. We expect that Erwinaze would receive data exclusivity in the United States through 2023 under the BPCIA. While Erwinaze has orphan drug marketing exclusivity for a seven-year period from its FDA approval in the United States until November 2018, and is expected to receive data exclusivity in the United States through 2023 under the BPCIA, it is possible that a potential competitor might obtain earlier approval from the FDA based upon an approval application that does not rely on or refer to data in our BLA for Erwinaze. In the European Union, the regulatory data protection and thus regulatory exclusivity period for Erwinaze has lapsed. This also means that any new marketing authorizations for Erwinaze in other European Union member states will not receive any regulatory data protection. If a biosimilar product to Erwinaze is approved in the future in the United States or in other countries where it is sold, a significant percentage of the prescriptions written for Erwinaze may be filled with the biosimilar version, resulting in a loss in sales of Erwinaze, and there may be a decrease in the price at which Erwinaze can be sold. Competition from a biosimilar product to Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, although there are patent applications for Asparec pending in the United States and 28 other countries, Asparec is not yet covered by any issued patents. Asparec was granted orphan drug designation by the FDA subject to certain conditions. In addition, the FDA has not yet clarified whether Asparec is eligible to receive data exclusivity under the BPCIA. If we fail to obtain orphan drug marketing exclusivity and/or data exclusivity, and if we also fail to successfully execute on other strategies to protect our intellectual property with respect to Asparec, including protection by one or more issued patents, Asparec would be subject to competition from a biosimilar product, which could have a material adverse effect on our ability to recognize any return on our investment in the development of this product as well as on our future growth prospects.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. While the ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to contractual limitations, these contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our innovations and other confidential information, then our ability to obtain patent protection or protect our proprietary information may be jeopardized. Moreover, a dispute may arise with our research and development collaborators over the ownership of rights to jointly developed intellectual property. Such disputes, if not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

***We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products.***

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and non-U.S. counterparts, and may file additional U.S. and non-U.S. patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted. Moreover, in part because of prior research performed and patent applications submitted in the same manner or similar fields, there can be no assurance that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents, our licensed patents or our partners' patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party's activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity. We are prosecuting lawsuits against the generic manufacturers who delivered Paragraph IV certifications to us with respect to Xyrem and FazaClo LD. See Item 3. "Legal Proceedings." We cannot assure you that these, or other lawsuits we may file in the future, will be successful in stopping the infringement of our patents, that any such litigation will be cost-effective, or that the litigation will have a satisfactory result for us.

A third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights, or that we or such partners are infringing, misappropriating or otherwise violating other intellectual property rights, and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Such lawsuits are costly and could affect our results of operations and divert the attention of management and development personnel. There is a risk that a court could decide that we or our partners are infringing, misappropriating or otherwise violating third party patent or other intellectual property rights, which could be very costly to us and have a material adverse effect on our business.

The pharmaceutical and life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many non-U.S. jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors' or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent and other intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We own patents and trade secrets that cover elements of the Xyrem Risk Management Program. As a result of the implementation of the FDAAA, we have submitted updated REMS documents to the FDA, which are intended to conform the relevant elements of the Xyrem Risk Management Program to the current REMS formatting requirements, as well as to make other updates to the program and its documentation. We have had communications with the FDA with respect to our submitted REMS documents. These communications are

ongoing, and we cannot predict the timing of finalization, or the final terms of, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem. In particular, if certain provisions of our Xyrem Risk Management Program that are currently protected by our patents are changed as part of updating our REMS documents, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced, as certain claims of our patents may not provide as much protection in a modified REMS structure. The interpretation of intellectual property protections and the effect of these protections are extremely complex, and we cannot predict the impact of any changes to our REMS documents on our business.

## **Risks Related to Our Industry**

***The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates.***

The research, testing, manufacturing, labeling, advertising and promotion, distributing and exporting of pharmaceutical products are subject to extensive regulation, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our product candidates. We are not permitted to market our product candidates in the United States or countries in Europe until we receive approval from the FDA or the competent European authorities, respectively, generally of a NDA or BLA. The application must contain information on the drug or biological candidate, including data from the preclinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability. Submission of an application does not assure approval for marketing in any jurisdiction, and we may encounter significant difficulties or costs in our efforts to obtain approval to market products. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs.

If the FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks, we may be required to include a proposed REMS as part of an NDA or otherwise, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide information to consumers about the drug's risks and benefits. For example, the FDA requires a REMS for Xyrem®, discussed in detail under the risk factor "*The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem*" above, and other products that we sell are or may become subject to a REMS specific to our product or shared with other products in the same class of drug. We cannot predict the impact that any new REMS requirements applicable to any of our products would have on our business.

***Healthcare law and policy changes, including those based on recently enacted legislation, may impact our business in ways that we cannot currently predict and these changes could have a material adverse effect on our business and financial condition.***

In March 2010, the President signed the Healthcare Reform Act. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, and fraud and abuse and enforcement. These changes will

impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. The Healthcare Reform Act also makes changes to the Medicaid Drug Rebate Program, discussed further herein, including increasing the minimum rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products.

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014 and thereafter, and their details will be shaped significantly by implementing regulations that have yet to be finalized. Earlier this year, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, the Supreme Court struck down a provision in the Healthcare Reform Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014 than anticipated when Congress passed the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall, which could impact our sales, business and financial condition.

While the constitutionality of key provisions of the Healthcare Reform Act was upheld by the Supreme Court, legislative changes to it remain possible. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates or could limit or eliminate our future spending on development projects.

In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Likewise, in the countries in the EU, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to health care cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third-party payors, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products.

To help patients afford our products, we have various programs to assist them, including patient assistance programs, a Xyrem free product voucher program and co-pay coupon programs for certain products. The co-pay coupon programs of other pharmaceutical manufacturers are the subject of ongoing class action lawsuits first filed in 2012 and challenging their legality under a variety of federal and state laws, and our co-pay coupon programs could become the target of similar lawsuits. In addition, co-pay coupon programs, including our program for Xyrem, have received some negative publicity related to their use to promote branded pharmaceutical products over other less costly alternatives. It is possible that the outcome of the pending

litigation against other manufacturers and/or the introduction and enactment of new legislation could restrict or otherwise negatively affect these programs, which could result in fewer patients using affected products and therefore could have a material adverse effect on our sales, business and financial condition.

***We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.***

*Oversight by FDA and Equivalent Non-U.S. Regulatory Authorities*

We are subject to significant ongoing regulatory obligations with respect to our marketed products, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of our products are, and any of our product candidates that may be approved by the FDA or European and other non-U.S. regulatory authorities will be, subject to extensive and ongoing regulatory requirements. These requirements apply both to us and to third parties we contract with to perform services and supply us with products. Failure by us or any of our third party partners, including suppliers, manufacturers and distributors and our central pharmacy for Xyrem, to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to approve a product candidate, withdrawal of product approval, notices of violation, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall or seizure, total or partial suspension of production or distribution, interruption of manufacturing or clinical trials, operating restrictions, injunctions; suspension of licenses, civil penalties and/or criminal prosecution, any of which could have a significant impact on our sales, business and financial condition.

If we receive regulatory approvals to sell our products, the FDA and other non-U.S. regulatory authorities in Europe or other countries where our products are approved may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the commercial potential of the product. If we become aware of problems with any of our products in the United States or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us. In such an instance, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits. Under regulations in Europe related to pharmacovigilance, or the assessment and monitoring of the safety of drugs, we may be required to conduct a labor intensive collection of data regarding the risks and benefits of marketed products and may be required to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time consuming and expensive and could impact our profitability.

The FDA approved the BLA for Erwinaze<sup>®</sup> in the United States in November 2011, subject to certain post marketing requirements, including developing and validating assays and conducting certain non-clinical studies. In addition, the BLA approval for Erwinaze is subject to compliance with numerous post marketing commitments, including certain commitments which must be met by the HPA with respect to product manufacturing, which are outside of our control. While activities are underway to complete the post marketing requirements and to comply with the post marketing commitments, if we or the HPA fail to do so within the timeframe established by the FDA, or if the results of the non-clinical studies raise concerns or other issues for the FDA, our approval to market Erwinaze in the United States may be withdrawn or otherwise jeopardized.

For a patient to be prescribed Prialt<sup>®</sup>, the patient must have a surgically implanted infusion pump and the FDA has approved Prialt for use with Medtronic's SynchroMed<sup>®</sup> II programmable implantable pump. Any regulatory action involving the pumps or Prialt's delivery via the pumps could materially adversely impact sales of Prialt.

In June 2009, the FDA posted an announcement regarding a potential safety signal associated with FazaClo®. The posting stated that FazaClo had been found to exhibit a higher proportion of adverse events with a fatal outcome versus total adverse events compared to other clozapine products. The posting also stated that the reported events in the cases with fatal outcome are similar for FazaClo and other clozapine products. Although Azur Pharma investigated and we believe that the difference in the cited ratio between FazaClo and other marketed clozapine products does not reflect an underlying adverse safety signal, we cannot assure you that additional information we may learn will not modify our current assessment, that the FDA will agree with this assessment or that the FDA will not take further actions related to the potential safety signal, any of which could have a material adverse effect on our results of operations.

We have not obtained marketing authorizations and/or may not have always sufficiently updated the marketing authorization approval dossiers for Erwinase and several other medicinal products or drugs in all of the countries in Europe in which we sell those products. For example, in some EU countries where we do not have a marketing authorization, Erwinase is being provided to patients on the basis of named patient programs or temporary use authorizations. In addition, we may not be able to maintain our marketing authorizations in all countries in which we currently have marketing authorizations. If any country's regulatory authorities determine that we are promoting Erwinase without a marketing authorization in place, we could be found to be in violation of pharmaceutical advertising law or the regulations permitting sales under named patient programs or temporary use authorizations, in which case we may be subject to financial or other penalties.

The FDA requires advertising and promotional labeling to be truthful and not misleading, and that products be marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA routinely provides its interpretations of that authority in informal communications and also in more formal communications such as untitled letters or warning letters, and although such communications are not final agency decisions, companies may decide not to contest the agency's interpretations so as to avoid disputes with the FDA, even if they believe the claims to be truthful, not misleading and otherwise lawful. For example, in September 2012, we received a warning letter from the FDA related to a direct-to-consumer patient brochure for FazaClo. We were no longer using the allegedly violative promotional materials at the time we received the letter, but reviewed all of our other promotional materials for FazaClo in accordance with the letter. We agreed with the FDA on plans for correcting the promotional materials and disseminating the corrective messages to healthcare providers, patients and consumers and began implementation of the corrective actions in accordance with the agreed-upon plans in February 2013. We believe that we have taken necessary actions required to fully address the agency's concerns. However, there can be no assurance that the FDA will agree with our assessment. The FDA could take further action, could require us to take further action, with respect to our FazaClo promotional materials, or could otherwise conclude we have not taken all appropriate corrective actions with respect to the warning letter. The FDA or other regulatory authorities may disagree with our response to the warning letter or challenge other of our promotional materials or activities in the future, through additional enforcement action, which may have a negative impact on our sales and/or may subject us to financial or other penalties.

The FDA and other governmental authorities also actively enforce regulations prohibiting off-label promotion, and the government has levied large civil and criminal fines against companies for alleged improper promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies. For example, a predecessor company to Jazz Pharmaceuticals, Inc. was investigated for off-label promotion of Xyrem, and, while Jazz Pharmaceuticals, Inc. was not prosecuted, as part of the settlement Jazz Pharmaceuticals, Inc. entered into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services, which extended through mid-2012. The investigation resulted in significant fines and penalties, which Jazz Pharmaceuticals, Inc. has paid, and the corporate integrity agreement required us to maintain a comprehensive compliance program. Failure to maintain a comprehensive and effective compliance program, and to integrate the operations of the Azur Pharma and EUSA Pharma compliance programs into a combined comprehensive and effective compliance program on a timely basis, could subject us

to a range of regulatory actions that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products.

Various state agencies oversee pharmaceutical compounding activities. Compounded drugs are made by certain pharmacies, typically by combining ingredients (prescription and/or over-the-counter) to make a formulation that is not readily available to patients and/or approved by the FDA. A number of problems have been associated with the making and use of compounded drugs, including product contamination and product toxicity. Improperly compounded products can pose serious public health issues, as evidenced by the recent fungal meningitis outbreak in the United States which was traced to compounded drugs from the New England Compounding Center. Pharmaceutical products administered intrathecally, such as Prialt, are frequently compounded by pharmacies for off-label use, a process over which we have no control. If any of our products are used in compounded drugs, we may have exposure to claims by patients treated with compounded formulations containing our products and to regulatory action by relevant government agencies. Any such claims or regulatory actions could result in harm to our reputation and have a negative effect on our business.

#### *Other Regulatory Authorities*

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the Department of Justice, the FTC, the U.S. Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those non-U.S. countries in which we commercialize our products. In addition to the FDCA, other federal, state and non-U.S. statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government healthcare programs. Our partners, including our suppliers, manufacturers and distributors and the central pharmacy for Xyrem, are subject to many of the same requirements.

These requirements include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. In addition to quota requirements, the DEA imposes various registration, importing, exporting, recordkeeping and reporting requirements, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the CSA. The states also impose similar requirements for handling controlled substances. The United States is a party to the 1971 Convention. In October 2012, the WHO sent a recommendation to the United Nations Commission on Narcotic Drugs, or CND, to reschedule GHB, under the 1971 Convention from its current Schedule IV status to Schedule II status. While the DEA imposes its own scheduling requirements in the United States under the CSA, the United States is obligated as a signatory to the 1971 Convention to ensure that drug scheduling in the United States is consistent with its obligations under the international treaties. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, if GHB is rescheduled internationally, Xyrem and/or sodium oxybate may be subject to more restrictive registration, recordkeeping, reporting, importing, exporting and other requirements. In the United States, under DEA regulations, the Xyrem finished product is currently classified as a Schedule III controlled substance, with sodium oxybate, classified as a Schedule I controlled substance. Although sodium oxybate and Xyrem are already subject to more restrictive regulations in the United States than required under the 1971 Convention, a decision by the CND to reschedule GHB would result in sodium oxybate and Xyrem being subject to more restrictive registration, recordkeeping, importing, exporting, reporting and other requirements in Europe and certain other countries than are currently in place given GHB's Schedule IV status under the 1971 Convention. The CND is expected to review the WHO recommendation at its annual meeting in March 2013. If GHB is rescheduled as a Schedule II substance under the 1971 Convention, we will likely be subject to additional regulatory requirements outside of the United States and may be subject to additional regulatory requirements in the United States. Failure by us or any of our partners, including suppliers,



manufacturers and distributors, to comply with such requirements could result in, among other things, additional operating costs to us, delays in shipments outside or into the United States and adverse regulatory actions.

In addition, pursuant to the Export Administration Regulations, we are required to obtain a license from the U.S. Department of Commerce prior to the exportation of certain materials and technical information related to Prialt, a synthesized conotoxin, which is a designated controlled biological toxin.

The U.S. federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. We seek to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

The Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. In addition, in recent years the government has pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. A number of states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Additional states are considering or recently have considered similar proposals. Non-U.S. governments often have similar regulations which we also will be subject to in those countries where we market and sell products.

Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. The FCPA generally prohibits the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. The UK Bribery Act prohibits companies which do business with the United Kingdom and their employees and representatives from giving, offering, or promising bribes to any person, including non-UK government officials, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition,

under the UK Bribery Act, companies may be held liable for failing to prevent employees and persons associated with the company from violating the Act. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. We have ongoing efforts that are designed to ensure our compliance with these laws, including training, policies, procedures, and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third party agents, although we may be liable for their actions. Any violation of these laws may result in civil and criminal penalties, and could have a material adverse impact on our business.

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU member states may interpret the legislation differently, which adds to its complexity, and guidance on implementation and compliance practices are often updated or otherwise revised. Fully understanding and implementing the legislation could be quite costly and timely, which could adversely affect our business. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration and, if adopted, could lead to additional and stricter requirements and penalties in the event of non-compliance.

The number and complexity of both federal and state laws continue to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations and the Physician Payment Sunshine provisions. The Physician Payment Sunshine provisions will require extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. CMS recently issued a final rule implementing the Physician Payment Sunshine provisions and clarified the scope of the reporting obligations. The final rule also provided that manufacturers must begin tracking on August 1, 2013 and must report payment data to CMS by March 31, 2014. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Compliance with the various federal and state laws that apply to pharmaceutical manufacturers is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and, in some cases, the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. For example, the FTC has been paying

increasing attention to the use of REMS by companies selling branded products, in particular whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner. Such a challenge or any challenge that we or our business partners have failed to comply with applicable laws and regulations could have a material adverse effect on our business, financial condition, results of operations and growth prospects. If we or the other parties with whom we work fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. We also participate in and have certain price reporting obligations to several state Medicaid supplemental rebate and other governmental pricing programs, and we have obligations to report average sales price for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the Centers for Medicare and Medicare Services, or CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug. Such data previously have not been submitted for our two radiopharmaceutical products, ProstaScint® (capromab pendetide) and Quadramet® (samarium sm 153 lexitronam injection). We have been engaged in interactions with CMS and a trade group regarding the reporting of Medicaid pricing data and paying Medicaid rebates on these and other radiopharmaceutical products and expect to begin making any required reports and paying required rebates on our products later this year. Any additional rebate liability resulting from this reporting will negatively impact our financial results.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebates are also due on the utilization of Medicaid managed care organizations. With regard to the amount of the rebates owed, the Healthcare Reform Act increased the minimum Medicaid rebate for all drugs; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the Healthcare Reform Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a new branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer will pay a prorated share of the branded prescription drug fee of \$2.8 billion in 2013 (and set to increase in ensuing years) based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

CMS has issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act and subsequent legislation but has not yet issued final regulations. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The Healthcare Reform Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. The Healthcare Reform Act exempts "orphan drugs"—those designated under section 526 of the FDCA—from the ceiling price requirements for these newly-eligible entities. The Health Resources and Services Administration, or HRSA, which administers the 340B program, has issued proposed regulations to implement the orphan drug exception, but has not yet issued final regulations. The issuance of final regulations will continue to increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

Federal law also requires that a company that participates in the Medicaid rebate program report average sales price, or ASP, information to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS as to what should or should not be considered in computing ASP. An ASP for each National Drug Code for a product that is subject to the ASP reporting requirement must be submitted to CMS no later than 30 days after the end of each calendar quarter. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Changes affecting the calculation of ASP could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to the CMS of our current average manufacturer prices and best prices for the quarter. If we become aware that our reporting for prior quarters was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations serve to increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the price that we are required to charge certain safety-net providers under the Public Health Service 340B drug discount program.

In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, average sales price, or best price information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Our failure to submit monthly/quarterly average manufacturer price, average sales price, and best price data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the submission is late beyond the due date. In the event that the CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, CMS and the Office of the Inspector General indicated that they intend more aggressively to pursue companies who fail to report these data to the government in a timely manner.

Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

The Healthcare Reform Act also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the program and to update the agreement that manufacturers must sign to participate in the program to obligate manufacturers to sell to covered entities if they sell to any other purchaser and to report to the government the ceiling prices for its drugs. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule, or FSS, pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator “covered drugs” available to the “Big Four” federal agencies—the VA, the Department of Defense, or DoD, the Public Health Service, and the Coast Guard—at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the “non-federal average manufacturer price,” or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of \$100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed “tracking customer.” Further, in addition to the “Big Four” agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies “negotiated pricing” for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor’s commercial “most favored customer” pricing. We offer one single FCP-based FSS contract price to all FSS purchasers for all products.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, or TMA, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, we have entered into a Section 703 Agreement with TMA under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the Annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the Federal False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***Reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably.***

In both U.S. and non-U.S. markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement and co-pay policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than other products, and third party payors may not provide coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because some of our products compete in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts, or the lack of reimbursement, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to effectively commercialize our products.

In recent years, there have been a number of legislative and regulatory changes in and proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. These changes and proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and the CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. Any failure to cover products appropriately under our DoD pricing agreements, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the Federal marketplace. As discussed above, recent legislative changes to the 340B drug pricing program, the Medicaid Drug Rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In various European countries we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. We have periodically increased the price of Xyrem, most recently in February 2013, and we have made and may in the future make similar price increases on our other products. We cannot assure you that such price adjustments will not negatively affect our ability to secure and maintain reimbursement coverage for our products, which could negatively impact our sales volumes.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologicals, will be reduced by up to 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, Pub. L. No. 112-25, or BCA, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, or ATRA. The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs, because Congress failed to enact legislation by January 15, 2012, to reduce federal deficits by \$1.2 trillion over ten years. The BCA caps the cuts to Medicare payments or items and services at 2%, and requires the cuts to be implemented on the first day of the first month following the issuance of a sequestration order. The ATRA delayed implementation of sequestration from January 2, 2013, to March 1, 2013, and as a result, the Medicare cuts will take effect April 1, 2013, unless Congress enacts legislation to cancel or delay the cuts. If implemented, these cuts could adversely impact payment for our products and related procedures.

***Product liability and product recalls could harm our business.***

The development, manufacture, testing, marketing and sale of pharmaceutical products are associated with significant risks of product liability claims or recalls. Side effects of, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Some of our products, including Xyrem, have boxed warnings in their labels. Further, another product, Luvox CR, is a selective serotonin reuptake inhibitor, and other products in that class are currently involved in product liability litigation.

Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class of injured patients. Further, third party payors, either individually or as a putative class, may bring actions seeking to recover monies spent on one of products. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe it is likely product liability claims will be made against us. The risk of product liability claims may also increase when a company receives a warning letter. We cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. Partly as a result of product liability lawsuits related to pharmaceutical products, product liability and other types of insurance have become more difficult and costly for pharmaceutical companies to obtain. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims by individuals and third party payors. In addition, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval. Similarly, any such regulatory action by the FDA could lead to product liability lawsuits as well.

## **Risks Relating to Our Financial Condition**

***We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position.***

As of December 31, 2012, we had approximately \$463.1 million in secured debt outstanding, all of which was incurred under our credit agreement entered into in connection with the EUSA Acquisition. Our debt may:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

Our ability to meet our debt service obligations will depend on our future performance, which will be subject to financial, business, and other factors affecting our operations, many of which are beyond our control. If we do not have sufficient funds to meet our debt service obligations, we may be required to refinance all or part of our existing debt, sell assets, borrow more money or sell securities, none of which we can assure you that we would be able to do in a timely manner or at all.

***Covenants in our credit agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.***

In June 2012, we entered into a credit agreement which provides for a six-year \$475.0 million term loan and a five-year \$100.0 million revolving credit facility. The credit agreement contains various covenants that limit our ability and/or our restricted subsidiaries' ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;
- make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

The credit agreement also includes, among other financial covenants, a financial covenant that requires us to maintain a maximum secured leverage ratio. Our ability to comply with this financial covenant may be affected by events beyond our control. Our failure to comply with any of the covenants could result in a default under the credit agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the revolving credit facility,



which could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. In addition, if we are unable to repay those amounts, the lenders under our credit agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business.

***To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business.***

The scope of our business and operations grew substantially in 2012 through the Azur Merger and the EUSA Acquisition. To continue to grow our business over the longer-term, we will need to commit substantial additional resources to in-licensing and/or acquiring new products and product candidates, and to costly and time-consuming product development and clinical trials of our product candidates. We also intend to continue to invest in our commercial operations in an effort to grow sales of our current products. Our future capital requirements will depend on many factors, including many of those discussed above, such as:

- the revenues from our commercial products, which may be affected by many factors, including the extent of generic competition for our products;
- the costs of our commercial operations;
- the costs of integration activities related to the Azur Merger, the EUSA Acquisition and any future strategic transactions we may engage in;
- the cost of acquiring and/or licensing any new products and product candidates;
- the scope, rate of progress, results and costs of our development and clinical activities;
- the cost and timing of obtaining regulatory approvals and of compliance with laws and regulations;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the cost of investigations, litigation and/or settlements related to regulatory oversight and third-party claims; and
- changes in laws and regulations, including, for example, healthcare reform legislation.

One of our corporate goals is to continue to expand our business through the licensing, acquisition and/or development of additional marketed or close to approval products and specialty product candidates. We cannot assure you that we will continue to identify attractive opportunities or that our funds will be sufficient to fund these activities if opportunities arise. We may be unable to expand our business if we do not have sufficient capital or cannot borrow or raise additional capital on attractive terms. In particular, the debt under our new credit agreement may limit our ability to borrow additional funds for acquisitions or to use our cash flow or obtain additional financing for future acquisitions. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose.

***We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.***

During the past several years, domestic and international financial markets have experienced extreme disruption from time to time, including, among other things, high volatility and significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. We may decide to access the capital or credit markets to supplement our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility to satisfy our needs for working capital, capital expenditures and debt service requirements or to continue to grow our business over the longer term through product acquisition and in-licensing, product development and clinical trials of product candidates, and expansion of our commercial operations. In the event of adverse capital and credit market conditions, we may not

be able to obtain capital market financing or credit on favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in our credit ratings issued by nationally recognized credit rating agencies could adversely affect our cost of financing and have an adverse effect on the market price of our securities.

***We may not be able to successfully maintain our tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.***

We are incorporated in Ireland and maintain subsidiaries in the United States, a number of other European jurisdictions and Bermuda. Azur Pharma was able to achieve a low average tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, including Ireland and Bermuda, together with intra-group service and transfer pricing agreements, each on an arm's length basis. We are continuing to use a substantially similar structure and arrangements. Taxing authorities, such as the U.S. Internal Revenue Service, or the IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. The IRS or other taxing authority may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal tax purposes.***

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because Azur Pharma was, and we continue to be, an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. Because we indirectly acquired all of Jazz Pharmaceuticals, Inc.'s assets through the acquisition of the shares of Jazz Pharmaceuticals, Inc. common stock in the Azur Merger at the closing, we could be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874.

For us to be treated as a foreign corporation for U.S. federal tax purposes under Section 7874 of the Code, either (1) the former stockholders of Jazz Pharmaceuticals, Inc. must have owned (within the meaning of Section 7874 of the Code) less than 80% (by both vote and value) of our ordinary shares by reason of holding shares in Jazz Pharmaceuticals, Inc., or (2) we must have substantial business activities in Ireland after the Azur Merger (taking into account the activities of our expanded affiliated group). The Jazz Pharmaceuticals, Inc. stockholders owned less than 80% of our share capital immediately after the Azur Merger by reason of their ownership of shares of Jazz Pharmaceuticals, Inc. common stock. As a result, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes.

It is possible that the IRS could disagree with the position that the ownership test is satisfied and assert that Section 7874 of the Code applies to treat us as a U.S. corporation following the Azur Merger. There is limited guidance regarding the Code Section 7874 provisions, including the application of the ownership test described above. The IRS continues to scrutinize transactions that are potentially subject to Section 7874, and issued new final and temporary regulations under Section 7874 in June 2012. These regulations apply only to acquisitions

completed on or after June 7, 2012, and therefore should not apply to the Azur Merger. Nevertheless, new statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have retroactive application to us, Jazz Pharmaceuticals, Inc., our respective shareholders, and/or the Azur Merger.

***Section 7874 of the Code likely will limit Jazz Pharmaceuticals, Inc. and its U.S. affiliates' ability to utilize their U.S. tax attributes to offset certain U.S. taxable income, if any, generated by taxable transactions following the Azur Merger for a period of time following the Azur Merger.***

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code limits the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, it is currently expected that this limitation should apply to us. As a result, it is not currently expected that Jazz Pharmaceuticals, Inc. or its U.S. affiliates will be able to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions following the Azur Merger. Notwithstanding this limitation, we plan to fully utilize Jazz Pharmaceuticals, Inc.'s U.S. net operating losses, or NOLs, prior to their expiration. As a result of this limitation, however, it may take Jazz Pharmaceuticals, Inc. longer to use its NOLs. Moreover, contrary to these plans, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent Jazz Pharmaceuticals, Inc. from fully utilizing its U.S. tax attributes prior to their expiration if Jazz Pharmaceuticals, Inc. does not generate sufficient taxable income.

***Our U.S. affiliates' ability to use their net operating losses to offset potential taxable income and related income taxes that would otherwise be due could be subject to further limitations if we do not generate taxable income in a timely manner or if the "ownership change" provisions of Sections 382 and 383 of the Code result in further annual limitations.***

Our U.S. affiliates have a significant amount of NOLs. Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, our U.S. affiliates will generate sufficient taxable income to use all of the NOLs. In addition, realization of NOLs to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the "ownership change" provisions of Sections 382 and 383 of the Code and similar state provisions, which may result in the expiration of additional NOLs before future utilization. In general, an "ownership change" occurs if, during a three-year rolling period, there is a change of 50% or more in the percentage ownership of a company by 5% shareholders (and certain persons treated as 5% shareholders), as defined in the Code and Treasury Regulations. In this regard, we currently estimate that, as a result of these ownership change provisions, we have an annual limitation on the utilization of certain NOLs of \$29 million for each of the years 2013 to 2016, \$12 million for 2017, and a combined total of \$3 million for 2018 to 2026. However, Sections 382 and 383 of the Code are extremely complex provisions with respect to which there are many uncertainties, and we have not requested a ruling from the IRS to confirm our analysis of the ownership change limitations related to the NOLs generated by our U.S. affiliates. Therefore, we have not established whether the IRS would agree with our analysis regarding the application of Sections 382 and 383 of the Code. If the IRS were to disagree with our analysis, or if our U.S. affiliates were to experience additional ownership changes in the future, our U.S. affiliates could be subject to further annual limitations on the use of the NOLs to offset potential taxable income and related income taxes that would otherwise be due.

