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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, 2019

or

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

For the transition period from to

Commission File Number: 001-33500

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Exact name of registrant as specified in its charter)

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

Fifth Floor, Waterloo Exchange
Waterloo Road, Dublin 4, Ireland D04 E5W7
011-353-1-634-7800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value $0.0001 per share	**JAZZ**	**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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $7,869,781,340 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 1,418,007 ordinary shares of the registrant held by executive officers, directors and shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of February 18, 2020, a total of 56,133,306 ordinary shares, nominal value $0.0001 per share, of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III, Items 10-14 of this Form 10-K is incorporated by reference to the registrant's definitive Proxy Statement for the 2020 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, provided that if such Proxy Statement is not filed within such period, such information will be included in an amendment to this Form 10-K to be filed within such 120-day period.

JAZZ PHARMACEUTICALS PLC
2019 ANNUAL REPORT ON FORM 10-K

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We own or have rights to various copyrights, trademarks, and trade names used in our business in the U.S. and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Sunosi® (solriamfetol), Defitelio® (defibrotide sodium), Defitelio® (defibrotide), Erwinaze® (asparaginase *Erwinia chrysanthemi*), Erwinase®, CombiPlex®, Vyxeos® (daunorubicin and cytarabine) liposome for injection and Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion. This report also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

NOTE REGARDING COMPANY REFERENCE

In this report, unless otherwise indicated or the context otherwise requires, all references to "Jazz Pharmaceuticals," "the registrant," "we," "us," and "our" refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries.

PART I