***We have significant intangible assets and goodwill. Consequently, the potential impairment of our intangible assets and goodwill may significantly impact our profitability.***

As of December 31, 2012, we had recorded \$1.3 billion of intangible assets and goodwill related to our past acquisitions. Intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of intangible assets and goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of intangible assets or goodwill occur.

***Our financial results could be adversely affected by foreign exchange fluctuations.***

We have significant operations in Europe as well as in the United States, but we report revenues, costs and earnings in U.S. dollars. Our primary currency translation exposures relate to our subsidiaries that have functional currencies denominated in the Euro and the British Pound Sterling, or GBP. Exchange rates between the U.S. dollar and each of the Euro and GBP are likely to fluctuate from period to period. Because our financial results are reported in U.S. dollars, we are exposed to foreign currency exchange risk as the local currency financial statements of non-U.S. subsidiaries are translated to U.S. dollars for reporting purposes. If we continue to expand our international operations, we will conduct more transactions in currencies other than the U.S. dollar. To the extent that non-U.S. revenue and expense transactions are not denominated in the local currency, we are also subject to the risk of transaction losses. Given the volatility of exchange rates, there is no assurance that we will be able to effectively manage currency transaction and/or conversion risks. We have not entered into derivative instruments to offset the impact of foreign exchange fluctuations. Fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations and financial condition.

### **Risks Relating to Our Ordinary Shares**

***The market price of our ordinary shares has been volatile and may continue to be volatile in the future, and the value of your investment could decline significantly.***

Investors who hold our ordinary shares may not be able to sell their shares at or above the price at which they purchased their ordinary shares (or the price at which they purchased their shares of Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger). The price of our ordinary shares has fluctuated significantly from time to time since the completion of the Azur Merger in January 2012, and the price of Jazz Pharmaceuticals, Inc.'s common stock historically fluctuated significantly. The risk factors described above relating to our business and products could cause the price of our ordinary shares to continue to fluctuate significantly. In addition, the stock market in general, including the market for life sciences companies, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our ordinary shares, regardless of our operating performance.

Our share price may be dependent upon the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, the market price of our ordinary shares could decline. In the past, following periods of volatility in the market or significant price decline, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In addition, the market price of our ordinary shares may decline if the integration of the acquired Azur Pharma and EUSA Pharma businesses is unsuccessful, takes longer than expected or fails to achieve financial

benefits to the extent anticipated by financial analysts or investors, or the effect of the business combinations on the financial results of our combined company is otherwise not consistent with the expectations of financial analysts or investors.

***Future sales of our ordinary shares in the public market could cause our share price to fall.***

Sales of a substantial number of our ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. As of February 20, 2013, we had 58,037,532 ordinary shares outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144.

As of February 20, 2013, the holders of up to approximately 6,549,000 ordinary shares, based on shares outstanding as of that date, were entitled to certain rights with respect to the registration of such shares under the Securities Act of 1933, as amended, or the Securities Act, under an amended and restated investor rights agreement that Jazz Pharmaceuticals, Inc. entered into with these holders in June 2007, which we assumed at the closing of the Azur Merger. If such holders, by exercising their registration rights or otherwise, sell a large number of shares, the sale could adversely affect the market price of our ordinary shares. If in the future we file a registration statement and include shares held by these holders pursuant to the exercise of their registration rights or otherwise, these sales may impair our ability to raise capital. In addition, we have filed a registration statement on Form S-8 under the Securities Act to register our ordinary shares reserved for issuance under our equity incentive and employee stock purchase plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

Pursuant to the terms of an investor rights agreement dated July 7, 2009 Jazz Pharmaceuticals, Inc. entered into in connection with a private placement completed on such date, which agreement we assumed at the closing of the Azur Merger, we agreed to file a registration statement under the Securities Act registering the resale of 1,584,092 ordinary shares now held by the investors in the July 2009 private placement, as well as the 947,867 ordinary shares now underlying the warrants held by such investors. In addition, if we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the investors in the private placement are entitled to notice of the registration and are entitled to include, at our expense, their ordinary shares in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration.

Pursuant to the terms of a registration rights agreement we entered into with the holders of Azur Pharma's outstanding ordinary shares in January 2012, we filed a shelf registration statement with the SEC covering the resale of ordinary shares held by these holders following the closing of the Azur Merger to permit these holders to immediately resell their ordinary shares.

***Our executive officers and directors, together with their respective affiliates, own a significant percentage of our shares and may be able to exercise significant influence over matters subject to shareholder approval.***

As of February 20, 2013, our executive officers and directors, together with the shareholders with which our executive officers and directors were affiliated or associated as of such date, beneficially owned approximately 23.4% of our ordinary shares. Accordingly, our executive officers and directors, together with their respective affiliates or associates, may be able to significantly influence matters subject to shareholder approval and will continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our ordinary shares, and may prevent attempts by our shareholders to replace or remove our board of directors or management.

***Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.***

It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Acts, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

***Provisions of our articles of association could delay or prevent a takeover of us by a third party.***

Our articles of association could delay, defer or prevent a third party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. For example, our articles of association:

- permit our board of directors to issue one or more series of preferred shares with rights and preferences designated by our board;
- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes; and
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association.

These provisions may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors other than the candidates nominated by our board.

***We have never declared or paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.***

We anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs. Even if we propose to pay dividends in the future, we may be unable to do so under Irish law. Under Irish law, dividends may only be paid, and share repurchases and redemptions must generally be funded only out of, “distributable reserves.” In addition, our ability to pay cash dividends on our ordinary shares is restricted under the terms of our 2012 credit agreement. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of our

credit agreement and other factors our board of directors deems relevant. Holders of our ordinary shares must rely on increases in the trading price of their shares for returns on their investment in the foreseeable future.

***A transfer of our ordinary shares may be subject to Irish stamp duty.***

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer. This duty is currently charged at the rate of 1.0% of the price paid or the market value of the shares acquired, if higher. Because our ordinary shares are traded on a recognized stock exchange in the United States, an exemption of this stamp duty is available to transfers by shareholders who hold our ordinary shares beneficially through brokers which in turn hold those shares through the Depository Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by a record holder who holds our ordinary shares directly in his, her or its own name could be subject to this stamp duty. We, in our absolute discretion and insofar as the Irish Companies Acts or any other applicable law permit, may, or may provide that a subsidiary of ours will, pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of our ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of our subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

***Dividends paid by us may be subject to Irish dividend withholding tax.***

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to our shareholders. Shareholders that are resident in the United States, European Union countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or us or our transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

***Our auditor, like other independent registered public accounting firms operating in Ireland and a number of other European countries, is not currently permitted to be subject to inspection by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, our investors currently do not have the benefits of PCAOB oversight.***

As an auditor of companies that are publicly-traded in the United States and as a firm registered with the PCAOB, our independent registered public accounting firm is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and the professional standards of the PCAOB. However, because our auditor is located in Ireland, a jurisdiction where the PCAOB is currently unable to conduct inspections, our auditor is not currently inspected by the PCAOB. Inspections of other auditors conducted by the PCAOB outside of Ireland have at times identified deficiencies in those auditor's audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections in Ireland prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. In addition, the inability of the PCAOB to conduct auditor inspections in Ireland makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors located outside of Ireland that are subject to regular PCAOB inspections. As a result, our investors are deprived of the benefits of PCAOB inspections, and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

## **Item 1B. Unresolved Staff Comments**

There are no material unresolved written comments that were received from the SEC staff 180 days or more before the end of our 2012 fiscal year relating to our periodic or current reports under the Exchange Act.

## **Item 2. Properties**

Our corporate headquarters are located in Dublin, Ireland and our U.S. operations are located in Palo Alto, California, Philadelphia, Pennsylvania and Langhorne, Pennsylvania.

We occupy approximately 12,000 square feet of office space in Dublin, Ireland under a lease which expires in May 2022. We have an option to terminate this lease in May 2017, with no less than six months' prior written notice and the payment of a termination fee. In Palo Alto, California, we occupy a total of approximately 61,000 square feet of office space, 44,000 square feet of which is occupied under a lease, or the Palo Alto Lease, that expires in August 2017, and 17,000 square feet of which is occupied under a sublease that expires in July 2017. We have the right to extend the term of the Palo Alto Lease for up to an additional two years. We also occupy approximately 16,000 square feet of office space in Philadelphia, Pennsylvania under a lease that expires in February 2016 and approximately 8,000 square feet of office space in Langhorne, Pennsylvania under a lease that expires in October 2016.

Our international division is headquartered in Oxford, United Kingdom, with offices in Lyon, France and elsewhere in Europe. We occupy approximately 5,000 square feet of office space in Oxford, United Kingdom under a lease that expires in March 2015. We also occupy approximately 9,000 square feet of office space in Lyon, France under a lease that expires January 2019. We have an option to terminate this lease in December 2015.

We believe that our existing properties are in good condition and suitable for the conduct of our business. As we continue to expand our operations, we may need to lease additional or alternative facilities.

## **Item 3. Legal Proceedings**

We are involved in several legal proceedings, including the following matters:

*Xyrem*<sup>®</sup> *ANDA Matters*: On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it had submitted an abbreviated new drug application, or ANDA, to the United States Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleged that all five patents then listed for Xyrem in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification in the United States District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA will be stayed until the earlier of (i) April 18, 2013, which is 30 months after our October 18, 2010 receipt of Roxane's Paragraph IV Certification, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. Two additional method of use patents covering the distribution system for Xyrem were issued in December 2010 and February 2011, respectively, and were listed in the Orange Book, and we filed lawsuits against Roxane in February 2011 and again in May 2011 to include these additional patents in the litigation in response to Roxane's Paragraph IV Certifications against each of these patents, and also to include another issued patent in the litigation which is not listed in the Orange Book. These additional lawsuits were subsequently consolidated with the action filed on November 22, 2010. On April 26, 2012, the District Court held a Markman hearing, a pretrial hearing following which the trial judge construes the claims of the patents at issue in a lawsuit, and the District Court issued a Markman order construing the claims of the patents then involved in the litigation in September



2012. New patents, one covering a formulation of Xyrem and the other covering use of Xyrem for treatment of narcolepsy, were issued in September 2012 and December 2012, respectively, and were listed in the Orange Book. In October 2012, we filed a new lawsuit in the District Court against Roxane in response to Roxane's Paragraph IV Certification against the new formulation patent, and in December 2012, we filed a lawsuit in the District Court against Roxane alleging infringement of the new treatment patent. Our original lawsuit against Roxane has been temporarily stayed while the District Court determines whether to consolidate the three lawsuits, and no trial date has been scheduled. We cannot predict the timing or outcome of this matter.

On December 10, 2012, we received a Paragraph IV Certification from Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Amneal's Paragraph IV Certification alleged that seven patents listed for Xyrem in the Orange Book are not infringed by Amneal's proposed generic product. Amneal's Paragraph IV Certification further alleged that an eighth patent listed in the Orange Book for Xyrem is invalid. On December 13, 2012, we received a supplemental Paragraph IV Certification alleging that a ninth patent listed in the Orange Book for Xyrem is invalid. On January 18, 2013, we filed a lawsuit against Amneal in response to Amneal's Paragraph IV Certifications in the District Court. We are seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Amneal, FDA approval of Amneal's ANDA will be stayed until the earlier of (i) June 10, 2015, which is 30 months after our receipt of Amneal's Paragraph IV Certification on December 10, 2012, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the outcome of this matter.

On May 18, 2012, we submitted a Citizen Petition to the FDA that addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem. Among other actions requested of the FDA, this petition requested that the FDA (i) not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs and (ii) require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On November 13, 2012, the FDA denied this Citizen Petition. On July 10, 2012, we submitted a second Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, that did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. We are evaluating the FDA's responses to both Citizen Petitions and potential further actions that we may take with respect to the issues raised in, and the FDA's denials of, the Citizen Petitions. The FDA's denial of the Citizen Petitions does not have a direct impact on the merits of our ongoing lawsuits with Roxane and Amneal. However, we cannot predict the effect of the denial of either of our Citizen Petitions, or the FDA's stated positions in its responses to the Citizen Petitions, on the timing of the potential introduction of a generic version of Xyrem.

*FazaClo® ANDA Matters:* Azur Pharma received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc.; Novel Laboratories, Inc.; and Mylan Pharmaceuticals, Inc., indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo LD. Azur Pharma and CIMA Labs Inc., or CIMA, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification: against Barr Laboratories, Inc. on August 21, 2008, against Novel Laboratories, Inc. on November 25, 2008, and against Mylan Pharmaceuticals, Inc. on July 23, 2010. Each case was filed in the United States District Court for the District of

Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr Laboratories, Inc., entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product at the end of August 2012. The Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc. matters have been stayed pending reexamination of the patents in the suit. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the reexamination proceedings, or when the stays will be lifted.

*Cutler Matter:* On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in California Superior Court in the County of Los Angeles, or the Superior Court. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to either a \$10.5 million or \$25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. On March 14, 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. We submitted a complaint in arbitration alleging that Dr. Cutler's suit had been improperly filed in Los Angeles and seeking a declaratory judgment that we have complied with all contractual obligations to Dr. Cutler. On July 25, 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the arbitration clause in the applicable contract. We have asked the Superior Court to vacate the arbitrator's dismissal of the arbitration and appealed the Superior Court's denial of our motion to the California Court of Appeal. In addition, on November 7, 2012, we filed challenges to the sufficiency of the complaint in the Superior Court, but the Superior Court case has been stayed pending the outcome of our appeal. This matter, like all litigation, carries certain risks, and there can be no assurance of the outcome.

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market Information

Our ordinary shares began trading on The NASDAQ Global Select Market under the trading symbol "JAZZ" on January 18, 2012. From June 1, 2007 until January 17, 2012, the common stock of Jazz Pharmaceuticals, Inc. was traded on The NASDAQ Global Select Market (or The NASDAQ Global Market prior to January 3, 2012) also under the trading symbol "JAZZ." The following table sets forth the high and low intraday sales prices of our ordinary shares (and for periods prior to January 18, 2012, the common stock of Jazz Pharmaceuticals, Inc.) on The NASDAQ Global Select Market (or The NASDAQ Global Market prior to January 3, 2012) for the periods indicated.

	<u>High</u>	<u>Low</u>
<b>Calendar Quarter—2011</b>		
First Quarter .....	\$33.83	\$18.85
Second Quarter .....	\$34.97	\$23.50
Third Quarter .....	\$47.88	\$31.87
Fourth Quarter .....	\$45.81	\$34.02
<b>Calendar Quarter—2012</b>		
First Quarter .....	\$53.10	\$37.90
Second Quarter .....	\$54.50	\$40.38
Third Quarter .....	\$58.94	\$43.38
Fourth Quarter .....	\$60.00	\$47.37

On February 20, 2013, the last reported sales price per share of our ordinary shares was \$57.67 per share.

#### Holder of Ordinary Shares

As of February 20, 2013, there were three holders of record of our ordinary shares. Because many of our ordinary shares are held by brokers, nominees and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

#### Dividends

No cash dividends have ever been declared or paid on the common equity to date by Jazz Pharmaceuticals, Inc. or us, and we do not currently plan to pay cash dividends in the foreseeable future. Under Irish law, dividends may only be paid, and share repurchases and redemptions must generally be funded only out of, "distributable reserves." In addition, the terms of our June 2012 credit agreement restrict our ability to make certain restricted payments, which include the payment of cash dividends, in excess of \$30 million plus a formula-based amount that is based on our consolidated net income, provided that, in the case of paying cash dividends pursuant to this formula, our total leverage ratio (as defined in the credit agreement) does not exceed a certain amount. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of our credit agreement and other factors our board of directors deems relevant.

#### Unregistered Sales of Equity Securities

Except as previously reported in our quarterly reports on Form 10-Q filed with the SEC during the year ended December 31, 2012, there were no unregistered sales of equity securities by us during the year ended December 31, 2012.

## **Irish Law Matters**

As we are an Irish incorporated company, the following matters of Irish law are relevant to the holders of our ordinary shares.

### *Irish Restrictions on Import and Export of Capital*

Except as indicated below, there are no restrictions on non-residents of Ireland dealing in Irish domestic securities, which includes ordinary shares of Irish companies. Dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. The Financial Transfers Act 1992 gives power to the Minister for Finance of Ireland to restrict financial transfers between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the European Union. The acquisition or disposal of interests in shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. At present the Financial Transfers Act, 1992 prohibits financial transfers involving the late Slobodan Milosevic and associated persons, Burma (Myanmar), Belarus, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, the late Osama bin Laden, Al-Qaida, the Taliban of Afghanistan, Democratic Republic of Congo, Democratic People's Republic of Korea (North Korea), Iran, Iraq, Côte d'Ivoire, Lebanon, Liberia, Zimbabwe, Sudan, Somalia, Republic of Guinea, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, and countries that harbor certain terrorist groups, without the prior permission of the Central Bank of Ireland.

Any transfer of, or payment in respect of, a share or interest in a share involving the government of any country that is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law.

### *Irish Taxes Applicable to U.S. Holders*

*Withholding Tax on Dividends.* While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish Dividend Withholding Tax, or DWT, at the standard rate of income tax (currently 20%), unless an exemption applies.

Dividends on our ordinary shares that are owned by residents of the United States and held beneficially through the Depositary Trust Company, or DTC, will not be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the United States.

Dividends on our ordinary shares that are owned by residents of the United States and held directly (outside of DTC) will not be subject to DWT provided that the shareholder has completed the appropriate Irish DWT form and this form remains valid. Such shareholders must provide the appropriate Irish DWT form to our transfer agent at least seven business days before the record date for the first dividend payment to which they are entitled.

If any shareholder who is resident in the United States receives a dividend subject to DWT, he or she should generally be able to make an application for a refund from the Irish Revenue Commissioners on the prescribed form.

While the United States/Ireland Double Tax Treaty contains provisions regarding withholding, due to the wide scope of the exemptions from DWT available under Irish domestic law, it would generally be unnecessary for a United States resident shareholder to rely on the treaty provisions.

*Income Tax on Dividends.* A shareholder who is neither resident nor ordinarily resident in Ireland and who is entitled to an exemption from DWT generally has no additional liability to Irish income tax or to the universal social charge on a dividend from us unless that shareholder holds our ordinary shares through a branch or agency in Ireland through which a trade is carried on.

A shareholder who is neither resident nor ordinarily resident in Ireland and who is not entitled to an exemption from DWT generally has no additional liability to Irish income tax or to the universal social charge on a dividend from us. The DWT deducted by us discharges the liability to Irish income tax and to the universal social charge. This however is not the case where the shareholder holds the ordinary shares through a branch or agency in Ireland through which a trade is carried on.

*Irish Tax on Capital Gains.* A shareholder who is neither resident nor ordinarily resident in Ireland and does not hold our ordinary shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency should not be within the charge to Irish tax on capital gains on a disposal of our ordinary shares.

*Capital Acquisitions Tax.* Irish capital acquisitions tax, or CAT, is comprised principally of gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 33% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (i) the relationship between the donor and the donee and (ii) the aggregation of the values of previous gifts and inheritances received by the donee from persons within the same category of relationship for CAT purposes. Gifts and inheritances passing between spouses are exempt from CAT. Our shareholders should consult their own tax advisers as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

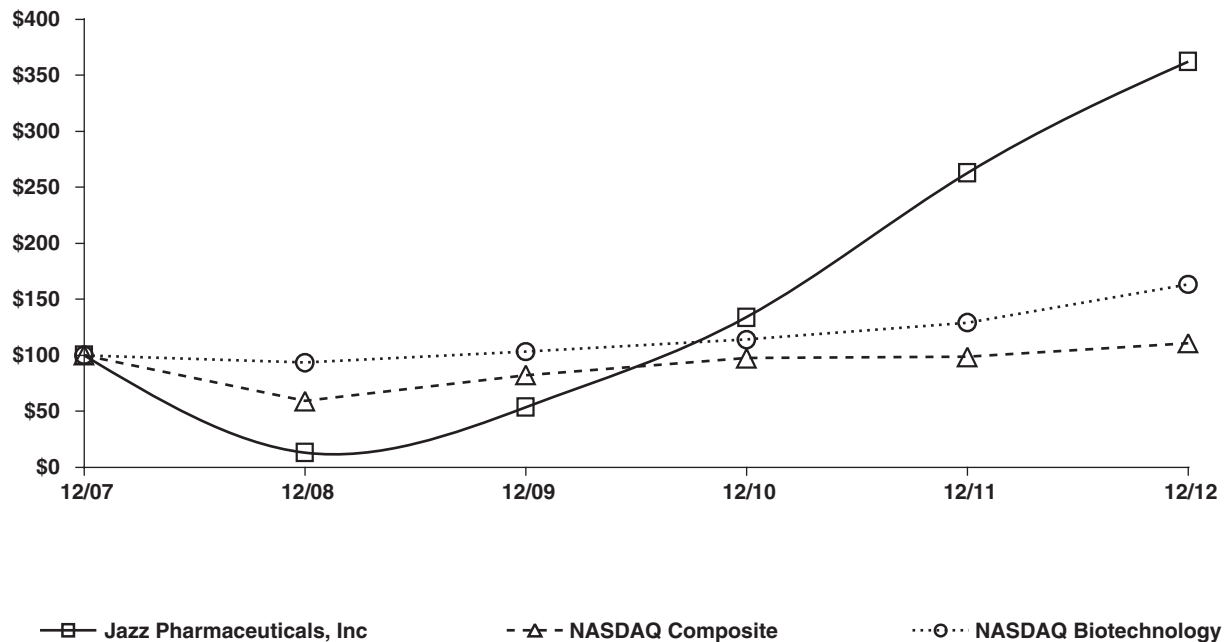
*Stamp Duty.* Irish stamp duty (if any) may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC will not be subject to Irish stamp duty. A transfer of our ordinary shares (i) by a seller who holds ordinary shares outside of DTC to any buyer, or (ii) by a seller who holds the ordinary shares through DTC to a buyer who holds the acquired ordinary shares outside of DTC, may be subject to Irish stamp duty (currently at the rate of 1% of the price paid or the market value of the ordinary shares acquired, if greater). The person accountable for payment of stamp duty is the buyer or, in the case of a transfer by way of a gift or for less than market value, all parties to the transfer.

A shareholder who holds ordinary shares outside of DTC may transfer those ordinary shares into DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC (and in exactly the same proportions) as a result of the transfer and at the time of the transfer into DTC there is no sale of those book-entry interests to a third party being contemplated by the shareholder. Similarly, a shareholder who holds ordinary shares through DTC may transfer those ordinary shares out of DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the ordinary shares (and in exactly the same proportions) as a result of the transfer, and at the time of the transfer out of DTC there is no sale of those ordinary shares to a third party being contemplated by the shareholder. In order for the share registrar to be satisfied as to the application of this Irish stamp duty treatment where relevant, the shareholder must confirm to us that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC (and in exactly the same proportions) (or vice-versa) as a result of the transfer and there is no agreement for the sale of the related book-entry interest or the ordinary shares or an interest in the ordinary shares, as the case may be, by the shareholder to a third party being contemplated.

### Performance Measurement Comparison(1)

The following graph shows the total shareholder return on the last day of each year of an investment of \$100 in cash as if made on December 31, 2007 in (i) our ordinary shares; (ii) the NASDAQ Composite Index; and (iii) the NASDAQ Biotechnology Index through December 31, 2012. Information set forth in the graph below represents the performance of the Jazz Pharmaceuticals, Inc. common stock from December 31, 2007 until January 17, 2012, the day before the consummation of the Azur Merger, and the performance of our ordinary shares from January 18, 2012 through December 31, 2012. Our ordinary share trade on the same exchange, the NASDAQ Global Select Market, and under the same trading symbol, "JAZZ," as the Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends; however we did not declare or pay any dividends on our common stock or ordinary share during the comparison period. The shareholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future shareholder returns.

### COMPARISON OF FIVE YEAR CUMULATIVE TOTAL RETURN(2)



\*\$100 invested on December 31, 2007 in stock or in index, including reinvestment of dividends. Fiscal year ending December 31.

- (1) This section is not "soliciting material", is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.
- (2) Information used in the graph was obtained from Research Data Group, Inc.

**Item 6. Selected Financial Data**

The following selected consolidated financial data should be read together with our consolidated financial statements and accompanying notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing elsewhere in this Annual Report on Form 10-K. The selected consolidated financial data in this section is not intended to replace our consolidated financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results.

We derived the consolidated statements of operations data for the years ended December 31, 2012, 2011 and 2010 and the consolidated balance sheet data as of December 31, 2012 and 2011 from the audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2009 and 2008, and the selected consolidated balance sheet data as of December 31, 2010, 2009 and 2008 are derived from audited consolidated financial statements not included in this Annual Report on Form 10-K. The selected consolidated financial data for periods prior to the year ended December 31, 2012 is that of Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries, our predecessor, while the selected consolidated financial data as of and for the year ended December 31, 2012 is that of Jazz Pharmaceuticals plc and its consolidated subsidiaries.

	Year Ended December 31,				
	2012(1)	2011	2010	2009	2008
	(In thousands, except per share amounts)				
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product sales, net	\$580,527	\$266,518	\$170,006	\$115,108	\$ 64,637
Royalties and contract revenues	5,452	5,759	3,775	13,341	2,877
Total revenues	585,979	272,277	173,781	128,449	67,514
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technologies and intangible asset impairment)	78,425	13,942	13,559	9,638	13,924
Selling, general and administrative	223,882	108,936	68,996	58,652	111,401
Research and development	20,477	14,120	25,612	36,561	69,963
Intangible asset amortization	65,351	7,448	7,825	7,668	12,828
Intangible asset impairment	—	—	—	—	29,763
Total operating expenses	388,135	144,446	115,992	112,519	237,879
Income (loss) from operations	197,844	127,831	57,789	15,930	(170,365)
Interest expense, net (including \$570, \$1,183 and \$1,179 for the years ended December 31, 2010, 2009 and 2008, respectively, pertaining to a related party)	(16,869)	(1,600)	(12,724)	(22,766)	(17,892)
Foreign currency loss	(3,620)	—	—	—	—
Gain on sale of product rights	—	—	—	—	3,918
Loss on extinguishment of debt (including \$701 for the year ended December 31, 2010 pertaining to a related party)	—	(1,247)	(12,287)	—	—
Income (loss) from continuing operations before income tax benefit	177,355	124,984	32,778	(6,836)	(184,339)
Income tax benefit	(83,794)	—	—	—	—
Income (loss) from continuing operations	261,149	124,984	32,778	(6,836)	(184,339)
Income from discontinued operations, net of taxes	27,437	—	—	—	—
Net income (loss)	\$288,586	\$124,984	\$ 32,778	\$ (6,836)	\$(184,339)
Basic income (loss) per ordinary share:(2)					
Income (loss) from continuing operations	\$ 4.61	\$ 3.01	\$ 0.90	\$ (0.23)	\$ (7.19)
Income from discontinued operations	0.48	—	—	—	—
Net income (loss)	\$ 5.09	\$ 3.01	\$ 0.90	\$ (0.23)	\$ (7.19)
Diluted income (loss) per ordinary share:(2)					
Income (loss) from continuing operations	\$ 4.34	\$ 2.67	\$ 0.83	\$ (0.23)	\$ (7.19)
Income from discontinued operations	0.45	—	—	—	—
Net income (loss)	\$ 4.79	\$ 2.67	\$ 0.83	\$ (0.23)	\$ (7.19)
Weighted-average number of ordinary shares outstanding:(2)					
Basic	56,643	41,499	36,343	30,018	25,646
Diluted	60,195	46,798	39,411	30,018	25,646



	As of December 31,				
	2012(1)	2011	2010	2009	2008
	(In thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities .....	\$ 387,196	\$ 157,898	\$ 44,794	\$ 15,595	\$ 25,907
Working capital (deficit) .....	360,034	146,261	14,522	(22,287)	(129,492)
Total assets .....	1,966,493	253,573	135,729	107,396	117,498
Long-term debt, current and non-current (including \$6,552 and \$6,747 as of December 31, 2009 and 2008, respectively, held by a related party) .....	456,761	—	40,693	114,866	118,534
Accumulated deficit .....	(61,296)	(349,882)	(474,866)	(507,644)	(500,808)
Total shareholders' equity (deficit) .....	1,121,292	192,788	30,551	(72,830)	(92,878)

- (1) On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in the Azur Merger pursuant to which all outstanding shares of Jazz Pharmaceuticals, Inc.'s common stock were canceled and converted into the right to receive, on a one-for-one basis, our ordinary shares. 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. On June 12, 2012, we completed the EUSA Acquisition. At the closing of the EUSA Acquisition, we paid \$678.4 million in cash, and agreed to make an additional contingent payment of \$50.0 million in cash if Erwinaze achieves U.S. net sales of \$124.5 million or more in 2013. In connection with the EUSA Acquisition, we entered into a \$575.0 million credit agreement consisting of a \$475.0 million term loan and a \$100.0 million revolving credit facility. We used all of the proceeds of the term loan, together with cash on hand, to finance the EUSA Acquisition. 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, are included in our consolidated financial statements since the effective dates of the Azur Merger and the EUSA Acquisition, respectively. See Note 3 to the notes to our consolidated financial statements for more information on these transactions.
- (2) All references to "ordinary shares" refer to Jazz Pharmaceuticals, Inc.'s common stock with respect to the comparative prior year periods and to our ordinary shares with respect to the year ended December 31, 2012. Our earnings per share in the comparative prior year periods were not impacted by the Azur Merger since each share of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and converted into the right to receive one ordinary share upon the consummation of the Azur Merger.

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and notes to consolidated financial statements included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that characterize our business. In particular, we encourage you to review the risks and uncertainties described in Part I Item 1A. "Risk Factors" included elsewhere in this report. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends.*

### Overview

We are a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing 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.

2012 was a transformational year for our company. In January 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction, or the Azur Merger. In June 2012, we completed the acquisition of EUSA Pharma Inc., or the EUSA Acquisition. In connection with the EUSA Acquisition, we entered into a \$575.0 million credit agreement consisting of a \$475.0 million term loan, which partially financed the EUSA Acquisition, and a \$100.0 million revolving credit facility.

*Merger with Azur Pharma.* On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in the Azur Merger, which was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with Jazz Pharmaceuticals, Inc. treated as the acquiring company in the Azur Merger for accounting purposes. The total acquisition consideration of \$576.5 million was determined based on the market value of our ordinary shares that were held by the historic Azur Pharma shareholders immediately following the closing of the Azur Merger. Accordingly, the operating results of Jazz Pharmaceuticals, Inc. are included in our consolidated financial statements for all periods presented in this report, whereas the operating results of Azur Pharma are included only since January 18, 2012. 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, Jazz Pharmaceuticals, Inc. was an independent specialty pharmaceutical company incorporated in Delaware.

*Acquisition of EUSA Pharma and Term Loan and Revolving Credit Facility.* On June 12, 2012, we completed the acquisition of EUSA Pharma. As part of the EUSA Acquisition, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc. At the closing of the EUSA Acquisition, we paid \$678.4 million in cash, and agreed to make an additional contingent payment of \$50.0 million in cash if Erwinaze (asparaginase *Erwinia chrysanthemi*), a product acquired in the EUSA Acquisition, achieves U.S. net sales of \$124.5 million or more in 2013. The operating results of EUSA Pharma are included in our consolidated financial statements since the effective date of the EUSA Acquisition on June 12, 2012. In connection with the EUSA Acquisition, we entered into a \$575.0 million credit agreement with Barclays Bank PLC and certain other lenders. The credit agreement provides for a six-year \$475.0 million term

loan and a five-year \$100.0 million revolving credit facility. The proceeds from the term loan were used to partially finance the EUSA Acquisition. Our obligations are secured by substantially all of the assets of certain of our subsidiaries. For a more detailed discussion, see “Liquidity and Capital Resources” below.

*Sale of Women’s Health Business.* In October 2012, we completed the sale of our women’s health business, which included six products and was acquired in the Azur Merger, to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl, or collectively, Meda, for net cash proceeds of \$93.9 million.

In 2012, we made substantial progress in the execution of our strategy. Sales of our lead product, Xyrem® (sodium oxybate) oral solution, increased 62% in 2012 compared to 2011. In addition, as a result of the EUSA Acquisition and Azur Merger, we significantly increased the number of products that we market and added products in therapeutic areas that are new to us, such as oncology and pain. Our marketed products address medical needs in the following therapeutic areas and include the following products:

**Narcolepsy:** 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 in patients with narcolepsy;

**Oncology:** Erwinaze® (asparaginase *Erwinia chrysanthemi*), called Erwinase® in ex-U.S. markets, a treatment for patients with acute lymphoblastic leukemia, or ALL, who have developed sensitivity to *E. coli*-derived asparaginase, and other products, including products for oncology supportive care;

**Pain:** Prialt® (ziconotide) intrathecal infusion, the only non-opioid intrathecal analgesic indicated for the management of severe chronic pain for patients who are intolerant of or refractory to other treatments; and

**Psychiatry & Other:** A portfolio of products, including FazaClo® (clozapine, USP) LD and FazaClo HD, orally disintegrating clozapine tablets indicated for treatment-resistant schizophrenia and Luvox CR® (fluvoxamine maleate) Extended-Release Capsules marketed for the treatment of obsessive compulsive disorder. In addition, in February 2013 the FDA approved a new drug application for Versacloz™ (clozapine, USP) oral suspension for treatment-resistant schizophrenia, which we have exclusive rights to market in the United States.

Our international division, based in Europe, commercializes Erwinase as well as a portfolio of other products outside of the United States. These products are primarily in the oncology, critical care and oncology supportive care therapeutic areas and include Caphosol® (supersaturated calcium phosphate rinse), Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole®, Kidrolase® (*Escherichia coli* L-asparaginase) and Xenazine® (tetrabenazine).

Our development pipeline projects currently include line extensions for existing products, the generation of additional clinical data for existing products and clinical development of new product candidates. These projects include two clinical trials involving Erwinaze: an ongoing pharmacokinetic clinical trial of the intravenous administration of Erwinaze in North America; and a planned clinical trial including pharmacokinetic efficacy measures to evaluate Erwinaze in adolescents and young adults with ALL who are hypersensitive to *E. coli*-derived asparaginase, which is expected to begin in the second half of 2013. In addition, we are developing two product candidates, including a Phase I clinical trial in Europe of Asparec® (mPEG-r-crisantaspase), a pegylated recombinant *Erwinia* asparaginase for the treatment of patients with ALL with *E. coli* asparaginase hypersensitivity; and a Phase III clinical trial in Europe of Leukotac® (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease. We expect that research and development expenses will be higher in 2013 compared to 2012 due to an expected increase in development activities and due to the inclusion of a full year of expense from the acquired Azur Pharma and EUSA Pharma businesses.

With the completion of the EUSA Acquisition and the Azur Merger in 2012, we gained not only an expanded portfolio of specialty pharmaceutical products and product candidates, but also an enhanced

commercial platform and a strengthened management team, adding EUSA Pharma's specialty commercial infrastructure in the United States and Europe and its international distribution network to our existing U.S. specialty product platform. Our international footprint now includes headquarters in Dublin, Ireland and multiple offices in the United States, the United Kingdom and other countries in Europe, with approximately 610 employees in eleven countries. We intend that our operations will function as an efficient platform for further growth, leveraging our commercial, medical and scientific experience to seek to maximize the potential of our existing products and expand our product portfolio through a combination of internal development, acquisition and in-licensing.

In 2013, we plan to focus on executing on our strategy. We anticipate that we will continue to face a number of challenges and risks to our business and our ability to execute our strategy. For example, while we now have a more diversified product portfolio than in the past, our financial results remain significantly influenced by sales of Xyrem, which accounted for 65% of our net product sales for 2012. As a result, we continue to place a high priority on seeking to maintain and increase sales of Xyrem in its approved indications, while remaining focused on ensuring the safe and effective use of the product, and lifecycle management of the product including enhancing and enforcing our intellectual property rights.

Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, including those discussed in Part I, Item 1A of this Annual Report on Form 10-K. In particular, there are two abbreviated new drug applications, or ANDAs, submitted to the FDA by third parties seeking to market generic versions of Xyrem. We have sued 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 or tentative approval of an ANDA resulting 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 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. We cannot predict the timing of finalization, or the final terms, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

The implementation of our strategy is also subject to other challenges and risks specific to our business, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations. In addition to risks related to Xyrem, other key challenges and risks that we face include risks and uncertainties related to:

- the challenges of protecting our intellectual property rights;
- 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;

- our dependence on sole source suppliers to continue to meet our ongoing commercial needs, especially when our supply demands are growing; and
- the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval.

All of these risks are discussed in greater detail, along with other risks, in Part I, Item 1A of this Annual Report on Form 10-K.

## Results of Operations

The following discussions of our results of continuing operations exclude the results related to the women's health business. This business has been segregated from continuing operations and reflected as a discontinued operation. See "Income from Discontinued Operations, Net of Taxes" below. The following table presents revenues and expenses from continuing operations for the years ended December 31, 2012, 2011 and 2010 (amounts in thousands):

	<u>2012</u>	<u>Change</u>	<u>2011</u>	<u>Change</u>	<u>2010</u>
Product sales, net . . . . .	\$580,527	118%	\$266,518	57%	\$170,006
Royalties and contract revenues . . . . .	5,452	(5)%	5,759	53%	3,775
Cost of product sales (excluding amortization of acquired developed technologies) . . . . .	78,425	463%	13,942	3%	13,559
Selling, general and administrative . . . . .	223,882	106%	108,936	58%	68,996
Research and development . . . . .	20,477	45%	14,120	(45)%	25,612
Intangible asset amortization . . . . .	65,351	777%	7,448	(5)%	7,825
Interest expense, net . . . . .	16,869	954%	1,600	(87)%	12,724
Foreign currency loss . . . . .	3,620	N/A(1)	—	N/A(1)	—
Loss on extinguishment of debt . . . . .	—	N/A(1)	1,247	(90)%	12,287
Income tax benefit . . . . .	83,794	N/A(1)	—	N/A(1)	—

(1) Comparison to prior period is not meaningful.

### Product Sales, Net

The following table presents product sales for the years ended December 31, 2012, 2011 and 2010 (amounts in thousands):

	<u>2012</u>	<u>Change</u>	<u>2011</u>	<u>Change</u>	<u>2010</u>
Xyrem . . . . .	\$378,663	62%	\$233,348	64%	\$142,630
Erwinaze/Erwinase . . . . .	72,083	N/A(1)	—	N/A(1)	—
Prialt . . . . .	26,360	N/A(1)	—	N/A(1)	—
Psychiatry:					—
Luvox CR . . . . .	42,419	28%	33,170	21%	27,376
FazaClo LD . . . . .	22,023	N/A(1)	—	N/A(1)	—
FazaClo HD . . . . .	12,047	N/A(1)	—	N/A(1)	—
Other . . . . .	26,932	N/A(1)	—	N/A(1)	—
Product sales, net . . . . .	<u>580,527</u>	118%	<u>266,518</u>	57%	<u>170,006</u>
Royalties and contract revenues . . . . .	<u>5,452</u>	(5)%	<u>5,759</u>	53%	<u>3,775</u>
Total revenues . . . . .	<u>\$585,979</u>	115%	<u>\$272,277</u>	57%	<u>\$173,781</u>

(1) Comparison to prior period is not meaningful.

Xyrem product sales increased in 2012 and 2011 compared to the immediately preceding years, primarily due to higher average net selling prices in the 2012 and 2011 periods resulting from price increases that we instituted in those periods and, to a lesser extent, increases in sales volume of 11% in both 2012 and 2011. Price increases were instituted based on market analysis. Growth in sales volumes in the 2012 and 2011 periods were driven by an increase in the average number of patients on Xyrem. This increase was due primarily to a greater number of Xyrem patients who refilled their Xyrem prescriptions on schedule and who remained on therapy, which we believe resulted from our efforts to increase physician knowledge about Xyrem and to improve patient support services. The sales volume increase in the 2012 period was also impacted by the deployment of a dedicated Xyrem sales force to increase physician awareness of narcolepsy and its diagnosis, and, more recently, by a higher number of prescriptions from new or previously infrequent physician prescribers. Sales of Erwinaze/Erwinase since the EUSA Acquisition on June 12, 2012 were \$72.1 million in 2012. Prialt product sales included sales of \$4.6 million in 2012 related to a supply agreement to provide Prialt to Eisai Co. Limited for distribution and sale in Europe. Luvox CR product sales increased in 2012 compared to 2011 due to price increases, partially offset by a decrease in sales volumes of 3%. Luvox CR product sales increased in 2011 compared to 2010, primarily due to price increases and to a lesser extent an increase in sales volume of 4%. In 2012, a generic version of FazaClo LD was launched, which has had a negative impact on sales of FazaClo LD and may have a negative impact on sales of FazaClo HD in future periods. We expect total product sales will increase in 2013 over 2012 primarily due to growth in sales of Xyrem, Erwinaze/Erwinase and Prialt, partially offset by decreases in sales of other products.

#### *Royalties and Contract Revenues*

Royalties and contract revenues in 2012 of \$5.5 million is consistent with prior year levels. Royalties and contract revenues increased in 2011 compared to 2010, primarily due to the recognition of a \$1.5 million milestone payment related to sales of Xyrem in Europe by UCB Pharma Limited, or UCB, under a license agreement. We expect royalties and contract revenues to increase slightly in 2013 as compared to 2012 primarily due to the inclusion of a full year of royalties from the acquired EUSA business.

#### *Cost of Product Sales*

Cost of product sales increased in 2012 compared to 2011, primarily due to cost of product sales in relation to products acquired in the Azur Merger and the EUSA Acquisition, including acquisition accounting inventory fair value step-up adjustments of \$16.8 million in 2012. Cost of product sales increased slightly in 2011 compared to 2010. Gross margins as a percentage of product sales were 86.5%, 94.8% and 92.0% in 2012, 2011 and 2010, respectively. Our gross margin percentage in 2012 as compared to 2011 was lower primarily due to the effect of the purchase accounting inventory fair value step-up adjustments recorded as cost of product sales and also due to the impact of our product mix in 2012. The gross margin on products acquired during 2012 is lower than the gross margins earned on our legacy products. Our gross margin percentage in 2011 as compared to 2010 was higher primarily due to increases in average selling prices. We expect our gross margin percentage to increase slightly in 2013 compared to 2012 primarily driven by a decrease in the amount of acquisition accounting inventory fair value step-up adjustments and also a change in product mix.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses were higher in 2012 compared to 2011 primarily due to an increase in salary and benefit related headcount expenses (including share-based compensation) of \$49.0 million driven primarily by increased headcount following the Azur Merger in January 2012 and the EUSA Acquisition in June 2012. In addition, sales and promotional expenses in 2012 increased by \$12.8 million compared to 2011 primarily due to the expansion of our organization, including our increased commercial presence. Transaction, integration and restructuring expenses were \$10.4 million higher in 2012 compared to 2011 primarily due to expenses related to the Azur Merger and the EUSA Acquisition. In 2011 we incurred transaction and integration costs related to the Azur Merger only. Professional and service fees increased in 2012 by \$15.2 million compared

to 2011 due to the continuing operations of the larger entity. Travel, facility and maintenance expenses increased in 2012 by \$15.5 million compared to 2011 primarily due to an increase in the number of facilities that we occupy in the United States and in Europe. Selling, general and administrative expenses were higher in 2011 compared to 2010 primarily due to an increase in employee-related expenses of \$15.9 million as a result of an increase in commercial activities, higher share-based compensation expense and higher legal and professional expenses of \$11.2 million associated with the Azur Merger. We expect that selling, general and administrative expenses will be higher in 2013 than in 2012 due to the inclusion of a full year of expense with respect to the acquired EUSA business, an increase in direct marketing spend on key products and increased headcount to support the larger, global corporate organization.

#### *Research and Development Expenses*

Research and development expenses consist primarily of personnel expenses, costs related to clinical studies and outside services, and other research and development costs. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Clinical study and outside services costs relate primarily to clinical studies performed by clinical research organizations, materials and supplies, and other third-party fees. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. We do not track fully-burdened research and development expenses on a project-by-project basis. We manage our research and development expenses by identifying the research and development activities that we anticipate will be performed during a given period and then prioritizing efforts based on our assessment of what development activities are important to our business and have a reasonable probability of success, and by dynamically allocating resources accordingly. We also continually review our development pipeline projects and the status of their development and, as necessary, reallocate resources among our development pipeline projects that we believe will best support the future growth of our business.

The following table provides a breakout of our research and development expenses by major categories of expense (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Personnel expenses . . . . .	\$10,432	\$10,581	\$11,422
Clinical studies and outside services . . . . .	8,566	2,145	12,320
Other . . . . .	1,479	1,394	1,870
Total . . . . .	<u>\$20,477</u>	<u>\$14,120</u>	<u>\$25,612</u>

Research and development expenses increased by \$6.4 million in 2012 compared to 2011 primarily due to increased clinical studies and outside services costs related to the generation of additional clinical data and the development of line extensions for existing products, and to a lesser extent, costs incurred to develop new product candidates that we acquired in the EUSA Acquisition and the Azur Merger. Personnel expenses and other research and development expenses in 2012 were consistent with prior year levels.

Research and development expenses decreased by \$11.5 million in 2011 compared to 2010 primarily due to lower clinical studies and outside services costs, and to a lesser extent, a decrease in personnel and other expenses. The decrease in 2011 was primarily due to our decision to discontinue the development of JPZ-6, our then product candidate for the treatment of fibromyalgia, as well as our discontinuation of certain research activities related to two line extension projects for existing products.

A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of our product candidates, and the consequences to our business, financial position and growth prospects can be found in “Risk Factors” in Part I, Item 1A of this report.

### *Intangible Asset Amortization*

We acquired finite-lived intangible assets in connection with the Azur Merger and the EUSA Acquisition that are expected to be amortized over their useful economic lives of two to 15 years. We recorded amortization related to these intangibles of \$59.7 million in 2012, which accounted for all of the increase in the amortization expense. During 2011 and 2010, our intangible assets consisted primarily of developed technology related to Xyrem and Luvox CR.

### *Interest Expense, Net*

Interest expense increased in 2012 as compared to 2011 primarily due to a larger debt balance. In June 2012, we entered into a credit agreement that provides for a term loan in an aggregate principal amount of \$475.0 million, which bears interest at a variable interest rate that was 5.25% as of December 31, 2012. In July 2011, we fully repaid a term loan outstanding at that time. Interest expense decreased in 2011 compared to 2010 due to lower average borrowings and lower interest rates.

### *Foreign Currency Loss*

The foreign currency loss in 2012 related to the translation of foreign currency net monetary assets, including intercompany balances.

### *Loss on Extinguishment of Debt*

In 2011, as a result of the repayment of a term loan and the termination of a credit agreement, we recorded a loss on extinguishment of debt of \$1.2 million, which consisted of a \$0.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount, with the remainder related to a prepayment penalty and a termination fee. The loss on extinguishment of debt in 2010 was due to the repayment of long-term debt and consisted of \$8.5 million of prepayment premiums and fees, and a \$3.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount.

### *Income Tax Benefit*

During 2012, we recognized an income tax benefit of \$83.8 million. This tax benefit included a deferred tax benefit of \$113.9 million, offset by an income tax provision of \$30.1 million, relating to the United States, Ireland and other foreign jurisdictions. The deferred tax benefit included a benefit of \$104.2 million primarily attributable to the release of a valuation allowance against substantially all of our U.S. federal and state deferred tax assets. Management determined that it was more likely than not that these deferred tax assets would be recoverable and the related valuation allowance was no longer needed based on an assessment of the relative impact of all positive and negative evidence that existed at December 31, 2012, including an evaluation of cumulative income in recent years, future sources of taxable income, and significant risks and uncertainties related to our business.

During 2011 and 2010, we had operations only in the United States and made no provision for income taxes due to our utilization of U.S. federal net operating loss carryforwards to offset both regular taxable income and alternative minimum taxable income and to our utilization of deferred state tax benefits. The 2012 effective income tax rate on continuing activities before utilization of NOL and tax credit carryforwards and release in valuation allowance in 2012 of 42.5% was higher than the Irish statutory rate of 12.5% due to a number of factors, including income taxable at a rate higher than the Irish statutory rate, losses in certain tax jurisdictions for which no tax benefit is available and various expenses not deductible for tax purposes.

### *Income from Discontinued Operations, Net of Taxes*

In 2012, we sold the women's health business to Meda for \$97.6 million, including \$2.6 million for certain inventory transferred to Meda upon the closing of the sale, less transaction costs of \$3.7 million. As part of the



transaction, Meda purchased six women’s health products from us. As part of the sale, approximately 60 employees who directly supported the women’s health business became Meda employees. We recorded a non-recurring gain on the sale of \$35.2 million.

Net revenue and income from discontinued operations were as follows (in thousands):

	<u>Year Ended December 31, 2012</u>
Product sales, net . . . . .	\$20,873
Loss from discontinued operations before income taxes . . . . .	\$ (5,787)
Income tax expense(1) . . . . .	<u>(2,020)</u>
Loss from discontinued operations, net of taxes . . . . .	(7,807)
Gain on sale of discontinued operations(2) . . . . .	<u>35,244</u>
Income from discontinued operations, net of taxes . . . . .	<u>\$27,437</u>

- (1) The income tax expense relates to profits generated by the women’s health business in 2012 which are attributable to the United States.
- (2) The gain on sale of discontinued operations was not impacted by income taxes as the value attributable to the women’s health business was held in a non-taxable jurisdiction.

**Non-GAAP Financial Measures**

To supplement our financial results presented on a GAAP basis, we use certain non-GAAP adjusted financial measures as shown in the table and footnotes below. We believe that these non-GAAP financial measures are helpful in understanding our past financial performance and potential future results, particularly in light of the effect of various acquisition and divestiture transactions effected by us during 2012. They are not meant to be considered in isolation or as a substitute for comparable GAAP measures, and should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP. Our management regularly uses these supplemental non-GAAP financial measures internally to understand, manage and evaluate our business and make operating decisions. Compensation of our executives is based in part on the performance of our business based on these non-GAAP measures. In addition, we believe that the use of these non-GAAP measures enhances the ability of investors to compare our results from period to period. The adjusted financial measures, as used by us in this report, may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by our competitors and other companies. Adjusted net income measures exclude from continuing operations intangible asset amortization, share-based compensation expense, acquisition accounting inventory fair value step-up adjustments, transaction and integration costs, restructuring charges, change in fair value of contingent consideration, loss on extinguishment of debt, other non-cash expense/income, tax related to acquisition restructuring and the release of the valuation allowance against substantially all of our U.S. deferred tax assets, and adjust the income tax provision to the estimated amount of taxes payable in cash.

A reconciliation of GAAP income from continuing operations to adjusted net income, a non-GAAP financial measure, and related per share amounts is as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2012	2011	2010
GAAP income from continuing operations	\$ 261,149	\$124,984	\$32,778
Intangible asset amortization	65,351	7,448	7,825
Share-based compensation expense	23,006	20,704	8,219
Acquisition accounting inventory fair value step-up	16,794	—	—
Transaction and integration costs	18,821	11,245	—
Restructuring charges	2,789	—	—
Change in fair value of contingent consideration	(300)	—	—
Loss on extinguishment of debt	—	1,247	12,287
Other non-cash expense (income)	2,860	(744)	(77)
Valuation allowance release(1)	(104,247)	—	—
Income tax adjustments(2)	4,171	—	—
Adjusted net income(3)	<u>\$ 290,394</u>	<u>\$164,884</u>	<u>\$61,032</u>
GAAP income from continuing operations per diluted share(4)	<u>\$ 4.34</u>	<u>\$ 2.67</u>	<u>\$ 0.83</u>
Adjusted net income per diluted share(3)(4)	<u>\$ 4.82</u>	<u>\$ 3.52</u>	<u>\$ 1.55</u>
Shares used in computing GAAP income from continuing operations and adjusted net income per diluted share amounts(4)	60,195	46,798	39,411

- (1) Reversal of valuation allowance against deferred tax assets, primarily in the United States.
- (2) Tax related to acquisition restructuring activities partially offset by adjustments to convert the income tax provision to the estimated amount of taxes payable in cash.
- (3) Adjusted net income and adjusted net income per diluted share as used in this report exclude the impact of discontinued operations.
- (4) All references to “share” or “shares” in the table above refer to Jazz Pharmaceuticals, Inc.’s common stock with respect to 2010 and 2011, and to Jazz Pharmaceuticals plc’s ordinary shares with respect to the current year periods. GAAP income from continuing operations per diluted share and adjusted net income per diluted share in the comparative prior year periods were not impacted by the Azur Merger since each share of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and automatically converted into and became the right to receive one ordinary share upon the consummation of the Azur Merger.

### Liquidity and Capital Resources

In January 2012, we completed the Azur Merger in an all stock transaction and, in June 2012, we acquired EUSA Pharma for \$678.4 million in cash. Most of the acquisition consideration for the EUSA Acquisition was funded by a \$475.0 million term loan under a new credit agreement, the terms of which are described in more detail below. Subsequently, in October 2012, we completed the sale of our women’s health business, a component of the acquired Azur Pharma business, for net cash proceeds of \$93.9 million. During 2012, 2011 and 2010, we generated cash flows from operations of \$249.8 million, \$151.6 million and \$58.9 million, respectively.

As of December 31, 2012, we had cash and cash equivalents of \$387.2 million, borrowing availability under our revolving credit facility of \$100.0 million and \$463.1 million principal amount outstanding under our term loan. We believe that our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future, including our obligations under the credit agreement and a potential contingent

payment of \$50.0 million, which we agreed to pay if Erwinaze achieves U.S. net sales of \$124.5 million or greater in 2013. This payment may become payable in 2014. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses as well as the other factors set forth in Part I, Item 1A of this Annual Report on Form 10-K under the headings “*Xyrem is our largest selling product, and our inability to maintain or increase sales of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects,*” “*If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected,*” “*The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem,*” and “*To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business.*” Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

Our term loan is repayable in quarterly installments equal to 5% of the original principal amount in the first year, 7.5% in the second year, 10% in each of the third and fourth years and 15% in each of the fifth and sixth years, with any remaining balance payable on the final maturity date. Through December 31, 2012 we have made payments of \$11.9 million principal amount as required under the agreement. Borrowings under the term loan bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.25% per annum (subject to a 1.0% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 3.25% per annum (subject to a 2.0% prime rate floor). As of December 31, 2012, the interest rate on the term loan was 5.25%. Borrowings under the revolving credit facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.00% per annum, or the prime lending rate, plus an applicable margin equal to 3.00% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. We may make prepayments of principal without premium or penalty, except that a 1% premium would apply to a repayment via a repricing of the loan under the term loan effected on or prior to June 12, 2013. We are required to make mandatory prepayments of borrowings under the term loan (without payment of a premium) with net cash proceeds from certain non-ordinary course asset sales, issuances of debt (other than certain permitted debt) and casualty proceeds and condemnation awards; and, beginning with the fiscal year ending December 31, 2013, with 50% of our excess cash flow, as defined in the credit agreement (subject to increase to 75% if our secured leverage ratio exceeds 2.25 to 1.0, or decrease to 25% or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.0 or 0.75 to 1.0, respectively). No mandatory repayment was made or is required to be made under our term loan as a result of the sale of our women’s health business.

Borrowings under the credit agreement are guaranteed by Jazz Pharmaceuticals plc and certain of its subsidiaries and are secured by substantially all of their assets. The credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to us, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement contains a financial covenant that requires us to maintain a maximum secured leverage ratio. Our failure to comply with any of the operating and financial covenants contained in the credit agreement would constitute an event of default under the credit agreement. The credit agreement contains other customary events of default. If one or more events of default occurs and continues beyond any applicable cure period, the administrative agent may, with the consent of the lenders holding a majority of the loans and commitments under the facilities, or will, at the request of such lenders, terminate the commitments of the lenders to make further loans and declare all of the obligations under the credit agreement to be immediately due and payable. In such event, we would not have sufficient cash resources to repay the full amount of the obligations. We are currently in compliance with the covenants under the credit agreement.

To grow our business over the longer-term, we will need to commit substantial resources to product acquisition and in-licensing costs, to expensive and time-consuming product development and clinical trials of our product candidates, and to expanding our commercial operations. We may need to raise additional funds to license or acquire additional products, product candidates or companies or seek to raise additional funds for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Net cash provided by operating activities . . . . .	\$ 249,752	\$151,596	\$ 58,868
Net cash used in investing activities . . . . .	(395,294)	(81,232)	(2,143)
Net cash provided by (used in) financing activities . . . . .	448,530	(33,082)	(27,526)
Effect of foreign currency exchange rates on cash and cash equivalents . . . . .	2,132	—	—
Net increase in cash and cash equivalents . . . . .	<u>\$ 305,120</u>	<u>\$ 37,282</u>	<u>\$ 29,199</u>

Net cash from operating activities increased by \$98.2 million in 2012 primarily due to an increase in net income of \$163.6 million, offset by adjustments for non-cash items primarily related to intangible asset amortization and deferred income taxes. Net cash from operating activities increased by \$92.7 million in 2011 primarily due to an increase in net income of \$92.2 million.

Net cash used in investing activities in 2012 primarily related to funding the EUSA Acquisition, partially offset by net proceeds of \$93.9 million from the sale of our women's health business and net proceeds from the sales and maturities of investments of \$75.8 million. Net cash used in investing activities in 2011 primarily related to purchases of marketable securities, scheduled payments under our agreement for the rights to market Luvox CR and to a lesser extent purchases of property and equipment, partially offset by proceeds from maturities of marketable securities and releases of restricted cash. Net cash used in investing activities in 2010 included scheduled payments under our agreement for the rights to market Luvox CR, partially offset by a decrease in restricted cash.

Net cash provided by financing activities in 2012 included net borrowings under a term loan of \$450.9 million and proceeds from employee share purchases, exercise of share options and warrant exercises of \$25.0 million, partially offset by payments totaling \$25.3 million of income tax withholdings on behalf of certain employees related to the net share settlement of exercised share options in connection with the Azur Merger. Net cash used in financing activities in 2011 included a repayment of \$41.7 million for the full principal amount outstanding under a term loan and \$7.4 million for net repayments of a revolving credit facility, partially offset by proceeds from employee stock option exercises and warrant exercises. Net cash used in financing activities in 2010 included the principal repayment of other long-term debt of \$119.5 million, offset by proceeds from a common stock offering of \$56.8 million and net cash inflows from a term loan of \$40.1 million.

## Contractual Obligations

The table below presents a summary of our contractual obligations as of December 31, 2012 (in thousands):

Contractual Obligations(1)	Payments due by period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Term loan—principal	\$463,126	\$ 29,688	\$ 89,063	\$130,625	\$213,750
Term loan—interest(2)	102,316	24,131	42,221	31,013	4,951
Purchase obligations(3)	72,220	70,100	360	400	1,360
Operating lease obligations(4)	24,736	6,631	11,593	6,512	—
Revolving credit facility(5)	2,256	507	1,014	735	—
Contingent consideration obligation(6)	50,000	—	50,000	—	—
Total	<u>\$714,654</u>	<u>\$131,057</u>	<u>\$194,251</u>	<u>\$169,285</u>	<u>\$220,061</u>

- (1) This table does not include potential future milestone payment or royalty obligations to third parties under asset purchase, product development and license agreements as the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, as the amount of such obligations are not estimable. Potential future milestone payments to third parties under these agreements could be up to an aggregate of \$170 million, of which up to \$120 million will become due and payable to Elan in tiered contingent payments, with the first such payment becoming due if net sales of Prialt of at least \$75 million are achieved in a calendar year. The remainder would become due and payable to other third parties upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones, the timing and likelihood of which are not known. We are also obligated under these agreements to pay royalties on net sales of certain products at specified rates, which royalties are dependent on future product sales and are not provided for in the table above as they are not estimable.
- (2) In June 2012, we entered into a credit agreement that provides for a term loan in an aggregate principal amount of \$475.0 million, which matures in June 2018, and a \$100.0 million revolving credit facility, which matures in June 2017. In June 2012, we borrowed \$475.0 million under the term loan, and we repaid principal of \$11.9 million in 2012. The interest rate was 5.25% at December 31, 2012, which we used to estimate interest owed on the term loan until the final maturity date.
- (3) Consists primarily of non-cancelable commitments to third party manufacturers.
- (4) Includes the minimum lease payments for our office buildings and automobile lease payments for our sales force.
- (5) The revolving credit facility described in note (2) has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.50% and assumed undrawn amounts of \$100.0 million to estimate commitment fees owed. No amount was borrowed under the revolving credit facility as of December 31, 2012.
- (6) This amount represents a contingent payment of \$50.0 million that we agreed to make if Erwinaze achieves U.S. net sales of \$124.5 million or greater in 2013. The amount set forth in the table has not been probability adjusted or discounted. The fair value of this contingent consideration as of December 31, 2012 was \$34.8 million and was recorded as a non-current liability on our consolidated balance sheet.

No provision for income tax in Ireland has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$604.2 million at December 31, 2012. In the event of the distribution of those earnings in the form of dividends or otherwise, we may be liable for income taxes, subject to an adjustment, if any, for foreign tax credits and foreign withholding taxes payable to certain foreign tax authorities. As of December 31, 2012, it is not practicable to determine the amount of the income tax liability related to these undistributed earnings due to a variety of factors.

As of December 31, 2012, our liability for unrecognized tax benefits amounted to \$7.3 million (including interest and penalties). Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we cannot make a reasonably reliable estimate of the amount and period of related future payments, if any. Therefore, our liability has been excluded from the above contractual obligations table. We do not expect a significant tax payment related to these obligations within the next year.

### **Critical Accounting Policies and Significant Estimates**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 1 of the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K, we believe the following accounting estimates and policies to be critical.

#### ***Revenue Recognition***

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured.

#### ***Product Sales, Net***

Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from our consigned inventory location for shipment directly to a patient.

A significant portion of our net product revenues are derived from sales of Xyrem. We sell Xyrem in the United States to a single central pharmacy, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or Express Scripts. In 2012, sales of Xyrem to Express Scripts accounted for 65% of our net product sales. We recognize revenues from sales of Xyrem within the United States upon transfer of title, which occurs when Express Scripts removes product from our consigned inventory location at its facility for shipment directly to a patient. We accept returns from and provide Express Scripts with a credit for any product returned by patients to Express Scripts with defects that were not reasonably discoverable upon receipt of the consigned product by Express Scripts. Based on our experience over the past seven years, product returns to Express Scripts from patients are rare; during 2012, we issued credits totaling \$0.3 million to Express Scripts for returned product.

*Items Deducted from Gross Sales.* Revenues from sales of products are recorded net of estimated allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and channel inventory data. We review the adequacy of our provisions for sales deductions on a quarterly basis. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. Because we derive most of our revenues from sales of Xyrem in the United States to one specialty pharmacy customer, Express Scripts, we have a much higher level of knowledge about each prescription than if we sold the product through the normal pharmaceutical wholesaler channel as we do with our other products. The most significant items deducted from gross revenues where we exercise judgment are rebates, sales returns and chargebacks.

The following table presents the activity and ending balances for our provisions for rebates, sale returns and chargebacks (in thousands):

	<u>Rebates Payable</u>	<u>Sales Returns Reserve</u>	<u>Chargebacks</u>	<u>Total</u>
Balance at December 31, 2009 .....	\$ 2,270	\$ —	\$ —	\$ 2,270
Provision .....	11,096	3,921	233	15,250
Payments/credits .....	<u>(6,746)</u>	<u>(382)</u>	<u>(221)</u>	<u>(7,349)</u>
Balance at December 31, 2010 .....	6,620	3,539	12	10,171
Provision .....	21,742	2,250	451	24,443
Payments/credits .....	<u>(17,585)</u>	<u>(1,487)</u>	<u>(443)</u>	<u>(19,515)</u>
Balance at December 31, 2011 .....	10,777	4,302	20	15,099
Additions relating to acquisitions .....	8,809	18,833	—	27,642
Provision .....	52,603	9,733	13,072	75,408
Payments/credits .....	<u>(46,942)</u>	<u>(6,483)</u>	<u>(10,556)</u>	<u>(63,981)</u>
Balance at December 31, 2012(1) .....	<u>\$ 25,247</u>	<u>\$26,385</u>	<u>\$ 2,536</u>	<u>\$ 54,168</u>

(1) Includes both continuing and discontinued operations to date of disposal.

For the years ended December 31, 2012, 2011 and 2010, total sales deductions related to rebates, sale returns and chargebacks were 11%, 8% and 8% of gross product sales, respectively. Included in these amounts are immaterial adjustments related to prior-year sales due to changes in estimates. Such amounts represented less than 1% of net product sales for each of the three years ended December 31, 2012.

#### *Rebates*

We are subject to rebates on sales made under governmental and managed-care pricing programs in the United States. The largest of these rebates is associated with sales covered by Medicaid. We participate in state government-managed Medicaid programs as well as certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating government entities. We offer rebates and discounts to managed health care organizations in the United States. In estimating our provisions for rebates, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers and group purchasing organizations. We estimate the rebate provision based on historical utilization rates, historical payment experience, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and channel inventory data obtained from our major U.S. wholesalers in accordance with our inventory management agreements.

#### *Sales returns*

For certain products, we allow customers to return product within a specified period before and after its expiration date and issue credits which may be applied against existing or future invoices. We account for sales returns as a reduction in net revenue at the time a sale is recognized, by establishing an accrual in an amount equal to the estimated value of products expected to be returned. The sales return accrual is estimated principally based on historical experience, the level and estimated shelf life of inventory in the distribution channel, our return policy and expected future market events including generic competition.

#### *Chargebacks*

We participate in chargeback programs with a number of entities, principally the U.S. Department of Defense, the U.S. Department of Veterans Affairs and other public parties whereby pricing on products below wholesalers' list prices is provided to participating entities. These entities purchase product through wholesalers

at the lower negotiated price, and the wholesalers charge back to us the difference between their acquisition cost and the lower negotiated price which we record as allowances against accounts receivable. We determine our estimate of the chargebacks provision primarily based on historical experience on a product and program basis, current contract prices under the chargeback programs and channel inventory data.

### ***Goodwill and Intangible Assets***

#### *Goodwill*

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. We test goodwill for impairment annually in October and when events or changes in circumstances indicate that the carrying value may not be recoverable. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then in the second step, the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. We have determined the fair value of our single reporting unit to be equal to our market capitalization, as determined by our traded share price, plus a control premium. The control premium used was based on a review of such premiums identified in recent acquisitions of companies of similar size and in similar industries. We performed our annual goodwill impairment test in October 2012 and concluded that goodwill was not impaired as the fair value of the reporting unit significantly exceeded its carrying amount, including goodwill. As of December 31, 2012, we had \$442.6 million of goodwill primarily resulting from the Azur Merger on January 18, 2012 and the EUSA Acquisition on June 12, 2012.

#### *Intangible Assets*

In connection with the Azur Merger and the EUSA Acquisition, we acquired a number of intangible assets, including intangible assets related to currently marketed products (developed technology) and intangible assets related to product candidates (IPR&D). When significant identifiable intangible assets are acquired, we engage an independent third-party valuation firm to assist in determining the fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, which require the use of significant estimates and assumptions, including but not limited to:

- estimating the timing of and expected costs to complete the in-process projects;
- projecting regulatory approvals;
- estimating future cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates and probability rates by project.

We believe the fair values that we assign to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates. No assurance can be given, however, that the underlying assumptions used to estimate expected cash flows will transpire as estimated. In addition, we are required to estimate the period of time over which to amortize the intangible assets, which requires significant judgment.

Our finite-lived intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from two to 15 years. The estimated useful lives associated with intangible assets are consistent with the estimated lives of the products and may be modified when circumstances warrant. Intangible assets with finite lives are reviewed for impairment whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Factors that we consider in deciding when to perform an impairment review include



significant under-performance of a product in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

IPR&D is not amortized but is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the asset. If the carrying value of the assets are not expected to be recovered, the assets are written down to their estimated fair values.

As of December 31, 2012, we had \$833.8 million of finite-lived intangible assets and \$36.2 million of IPR&D assets primarily related to the marketed products and the IPR&D projects that we acquired in the Azur Merger and the EUSA Acquisition. Please refer to the footnotes to the consolidated financial statements included elsewhere in this report for further information about the intangible assets acquired during 2012 and the remaining useful lives of our finite-lived intangible assets as of December 31, 2012.

### ***Income Taxes***

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amount and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. We provide a valuation allowance when it is more-likely-than-not that deferred tax assets will not be realized.

Our most significant tax jurisdictions are Ireland, the United States and France. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on management's interpretations of jurisdiction-specific tax laws or regulations and the likelihood of settlement related to tax audit issues. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, the impact of accounting for share-based compensation, changes in our international organization, likelihood of settlement, and changes in overall levels of income before taxes.

Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence, including cumulative income in recent fiscal years, our forecast of future taxable income exclusive of reversing temporary differences and significant risks and uncertainties related to our business. In determining future taxable income, we are responsible for assumptions utilized including the amount of state, federal and international pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage our underlying business.

Based on available objective evidence at December 31, 2012, we reversed the valuation allowance recorded against substantially all of our deferred tax assets in the United States, resulting in a tax benefit of \$104.2 million. Management determined that a valuation allowance was no longer needed on these deferred tax assets based on an assessment of the relative impact of all positive and negative evidence that existed at December 31, 2012, including an evaluation of cumulative income in recent years, our forecast of future sources of taxable income exclusive of reversing temporary differences, and significant risks and uncertainties related to our business. We continue to maintain a valuation allowance against certain other deferred tax assets where realizability is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowances to the extent we believe a portion will not be

realized. This determination depends on a variety of factors, some of which are subjective, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. If we determine that the deferred tax assets are not realizable in a future period, we would record material changes to income tax expense in that period.

We have also provided for uncertain tax positions that we believe are not more-likely-than-not to be sustained upon examination by tax authorities. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate uncertain tax positions on a quarterly basis and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the more-likely-than-not threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax provision (benefit).

### ***Contingent Consideration***

As part of the EUSA Acquisition, we agreed to make an additional contingent payment of \$50.0 million in cash if Erwinaze achieves U.S. net sales of \$124.5 million or greater in 2013. Contingent consideration is initially recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in earnings. The estimate of fair value contains uncertainties as it involves assumptions about the probability of 2013 U.S. net sales of Erwinaze equaling or exceeding the \$124.5 million threshold and the discount rate. A significant increase or decrease in the estimated probability of meeting the milestone threshold would result in a significantly higher or lower fair value measurement, respectively. As of December 31, 2012, we estimated that the fair value of this contingent consideration was \$34.8 million.

### ***Share-Based Compensation***

We have elected to use the Black-Scholes option pricing model to calculate the fair value of share option grants under our equity incentive plans and grants under our employee stock purchase plan, or ESPP, and we are using the straight-line method to allocate compensation cost to reporting periods. The fair value of share options was estimated using the following assumptions:

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Volatility .....	64%	72%	85%
Expected term (years) .....	4.6	5.2	6.0
Range of risk-free rates .....	0.5-1.1%	0.0-2.7%	1.5-3.1%
Expected dividend yield .....	— %	— %	— %

The two inputs which require the greatest judgment and have a large impact on fair values are expected term and volatility.

The expected term of share option grants represents the weighted-average period the awards are expected to remain outstanding. For share options granted in 2012 and 2011, we estimated the weighted-average expected term based on historical exercise data. Prior to 2011, the expected term was estimated by assuming share options would be exercised at the mid-point between the vest date and the contractual term due, at that time, to limited historical exercise data.

Prior to 2012, we used a blend of the historical volatility and implied volatility of our ordinary shares, as well as the historical volatility of a peer group, to determine expected volatility for share option grants, and we used the implied volatility of our ordinary shares for grants under our ESPP. We included consideration of the historical volatility of a peer group to estimate expected volatility for share option grants since the trading history of our ordinary shares was less than the expected term of the share options. Beginning in the year ended December 31, 2012, we rely only on a blend of the historical and implied volatilities of our own ordinary shares to determine expected volatility for share option grants because our trading history now exceeds the expected term of the share options. In addition, we use a single volatility estimate for each share option grant. The weighted average volatility is determined by calculating the weighted average of volatilities for all share options granted in a given year.

### **Recent Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2013-02, “Other Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income,” or ASU No. 2013-02. ASU No. 2013-02 supersedes the presentation requirements for reclassifications out of accumulated other comprehensive income in ASUs 2011-05 and 2011-12 and requires an entity to provide additional information about reclassifications out of accumulated other comprehensive income. ASU No. 2013-02 became effective for us beginning January 1, 2013. The adoption of this amendment will not have a material impact on our results of operations or financial position.

In July 2012, the FASB issued ASU No. 2012-02, “Intangibles—Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment,” or ASU No. 2012-02. ASU No. 2012-02 simplifies how an entity tests indefinite-lived intangible assets (other than goodwill) for impairment by providing entities with an option to perform a qualitative assessment to determine whether further impairment testing is necessary. An entity would continue to calculate the fair value of an indefinite-lived intangible asset if the asset fails the qualitative assessment, while no further analysis would be required if it passes. ASU No. 2012-02 is effective for annual and interim indefinite-lived intangible asset impairment tests performed for fiscal years beginning after September 15, 2012, and early adoption is permitted. The adoption of this amendment will not have a material impact on our results of operations or financial position.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **Related Parties**

In connection with the Azur Merger, we assumed a lease for office space in Dublin, Ireland. The lease agreement was with Seamus Mulligan, the former Chief Executive Officer of Azur Pharma, who is a member of our board of directors. Rentals paid on this lease amounted to \$0.3 million in 2012. In November 2012, we terminated this lease at a cost of \$1.2 million, which was the carrying value of our above market lease liability. There was no resulting gain or loss on the lease termination.

In 2011, Azur Pharma entered into an agreement with Circ Pharma Limited/Circ Pharma Research and Development Limited, or Circ, companies controlled by Seamus Mulligan, whereby Azur Pharma obtained an option to license certain rights and assets in relation to Tramadol (a chronotherapeutic formulation) and to conduct certain development activities. Azur Pharma paid Circ \$0.3 million for this option in 2011. In 2012, we terminated the agreement at no cost.

In 2012, we entered into an underwriting agreement with two underwriters and certain selling shareholders, pursuant to which the selling shareholders agreed to sell to the underwriters 7.9 million of our ordinary shares, resulting in aggregate gross proceeds to the selling shareholders of approximately \$390.7 million. The selling

shareholders included entities affiliated with certain members of our board of directors, four of our directors and four of our executive officers at the time of the agreement. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the offering, and we paid expenses of approximately \$0.4 million in connection with the offering.

In 2010, we repaid in full all of our then outstanding senior secured notes, of which \$6.8 million principal amount was paid to an entity affiliated with Kohlberg, Kravis & Roberts & Co. L.P., or KKR, a significant stockholder. In addition, in 2010, we paid prepayment penalties and a fee to the holders of the senior secured notes totaling \$8.5 million of which \$0.5 million was paid to the KKR affiliate. Cash paid for interest with respect to then outstanding senior secured notes held by the KKR affiliate was \$0.5 million in 2010. All payments to KKR were in proportion to its ownership of the senior secured notes.

In 2010, we issued 7,000,000 shares of our common stock in an underwritten public offering of which 821,851 shares and 16,472 shares were purchased from the underwriter by Longitude Venture Partners, L.P. and Longitude Capital Associates, L.P., respectively, which are entities affiliated with Patrick G. Enright, a member of our board of directors. The remaining shares were purchased from the underwriter by third party investors on the same terms and conditions.

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

As of December 31, 2012, our exposure to market risk was confined to our cash equivalents which have maturities of less than one year and bear interest rates at variable rates and are denominated in, and pay interest in, U.S. dollars. The fair value of items exposed to market risk was \$43.6 million as of December 31, 2012. The primary objectives of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including 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. Our cash equivalents as of December 31, 2012 consisted of money market funds. The effect of a 50 basis point change in the average yield earned on our cash equivalents would have a *de minimis* effect on our interest income and, due to the nature of the investments, would not have had an impact on their fair value. For additional information see Note 4 of the Notes to the Financial Statements included elsewhere in this Annual Report on Form 10-K.

*Interest Rate Risk.* In June 2012, we entered into a credit agreement that provides for a six-year \$475.0 million term loan and a five-year \$100.0 million revolving credit facility. On June 12, 2012, we borrowed \$475.0 million under the term loan. We are exposed to risks associated with changes in interest rates as a result of borrowings under our term loan. Our indebtedness outstanding under our term loan is subject to a LIBOR floor of 1.0%. Currently LIBOR rates are below the floor of 1%, and therefore an increase in interest rates would only impact our net interest expense to the extent it exceeds the floor of 1%. Based on variable rate debt levels of \$463.1 million as of December 31, 2012, a 1.0% change in interest rates, above the LIBOR floor, would impact net interest expense for 2013 by approximately \$4.6 million.

*Foreign Exchange Risk.* As a result of the EUSA Acquisition, we have significant operations in Europe as well as in the United States. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the local currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The

cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive income (loss) in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposures are related to our subsidiaries that have functional currencies denominated in the Euro and the British Pound Sterling, or GBP. A 10% strengthening/(weakening) in the rates used to translate the results of our foreign subsidiaries would have increased/(decreased) net income for the year ended December 31, 2012 by approximately \$3 million.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in the foreign currency loss in the consolidated statements of income. At December 31, 2012, our primary exposure to transaction risk related to U.S. dollar net monetary assets held by subsidiaries with a Euro functional currency. At December 31, 2012, a 10% strengthening/(weakening) in the U.S. dollar against the Euro would have increased/(decreased) net income by approximately \$4 million.

## **Item 8. Financial Statements and Supplementary Data**

Our consolidated financial statements as listed below are included in this Annual Report on Form 10-K as pages F-1 through F-41.

	<u>Page</u>
<b>Jazz Pharmaceuticals plc</b>	
Reports of Independent Registered Public Accounting Firms .....	F-1
Consolidated Balance Sheets .....	F-3
Consolidated Statements of Income .....	F-4
Consolidated Statements of Comprehensive Income .....	F-5
Consolidated Statements of Shareholders' Equity .....	F-6
Consolidated Statements of Cash Flows .....	F-8
Notes to Consolidated Financial Statements .....	F-10

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

### **Item 9A. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.* We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2012.

*Limitations on the Effectiveness of Controls.* A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

*Changes in Internal Control over Financial Reporting.* On January 18, 2012, we completed the Azur Merger, which was accounted for as a reverse acquisition under the acquisition method of accounting, with Jazz Pharmaceuticals, Inc. treated as the acquirer in the Azur Merger for accounting purposes. The results of operations of the acquired Azur Pharma business have been included in the results of operations of Jazz Pharmaceuticals plc beginning on January 18, 2012. We have integrated Azur Pharma's historical internal controls over financial reporting with ours.

On June 12, 2012, we completed the EUSA Acquisition. The EUSA Acquisition was accounted for using the acquisition method of accounting. The results of operations of the acquired EUSA Pharma business have been included in the results of operations of Jazz Pharmaceuticals plc since June 12, 2012, and we have integrated EUSA Pharma's historical internal controls over financial reporting with ours.

During the quarter ended December 31, 2012, other than changes related to the integration of our internal control processes resulting from the Azur Merger and the EUSA Acquisition as discussed above, there were no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Management's Report on Internal Control over Financial Reporting.* The following report is provided by management in respect of our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act):

1. Our management is responsible for establishing and maintaining adequate internal control over financial reporting.
2. Our management used the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO framework, to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.

3. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2012 and has concluded that such internal control over financial reporting was effective. There were no material weaknesses in internal control over financial reporting identified by management.

4. KPMG, our independent registered public accounting firm, has audited the consolidated financial statements of Jazz Pharmaceuticals plc as of and for the year ended December 31, 2012, included herein, and has issued an audit report on our internal control over financial reporting which is included below.

## Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders  
Jazz Pharmaceuticals plc

We have audited Jazz Pharmaceutical plc's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Jazz Pharmaceutical plc's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Jazz Pharmaceuticals plc maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Jazz Pharmaceuticals plc and subsidiaries as of December 31, 2012, and the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows for the year then ended, and the related financial statement schedule for the year ended December 31, 2012, and our report dated February 26, 2013 expressed an unqualified opinion on those consolidated financial statements and the related financial statement schedule.

/s/ KPMG

Dublin, Ireland  
February 26, 2013



## **Item 9B. Other Information**

Not applicable.

## **PART III**

Certain information required by Part III is omitted from this Annual Report on Form 10-K and incorporated by reference to our definitive proxy statement for our 2013 annual general meeting of shareholders to be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended. If such definitive proxy statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

## **Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item relating to our directors and nominees for director is to be found under the section entitled “Proposal 1—Election of Directors” in the proxy statement for our 2013 annual general meeting of shareholders. Such information is incorporated herein by reference. The information required by this item relating to our executive officers is to be found under the section entitled “Executive Officers” in the proxy statement for our 2013 annual general meeting of shareholders. Such information is incorporated herein by reference. The information required by this item relating to our audit committee, audit committee financial expert and procedures by which shareholders may recommend nominees to our board of directors, may be found under the section entitled “Corporate Governance and Board Matters” appearing in the proxy statement for our 2013 annual general meeting of shareholders. Such information is incorporated herein by reference. Information regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, is to be found under the section entitled “Section 16(a) Beneficial Ownership Reporting Compliance” appearing in our proxy statement for our 2013 annual general meeting of shareholders. Such information is incorporated herein by reference.

Our Code of Conduct applies to all of our employees, directors and officers, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and those of our subsidiaries. The Code of Conduct is available on our website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) under the section entitled “About Us” at “Corporate Responsibility.” Shareholders may request a free copy of the Code of Conduct by submitting a written request to Jazz Pharmaceuticals plc, Attention: Investor Relations, Fourth Floor, Connaught House, 1 Burlington Road, Dublin 4, Ireland. We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Conduct by posting such information on our website at the website address and location specified above.

## **Item 11. Executive Compensation**

The information required by this item is to be included in our proxy statement for our 2013 annual general meeting of shareholders under the sections entitled “Executive Compensation,” “Director Compensation,” “Corporate Governance and Board Matters—Compensation Committee Interlocks and Insider Participation” and “Corporate Governance and Board Matters—Compensation Committee Report” and is incorporated herein by reference.

## **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item with respect to equity compensation plans is to be included in our proxy statement for our 2013 annual general meeting of shareholders under the section entitled “Equity

Compensation Plan Information” and is incorporated herein by reference. The information required by this item with respect to security ownership of certain beneficial owners and management is to be included in our proxy statement for our 2013 annual general meeting of shareholders under the section entitled “Security Ownership of Certain Beneficial Owners and Management.”

### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this item is to be included in our proxy statement for our 2013 annual general meeting of shareholders under the sections entitled “Certain Relationships and Related Transactions” and “Corporate Governance and Board Matters—Independence of Jazz Pharmaceuticals’ Board of Directors” and is incorporated herein by reference.

### **Item 14. Principal Accountant Fees and Services**

The information required by this item is to be included in our proxy statement for our 2013 annual general meeting of shareholders under the section entitled “Proposal 2—Approval of the Appointment of Independent Auditors and Auditors’ Remuneration” and is incorporated herein by reference.

## **PART IV**

### **Item 15. Exhibits and Financial Statement Schedules**

*(a) The following documents are filed as part of this Annual Report on Form 10-K*

*1. Index to Financial Statements:*

See Index to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K.

*2. Financial Statement Schedules:*

The following financial statement schedule of Jazz Pharmaceuticals plc is filed as part of this Annual Report on Form 10-K on page F-41 and should be read in conjunction with the consolidated financial statements of Jazz Pharmaceuticals plc.

Schedule II: Valuation and Qualifying Accounts

All other schedules are omitted because they are not applicable, not required under the instructions, or the requested information is shown in the consolidated financial statements or related notes thereto.

*(b) Exhibits—The following exhibits are included herein or incorporated herein by reference:*

<b>Exhibit Number</b>	<b>Description of Document</b>
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors’ Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.’s current report on Form 8-K (File No. 001-33500) filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors’ Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc’s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).

**Exhibit  
Number**

**Description of Document**

- 2.3 Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
- 2.4 Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
- 2.5 Asset Purchase Agreement, dated as of September 5, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals International II Limited, Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 15, 2012).
- 3.1 Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
- 4.1 Reference is made to Exhibit 3.1.
- 4.2A Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
- 4.2B Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500), for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
- 4.2C Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
- 4.2D Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
- 4.2E Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
- 4.3 Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.4 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

<u>Exhibit Number</u>	<u>Description of Document</u>
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.5 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.5	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. on July 7, 2009 (incorporated herein by reference to Exhibit 4.6 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6A	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.6B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.7	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1†	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between Jazz Pharmaceuticals, Inc. and Patheon Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.50 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007).
10.2†	Quality Agreement, dated as of March 13, 2007, by and between Jazz Pharmaceuticals, Inc. and Patheon Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.51 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007).
10.3†	Supply Agreement, dated as of April 1, 2010, by and between Jazz Pharmaceuticals, Inc. and Siegfried (USA) Inc. (incorporated herein by reference to Exhibit 10.54 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2010, as filed with the SEC on May 6, 2010).
10.4	Master Services Agreement, dated April 15, 2011, by and between Jazz Pharmaceuticals, Inc., CuraScript, Inc. and Express Scripts Specialty Distribution Services, Inc. (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2011, as filed with the SEC on May 9, 2011).
10.5	Escrow Agreement made and entered into as of January 18, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., Seamus Mulligan, solely in his capacity as Indemnitors' Representative, and Deutsche Bank National Trust Association, as escrow agent (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).

<b>Exhibit Number</b>	<b>Description of Document</b>
10.6†	Royalty Bearing License Agreement and Supply Agreement Re Erwinia-Derived Asparaginase, dated July 22, 2005, between the Health Protection Agency and EUSA Pharma SAS (formerly OPi, S.A.), as amended on each of December 22, 2009, March 23, 2012 and August 8, 2012 (incorporated herein by reference to Exhibit 10.11 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q/A (File No. 001-33500), as filed with the SEC on August 9, 2012).
10.7	Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., the Lenders and Barclays Bank PLC, as Administrative Agent, Collateral Agent, Swing Line Lender and L/C Issuer (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
10.8	Commercial Lease, dated as of June 2, 2004, by and between Jazz Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.52 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007).
10.9	Lease Agreement, dated October 20, 2008, between Seamus Mulligan, as lessor, and Jazz Pharmaceuticals plc, as lessee (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.10	First Amendment of Lease, dated June 1, 2009, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.86 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 4, 2009).
10.11	Second Amendment of Lease, dated February 28, 2012, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.31 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12	Lease, dated May 8, 2012, by and between John Ronan and Castle Cove Property Developments Limited and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.13	Surrender of Lease of 45 Fitzwilliam Square Dublin 2, dated November 9, 2012, between Seamus Mulligan, as lessor, and Jazz Pharmaceuticals plc, as lessee.
10.14+	Form of Indemnification Agreement between Jazz Pharmaceuticals plc and its officers and directors (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.15+	Offer Letter from Jazz Pharmaceuticals, Inc. to Kathryn Falberg (incorporated herein by reference to Exhibit 10.92 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on December 3, 2009).
10.16+	Employment Agreement by and between Seamus Mulligan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).

<u>Exhibit Number</u>	<u>Description of Document</u>
10.17+	Noncompetition Agreement by and between Seamus Mulligan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.18+	Offer Letter from Jazz Pharmaceuticals, Inc. to Jeffrey Tobias, M.D. (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 8, 2011).
10.19+	Separation Agreement, dated January 18, 2012, by and between Jazz Pharmaceuticals plc and Carol Gamble (incorporated herein by reference to Exhibit 10.27 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.20+	Offer Letter from Jazz Pharmaceuticals, Inc. to Suzanne Sawochka Hooper (incorporated herein by reference to Exhibit 10.19 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on May 8, 2012).
10.21+	Amendment to Employment Agreement by and between Jazz Pharmaceuticals plc and Seamus Mulligan (incorporated herein by reference to Exhibit 10.20 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on May 8, 2012).
10.22+	Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.23+	Amendment to Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.24+	Noncompetition Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.25A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc. and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.57A in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.25B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney's Office for the Eastern District of New York and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.57B in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.25C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.57C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.25D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.57D in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).

<b>Exhibit Number</b>	<b>Description of Document</b>
10.26A+	Jazz Pharmaceuticals plc 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.5 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.26B+	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.22 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.26C+	Form of Letter, amending outstanding options granted under the Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.60 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
10.27A+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.3 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.27B+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.3B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).
10.27C+	Form of Notice of Grant of Stock Options and Form of Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan.
10.27D+	Form of Notice of Grant of Stock Options and Form of Option Agreement (Irish) under Jazz Pharmaceuticals plc 2007 Equity Incentive Plan.
10.27E+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan.
10.27F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan.
10.28A+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.1 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.28B+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.39B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).
10.28C+	Form of Option Grant Notice and Form of Stock Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.28D+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).

<b><u>Exhibit Number</u></b>	<b><u>Description of Document</u></b>
10.28E+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.28F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.9 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.28G+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.10 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.28H+	Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.29+	Jazz Pharmaceuticals plc Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 99.6 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.30A+	Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 99.4 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.30B+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan.
10.31A+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan, as amended and restated.
10.31B+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Sub-Plan Governing Purchase Rights to Participants in the Republic of Ireland (incorporated by reference herein to Exhibit 10.4C in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2012, as filed with the SEC on August 7, 2012).
10.32A+	Jazz Pharmaceuticals plc Cash Bonus Plan, (incorporated herein by reference to Exhibit 10.33 in the annual report on Form 10-K/A (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.32B+	Jazz Pharmaceuticals plc Cash Bonus Plan for U.S. Affiliates.
10.32C+	Jazz Pharmaceuticals Cash Bonus Plan for International Affiliates (2013).
10.33+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.34 in the annual report on Form 10-K/A (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.34+	Jazz Pharmaceuticals plc 2012 Non-Employee Director Compensation Arrangements (incorporated herein by reference to Exhibit 10.32 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).



<u>Exhibit Number</u>	<u>Description of Document</u>
10.35+	Jazz Pharmaceuticals plc 2012 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
21.1	Subsidiaries of Jazz Pharmaceuticals plc.
23.1	Consent of KPMG, Independent Registered Public Accounting Firm.
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page hereto).
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS++	XBRL Instance Document
101.SCH++	XBRL Taxonomy Extension Schema Document
101.CAL++	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF++	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB++	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE++	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

\* The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 26, 2013

**Jazz Pharmaceuticals Public Limited Company**  
(Registrant)

/s/ BRUCE C. COZADD

---

**Bruce C. Cozadd**  
**Chairman and Chief Executive Officer and Director**  
**(Principal Executive Officer)**

/s/ KATHRYN E. FALBERG

---

**Kathryn E. Falberg**  
**Executive Vice President and Chief Financial Officer**  
**(Principal Financial Officer)**

/s/ KAREN J. WILSON

---

**Karen J. Wilson**  
**Senior Vice President, Finance**  
**(Principal Accounting Officer)**

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bruce C. Cozadd, Kathryn E. Falberg, and Karen J. Wilson, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, the following persons on behalf of the registrant and in the capacities and on the dates indicated have signed this report below:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ BRUCE C. COZADD</u> <b>Bruce C. Cozadd</b>	Chairman, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 26, 2013
<u>/s/ KATHRYN E. FALBERG</u> <b>Kathryn E. Falberg</b>	Executive Vice President and Chief Financial Officer <i>(Principal Financial Officer)</i>	February 26, 2013
<u>/s/ KAREN J. WILSON</u> <b>Karen J. Wilson</b>	Senior Vice President, Finance <i>(Principal Accounting Officer)</i>	February 26, 2013
<u>/s/ PAUL L. BERNS</u> <b>Paul L. Berns</b>	Director	February 26, 2013
<u>/s/ PATRICK G. ENRIGHT</u> <b>Patrick G. Enright</b>	Director	February 26, 2013
<u>/s/ JAMES C. MOMTAZEE</u> <b>James C. Momtazee</b>	Director	February 26, 2013
<u>/s/ SEAMUS C. MULLIGAN</u> <b>Seamus C. Mulligan</b>	Director	February 26, 2013
<u>/s/ KENNETH W. O'KEEFE</u> <b>Kenneth W. O'Keefe</b>	Director	February 26, 2013
<u>/s/ CATHERINE A. SOHN</u> <b>Catherine A. Sohn</b>	Director	February 26, 2013
<u>/s/ RICK E WINNINGHAM</u> <b>Rick E Winningham</b>	Director	February 26, 2013

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## Report of KPMG, Independent Registered Public Accounting Firm

The Board of Directors and Shareholders  
Jazz Pharmaceuticals plc

We have audited the accompanying consolidated balance sheet of Jazz Pharmaceuticals plc and subsidiaries (the Company) as of December 31, 2012, and the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows for the year then ended. In connection with our audit of the consolidated financial statements, we also have audited the financial statement schedule at Item 15(a)2 for the year ended December 31, 2012. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Jazz Pharmaceuticals plc and subsidiaries as of December 31, 2012, and the results of their operations and their cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for the year ended December 31, 2012, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Jazz Pharmaceuticals plc's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 26, 2013 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG

Dublin, Ireland  
February 26, 2013

**Report of Ernst & Young LLP, Independent Registered Public Accounting Firm**

The Board of Directors and Stockholder of  
Jazz Pharmaceuticals, Inc., a wholly-owned subsidiary of Jazz Pharmaceuticals plc

We have audited the accompanying consolidated balance sheet of Jazz Pharmaceuticals, Inc. as of December 31, 2011 and the related consolidated statements of operations, comprehensive income, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2011. Our audits also included the financial statement schedule for 2011 and 2010 listed in the Index at Item 15(a)2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Jazz Pharmaceuticals, Inc. at December 31, 2011 and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

Redwood City, California  
February 28, 2012

**JAZZ PHARMACEUTICALS PLC**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except per share amounts)

	December 31,	
	2012	2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 387,196	\$ 82,076
Marketable securities	—	75,822
Accounts receivable, net of allowances of \$3,779 and \$366 at December 31, 2012 and 2011, respectively	75,480	34,374
Inventories	26,525	3,909
Prepaid expenses	7,445	1,690
Deferred tax assets, net	35,813	—
Other current assets	19,113	1,260
Total current assets	551,572	199,131
Property and equipment, net	7,281	1,557
Intangible assets, net	869,952	14,585
Goodwill	442,600	38,213
Deferred tax assets, net, non-current	74,850	—
Deferred financing costs	16,576	—
Other long-term assets	3,662	87
Total assets	\$1,966,493	\$ 253,573
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 15,887	\$ 5,129
Accrued liabilities	104,666	34,783
Current portion of long-term debt	29,688	—
Income taxes payable	39,884	—
Deferred tax liability, net	275	—
Purchased product rights liability	—	4,500
Liability under government settlement	—	7,320
Deferred revenue	1,138	1,138
Total current liabilities	191,538	52,870
Deferred revenue, non-current	6,776	7,915
Long-term debt, less current portion	427,073	—
Contingent consideration	34,800	—
Deferred tax liability, net, non-current	178,393	—
Other non-current liabilities	6,621	—
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Preferred stock, \$0.0001 par value per share; zero and 20,000 shares authorized; no shares issued and outstanding at December 31, 2012 and 2011, respectively	—	—
Ordinary shares, nominal value \$0.0001 per share; 300,000 and 150,000 shares authorized; 58,014 and 42,468 shares issued and outstanding at December 31, 2012 and 2011, respectively	6	4
Non-voting euro deferred shares, €0.01 par value per share; 4,000 and no shares authorized, issued and outstanding at December 31, 2012 and 2011, respectively	55	—
Capital redemption reserve	471	—
Additional paid-in capital	1,151,010	542,697
Accumulated other comprehensive income (loss)	31,046	(31)
Accumulated deficit	(61,296)	(349,882)
Total shareholders' equity	1,121,292	192,788
Total liabilities and shareholders' equity	\$1,966,493	\$ 253,573

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

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

	Year Ended December 31,		
	2012	2011	2010
Revenues:			
Product sales, net .....	\$580,527	\$266,518	\$170,006
Royalties and contract revenues .....	5,452	5,759	3,775
Total revenues .....	<u>585,979</u>	<u>272,277</u>	<u>173,781</u>
Operating expenses:			
Cost of product sales (excluding amortization of acquired developed technologies) .....	78,425	13,942	13,559
Selling, general and administrative .....	223,882	108,936	68,996
Research and development .....	20,477	14,120	25,612
Intangible asset amortization .....	65,351	7,448	7,825
Total operating expenses .....	<u>388,135</u>	<u>144,446</u>	<u>115,992</u>
Income from operations .....	197,844	127,831	57,789
Interest expense, net (including \$570 for the year ended December 31, 2010 pertaining to a related party) .....	(16,869)	(1,600)	(12,724)
Foreign currency loss .....	(3,620)	—	—
Loss on extinguishment of debt (including \$701 for the year ended December 31, 2010 pertaining to a related party) .....	—	(1,247)	(12,287)
Income from continuing operations before income tax benefit .....	177,355	124,984	32,778
Income tax benefit .....	(83,794)	—	—
Income from continuing operations .....	261,149	124,984	32,778
Income from discontinued operations, net of taxes .....	27,437	—	—
Net income .....	<u>\$288,586</u>	<u>\$124,984</u>	<u>\$ 32,778</u>
Basic income per ordinary share:			
Income from continuing operations .....	\$ 4.61	\$ 3.01	\$ 0.90
Income from discontinued operations .....	0.48	—	—
Net income .....	<u>\$ 5.09</u>	<u>\$ 3.01</u>	<u>\$ 0.90</u>
Diluted income per ordinary share:			
Income from continuing operations .....	\$ 4.34	\$ 2.67	\$ 0.83
Income from discontinued operations .....	0.45	—	—
Net income .....	<u>\$ 4.79</u>	<u>\$ 2.67</u>	<u>\$ 0.83</u>
Weighted-average ordinary shares used in per share computations:			
Basic .....	<u>56,643</u>	<u>41,499</u>	<u>36,343</u>
Diluted .....	<u>60,195</u>	<u>46,798</u>	<u>39,411</u>

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



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

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Net income .....	\$288,586	\$124,984	\$32,778
Other comprehensive income (loss):			
Foreign currency translation adjustments .....	31,046	—	—
Available-for-sale securities:			
Net unrealized gain (loss) on available-for-sale securities, net of income taxes .....	8	(31)	—
Reclassification adjustments for gains included in earnings, net of income taxes .....	23	—	—
Other comprehensive income (loss) .....	<u>31,077</u>	<u>(31)</u>	<u>—</u>
Total comprehensive income .....	<u>\$319,663</u>	<u>\$124,953</u>	<u>\$32,778</u>
Total comprehensive income arises from:			
Continuing operations .....	\$292,226	\$124,953	\$32,778
Discontinued operations .....	<u>27,437</u>	<u>—</u>	<u>—</u>
Total comprehensive income .....	<u>\$319,663</u>	<u>\$124,953</u>	<u>\$32,778</u>

Form 10-K

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

**JAZZ PHARMACEUTICALS PLC**  
**CONSOLIDATED STATEMENTS OF**  
**SHAREHOLDERS' EQUITY**  
(In thousands)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount					
<b>Balance at December 31, 2009</b>	31,255	\$ 3	—	—	\$—	\$434,811	\$—	\$(507,644)	\$(72,830)
Stock issuable under directors deferred compensation plan . . . . .	—	—	—	—	—	198	—	—	198
Issuance of common stock in conjunction with exercise of stock options . . . . .	955	—	—	—	—	3,682	—	—	3,682
Issuance of common stock in conjunction with vesting of restricted stock units . . . . .	13	—	—	—	—	—	—	—	—
Issuance of common stock under employee stock purchase plan . . . . .	520	—	—	—	—	529	—	—	529
Issuance of common stock in conjunction with offering, net of issuance costs . . . . .	7,000	1	—	—	—	56,816	—	—	56,817
Issuance of common stock in conjunction with exercise of warrants . . . . .	216	—	—	—	—	1,380	—	—	1,380
Stock-based compensation . . . . .	—	—	—	—	—	7,997	—	—	7,997
Net income and comprehensive income . . . . .	—	—	—	—	—	—	—	32,778	32,778
<b>Balance at December 31, 2010</b>	39,959	4	—	—	—	505,413	—	(474,866)	30,551
Stock issued/issuable under directors deferred compensation plan . . . . .	13	—	—	—	—	368	—	—	368
Issuance of common stock in conjunction with exercise of stock options . . . . .	1,400	—	—	—	—	12,214	—	—	12,214
Issuance of common stock in conjunction with vesting of restricted stock units . . . . .	13	—	—	—	—	—	—	—	—
Issuance of common stock under employee stock purchase plan . . . . .	359	—	—	—	—	1,546	—	—	1,546
Issuance of common stock in conjunction with exercise of warrants . . . . .	724	—	—	—	—	2,659	—	—	2,659
Stock-based compensation . . . . .	—	—	—	—	—	20,497	—	—	20,497
Other comprehensive loss . . . . .	—	—	—	—	—	—	(31)	—	(31)
Net income . . . . .	—	—	—	—	—	—	—	124,984	124,984
<b>Balance at December 31, 2011</b>	42,468	4	—	—	—	542,697	(31)	(349,882)	192,788

**JAZZ PHARMACEUTICALS PLC**  
**CONSOLIDATED STATEMENTS OF**  
**SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)**  
(In thousands)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount					
<b>Balance at</b>									
<b>December 31, 2011</b>	42,468	\$ 4	—	\$—	\$—	\$ 542,697	\$ (31)	\$(349,882)	\$ 192,788
Merger with Azur Pharma . . . . .	12,360	2	4,000	55	471	575,936	—	—	576,464
Issuance costs related to Azur Merger . . . . .	—	—	—	—	—	(241)	—	—	(241)
Shares issued under directors deferred compensation plan . . . . .	45	—	—	—	—	—	—	—	—
Issuance of ordinary shares in conjunction with exercise of share options . . . . .	1,951	—	—	—	—	14,212	—	—	14,212
Issuance of ordinary shares under employee stock purchase plan . . . . .	151	—	—	—	—	3,707	—	—	3,707
Shares withheld for payment of employee's withholding tax liability . . . . .	—	—	—	—	—	(25,299)	—	—	(25,299)
Issuance of ordinary shares in conjunction with exercise of warrants . . . . .	1,039	—	—	—	—	7,084	—	—	7,084
Share-based compensation . . . . .	—	—	—	—	—	23,129	—	—	23,129
Excess tax benefits from employee share options . . . . .	—	—	—	—	—	9,785	—	—	9,785
Other comprehensive income . . . . .	—	—	—	—	—	—	31,077	—	31,077
Net income . . . . .	—	—	—	—	—	—	—	288,586	288,586
<b>Balance at</b>									
<b>December 31, 2012</b>	<u>58,014</u>	<u>\$ 6</u>	<u>4,000</u>	<u>\$ 55</u>	<u>\$471</u>	<u>\$1,151,010</u>	<u>\$31,046</u>	<u>\$ (61,296)</u>	<u>\$1,121,292</u>

Form 10-K

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

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

	Year Ended December 31,		
	2012	2011	2010
<b>Operating activities</b>			
Net income	\$ 288,586	\$124,984	\$32,778
Adjustments to reconcile net income to net cash provided by operating activities:			
Amortization of intangible assets	72,922	7,448	7,825
Depreciation	1,307	379	886
Loss on disposal of property and equipment	163	33	279
Share-based compensation	23,006	20,704	8,219
Excess tax benefit from share-based compensation	(9,785)	—	—
Acquisition accounting inventory fair value step-up	19,939	—	—
Change in fair value of contingent consideration	(300)	—	—
Deferred income taxes	(113,862)	—	—
Gain on sale of business	(35,244)	—	—
Provision for losses on accounts receivable and inventory	4,654	59	(105)
Other non-cash transactions	3,523	394	2,406
Loss on extinguishment of debt	—	1,247	12,287
Changes in assets and liabilities:			
Accounts receivable	(4,724)	(12,293)	(9,768)
Inventories	1,697	1,239	(1,539)
Prepaid expenses and other current assets	(13,091)	(934)	426
Other long-term assets	(3,491)	186	—
Accounts payable	(7,286)	2,080	891
Accrued liabilities	(1,643)	11,211	9,276
Income taxes payable	29,555	—	—
Deferred revenue	(1,205)	(1,273)	(2,540)
Other non-current liabilities	2,351	(82)	53
Liability under government settlement	(7,320)	(3,786)	(2,506)
Net cash provided by operating activities	<u>249,752</u>	<u>151,596</u>	<u>58,868</u>
<b>Investing activities</b>			
Acquisitions, net of cash acquired	(542,531)	—	—
Purchases of marketable securities	(37,443)	(79,886)	—
Net proceeds from sale of business	93,922	—	—
Proceeds from sale of marketable securities	81,246	—	—
Proceeds from maturities of marketable securities	31,988	4,033	—
Purchases of property and equipment	(5,976)	(1,279)	(731)
Purchase of product rights	(16,500)	(4,500)	(4,000)
Decrease in restricted cash	—	400	2,588
Net cash used in investing activities	<u>(395,294)</u>	<u>(81,232)</u>	<u>(2,143)</u>

**JAZZ PHARMACEUTICALS PLC**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)**  
(In thousands)

	Year Ended December 31,		
	2012	2011	2010
<b>Financing activities</b>			
Net proceeds from issuance of debt . . . . .	450,916	—	48,427
Proceeds from employee share purchases, exercise of share options and warrants . . . . .	25,003	16,419	5,591
Payment of employee withholding taxes upon exercise of share-based awards . . . . .	(25,299)	—	—
Excess tax benefit from share-based compensation . . . . .	9,785	—	—
Repayment of long-term debt (including \$6,816 for the year ended December 31, 2010 paid to a related party) . . . . .	(11,875)	(41,668)	(127,828)
Payments of debt extinguishment costs (including \$484 for the year ended December 31, 2010 paid to a related party) . . . . .	—	(483)	(8,484)
Proceeds from offerings of common stock, net of issuance costs . . . . .	—	—	56,817
Net repayments under revolving credit facility . . . . .	—	(7,350)	(2,049)
Net cash provided by (used in) financing activities . . . . .	<u>448,530</u>	<u>(33,082)</u>	<u>(27,526)</u>
Effect of exchange rates on cash and cash equivalents . . . . .	2,132	—	—
Net increase in cash and cash equivalents . . . . .	305,120	37,282	29,199
Cash and cash equivalents, at beginning of period . . . . .	82,076	44,794	15,595
Cash and cash equivalents, at end of period . . . . .	<u>\$387,196</u>	<u>\$ 82,076</u>	<u>\$ 44,794</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest (including \$461 for the year ended December 31, 2010 paid to a related party) . . . . .	\$ 14,192	\$ 1,621	\$ 10,234
Cash paid for income taxes . . . . .	\$ 9,143	\$ —	\$ —
Non-cash investing activities:			
Acquisition consideration for Azur Merger . . . . .	\$576,464	\$ —	\$ —

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

**JAZZ PHARMACEUTICALS PLC**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Description of Business**

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 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. Upon the consummation of the Azur Merger, the historical financial statements of Jazz Pharmaceuticals, Inc. became our historical financial statements. Accordingly, the historical financial statements of Jazz Pharmaceuticals, Inc. only are included in the comparative prior periods. For additional information regarding the Azur Merger see Note 3.

On June 12, 2012, we completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, or the EUSA Acquisition. As part of the EUSA Acquisition, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc. For additional information regarding the EUSA Acquisition see Note 3.

Unless otherwise indicated or the context otherwise requires, 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., except that all such references prior to the effective time of the Azur Merger on January 18, 2012 are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. 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. The disclosures in this report relating to the pre-Azur Merger business of Jazz Pharmaceuticals plc, unless noted as being the business of Azur Pharma prior to the Azur Merger, pertain to the business of Jazz Pharmaceuticals, Inc. prior to the Azur Merger. All references to "EUSA Pharma" in this report are references to EUSA Pharma Inc. and its consolidated subsidiaries prior to the effective time of the EUSA Acquisition.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements include the accounts of Jazz Pharmaceuticals plc and our wholly-owned subsidiaries and intercompany transactions and balances have been eliminated. 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, are included in our consolidated financial statements since the effective dates of the Azur Merger and the EUSA Acquisition, respectively.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *Significant Risks and Uncertainties*

Our financial results are significantly influenced by sales of Xyrem<sup>®</sup> (sodium oxybate) oral solution, and 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 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 or tentative approval of an ANDA resulting 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 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. We cannot predict the timing of finalization, or the final terms, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, 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; 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, 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; our dependence on sole source suppliers to continue to meet our ongoing commercial needs, especially when our supply demands are growing; and the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval.

#### *Business Acquisitions*

Our consolidated financial statements include the operations of an acquired business after the completion of the acquisition. We account for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, with limited exceptions, and that the fair value of acquired in-process research and development, or IPR&D, be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the acquisition consideration over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in earnings.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *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 December 31, 2012, five customers accounted for 78% of gross accounts receivable including Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, which accounted for 51% of gross accounts receivable and Accredo Health Group, Inc. which accounted for 11% of gross accounts receivable. As of December 31, 2011, Express Scripts accounted for 79% of gross accounts receivable.

We rely on certain sole suppliers for drug substance and certain sole manufacturing partners for certain of our marketed products and product candidates.

#### *Cash Equivalents and Marketable Securities*

We consider all highly liquid investments, readily convertible to cash, that mature within three months or less from date of purchase to be cash equivalents.

Marketable securities are investments in debt securities with maturities of less than one year from the balance sheet date, or securities with maturities of greater than one year that are specifically identified to fund current operations. Collectively, cash equivalents, restricted cash and marketable securities are considered available-for-sale and are recorded at fair value. Unrealized gains and losses, net of tax, are recorded in accumulated other comprehensive income (loss) in shareholders' equity. We use the specific-identification method for calculating realized gains and losses on securities sold. Realized gains and losses and declines in value judged to be other than temporary on marketable securities are included in interest expense, net in the consolidated statements of income. Realized gains and losses on sales of marketable securities have not been significant.

#### *Inventories*

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular



## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

product. If the estimate of future demand is too high, we may have to increase the reserve for excess inventory for that product and record a charge to cost of product sales. For product candidates that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the clinical trial. Prior to receiving FDA approval, costs related to purchases of the active pharmaceutical ingredient and the manufacturing of the product candidate are recorded as research and development expense. All direct manufacturing costs incurred after approval are capitalized into inventory. As of December 31, 2012, the fair value of inventories acquired included a step-up in the value of inventories of \$4.0 million.

#### *Property and Equipment*

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from three to 10 years. Leasehold improvements are amortized over the shorter of the noncancelable term of our operating lease or their economic useful lives. Maintenance and repairs are expensed as incurred.

#### *Goodwill*

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then in the second step, the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. We test goodwill for impairment annually in October and when events or changes in circumstances indicate that the carrying value may not be recoverable.

#### *Intangible Assets*

Intangible assets with finite useful lives consist primarily of purchased developed technology and are amortized on a straight-line basis over their estimated useful lives, which range from two to 15 years. The estimated useful lives associated with finite-lived intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Intangible assets with finite lives are reviewed for impairment when events or circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset.

The fair value of IPR&D acquired through a business combination is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. IPR&D is not amortized but is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the asset. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized over their estimated useful lives.

#### *Revenue Recognition*

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *Product Sales, Net*

Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from our consigned inventory location for shipment directly to a patient.

Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (i) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (ii) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (iii) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product, (iv) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (v) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (vi) the amount of future returns can be reasonably estimated.

Revenues from sales of products are recorded net of estimated allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans. Provisions for returns, specialty distributor fees, wholesaler fees, government rebates, coupon programs and rebates under managed care plans are included within current liabilities in our consolidated balance sheets. Provisions for government chargebacks and prompt payment discounts are shown as a reduction in accounts receivable. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and channel inventory data. Adjustments to estimates for these allowances have not been material.

#### *Royalties and Contract Revenues*

We receive royalties from third parties based on sales of our products under licensing and distribution arrangements. For those arrangements where royalties are reasonably estimable, we recognize revenues based on estimates of royalties earned during the applicable period, and adjust for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been significant.

Our contract revenues consist of fees and milestone payments. Non-refundable fees where we have no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. In situations where we have continuing performance obligations, non-refundable fees are deferred and are recognized ratably over our projected performance period. We recognize at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. Sales-based milestone payments are typically payments made to us that are triggered when aggregate net sales of a product by a collaborator for a specified period (for example, an annual period) reach an agreed upon threshold amount. We recognize sales-based milestone payments from a collaborator when the event which triggers the obligation of payment has occurred, there is no further obligation on our part in connection with the payment, and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when our performance obligations are completed.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *Cost of Product Sales*

Cost of product sales includes third party manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability and cargo insurance, FDA user fees, freight, shipping, handling and storage costs and salaries and related costs of employees involved with production. Cost of product sales in 2012 included \$16.8 million of inventory costs associated with the fair value step-up in acquired inventory. Excluded from cost of product sales, as shown on the consolidated statements of income, is amortization of acquired developed technology of \$65.1 million for 2012 and \$7.2 million during each of 2011 and 2010.

#### *Research and Development*

Research and development expenses consist primarily of personnel expenses, costs related to clinical studies and outside services, and other research and development costs. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Clinical study and outside services costs relate primarily to clinical studies performed by clinical research organizations, materials and supplies, and other third-party fees. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. Research and development costs are expensed as incurred, including payments made under license agreements. For product candidates that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the trial and therefore is not included in inventory.

#### *Advertising Expenses*

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses for 2012, 2011 and 2010 were \$0.7 million, \$1.0 million and \$1.6 million, respectively.

#### *Income Taxes*

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amount and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more-likely-than-not that some portion or all of a deferred tax asset will not be realized. We account for uncertain tax positions using a “more-likely-than-not” threshold for recognizing and resolving uncertain tax positions. A recognized tax position is then measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon settlement. Interest and penalties related to uncertain tax positions are included in the income tax provision (benefit) and classified with the related liability on the consolidated balance sheets.

#### *Foreign Currency*

Our functional and reporting currency is the U.S. dollar. The assets and liabilities of our subsidiaries that have a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date with the results of operations of subsidiaries translated at the average exchange rate for the reporting period. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive income (loss) in shareholders' equity.

Transactions in foreign currencies are translated into the functional currency of the relevant subsidiary at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

transactions are translated into the relevant functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign currency loss in the our consolidated statements of income.

***Financing Costs***

Deferred financing costs are reported at cost, less accumulated amortization and the related amortization expense is included in interest expense, net in our consolidated statements of income. The carrying amount of debt includes any related unamortized original issue discount.

***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 consolidated financial statements and 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):

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Numerator:			
Income from continuing operations . . . . .	\$261,149	\$124,984	\$32,778
Income from discontinued operations . . . . .	<u>27,437</u>	<u>—</u>	<u>—</u>
Net income . . . . .	<u>\$288,586</u>	<u>\$124,984</u>	<u>\$32,778</u>
Denominator:			
Weighted-average ordinary shares—basic . . . . .	56,643	41,499	36,343
Dilutive effect of employee equity incentive and purchase plans . . . . .	1,536	2,715	1,720
Dilutive effect of warrants . . . . .	<u>2,016</u>	<u>2,584</u>	<u>1,348</u>
Weighted-average ordinary shares—diluted . . . . .	<u>60,195</u>	<u>46,798</u>	<u>39,411</u>
Basic income per ordinary share:			
Income from continuing operations . . . . .	\$ 4.61	\$ 3.01	\$ 0.90
Income from discontinued operations . . . . .	0.48	—	—
Net income . . . . .	<u>\$ 5.09</u>	<u>\$ 3.01</u>	<u>\$ 0.90</u>
Diluted income per ordinary share:			
Income from continuing operations . . . . .	\$ 4.34	\$ 2.67	\$ 0.83
Income from discontinued operations . . . . .	0.45	—	—
Net income . . . . .	<u>\$ 4.79</u>	<u>\$ 2.67</u>	<u>\$ 0.83</u>

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Potentially dilutive ordinary shares from employee equity plans and warrants are determined by applying the treasury stock method to the assumed exercise of warrants and share options, the assumed vesting of outstanding restricted stock units, or RSUs, and the assumed issuance of ordinary shares under our employee stock purchase plan. The following table represents the weighted-average ordinary shares that were excluded from the computation of diluted net income per ordinary share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Options to purchase ordinary shares and RSUs . . . . .	1,506	1,038	3,211

All references to “ordinary shares” in the discussion and tables above refer to Jazz Pharmaceuticals, Inc.’s common stock with respect to the comparative prior year periods and to Jazz Pharmaceuticals plc’s ordinary shares with respect to the year ended December 31, 2012. Our earnings per share in the comparative prior year periods were not impacted by the Azur Merger since each share of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and automatically converted into and became the right to receive one ordinary share upon the consummation of the Azur Merger. This one-for-one conversion ratio is referred to in this report as the Azur exchange ratio.

#### ***Share-Based Compensation***

We account for compensation cost for all share-based awards at fair value on the date of grant. The fair value is recognized as expense over the service period, net of estimated forfeitures, using the straight-line method for share options and restricted stock units and using the ratable method for awards under our employee stock purchase program. The estimation of share-based awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. We primarily consider historical experience when estimating expected forfeitures.

#### ***Recent Accounting Pronouncements***

In February 2013, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2013-02, “Other Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income,” or ASU No. 2013-02. ASU No. 2013-02 supersedes the presentation requirements for reclassifications out of accumulated other comprehensive income in ASUs 2011-05 and 2011-12 and requires an entity to provide additional information about reclassifications out of accumulated other comprehensive income. ASU No. 2013-02 became effective for us beginning January 1, 2013. The adoption of this amendment will not have a material impact on our results of operations or financial position.

In July 2012, the FASB issued ASU No. 2012-02, “Intangibles—Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment,” or ASU No. 2012-02. ASU No. 2012-02 simplifies how an entity tests indefinite-lived intangible assets (other than goodwill) for impairment by providing entities with an option to perform a qualitative assessment to determine whether further impairment testing is necessary. An entity would continue to calculate the fair value of an indefinite-lived intangible asset if the asset fails the qualitative assessment, while no further analysis would be required if it passes. ASU No. 2012-02 is effective for annual and interim indefinite-lived intangible asset impairment tests performed for fiscal years beginning after September 15, 2012, and early adoption is permitted. The adoption of this amendment will not have a material impact on our results of operations or financial position.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### 3. Business Combinations

##### *Merger with Azur Pharma*

On January 18, 2012, pursuant to an Agreement and Plan of Merger and Reorganization dated as of September 19, 2011, as amended, 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. We believe the Azur Merger resulted in a company with a strengthened management team, a broader commercial organization and an efficient platform for further growth, with resources to build our product portfolio and a future pipeline.

At the effective time of the Azur Merger, each share of the common stock of Jazz Pharmaceuticals, Inc. issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and automatically converted into and became the right to receive one ordinary share of Jazz Pharmaceuticals plc. Further, the stock options and stock awards outstanding under Jazz Pharmaceuticals, Inc.'s equity incentive plans were converted into stock options and stock awards to purchase or receive an equal number of ordinary shares of Jazz Pharmaceuticals plc with substantially the same terms and conditions, including the same per share exercise price. In addition, outstanding warrants to purchase Jazz Pharmaceuticals, Inc. common stock were converted into substantially the same warrants to purchase an equal number of ordinary shares of Jazz Pharmaceuticals plc at the same per share exercise price. Our ordinary shares trade on the same exchange, The NASDAQ Global Select Market, and under the same trading symbol, "JAZZ," as the Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger. We are deemed to be the successor to Jazz Pharmaceuticals, Inc. pursuant to Rule 12g-3(a) under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The Azur Merger was accounted for as a reverse acquisition under the acquisition method of accounting, with Jazz Pharmaceuticals, Inc. treated as the accounting acquirer. Under the acquisition method of accounting, assets and liabilities of Azur Pharma were recorded at their respective estimated fair values as of the date of the Azur Merger and added to those of Jazz Pharmaceuticals, Inc., including an amount for goodwill representing the difference between the acquisition consideration and the estimated fair value of the identifiable net assets. The results of operations of the acquired Azur Pharma business and the estimated fair values of the assets acquired and liabilities assumed have been included in our consolidated financial statements since the date of the Azur Merger.

The total acquisition consideration of \$576.5 million was determined based on the market value of our ordinary shares that were held by the historic Azur Pharma shareholders immediately following the closing of the Azur Merger. The closing price of the Jazz Pharmaceuticals, Inc. common stock on January 17, 2012 (\$46.64) was used to determine the fair value of consideration because the closing of the transaction on January 18, 2012 occurred prior to the opening of regular trading on January 18, 2012. Immediately following the consummation of the Azur Merger, 12,360,000, or 22%, of our ordinary shares were held by the persons and entities who acquired ordinary shares of Azur Pharma prior to the Azur Merger, and the remaining 43,838,000, or 78%, of the ordinary shares were held by the former stockholders of Jazz Pharmaceuticals, Inc.

In 2012, we incurred \$2.3 million in transaction costs related to the Azur Merger, which primarily consisted of banking, legal, accounting and valuation-related expenses. These expenses were recorded in selling, general and administrative expense in our consolidated statements of income. In 2012, the contribution of the acquired Azur Pharma business to our total revenues from continuing operations was \$65.8 million. This excludes revenues of \$20.9 million in 2012 related to our women's health business, which we sold in October 2012. For more details regarding this sale, see Note 19. The portion of total expenses and net income associated with the acquired Azur Pharma business was not separately identifiable due to the integration with our operations.

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The fair values of assets acquired and liabilities assumed at the closing date of the Azur Merger are summarized below (in thousands):

Cash and cash equivalents	\$ 81,751
Accounts receivable (1)	12,975
Inventories	15,344
Property and equipment	370
Intangible assets	325,000
Goodwill	201,524
Other assets	4,862
Accounts payable and accrued liabilities	(52,148)
Purchased product rights liability	(11,899)
Above market lease obligation	(1,315)
Total acquisition consideration	<u>\$576,464</u>

- (1) The estimated fair value of trade receivables acquired was \$13.0 million. The gross contractual amount of trade receivables was \$13.8 million and was recorded net of allowances for wholesaler chargebacks related to government rebate programs and cash discounts for prompt payment. We expect that \$0.8 million of the gross contractual amount of trade receivables will be uncollectible.

The intangible assets as of the closing date of the Azur Merger included (in thousands):

Acquired developed technologies:	
Prialt®	\$231,000
Women's health products	49,000
FazaClo HD®	18,000
FazaClo LD®	18,000
Other central nervous system products	7,000
Total acquired developed technologies	<u>323,000</u>
In-process research and development:	
Versacloz™ (clozapine, USP)	<u>2,000</u>
Total intangible assets	<u>\$325,000</u>

Intangible assets related to acquired developed technologies reflect the estimated fair value of the rights we acquired to those products in the Azur Merger. The fair value was determined using an income approach, which recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs for each product line. Indications of value are developed by discounting these benefits to their present worth at a discount rate that reflects the current return requirements of the market. Acquired developed technologies are finite-lived intangible assets and are being amortized over their estimated lives ranging from two to 15 years.

The excess of the total acquisition consideration over the fair value amounts assigned to the assets acquired and the liabilities assumed represents the goodwill amount resulting from the Azur Merger. We believe that the factors that contributed to goodwill include synergies that are specific to our consolidated business and not available to market participants and the acquisition of a talented workforce that expands our expertise in business development and commercializing pharmaceutical products, as well as other intangible assets that do not qualify for separate recognition. We do not expect any portion of this goodwill to be deductible for tax purposes.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *Acquisition of EUSA Pharma*

On June 12, 2012, pursuant to an Agreement and Plan of Merger dated as of April 26, 2012, or the EUSA Acquisition Agreement, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc. The EUSA Acquisition has contributed to our expanded portfolio of specialty pharmaceutical products and product candidates, including in particular, Erwinaze, as well as given us a strengthened management team and an enhanced commercial platform, adding EUSA Pharma's specialty commercial infrastructure in the United States and Europe and its international distribution network to our existing U.S. specialty product platform.

The EUSA Acquisition was accounted for using the acquisition method of accounting under which assets and liabilities of EUSA Pharma were recorded at their respective estimated fair values as of the date of the EUSA Acquisition and added to those of Jazz Pharmaceuticals plc including an amount for goodwill representing the difference between the acquisition consideration and the estimated fair value of the identifiable net assets. The results of operations of EUSA Pharma and the estimated fair values of the assets acquired and liabilities assumed have been included in our consolidated financial statements since the date of the EUSA Acquisition.

At the closing of the EUSA Acquisition, we made an upfront cash payment of \$678.4 million. Under the EUSA Acquisition Agreement, we also agreed to make an additional contingent payment of \$50.0 million in cash if Erwinaze achieves U.S. net sales (as defined in the EUSA Acquisition Agreement) of \$124.5 million or greater in 2013. \$50.0 million of the amount paid at closing was deposited in an escrow account, to be held for 12 months as partial security for our indemnification rights under the EUSA Acquisition Agreement. In October 2012, we received a working capital adjustment of \$2.3 million, decreasing the escrow account balance to \$47.7 million. \$25.0 million of the potential contingent payment, if payable, would be subject to reduction for indemnification claims, if any, that are not fully satisfied by the funds in the escrow account. The initial estimate of fair value of the contingent consideration was \$35.1 million, which was recorded as a non-current liability and included in the total acquisition consideration as summarized below:

Base payment . . . . .	\$650,000
Cash acquired . . . . .	54,117
Working capital and other adjustments . . . . .	<u>(25,719)</u>
Upfront payment in accordance with agreement . . . . .	678,398
Estimated fair value of contingent consideration . . . . .	<u>35,100</u>
Total acquisition consideration . . . . .	<u><u>\$713,498</u></u>

In 2012, we incurred \$9.9 million in transaction costs related to the EUSA Acquisition, which primarily consisted of banking, legal, accounting and valuation-related expenses. These expenses were recorded in selling, general and administrative expense in our consolidated statements of income.

In 2012, the contribution of the acquired EUSA Pharma business to our total revenues was \$95.6 million as measured from the date of the EUSA Acquisition. The portion of total expenses and net income associated with the acquired EUSA Pharma business was not separately identifiable due to the integration with our operations.



**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The fair values of assets acquired and liabilities assumed at the closing date of the EUSA Acquisition are summarized below (in thousands):

Cash and cash equivalents	\$ 54,117
Accounts receivable (1)	23,354
Inventories	36,360
Prepaid assets	6,212
Property and equipment	764
Intangible assets	616,970
Goodwill	206,452
Other assets	436
Accounts payable and accrued liabilities	(44,502)
Deferred tax liability	(186,591)
Other liabilities	(74)
Total acquisition consideration	<u>\$ 713,498</u>

- (1) The estimated fair value of trade receivables acquired was \$23.4 million. The gross contractual amount of trade receivables was \$25.1 million and was recorded net of allowances for wholesaler chargebacks related to government rebate programs, cash discounts for prompt payment and doubtful accounts. We expect that \$1.7 million of the gross contractual amount of trade receivables will be uncollectible.

The intangible assets as of the closing date of the EUSA Acquisition included (in thousands):

Acquired developed technologies:	
Erwinaze®/Erwinase®	\$472,000
Caphosol® and ProstaScint®	50,000
Collatamp®	21,000
Other pharmaceutical products	41,470
Total acquired developed technologies	<u>584,470</u>
In-process research and development:	
Asparec®	30,000
Leukotac®	2,500
Total in-process research and development	<u>32,500</u>
Total intangible assets	<u>\$616,970</u>

Intangible assets related to acquired developed technologies reflect the estimated fair value of the rights we acquired to those products in the EUSA Acquisition. The fair value was determined using an income approach, which recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs for each product line. Indications of value are developed by discounting these benefits to their present worth at a discount rate that reflects the current return requirements of the market. Acquired developed technologies are finite-lived intangible assets and are being amortized over their estimated lives ranging from two to 14 years.

The excess of the total acquisition consideration over the fair value amounts assigned to the assets acquired and the liabilities assumed represents the goodwill amount resulting from the acquisition. We believe that the factors that contributed to goodwill include synergies that are specific to our consolidated business and not available to market participants and the acquisition of a talented workforce and a platform for developing and

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

commercializing pharmaceutical products, as well as other intangible assets that do not qualify for separate recognition. We do not expect any portion of this goodwill to be deductible for tax purposes.

#### *Pro forma financial information (unaudited)*

The following unaudited supplemental pro forma information presents the combined historical results of operations of Jazz Pharmaceuticals, Inc., Azur Pharma and EUSA Pharma for 2012 and 2011 as if the Azur Merger and the EUSA Acquisition had each been completed on January 1, 2011. The pro forma financial information includes adjustments to reflect one time charges and amortization of fair value adjustments in the appropriate pro forma periods as though the companies were combined as of the beginning of 2011. These adjustments include:

- An increase in amortization expense of \$6.3 million and \$68.1 million in 2012 and 2011, respectively, related to the fair value of acquired identifiable intangible assets.
- The exclusion of transaction-related expenses of \$33.1 million and \$14.2 million in 2012 and 2011, respectively.
- A decrease in interest expense of \$2.5 million in 2012 and an increase of \$17.3 million in 2011, incurred on additional borrowings made to fund the EUSA Acquisition, as if the borrowings had occurred on January 1, 2011, offset by the elimination of actual interest expense incurred by EUSA Pharma during the periods presented.
- The exclusion of other non-recurring expenses of \$69.7 million in 2012 and the inclusion of \$24.1 million in 2011 primarily related to the fair value step-up to acquired inventory, share-based compensation incurred from the acceleration of stock option vesting upon closing of the Azur Merger and the EUSA Acquisition, a share-based liability granted to certain former Azur Pharma shareholders and integration-related expenses.

The unaudited pro forma results do not assume any operating efficiencies as a result of the consolidation of operations (in thousands, except per share data):

	Year Ended December 31,	
	2012	2011
Revenues .....	\$668,924	\$429,778
Net income .....	\$343,897	\$ 20,203
Net income per ordinary share—basic .....	\$ 6.01	\$ 0.38
Net income per ordinary share—diluted .....	\$ 5.66	\$ 0.34

#### 4. Fair Value Measurement

Cash, cash equivalents and marketable securities consisted of the following (in thousands):

	December 31, 2012					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash .....	\$343,548	\$—	\$—	\$343,548	\$343,548	\$—
Money market funds .....	43,648	—	—	43,648	43,648	—
Totals .....	\$387,196	\$—	\$—	\$387,196	\$387,196	\$—

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

	December 31, 2011					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash .....	\$ 33,307	\$—	\$—	\$ 33,307	\$33,307	\$ —
Money market funds .....	48,518	—	—	48,518	48,518	—
Certificates of deposit .....	7,300	—	(6)	7,294	—	7,294
Corporate debt securities .....	50,371	7	(34)	50,344	—	50,344
Obligations of U.S. government agencies ..	18,433	3	(1)	18,435	251	18,184
Totals .....	<u>\$157,929</u>	<u>\$ 10</u>	<u>\$ (41)</u>	<u>\$157,898</u>	<u>\$82,076</u>	<u>\$75,822</u>

Collectively, cash equivalents and marketable securities are considered available-for-sale. We use the specific-identification method for calculating realized gains and losses on securities sold and include them in interest expense, net in the consolidated statements of income. Proceeds from sales of available-for-sale securities in 2012 were \$81.2 million and were used to partially fund the EUSA Acquisition. Gross realized gains and losses in 2012 were insignificant. All available-for-sale securities held as of December 31, 2012 were cash and cash equivalents.

The following table summarizes, by major security type, our available-for-sale securities and liabilities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	December 31, 2012			December 31, 2011		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
<b>Assets:</b>						
Available-for-sale securities:						
Money market funds .....	\$43,648	\$ —	\$43,648	\$48,518	\$ —	\$ 48,518
Certificates of deposit .....	—	—	—	—	7,294	7,294
Corporate debt securities .....	—	—	—	—	50,344	50,344
Obligations of U.S. government agencies .....	—	—	—	—	18,435	18,435
Total available-for-sale securities at fair value .....	<u>\$43,648</u>	<u>\$ —</u>	<u>\$43,648</u>	<u>\$48,518</u>	<u>\$76,073</u>	<u>\$124,591</u>
<b>Liabilities:</b>						
Contingent consideration .....	<u>\$ —</u>	<u>\$34,800</u>	<u>\$34,800</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2012, our available-for-sale securities included money market funds and their carrying values were approximately equal to their fair values. There were no transfers between the different levels of the fair value hierarchy in 2012.

As of December 31, 2011, our available-for-sale securities included corporate debt securities, obligations of U.S. government agencies and certificates of deposit which were measured at fair value using Level 2 inputs and money market funds which were measured at fair value using Level 1 inputs. We reviewed trading activity and pricing for these investments as of the measurement date. Level 2 inputs, obtained from various third party data

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

providers, represent quoted prices for similar assets in active markets, or these inputs were derived from observable market data, or if not directly observable, were derived from or corroborated by other observable market data. Level 1 inputs are quoted prices in active markets for identical assets or liabilities. As of December 31, 2011, the aggregate fair value of available-for-sale securities which had unrealized losses was \$43.6 million.

As part of the EUSA Acquisition, we agreed to make an additional contingent payment of \$50.0 million in cash if Erwinaze achieves U.S. net sales of \$124.5 million or greater in 2013. The fair value measurement of this contingent consideration obligation is determined using unobservable Level 3 inputs. These inputs include the probability of 2013 U.S. net sales of Erwinaze equaling or exceeding the \$124.5 million threshold and the discount rate. A significant increase or decrease in the estimated probability of meeting the milestone threshold would result in a significantly higher or lower fair value measurement, respectively. The range of the estimated contingent payment is from zero if 2013 U.S. net sales of Erwinaze are less than \$124.5 million to \$50.0 million if 2013 U.S. net sales of Erwinaze equal or exceed \$124.5 million.

The changes in fair value of the contingent consideration payable was estimated as follows (in thousands):

	<b>Level 3</b>
Balance at December 31, 2011 .....	\$ —
Amount acquired on June 12, 2012 .....	35,100
Fair value adjustment recorded within selling, general and administrative expenses .....	(300)
Balance at December 31, 2012 .....	<b>\$34,800</b>

In 2012, the fair value adjustment reflects a change in the estimated probability of meeting the milestone threshold offset by the impact of discounting as a result of the passage of time.

As of December 31, 2012, the estimated fair value of our \$475.0 million term loan was \$472.4 million and the carrying amount was \$456.8 million. The fair value was determined using quotes from the administrative agent of our credit facility that are based on bid/ask prices of our term loan (Level 2). For additional information regarding our term loan see Note 9.

**5. Inventories**

Inventories consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Raw materials .....	\$ 9,179	\$1,937
Work in process .....	1,210	524
Finished goods .....	16,136	1,448
Total inventories .....	<b>\$26,525</b>	<b>\$3,909</b>

As of December 31, 2012, inventories included \$4.0 million related to acquisition accounting inventory fair value step-up.

**JAZZ PHARMACEUTICALS PLC**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**6. Property and Equipment**

Property and equipment consisted of the following (in thousands):

	December 31,	
	2012	2011
Computer software . . . . .	\$ 4,292	\$ 4,010
Leasehold improvements . . . . .	3,899	763
Computer equipment . . . . .	3,687	2,046
Furniture and fixtures . . . . .	1,953	556
Construction-in-progress . . . . .	1,135	689
Machinery and equipment . . . . .	94	76
Subtotal . . . . .	15,060	8,140
Less accumulated depreciation and amortization . . . . .	(7,779)	(6,583)
Property and equipment, net . . . . .	<u>\$ 7,281</u>	<u>\$ 1,557</u>

**7. Accrued liabilities**

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2012	2011
Rebates and other sales deductions . . . . .	\$ 29,235	\$12,378
Sales returns reserve . . . . .	26,385	4,302
Employee compensation and benefits . . . . .	24,900	11,643
Royalties . . . . .	3,271	267
Professional fees . . . . .	2,163	4,021
Other . . . . .	18,712	2,172
Total accrued liabilities . . . . .	<u>\$104,666</u>	<u>\$34,783</u>

**8. Goodwill and Intangible Assets**

The gross carrying amount of goodwill was as follows (in thousands):

Balance at December 31, 2011 . . . . .	\$ 38,213
Goodwill arising from the Azur Merger . . . . .	201,524
Goodwill arising from the EUSA Acquisition . . . . .	206,452
Goodwill allocated to the divested women's health business(1) . . . . .	(12,916)
Foreign exchange . . . . .	9,327
Balance at December 31, 2012 . . . . .	<u>\$442,600</u>

(1) In 2012, we sold our women's health business. See Note 19 for information regarding discontinued operations.

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	Remaining Weighted- Average Useful Life (In years)	December 31, 2012			December 31, 2011		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Acquired developed technologies . . . .	12.3	\$930,834	\$(97,578)	\$833,256	\$49,400	\$(35,634)	\$13,766
Trademarks . . . . .	2.0	2,600	(2,054)	546	2,600	(1,781)	819
Total finite-lived intangible assets . . . . .		933,434	(99,632)	833,802	52,000	(37,415)	14,585
Acquired IPR&D assets . . . . .		36,150	—	36,150	—	—	—
Total intangible assets . . . . .		<u>\$969,584</u>	<u>\$(99,632)</u>	<u>\$869,952</u>	<u>\$52,000</u>	<u>\$(37,415)</u>	<u>\$14,585</u>

Based on finite-lived intangible assets recorded as of December 31, 2012, and assuming the underlying assets will not be impaired in the future and that we will not change the expected lives of the assets, future amortization costs were estimated as follows (in thousands):

<u>Year Ending December 31,</u>	<u>Estimated Amortization Expense</u>
2013 . . . . .	\$ 77,432
2014 . . . . .	77,232
2015 . . . . .	71,190
2016 . . . . .	67,868
2017 . . . . .	67,868
Thereafter . . . . .	<u>472,212</u>
Total . . . . .	<u>\$833,802</u>

Intangible assets related to the divested women's health business had a net book value of \$41.4 million. See Note 19 for information regarding discontinued operations.

**9. Long-Term Debt**

*Term Loan and Revolving Credit Facility*

On June 12, 2012, Jazz Pharmaceuticals plc, as guarantor, and Jazz Pharmaceuticals, Inc., as borrower, entered into a \$575.0 million credit agreement with Barclays Bank PLC, as administrative agent and certain other lenders. The credit agreement provides for a six-year \$475.0 million term loan and a five-year \$100.0 million revolving credit facility, which includes a \$10.0 million swing line loan sub facility and a \$10.0 million letter of credit sub facility. The proceeds from the term loan were used to partially finance the EUSA Acquisition. Borrowings under the term loan bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.25% per annum (subject to a 1.0% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 3.25% per annum (subject to a 2.0% prime rate floor). Borrowings under the revolving credit facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.00% per annum, or the prime lending rate, plus an applicable margin equal to 3.00% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The obligations of Jazz Pharmaceuticals, Inc. under the credit agreement and any hedging or cash management obligations entered into with a lender are guaranteed by Jazz Pharmaceuticals plc and certain of its subsidiaries and are secured by substantially all of their assets.

We may make prepayments of principal without premium or penalty, except that a 1% premium would apply to a repayment via a repricing of the loan under the term loan effected on or prior to June 12, 2013. We are required to make mandatory prepayments of borrowings under the term loan (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), (3) beginning with the fiscal year ending December 31, 2013, 50% of our excess cash flow as defined in the credit agreement (subject to increase to 75% if our secured leverage ratio exceeds 2.25 to 1.0, or decrease to 25% or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.0 or 0.75 to 1.0, respectively), and (4) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions). No mandatory repayment was made or is required to be made under our term loan as a result of the sale of our women's health business.

Principal repayments of the term loan are due quarterly and are equal to 5.0% of the original principal amount in the first year, 7.5% in the second year, 10.0% in each of the third and fourth years and 15.0% in each of the fifth and sixth years, with any remaining balance payable on the final maturity date. In 2012, \$11.9 million of debt principal was repaid.

Scheduled maturities with respect to the term loan are as follows (in thousands):

<u>Year ending December 31,</u>	<u>Scheduled Term Loan Maturities</u>
2013 .....	\$ 29,688
2014 .....	41,563
2015 .....	47,500
2016 .....	59,375
2017 .....	71,250
Thereafter .....	<u>213,750</u>
Total .....	<u>\$463,126</u>

The credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to Jazz Pharmaceuticals plc and its restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement contains a financial covenant that requires Jazz Pharmaceuticals plc and its restricted subsidiaries to maintain a maximum secured leverage ratio. We are currently in compliance with our financial covenants.

The \$475.0 million principal amount of the term loan was recorded net of an original issue discount of \$7.1 million. We incurred \$15.0 million of debt issuance costs associated with the term loan. As of December 31, 2012, the interest rate on the term loan was 5.25%. Interest expense associated with the term loan is recorded using the interest method and includes non-cash interest related to the debt discount and debt issuance costs. The effective interest rate on the term loan is 6.7%. The current portion of the carrying amount of the term loan was \$29.7 million as of December 31, 2012.

Financing costs of \$3.5 million associated with the revolving credit facility were deferred and are being amortized to interest expense on a straight-line basis over the life of the facility. As of December 31, 2012, we had not borrowed under the revolving credit facility.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In 2011, we terminated a credit agreement and repaid a term loan in full and as a result, we recorded a loss on extinguishment of debt of \$1.2 million, which consisted of a \$0.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount and the remainder related to a prepayment penalty and a termination fee. In 2010, we repaid \$119.5 million principal amount due under a previous debt agreement. As a result of the repayment of amounts due under the previous debt agreement, we recorded a loss on extinguishment of debt of \$12.3 million in 2010, which consisted of a \$3.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount and an \$8.5 million prepayment penalty.

#### 10. Other Liabilities

##### *Deferred Revenue*

We have an agreement with UCB under which UCB has the right to market Xyrem for certain indications in various countries outside of the United States. We recognized contract revenues of \$1.1 million during each of 2012, 2011, and 2010 relating to two upfront payments received from UCB in 2006 totaling \$15.0 million. As of December 31, 2012, \$7.9 million was recorded as deferred revenues related to this agreement, of which \$1.1 million is a current liability. The deferred revenue balance is being recognized ratably through 2019.

##### *Purchased Product Rights Liability*

In 2007, we entered into a product license agreement with Solvay Pharmaceuticals, Inc., which was subsequently acquired by Abbott Laboratories, for the rights to market Luvox CR and Luvox in the United States, which agreement was subsequently amended. Under the amended agreement we paid \$4.5 million in each of 2012 and 2011, and \$4.0 million in 2010. Our payments in 2012 were the final payments under this amended agreement.

##### *Liability Under Government Litigation Settlement*

In 2007, we and Orphan Medical, LLC, formerly Orphan Medical, Inc., or Orphan Medical, entered into agreements with a number of government entities to settle various matters associated with an investigation relating to the sale and marketing of Xyrem by Orphan Medical, which we acquired in June 2005. Under these agreements we paid \$7.3 million in 2012, which was our remaining obligation under these agreements, and \$4.2 million and \$3.0 million in 2011 and 2010, respectively.

#### 11. Commitments and Contingencies

##### *Indemnification*

In the normal course of business, we enter into agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights. Our exposure under these agreements is unknown because it involves future claims that may be made but have not yet been made against us. To date, we have not paid any claims or been required to defend any action related to these indemnification obligations.

We have agreed to indemnify our officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other



**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we have not recognized any liabilities relating to these obligations as of December 31, 2012 and December 31, 2011. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

***Lease and Other Commitments***

We have noncancelable operating leases for our office buildings and we are obligated to make payments under noncancelable operating leases for automobiles used by our sales force.

Rent expense under all operating leases was as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Rent expense .....	\$3,074	\$2,593	\$2,323

Future minimum lease payments under our noncancelable operating leases at December 31, 2012, were as follows (in thousands):

<b>Year ending December 31,</b>	<b>Lease Payments</b>
2013 .....	\$ 6,631
2014 .....	6,100
2015 .....	5,493
2016 .....	4,067
2017 .....	2,445
Total .....	\$24,736

In 2012, we entered into an operating lease agreement for our new headquarters in Dublin for a term of 10 years. We have an option to terminate this lease in May 2017, with no less than six months' prior written notice and the payment of a termination fee. We amended and extended the operating lease for our existing Philadelphia office building for a term of 4 years, we renewed the operating lease for our existing Palo Alto office building for a term of 5 years and we entered into a new operating sublease for additional office space in Palo Alto near our existing office location for a term of 5 years.

As of December 31, 2012 and 2011, we had \$70.1 million and \$5.7 million, respectively, of noncancelable purchase commitments under agreements with contract manufacturers due within one year.

***Legal Proceedings***

We are involved in several legal proceedings, including the following matters:

*Xyrem® ANDA Matters:* On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it had submitted an abbreviated new drug application, or ANDA, to the United States Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleged that all five patents then listed for Xyrem in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification in the United States District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA will be stayed until the earlier of (i) April 18, 2013, which is 30 months after our October 18, 2010 receipt of Roxane's Paragraph IV Certification, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. Two additional method of use patents covering the distribution system for Xyrem were issued in December 2010 and February 2011, respectively, and were listed in the Orange Book, and we filed lawsuits against Roxane in February 2011 and again in May 2011 to include these additional patents in the litigation in response to Roxane's Paragraph IV Certifications against each of these patents, and also to include another issued patent in the litigation which is not listed in the Orange Book. These additional lawsuits were subsequently consolidated with the action filed on November 22, 2010. On April 26, 2012, the District Court held a Markman hearing, a pretrial hearing following which the trial judge construes the claims of the patents at issue in a lawsuit, and the District Court issued a Markman order construing the claims of the patents then involved in the litigation in September 2012. New patents, one covering a formulation of Xyrem and the other covering use of Xyrem for treatment of narcolepsy, were issued in September 2012 and December 2012, respectively, and were listed in the Orange Book. In October 2012, we filed a new lawsuit in the District Court against Roxane in response to Roxane's Paragraph IV Certification against the new formulation patent, and in December 2012, we filed a lawsuit in the District Court against Roxane alleging infringement of the new treatment patent. Our original lawsuit against Roxane has been temporarily stayed while the District Court determines whether to consolidate the three lawsuits, and no trial date has been scheduled. We cannot predict the timing or outcome of this matter.

On December 10, 2012, we received a Paragraph IV Certification from Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Amneal's Paragraph IV Certification alleged that seven patents listed for Xyrem in the Orange Book are not infringed by Amneal's proposed generic product. Amneal's Paragraph IV Certification further alleged that an eighth patent listed in the Orange Book for Xyrem is invalid. On December 13, 2012, we received a supplemental Paragraph IV Certification alleging that a ninth patent listed in the Orange Book for Xyrem is invalid. On January 18, 2013, we filed a lawsuit against Amneal in response to Amneal's Paragraph IV Certifications in the District Court. We are seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Amneal, FDA approval of Amneal's ANDA will be stayed until the earlier of (i) June 10, 2015, which is 30 months after our receipt of Amneal's Paragraph IV Certification on December 10, 2012, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the outcome of this matter.

On May 18, 2012, we submitted a Citizen Petition to the FDA that addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem. Among other actions requested of the FDA, this petition requested that the FDA (i) not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs and (ii) require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On November 13, 2012, the FDA denied this Citizen Petition. On July 10, 2012, we submitted a second Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, that did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. We are evaluating the FDA's responses to both Citizen Petitions and potential further actions that we may take with respect to the issues raised in, and the FDA's denials of, the Citizen Petitions. The FDA's denial of the Citizen Petitions does not have a direct impact on the merits of our ongoing lawsuits with Roxane and Amneal. However, we cannot predict the effect of the denial of either of our Citizen Petitions, or the FDA's stated positions in its responses to the Citizen Petitions, on the timing of the potential introduction of a generic version of Xyrem.

*FazaClo® ANDA Matters:* Azur Pharma received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc.; Novel Laboratories, Inc.; and Mylan Pharmaceuticals, Inc., indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo LD. Azur Pharma and CIMA Labs Inc., or CIMA, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification: against Barr Laboratories, Inc. on August 21, 2008, against Novel Laboratories, Inc. on November 25, 2008, and against Mylan Pharmaceuticals, Inc. on July 23, 2010. Each case was filed in the United States District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr Laboratories, Inc., entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product at the end of August 2012. The Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc. matters have been stayed pending reexamination of the patents in the suit. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the reexamination proceedings, or when the stays will be lifted.

*Cutler Matter:* On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in California Superior Court in the County of Los Angeles, or the Superior Court. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to either a \$10.5 million or \$25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. On March 14, 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. We submitted a complaint in arbitration alleging that Dr. Cutler's suit had been improperly filed in Los Angeles and seeking a declaratory judgment that we have complied with all contractual obligations to Dr. Cutler. On July 25, 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the arbitration clause in the applicable contract. We have asked the Superior Court to vacate the arbitrator's dismissal of the arbitration and appealed the Superior Court's denial of our motion to the California Court of Appeal. In addition, on November 7, 2012, we filed challenges to the sufficiency of the complaint in the Superior Court, but the Superior Court case has been stayed pending the outcome of our appeal. This matter, like all litigation, carries certain risks, and there can be no assurance of the outcome.

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

**12. Shareholders' Equity**

*Shares and Additional Paid-In Capital*

Following the Azur Merger, our capital structure is comprised of ordinary shares and euro deferred shares. The outstanding 4,000,000 non-voting euro deferred shares of €0.01 par value each are held by nominees and were issued to satisfy the statutory minimum Euro-denominated share capital required for a public limited company incorporated in Ireland. The non-voting euro deferred shares have no right to receive dividends, no rights to attend and vote at our general meetings, are redeemable only at our option and have no substantive right to participate in a distribution of assets upon a winding up of our company. All references to common stock in the comparative prior year periods in the discussion and table below were replaced with references to ordinary shares to reflect the capital structure of Azur Pharma, the legal acquirer in the Azur Merger. Our earnings per share in comparative prior year periods were not impacted by the Azur Merger as a result of the one-for-one Azur exchange ratio.

The total acquisition consideration of \$576.5 million related to the Azur Merger was recorded by increasing total par value of our ordinary shares and euro deferred shares by \$1,236 and \$54,862, respectively; by creating a capital redemption reserve of \$0.5 million as required by Irish company law to preserve permanent capital in our company; and by increasing our additional paid-in capital by \$575.9 million.

In 2012, we paid \$25.3 million of income tax withholdings on behalf of certain employees of Jazz Pharmaceuticals, Inc. related to the net share settlement of exercised share options in connection with the Azur Merger. The number of shares issued to employees upon the net share settlement of the exercised share options was decreased by a number of shares having a total fair value on the date of the net share settlement equal to the amount of the income tax withholdings paid. The \$25.3 million of income tax withholdings paid was recorded as a reduction to additional paid-in capital.

*Authorized But Unissued Ordinary Shares*

We had reserved the following shares of authorized but unissued ordinary shares (in thousands):

	<b>As of December 31, 2012</b>
2011 Equity Incentive Plan . . . . .	7,344
2007 Equity Incentive Plan . . . . .	1,000
2007 Employee Stock Purchase Plan . . . . .	851
Amended and Restated 2007 Non-Employee Directors Stock Option Plan . . . . .	374
Amended and Restated Directors Deferred Compensation Plan . . . . .	183
Exercise of warrants . . . . .	2,023
Total . . . . .	11,775

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**Warrants**

As of December 31, 2012, we had ordinary shares issuable under the following warrants (in thousands):

<u>Warrants Issued</u>	<u>Expiration Date</u>	<u>Shares of Common Stock</u>	<u>Exercise Price</u>
Warrants issued in 2008 in conjunction with long-term debt . . . . .	March 16, 2013	471	\$9.34
Warrants issued in 2008 in conjunction with registered direct public offering . . . . .	July 20, 2014	604	\$7.37
Warrants issued in 2009 in conjunction with private placement . . . . .	July 5, 2016	948	\$4.00
		<u>2,023</u>	

The fair values of these warrants were recorded in shareholders' equity when they were originally issued.

**13. Comprehensive Income/(Loss)**

Comprehensive income/(loss) includes net income/(loss) and all changes in shareholders' equity during a period, except for those changes resulting from investments by shareholders or distributions to shareholders.

**Accumulated Other Comprehensive Income/(Loss)**

The components of accumulated other comprehensive income/(loss) at December 31, 2012 and December 31, 2011 were as follows (in thousands):

	<u>Net Unrealized Gains (Losses) On Available- For-Sale Securities</u>	<u>Foreign Currency Translation Adjustments</u>	<u>Total Accumulated Other Comprehensive Income/(Loss)</u>
Balance at December 31, 2011 . . . . .	\$ (31)	\$ —	\$ (31)
Other comprehensive income . . . . .	31	31,046	31,077
Balance at December 31, 2012 . . . . .	<u>\$—</u>	<u>\$31,046</u>	<u>\$31,046</u>

**14. Share-Based Compensation**

**2011 Equity Incentive Plan**

In connection with the Azur Merger, Jazz Pharmaceuticals, Inc.'s board of directors adopted the 2011 Equity Incentive Plan, or the 2011 Plan, in October 2011 and its stockholders approved the 2011 Plan at the special meeting of the stockholders held in December 2011 in connection with the Azur Merger. The 2011 Plan became effective immediately before the consummation of the Azur Merger and was assumed and adopted by us upon the consummation of the Azur Merger. The terms of the 2011 Plan provide for the grant of stock options, stock appreciation rights, restricted stock awards, RSUs, other stock awards, and performance awards that may be settled in cash, shares, or other property. All of the grants under the 2011 Plan were granted to employees and vest ratably over service periods of four years and expire no more than 10 years after the date of grant. As of December 31, 2012, a total of 8,335,255 of our ordinary shares had been authorized for issuance under the 2011 Plan (5,000,000 ordinary shares effective as of the closing of the Azur Merger plus 3,335,255 ordinary shares subject to outstanding options granted under the 2007 Equity Incentive Plan and the 2003 Equity Incentive Plan as of January 18, 2012). In addition, the share reserve under the 2011 Plan will automatically increase on January 1 of each year for a period of 10 years, starting on January 1, 2013 and continuing through January 1, 2022, by the least of (a) 4.5% of the total number of ordinary shares outstanding on December 31 of the preceding calendar year, (b) 5,000,000 shares, or (c) such lesser number of ordinary shares as determined by our board of directors. On January 1, 2013, the share reserve under the 2011 Plan increased by 2,629,000 ordinary shares pursuant to this automatic share provision.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *2007 Equity Incentive Plan*

The 2007 Equity Incentive Plan, or the 2007 Plan, which was initially adopted by the Jazz Pharmaceuticals, Inc. board of directors and approved by the Jazz Pharmaceuticals, Inc. stockholders in connection with its initial public offering, was continued and assumed by us upon consummation of the Azur Merger. The 2007 Plan provided for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, RSUs, stock appreciation rights, performance stock awards and other forms of equity compensation to employees, including officers, non-employee directors and consultants. Prior to the consummation of the Azur Merger, all of the grants under the 2007 Plan were granted to employees and vest ratably over service periods of three to five years and expire no more than 10 years after the date of grant. Effective as of the closing of the Azur Merger on January 18, 2012, the number of shares reserved for issuance under the 2007 Plan was set to 1,000,000 ordinary shares and there will be no further automatic increases to the share reserve of the 2007 Plan. Since the Azur Merger, all of the new grants under the 2007 Plan were granted to non-employee directors and vest ratably over service periods of one to three years and expire no more than 10 years after the date of grant.

#### *2007 Employee Stock Purchase Plan*

In 2007, Jazz Pharmaceuticals, Inc.'s employees became eligible to participate in the Employee Stock Purchase Plan, or ESPP. The ESPP was amended and restated by Jazz Pharmaceuticals, Inc.'s board of directors in October 2011 and approved by its stockholders in December 2011. The amended ESPP became effective immediately prior to the effective time of the Azur Merger and was assumed by us upon the consummation of the Azur Merger. The ESPP allows our eligible employee participants (including employees of any of a parent or subsidiary company if our board of directors designates such company as eligible to participate) to purchase our ordinary shares at a discount of 15% through payroll deductions. The ESPP consists of a fixed offering period of 24 months with four purchase periods within each offering period. The number of shares available for issuance under our ESPP during any six month purchase period is 175,000 shares. As of December 31, 2012, a total of 2,660,000 of our ordinary shares had been authorized for issuance under the ESPP.

#### *Amended and Restated 2007 Non-Employee Directors Stock Option Plan*

The Amended and Restated 2007 Non-Employee Directors Stock Option Plan, or the 2007 Directors Option Plan, which was initially adopted by the Jazz Pharmaceuticals, Inc. board of directors and approved by the Jazz Pharmaceuticals, Inc. stockholders in connection with its initial public offering, was continued and assumed by us upon the consummation of the Azur Merger. Until October 2011, the 2007 Directors Option Plan provided for the automatic grant of nonstatutory stock options to purchase shares of Jazz Pharmaceuticals, Inc.'s common stock to its non-employee directors initially at the time any individual first became a non-employee director, which vest over three years, and then annually over their period of service on its board of directors, which vest over one year. On October 24, 2011, Jazz Pharmaceuticals, Inc.'s board of directors amended the 2007 Directors Option Plan to eliminate all future initial and annual automatic grants so that future automatic grants would not be made that would be subject to the excise tax imposed by Section 4985 of the Internal Revenue Code of 1986, as amended, in connection with the merger with Azur Pharma. Accordingly, all future stock option grants under the 2007 Directors Option Plan will be at the discretion of our board of directors. Since the date of the Azur Merger and as of the date of this report, our board of directors has approved one grant to a non-employee director under the 2007 Directors Option Plan. In addition, the 2007 Directors Option Plan provides the source of shares to fund distributions made prior to August 15, 2010 under the Directors Deferred Compensation Plan described below. As of December 31, 2012, a total of 777,713 of our ordinary shares had been authorized for issuance under the 2007 Directors Option Plan.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *Amended and Restated Directors Deferred Compensation Plan*

In May 2007, the Jazz Pharmaceuticals, Inc. board of directors adopted the Directors Deferred Compensation Plan, or the Directors Deferred Plan, which was amended in December 2008 and was then amended and restated in August 2010, and which was continued and assumed by us upon consummation of the Azur Merger. The Directors Deferred Plan allows each non-employee director to elect to defer receipt of all or a portion of his or her annual retainer fees to a future date or dates. Amounts deferred under the Directors Deferred Plan are credited as shares of Jazz Pharmaceuticals, Inc.'s common stock (or our ordinary shares following the Azur Merger) to a phantom stock account, the number of which are based on the amount of the retainer fees deferred divided by the market value of Jazz Pharmaceuticals, Inc.'s common stock (or our ordinary shares following the Azur Merger) on the first trading day of the first open window period following the date the retainer fees are deemed earned. On the 10th business day following the day of separation from the board of directors or the occurrence of a change in control, or as soon thereafter as practical once the non-employee director has provided the necessary information for electronic deposit of the deferred shares, each non-employee director will receive (or commence receiving, depending upon whether the director has elected to receive distributions from his or her phantom stock account in a lump sum or in installments over time) a distribution of his or her phantom stock account, in shares of our ordinary shares (i) reserved under the 2007 Directors Option Plan prior to August 15, 2010 and (ii) from a new reserve of 200,000 shares set up under the Directors Deferred Plan on August 15, 2010. We recorded no expense in 2012 related to retainer fees earned and deferred, and in 2011 and 2010 we incurred expense of \$0.4 million and \$0.2 million, respectively. As of December 31, 2012, 19,170 of our ordinary shares were unissued related to retainer fees that were deferred under the Directors Deferred Plan.

#### *Share-Based Compensation*

The table below shows, for all share option grants, the weighted-average assumptions used in the Black-Scholes option pricing model and the resulting weighted-average grant date fair value of share options granted in each of the past three years:

	Year Ended December 31,		
	2012	2011	2010
Grant date fair value .....	\$ 25.28	\$ 17.38	\$ 7.84
Volatility .....	64%	72%	85%
Expected term (years) .....	4.6	5.2	6.0
Range of risk-free rates .....	0.5-1.1%	0.0-2.7%	1.5-3.1%
Expected dividend yield .....	— %	— %	— %

Prior to 2012, we used a blend of the historical volatility and implied volatility of our ordinary shares, as well as the historical volatility of a peer group, to determine expected volatility for share option grants, and we used the implied volatility of our ordinary shares for grants under our ESPP. We included consideration of the historical volatility of a peer group to estimate expected volatility for share option grants since the trading history of our ordinary shares was less than the expected term of the share options. Beginning in the year ended December 31, 2012, we rely only on a blend of the historical and implied volatilities of our own ordinary shares to determine expected volatility for share option grants because our trading history now exceeds the expected term of the share options. In addition, we use a single volatility estimate for each share option grant. The weighted average volatility is determined by calculating the weighted average of volatilities for all share options granted in a given year.

The expected term of share option grants represents the weighted-average period the awards are expected to remain outstanding. For share options granted in 2012 and 2011, we estimated the weighted-average expected

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

term based on historical exercise data. Prior to 2011, the expected term was estimated by assuming share options would be exercised at the mid-point between the vest date and the contractual term. The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of our share option grants. The expected dividend yield assumption was based on our history and expectation of dividend payouts.

Share-based compensation expense in continuing operations related to share options, RSUs, ordinary shares credited to the directors' phantom share accounts and grants under our ESPP was as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2012</b>	<b>2011(1)</b>	<b>2010</b>
Selling, general and administrative .....	\$18,950	\$15,592	\$5,924
Research and development .....	2,640	4,488	2,004
Cost of product sales .....	1,416	624	291
Total share-based compensation expense, pre-tax .....	23,006	20,704	8,219
Tax benefit from share-based compensation expense .....	(7,499)	—	—
Total share-based compensation expense, net of tax .....	\$15,507	\$20,704	\$8,219

- (1) Includes expense of \$7.3 million related to the acceleration of vesting in December 2011 of certain non-qualified share options held by 17 executives and non-employee directors in connection with the Azur Merger, of which \$6.9 million was recorded in selling, general and administrative and \$0.4 million was recorded in research and development.

For the year ended December 31, 2012, we realized tax benefits related to share option exercises of \$18.3 million and none in 2011 and 2010.

***Share Options***

The following table summarizes information as of December 31, 2012 and activity during 2012 related to our share option plans:

	<b>Shares Subject to Outstanding Options (In thousands)</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value (In thousands)</b>
Outstanding at January 1, 2012 .....	5,506	\$16.00		
Options granted .....	2,158	49.20		
Options exercised .....	(3,163)	15.05		
Options forfeited .....	(323)	34.54		
Options expired .....	—	—		
Outstanding at December 31, 2012 .....	4,178	32.21	8.2	\$88,174
Vested and expected to vest at December 31, 2012 .....	3,728	30.86	8.0	83,683
Exercisable at December 31, 2012 .....	1,306	13.86	6.4	51,463

Aggregate intrinsic value shown in the table above is equal to the difference between the exercise price of the underlying share options and the fair value of our ordinary shares for share options that were in the money. The aggregate intrinsic value changes based on the fair market value of our ordinary shares. The aggregate intrinsic value of share options exercised was \$106.5 million, \$33.5 million and \$9.7 million, during 2012, 2011 and 2010, respectively. We issued new ordinary shares upon exercise of share options.



**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

As of December 31, 2012, total compensation cost not yet recognized related to unvested share options was \$75.6 million, which is expected to be recognized over a weighted-average period of 2.9 years. As of December 31, 2012, total compensation cost not yet recognized related to grants under the ESPP was \$1.6 million, which is expected to be recognized over a weighted-average period of less than one year.

***Restricted Stock Units***

In 2012, we granted RSUs covering an equal number of our ordinary shares to employees with a weighted-average grant date fair value of \$49.24. The fair value of RSUs is determined on the date of grant based on the market price of our ordinary shares as of that date. The fair value of the RSUs is recognized as expense ratably over the vesting period of four years.

As of December 31, 2012, total compensation cost not yet recognized related to unvested RSUs was \$30.6 million, which is expected to be recognized over a weighted-average period of 3.4 years.

The following table summarizes information as of December 31, 2012 and activity during 2012 related to our RSUs:

	Number of RSUs (in thousands)	Weighted- Average Grant-Date Fair Value	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2012 .....	—	\$ —		
RSUs granted .....	1,040	49.24		
RSUs released .....	—	—		
RSUs forfeited .....	(84)	51.44		
RSUs expired .....	—	—		
Outstanding at December 31, 2012 .....	<u>956</u>	49.04	1.9	\$50,899

**15. Segment and Other Information**

Our operating segment is reported in a manner consistent with the internal reporting provided to the chief operating decision maker or, CODM. Our CODM has been identified as our chief executive officer. We have determined that we operate in one business segment, which is the development and commercialization of specialty pharmaceutical products. The following table presents a summary of total revenues (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Xyrem .....	\$378,663	\$233,348	\$142,630
Erwinaze/Erwinase .....	72,083	—	—
Prialt .....	26,360	—	—
Psychiatry:			
Luvox CR .....	42,419	33,170	27,376
FazaClo LD .....	22,023	—	—
FazaClo HD .....	12,047	—	—
Other .....	<u>26,932</u>	—	—
Product sales, net .....	580,527	266,518	170,006
Royalties and contract revenues .....	5,452	5,759	3,775
Total revenues .....	<u>\$585,979</u>	<u>\$272,277</u>	<u>\$173,781</u>

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The following table presents a summary of total revenues attributed to geographic sources (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
United States .....	\$538,219	\$265,718	\$169,317
Europe .....	38,590	6,224	4,169
All other .....	9,170	335	295
Total revenues .....	<u>\$585,979</u>	<u>\$272,277</u>	<u>\$173,781</u>

The following table presents a summary of total revenues from customers that represented more than 10% of our total revenues:

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Express Scripts .....	64%	85%	82%

The following table presents total long-lived assets by location (in thousands):

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
Ireland .....	\$2,437	\$ —
United States .....	4,451	1,557
Other .....	393	—
Total long-lived assets (1) .....	<u>\$7,281</u>	<u>\$1,557</u>

(1) Long-lived assets consist of property and equipment.

**16. Income Taxes**

The components of income from continuing operations before the income tax provision (benefit) were as follows (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Republic of Ireland .....	\$(73,949)	\$ —	\$ —
United States .....	250,348	124,984	32,778
Other .....	956	—	—
Total .....	<u>\$177,355</u>	<u>\$124,984</u>	<u>\$32,778</u>

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The following table sets forth the details of the income tax provision (benefit) (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Current			
Republic of Ireland . . . . .	\$ (10,733)	\$—	\$—
United States . . . . .	33,387	—	—
Other . . . . .	7,414	—	—
Total current income tax . . . . .	<u>30,068</u>	<u>—</u>	<u>—</u>
Deferred			
Republic of Ireland . . . . .	(315)	—	—
United States . . . . .	(103,932)	—	—
Other . . . . .	(9,615)	—	—
Total deferred income tax benefit . . . . .	<u>(113,862)</u>	<u>—</u>	<u>—</u>
Total income tax benefit . . . . .	<u>\$ (83,794)</u>	<u>\$—</u>	<u>\$—</u>

During 2011 and 2010, we had operations only in the United States and made no provision for income taxes due to our utilization of federal net operating loss carryforwards, or NOLs, to offset both regular taxable income and alternative minimum taxable income and to our utilization of deferred state tax benefits for which the related deferred tax assets were offset by a valuation allowance. As discussed in Note 1, in January 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction accounted for as a reverse acquisition and the combined company changed its domicile from the United States to Ireland. In June 2012, we completed the EUSA Acquisition, which further expanded our global operations.

During 2012, we recognized an income tax benefit of \$83.8 million which resulted primarily from reversal of a valuation allowance on most of our U.S. federal and state deferred tax assets, as described below. We are currently paying taxes in Ireland, the United States and certain other foreign jurisdictions where we have operations and either all NOLs have been utilized, or are restricted as a result of the Azur Merger.

Following the Azur Merger and the change in the combined company's domicile in 2012, the statutory income tax rate changed from the U.S. rate (35.0%) to the Irish rate (12.5%). A reconciliation of income taxes at the statutory income tax rate to our effective income tax rate was as follows (in thousands):

	<u>December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Statutory income tax rate . . . . .	<u>12.5%</u>	<u>35.0%</u>	<u>35.0%</u>
Income tax provision at statutory rate . . . . .	\$ 22,169	43,744	11,472
Acquisition-related costs . . . . .	763	3,552	—
Research and other tax credits . . . . .	(100)	(1,323)	(380)
Share-based compensation . . . . .	873	670	1,083
Foreign income tax rate differential . . . . .	52,066	—	—
Uncertain tax positions . . . . .	2,249	—	—
Prior period adjustments . . . . .	(2,524)	—	—
Other . . . . .	(132)	353	(80)
Change in valuation allowance . . . . .	<u>(159,158)</u>	<u>(46,996)</u>	<u>(12,095)</u>
Income tax benefit . . . . .	<u>\$ (83,794)</u>	<u>\$ —</u>	<u>\$ —</u>
Effective income tax rate . . . . .	<u>(47.2)%</u>	<u>— %</u>	<u>— %</u>

**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The change in valuation allowance of \$159.2 million is comprised of NOL and tax credit carryforwards utilized in 2012 of \$55.0 million and a release in valuation allowance of \$104.2 million as described below.

Deferred income taxes reflect the tax effects of NOLs and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes using currently enacted tax rates and regulations that are expected to be in effect when the differences are expected to be recovered or settled. Significant components of our net deferred tax assets/(liabilities) were as follows (in thousands):

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 71,636	\$ 67,762
Tax credit carryforwards .....	6,034	15,140
Intangible assets .....	13,940	8,309
Share-based compensation .....	3,875	6,293
Accruals .....	32,594	8,188
Deferred revenue and other .....	13,797	5,496
Total deferred tax assets .....	141,876	111,188
Valuation allowance .....	(17,471)	(111,188)
Net deferred tax assets .....	124,405	—
Deferred tax liabilities:		
Acquired intangible assets .....	(191,341)	—
Other .....	(1,069)	—
Net deferred tax liabilities .....	\$ (68,005)	\$ —

The following table presents the breakdown between current and non-current deferred tax assets/(liabilities) (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>
Current deferred tax assets .....	\$ 35,813	\$—
Current deferred tax liabilities .....	(275)	—
Non-current deferred tax assets .....	74,850	—
Non-current deferred tax liabilities .....	(178,393)	—
Net deferred tax liabilities .....	\$ (68,005)	\$—

As of December 31, 2012, we had NOL carryforwards and tax credit carryforwards for U.S. federal income tax purposes of approximately \$197.4 million and \$12.7 million, respectively, available to reduce future income subject to income taxes. The NOL carryforwards are inclusive of \$5.1 million from the Azur Merger and \$116.7 million from the EUSA Acquisition in 2012. The federal NOL carryforwards will expire, if not utilized, in the tax years 2022 to 2030, and the federal tax credits will expire, if not utilized, in the tax years 2018 to 2032. In addition, we had approximately \$237.4 million of NOL carryforwards and \$2.4 million of tax credit carryforwards as of December 31, 2012 available to reduce future taxable income for state income tax purposes. The state NOL carryforwards will expire, if not utilized, in the tax years 2013 to 2032. The state tax credits have no expiration date. In addition, as of December 31, 2012, there were NOL carryforwards for income tax purposes

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

of approximately \$56.2 million and \$4.5 million available to reduce future income subject to income taxes in the United Kingdom and Germany, respectively. The NOLs generated in the United Kingdom and Germany have no expiration period and we maintain a full valuation allowance against the associated deferred tax assets.

Approximately \$35.3 million of both the U.S. federal and state NOL carryforwards as of December 31, 2012 resulted from exercises of employee share options and certain sales by employees of shares issued under other employee equity compensation plans. We have not recorded the tax benefit of the deduction related to these exercises and sales as deferred tax assets on our balance sheet. When we realize the tax benefit as a reduction to taxable income in our tax returns, we will account for the tax benefit as a credit to shareholders' equity rather than as a reduction of our income tax provision in our financial statements.

Valuation allowances require an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. Such assessment is required on a jurisdiction by jurisdiction basis. During the fourth quarter of 2012, we recognized an income tax benefit of \$104.2 million relating to the reversal of a valuation allowance against substantially all of our U.S. federal and state deferred tax assets. Management determined that a valuation allowance was no longer needed on these deferred tax assets based on an assessment of the relative impact of all positive and negative evidence that existed at December 31, 2012, including an evaluation of cumulative income in recent years, future sources of taxable income exclusive of reversing temporary differences, and significant risks and uncertainties related to our business. As of December 31, 2012, we continued to maintain a valuation allowance of \$17.5 million for certain U.S. state and foreign deferred tax assets until sufficient positive evidence exists to support reversal. We periodically evaluate the likelihood of the realization of deferred tax assets and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of tax audits and the regulatory approval of products currently under development.

Utilization of certain of our NOL and tax credit carryforwards in the United States is subject to annual limitation due to the ownership change limitations provided by Sections 382 and 383 of the Internal Revenue Code and similar state provisions. Such an annual limitation may result in the expiration of certain NOLs and tax credits before future utilization. We currently estimate that we have an annual limitation on the utilization of certain acquired federal NOLs of \$29 million for each of the years 2013 to 2016, \$12 million for 2017, and a combined total of \$3 million for 2018 to 2026.

No provision for income tax in Ireland has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$604.2 million at December 31, 2012. In the event of the distribution of those earnings in the form of dividends or otherwise, we may be liable for income taxes, subject to an adjustment, if any, for foreign tax credits and foreign withholding taxes payable to certain foreign tax authorities. As of December 31, 2012, it is not practicable to determine the amount of the income tax liability related to these undistributed earnings due to a variety of factors.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

We are required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As a result, we have established a liability for certain tax benefits which we judge may not be sustained upon examination. A reconciliation of our unrecognized tax benefits follows (in thousands):

	December 31,		
	2012	2011	2010
Balance at the beginning of the year . . . . .	\$3,764	\$ 4,852	\$4,711
Increases related to current year tax positions . . . . .	3,492	242	164
Increases related to prior year tax positions . . . . .	40	213	—
Decreases related to prior year tax positions . . . . .	(8)	(1,543)	—
Lapse of applicable statute of limitations . . . . .	—	—	(23)
Balance at the end of the year . . . . .	\$7,288	\$ 3,764	\$4,852

Interest related to our unrecognized tax benefits is recorded in income tax provision (benefit) in our consolidated statements of income. As of December 31, 2012 and 2011, our accrued interest and penalties related to uncertain tax positions were not significant. Included in the balance of unrecognized tax benefits at December 31, 2012 are potential benefits of \$5.5 million that, if recognized, would affect the effective tax rate on income. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

We file income tax returns in Ireland, the U.S. federal and various state jurisdictions and foreign jurisdictions, including France, which typically have three to four tax years open at any point in time. Because of our net operating loss and tax credit carryforwards, substantially all of our tax years remain open to federal, state, and foreign tax examination. We are currently under examination by the French tax authorities for fiscal years 2010 and 2011.

#### 17. Related Party Transactions

In connection with the Azur Merger, we assumed a lease for office space in Dublin, Ireland. The lease agreement was with Seamus Mulligan, the former Chief Executive Officer of Azur Pharma, who is a member of our board of directors. Rentals paid on this lease amounted to \$0.3 million in 2012. In November 2012, we terminated this lease at a cost of \$1.2 million, which was the carrying value of our above market lease liability. There was no resulting gain or loss on the lease termination.

In 2011, Azur Pharma entered into an agreement with Circ Pharma Limited/Circ Pharma Research and Development Limited, or Circ, companies controlled by Seamus Mulligan, whereby Azur Pharma obtained an option to license certain rights and assets in relation to Tramadol (a chronotherapeutic formulation) and to conduct certain development activities. Azur Pharma paid Circ \$0.3 million for this option in 2011. In 2012, we terminated the agreement at no cost.

In 2012, we entered into an underwriting agreement with two underwriters and certain selling shareholders, pursuant to which the selling shareholders agreed to sell to the underwriters 7.9 million of our ordinary shares, resulting in aggregate gross proceeds to the selling shareholders of approximately \$390.7 million. The selling shareholders included entities affiliated with certain members of our board of directors, four of our directors and four of our executive officers at the time of the agreement. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the offering, and we paid expenses of approximately \$0.4 million in connection with this offering.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In 2010, we repaid in full all of our then outstanding senior secured notes, of which \$6.8 million principal amount was paid to an entity affiliated with Kohlberg, Kravis & Roberts & Co. L.P., or KKR, a significant stockholder. In addition, in 2010, we paid prepayment penalties and a fee to the holders of the senior secured notes totaling \$8.5 million of which \$0.5 million was paid to the KKR affiliate. Cash paid for interest with respect to then outstanding senior secured notes held by the KKR affiliate was \$0.5 million in 2010. All payments to KKR were in proportion to its ownership of the senior secured notes.

In 2010, we issued 7,000,000 shares of our common stock in an underwritten public offering of which 821,851 shares and 16,472 shares were purchased from the underwriter by Longitude Venture Partners, L.P. and Longitude Capital Associates, L.P., respectively, which are entities affiliated with Patrick G. Enright, a member of our board of directors. The remaining shares were purchased from the underwriter by third party investors on the same terms and conditions.

#### 18. Restructuring

In June 2012, we initiated a restructuring plan to re-align certain support functions across the company following the Azur Merger and the EUSA Acquisition. In connection with this restructuring, we will incur costs of severance for terminated employees as well as retention bonus costs for certain employees retained to assist with the transition process, which is estimated to be completed by the second quarter of 2013. The one-time termination benefits are being recorded over the remaining service period where employees are required to stay through their termination date to receive the benefits. During the year ended December 31, 2012, we recorded \$2.8 million of costs related to these one-time termination benefits, which are recorded within selling, general and administrative expenses in our consolidated statements of income. We expect to incur approximately \$0.3 million in additional costs in connection with this plan. There were no restructuring activities during 2011 or 2010.

The following table summarizes the amounts related to one-time termination benefits for the year ended December 31, 2012 (in thousands):

	<b>Total Termination Benefits</b>
Balance at January 1, 2012 .....	\$ —
Costs incurred during the period .....	2,789
Cash payments .....	<u>(1,562)</u>
Balance at December 31, 2012 .....	<u>\$ 1,227</u>

The balance for termination benefits at December 31, 2012 is included within accrued liabilities in our consolidated balance sheet.

#### 19. Discontinued Operations

In 2012, we sold the women's health business, a component of the acquired Azur Pharma business, to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl, or collectively, Meda, for \$97.6 million, including \$2.6 million for certain inventory transferred to Meda upon the closing of the sale, less transaction costs of \$3.7 million. As part of the transaction, Meda purchased six women's health products from us and offered positions to approximately 60 of our employees who directly supported the women's health business. We recorded a non-recurring gain on the sale of \$35.2 million.

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

We decided to sell our women's health business to concentrate our commercial efforts on our core products in our target therapeutic areas. The results of the women's health business are included in income from discontinued operations in 2012. As the women's health business was acquired in the Azur Merger, it is not included in the results for 2011 or 2010. Goodwill was allocated to the divested women's health business using the relative fair value method.

Net revenue and income from discontinued operations were as follows (in thousands):

	<u>Year Ended December 31, 2012</u>
Product sales, net .....	\$20,873
Loss from discontinued operations before income taxes .....	\$ (5,787)
Income tax expense(1) .....	<u>(2,020)</u>
Loss from discontinued operations, net of taxes .....	(7,807)
Gain on sale of discontinued operations(2) .....	<u>35,244</u>
Income from discontinued operations, net of taxes .....	<u>\$27,437</u>

(1) The income tax expense relates to profits generated by the women's health business in 2012 which are attributable to the United States.

(2) The gain on sale of discontinued operations was not impacted by income taxes as the value attributable to the women's health business was held in a non-taxable jurisdiction.

#### 20. Employee Benefit Plans

We operate a number of defined contribution retirement plans. The costs of these plans are charged to the income statement in the period they are incurred. We recorded expense related to our defined contribution plans of \$0.3 million in 2012 and none in 2011 and 2010. In the United Kingdom, we operate a defined contribution plan in which we contribute up to 12% of an employee's eligible earnings. We recorded expense of \$0.2 million in 2012 and none in 2011 and 2010, in connection with contributions we made under the U.K. defined contribution plan. In France, we accrue for a potential liability which is payable if an employee retires and we recorded expense of \$0.1 million in 2012 and none in 2011 and 2010 related to this plan. In the United States, we provide a qualified 401(k) savings plan for our U.S. based employees. All U.S. based employees are eligible to participate, provided they meet the requirements of the plan. While we can elect to match employee contributions under the 401(k) savings plan, no such matching contributions were made through December 31, 2012.



**JAZZ PHARMACEUTICALS PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**21. Quarterly Financial Data (Unaudited)**

The following interim financial information presents our 2012 and 2011 results of operations on a quarterly basis (in thousands, except per share amounts):

	<u>2012</u>			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Revenues(1) . . . . .	\$102,530	\$124,231	\$175,515	\$183,703
Gross margin(1)(2) . . . . .	93,708	110,714	141,501	156,179
Income from continuing operations . . . . .	30,235	31,113	33,595	166,206
Income (loss) from discontinued operations . . . . .	(2,554)	(3,968)	(386)	34,345
Net income . . . . .	27,681	27,145	33,209	200,551
Net income per ordinary share, basic . . . . .	0.51	0.48	0.58	3.46
Net income per ordinary share, diluted . . . . .	0.48	0.45	0.55	3.28

	<u>2011</u>			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Revenues . . . . .	\$50,881	\$64,567	\$73,293	\$83,536
Gross margin(2) . . . . .	47,094	60,094	68,315	77,073
Net income . . . . .	21,827	33,202	32,482	37,473
Net income per ordinary share, basic . . . . .	0.54	0.81	0.77	0.88
Net income per ordinary share, diluted . . . . .	0.48	0.71	0.69	0.79

(1) In 2012, we sold our women's health business. The women's health business met the discontinued operations criteria in the third quarter of 2012. See Note 19 for information regarding discontinued operations. As a result, revenues and gross margin for the first two quarters of 2012 have been restated to reflect only our continuing operations. There was no effect on previously reported net income. Below is a reconciliation of the revenues and gross margin amounts as previously reported in our quarterly reports on Form 10-Q to the restated amounts reported above.

	<u>2012</u>	
	<u>March 31</u>	<u>June 30</u>
Revenues, as previously reported . . . . .	\$108,414	\$129,539
Less product sales from discontinued operations . . . . .	(5,884)	(5,308)
Revenues, as adjusted . . . . .	<u>\$102,530</u>	<u>\$124,231</u>
Gross margin, as previously reported . . . . .	\$ 96,578	\$112,940
Less gross margin from discontinued operations . . . . .	(2,870)	(2,226)
Gross margin, as adjusted . . . . .	<u>\$ 93,708</u>	<u>\$110,714</u>

(2) Gross margin excludes amortization of acquired developed technology of \$10.7 million, \$12.9 million, \$19.7 million and \$21.8 million in the first, second, third and fourth quarters of 2012, respectively, and \$1.8 million in each quarter of 2011.

The tables above include the following unusual or infrequently occurring items:

- We completed the Azur Merger on January 18, 2012 and the EUSA Acquisition on June 12, 2012 and contributions of the acquired businesses to our total revenues from continuing operations were \$18.4 million, \$23.5 million, \$59.9 million and \$59.6 million in the first, second, third and fourth quarters of

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

2012, respectively, as measured from the date of each acquisition. The portion of gross margin and net income associated with the acquired businesses was not separately identifiable due to the integration with our operations;

- A gain from the sale of our women's health business of \$35.2 million recorded in the fourth quarter of 2012;
- A tax benefit of \$104.2 million on the release of an income tax valuation allowance in the fourth quarter of 2012;
- Acquisition accounting inventory fair value step-up adjustments in continuing operations of \$1.3 million, \$3.0 million, \$10.3 million and \$2.1 million in the first, second, third and fourth quarters of 2012, respectively;
- Transaction costs of \$3.5 million and \$8.9 million in the first and second quarters of 2012, respectively;
- Transaction costs of \$6.0 million and \$5.3 million related to the Azur Merger were recorded in the third and fourth quarters of 2011, respectively;
- Share-based compensation expense of \$7.3 million recorded in the fourth quarter of 2011 as a result of the vesting acceleration of non-qualified share options held by certain executives and non-employee directors; and
- A loss on extinguishment of debt of \$1.1 million in the third quarter of 2011.

**Schedule II**  
**Valuation and Qualifying Accounts**  
(In thousands)

		<u>Balance at beginning of period</u>	<u>Additions charged to costs and expenses</u>	<u>Other Additions</u>	<u>Deductions</u>	<u>Balance at end of period</u>
For the year ended December 31, 2012						
Allowance for doubtful accounts	(1)	\$ 50	\$ 678	\$ —	\$ (13)	\$ 715
Allowance for sales discounts	(1)	296	6,022	—	(5,790)	528
Allowance for chargebacks	(1)	20	13,072	—	(10,556)	2,536
Deferred tax asset valuation allowance	(2),(3)	111,188	3,421	62,971	(160,109)	17,471
For the year ended December 31, 2011						
Allowance for doubtful accounts	(1)	\$ 50	\$ 3	\$ —	\$ (3)	\$ 50
Allowance for sales discounts	(1)	420	3,604	—	(3,728)	296
Allowance for chargebacks	(1)	12	451	—	(443)	20
Deferred tax asset valuation allowance	(3)	155,519	—	—	(44,331)	111,188
For the year ended December 31, 2010						
Allowance for doubtful accounts	(1)	\$ 50	\$ (9)	\$ —	\$ 9	\$ 50
Allowance for sales discounts	(1)	238	3,829	—	(3,647)	420
Allowance for chargebacks	(1)	—	233	—	(221)	12
Deferred tax asset valuation allowance	(3)	162,661	—	—	(7,142)	155,519

- (1) Shown as a reduction of accounts receivable. Charges related to sales discounts and chargebacks are reflected as a reduction of revenue.
- (2) Other additions to the deferred income tax asset valuation allowance resulted from the Azur Merger and the EUSA Acquisition.
- (3) Deductions to the deferred tax asset valuation allowance include movements relating to utilization of NOLs and tax credit carryforwards, release in valuation allowance and other movements including adjustments following finalization of tax returns.

The schedule above does not include rebates and sales returns reserves which are reported in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report on Form 10-K.

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## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Document</u>
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500) filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
2.5	Asset Purchase Agreement, dated as of September 5, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals International II Limited, Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 15, 2012).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500), for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
4.2D	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).

<u>Exhibit Number</u>	<u>Description of Document</u>
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.4 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.5 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.5	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. on July 7, 2009 (incorporated herein by reference to Exhibit 4.6 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6A	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.6B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.7	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1†	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between Jazz Pharmaceuticals, Inc. and Patheon Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.50 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007).
10.2†	Quality Agreement, dated as of March 13, 2007, by and between Jazz Pharmaceuticals, Inc. and Patheon Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.51 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007).
10.3†	Supply Agreement, dated as of April 1, 2010, by and between Jazz Pharmaceuticals, Inc. and Siegfried (USA) Inc. (incorporated herein by reference to Exhibit 10.54 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2010, as filed with the SEC on May 6, 2010).
10.4	Master Services Agreement, dated April 15, 2011, by and between Jazz Pharmaceuticals, Inc., CuraScript, Inc. and Express Scripts Specialty Distribution Services, Inc. (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2011, as filed with the SEC on May 9, 2011).

**Exhibit  
Number**

**Description of Document**

- 10.5 Escrow Agreement made and entered into as of January 18, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., Seamus Mulligan, solely in his capacity as Indemnitors' Representative, and Deutsche Bank National Trust Association, as escrow agent (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
- 10.6† Royalty Bearing License Agreement and Supply Agreement Re Erwinia-Derived Asparaginase, dated July 22, 2005, between the Health Protection Agency and EUSA Pharma SAS (formerly OPi, S.A.), as amended on each of December 22, 2009, March 23, 2012 and August 8, 2012 (incorporated herein by reference to Exhibit 10.11 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q/A (File No. 001-33500), as filed with the SEC on August 9, 2012).
- 10.7 Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., the Lenders and Barclays Bank PLC, as Administrative Agent, Collateral Agent, Swing Line Lender and L/C Issuer (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
- 10.8 Commercial Lease, dated as of June 2, 2004, by and between Jazz Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.52 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007).
- 10.9 Lease Agreement, dated October 20, 2008, between Seamus Mulligan, as lessor, and Jazz Pharmaceuticals plc, as lessee (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
- 10.10 First Amendment of Lease, dated June 1, 2009, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.86 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 4, 2009).
- 10.11 Second Amendment of Lease, dated February 28, 2012, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.31 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
- 10.12 Lease, dated May 8, 2012, by and between John Ronan and Castle Cove Property Developments Limited and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
- 10.13 Surrender of Lease of 45 Fitzwilliam Square Dublin 2, dated November 9, 2012, between Seamus Mulligan, as lessor, and Jazz Pharmaceuticals plc, as lessee.
- 10.14+ Form of Indemnification Agreement between Jazz Pharmaceuticals plc and its officers and directors (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
- 10.15+ Offer Letter from Jazz Pharmaceuticals, Inc. to Kathryn Falberg (incorporated herein by reference to Exhibit 10.92 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on December 3, 2009).
- 10.16+ Employment Agreement by and between Seamus Mulligan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).

<u>Exhibit Number</u>	<u>Description of Document</u>
10.17+	Noncompetition Agreement by and between Seamus Mulligan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.18+	Offer Letter from Jazz Pharmaceuticals, Inc. to Jeffrey Tobias, M.D. (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 8, 2011).
10.19+	Separation Agreement, dated January 18, 2012, by and between Jazz Pharmaceuticals plc and Carol Gamble (incorporated herein by reference to Exhibit 10.27 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.20+	Offer Letter from Jazz Pharmaceuticals, Inc. to Suzanne Sawochka Hooper (incorporated herein by reference to Exhibit 10.19 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on May 8, 2012).
10.21+	Amendment to Employment Agreement by and between Jazz Pharmaceuticals plc and Seamus Mulligan (incorporated herein by reference to Exhibit 10.20 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on May 8, 2012).
10.22+	Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.23+	Amendment to Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.24+	Noncompetition Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.25A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc. and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.57A in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.25B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney's Office for the Eastern District of New York and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.57B in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.25C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.57C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.25D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.57D in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.26A+	Jazz Pharmaceuticals plc 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.5 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).



**Exhibit  
Number**

**Description of Document**

- 10.26B+ Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.22 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
- 10.26C+ Form of Letter, amending outstanding options granted under the Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.60 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
- 10.27A+ Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.3 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
- 10.27B+ Jazz Pharmaceuticals plc 2007 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.3B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).
- 10.27C+ Form of Notice of Grant of Stock Options and Form of Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan.
- 10.27D+ Form of Notice of Grant of Stock Options and Form of Option Agreement (Irish) under Jazz Pharmaceuticals plc 2007 Equity Incentive Plan.
- 10.27E+ Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan.
- 10.27F+ Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan.
- 10.28A+ Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.1 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
- 10.28B+ Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.39B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).
- 10.28C+ Form of Option Grant Notice and Form of Stock Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
- 10.28D+ Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
- 10.28E+ Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
- 10.28F+ Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.9 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).

<u>Exhibit Number</u>	<u>Description of Document</u>
10.28G+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.10 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.28H+	Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.29+	Jazz Pharmaceuticals plc Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 99.6 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.30A+	Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 99.4 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.30B+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan.
10.31A+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan, as amended and restated.
10.31B+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Sub-Plan Governing Purchase Rights to Participants in the Republic of Ireland (incorporated by reference herein to Exhibit 10.4C in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2012, as filed with the SEC on August 7, 2012).
10.32A+	Jazz Pharmaceuticals plc Cash Bonus Plan, (incorporated herein by reference to Exhibit 10.33 in the annual report on Form 10-K/A (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.32B+	Jazz Pharmaceuticals plc Cash Bonus Plan for U.S. Affiliates.
10.32C+	Jazz Pharmaceuticals Cash Bonus Plan for International Affiliates (2013).
10.33+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.34 in the annual report on Form 10-K/A (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.34+	Jazz Pharmaceuticals plc 2012 Non-Employee Director Compensation Arrangements (incorporated herein by reference to Exhibit 10.32 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).
10.35+	Jazz Pharmaceuticals plc 2012 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
21.1	Subsidiaries of Jazz Pharmaceuticals plc.
23.1	Consent of KPMG, Independent Registered Public Accounting Firm.
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page hereto).

<u>Exhibit Number</u>	<u>Description of Document</u>
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS++	XBRL Instance Document
101.SCH++	XBRL Taxonomy Extension Schema Document
101.CAL++	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF++	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB++	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE++	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

\* The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

**EXHIBIT 21.1****Subsidiaries of the Registrant**

<b>Name of Subsidiary</b>	<b>State or Jurisdiction of Incorporation or Organization</b>
Jazz Pharmaceuticals Ireland Limited	Ireland
Jazz Pharmaceuticals, Inc.	Delaware
Jazz Pharmaceuticals International Limited	Bermuda
Jazz Pharmaceuticals International II Limited	Bermuda
EUSA Pharma SAS	France
EUSA Pharma Holdings SAS	France
EUSA Pharma International Limited	Gibraltar

**Consent of KPMG, Independent Registered Public Accounting Firm**

The Board of Directors  
Jazz Pharmaceuticals plc

We consent to the incorporation by reference in the registration statement (No. 333-179075) on Form S-8, and the registration statement (No. 333-179080) on Form S-3, of Jazz Pharmaceuticals plc of our reports dated February 26, 2013, with respect to the consolidated balance sheet of Jazz Pharmaceuticals plc as of December 31, 2012, and the related consolidated statements of income, comprehensive income, shareholders' equity and cash flows for the year then ended, and the related financial statement schedule for the year ended December 31, 2012, and the effectiveness of internal control over financial reporting as of December 31, 2012, which reports appear in the December 31, 2012 annual report on Form 10-K of Jazz Pharmaceuticals plc.

/s/ KPMG

Dublin, Ireland  
February 26, 2013

**Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-179075) pertaining to the 2011 Equity Incentive Plan, the 2007 Equity Incentive Plan, the 2003 Equity Incentive Plan, the 2007 Employee Stock Purchase Plan, the Amended and Restated 2007 Non-Employee Directors Stock Option Plan and the Amended and Restated Directors Deferred Compensation Plan of Jazz Pharmaceuticals plc (the Successor), and the Registration Statement (Form S-3 No. 333-179080) of Jazz Pharmaceuticals plc and in the related prospectuses, of our report dated February 28, 2012, with respect to the consolidated balance sheet of Jazz Pharmaceuticals, Inc. (the Predecessor) and its subsidiaries as of December 31, 2011, the related consolidated statements of income, comprehensive income, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2011, and the related financial statement schedule for 2011 and 2010, included in this Annual Report (Form 10-K) for the year ended December 31, 2012.

/s/ ERNST & YOUNG LLP

Redwood City, California  
February 26, 2013



**CERTIFICATION**

I, Kathryn E. Falberg, certify that:

1. I have reviewed this Annual Report on Form 10-K of Jazz Pharmaceuticals Public Limited Company;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2013

By: \_\_\_\_\_ /s/ KATHRYN E. FALBERG

**Kathryn E. Falberg**  
**Executive Vice President and Chief Financial Officer**



**CERTIFICATION<sup>(1)</sup>**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Bruce C. Cozadd, Chief Executive Officer of Jazz Pharmaceuticals Public Limited Company (the “Company”), and Kathryn E. Falberg, Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2012, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2013

/s/ BRUCE C. COZADD

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**Bruce C. Cozadd**  
Chairman and Chief Executive Officer

/s/ KATHRYN E. FALBERG

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**Kathryn E. Falberg**  
Executive Vice President and Chief Financial Officer

(1) This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Jazz Pharmaceuticals Public Limited Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Jazz Pharmaceuticals Public Limited Company and will be retained by Jazz Pharmaceuticals Public Limited Company and furnished to the Securities and Exchange Commission or its staff upon request.

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# COMPANY INFORMATION

## Board of Directors

Bruce C. Cozadd  
*Chairman and Chief Executive Officer, Jazz Pharmaceuticals plc*

Paul L. Berns  
*Consultant to Pharmaceutical Industry*

Patrick G. Enright  
*Managing Director, Longitude Capital*

Peter Gray  
*Chairman, United Drug plc*

Heather Ann McSharry  
*Director, CRH plc and Greencore plc*

James C. Momtazee  
*Member, KKR Management LLLC*

Seamus Mulligan  
*Executive Chairman, Circ Pharma Limited*

Kenneth W. O'Keefe  
*Managing Partner, Beecken Petty O'Keefe & Company*

Norbert G. Riedel, Ph.D.  
*Retired Chief Science and Innovation Officer, Baxter International Inc.*

Catherine A. Sohn  
*Founder, Sohn Health Strategies*

Rick E. Winningham  
*Chairman and Chief Executive Officer, Theravance, Inc.*

## Ordinary Shares

Jazz Pharmaceuticals plc ordinary shares are traded on the NASDAQ Global Select market under the symbol "JAZZ."

## Company Secretary

Shawn Mindus  
*Vice President, Financial Planning, Analysis & Strategy*

## Registrar and Transfer Agent

Computershare  
[www.computershare.com](http://www.computershare.com)

### Ireland:

+353 1 447 5566  
+353 1 447 5571 fax

Heron House  
Corrig Road  
Sandyford Industrial Estate  
Dublin 18, Ireland

### United States:

+1 781 575 4238 (outside U.S.)  
+1 877 373 6374 (inside U.S.)

P.O. Box 43023  
Providence, RI 02940 U.S.A.

## Executive Team

Bruce C. Cozadd  
*Chairman and Chief Executive Officer*

Russell J. Cox  
*Executive Vice President and Chief Commercial Officer*

Kathryn E. Falberg  
*Executive Vice President and Chief Financial Officer*

Suzanne Sawochka Hooper  
*Executive Vice President and General Counsel*

Fintan Keegan  
*Executive Vice President, Technical Operations*

Jeffrey Tobias, M.D.  
*Executive Vice President, Research and Development and Chief Medical Officer*

Heather McGaughey  
*Senior Vice President, Human Resources*

Iain McGill  
*Head of EUSA International and Senior Vice President, Jazz Pharmaceuticals*

Robert McKague  
*Senior Vice President and Chief Compliance Officer*

## Jazz Pharmaceuticals plc Corporate Headquarters

Fourth Floor, Connaught House  
One Burlington Road, Dublin 4  
Ireland  
+ 353 1 634 7800  
+ 353 1 634 7850 fax  
[www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com)

## Independent Registered Public Accounting Firm

KPMG, Dublin, Ireland

## Annual Meeting

The annual general meeting of shareholders will be held at 10:30 a.m. local time on August 1, 2013 at our Corporate Headquarters located at Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland.

## For More Information

Information about Jazz Pharmaceuticals plc can be found on the Internet at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com). Inquiries regarding Jazz Pharmaceuticals plc and its activities may be directed to the Investor Relations Department at [investorinfo@jazzpharma.com](mailto:investorinfo@jazzpharma.com) or +353 1 634 7892 (Ireland) or + 650 496 2800 (U.S.). Communications concerning shares and transfer requirements, lost certificates or changes of address should be directed to the Transfer Agent.

## "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This proxy statement and 2012 annual report contains forward-looking statements, including, but not limited to, statements related to Jazz Pharmaceuticals' growth potential and the growth potential of its products, future financial results, strategy, potential product acquisitions and R&D investments, future share repurchases and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: maintaining and increasing sales of and revenue from Xyrem, such as the potential introduction of generic competition and changed or increased regulatory restrictions on or requirements with respect to Xyrem, as well as similar risks related to effectively commercializing the company's other marketed products, including Erwinaze and Prialt; protecting the company's intellectual property rights; obtaining appropriate pricing and reimbursement for the company's products in an increasingly challenging environment; ongoing regulation and oversight by U.S. and non-U.S. regulatory agencies; dependence on key customers and sole source suppliers, including the risk that the company may not be able to timely resolve potential product supply shortages and meet product demand; the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval; the company's ability to identify and acquire, in-license or develop additional products or product candidates to grow its business; and potential restrictions on the company's ability and flexibility to pursue future opportunities as a result of its substantial outstanding debt obligations; as well as risks related to future opportunities and plans, including the uncertainty of expected future financial performance and results; and those risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including in the Form 10-Q for the period ended March 31, 2013 and future filings and reports by the company. Jazz Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this proxy statement and 2012 annual report as a result of new information, future events or changes in its expectations.



**Jazz Pharmaceuticals**

Innovation that performs

Fourth Floor, Connaught House  
One Burlington Road  
Dublin 4  
Ireland  
+ 353 1 634 7800  
[www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com)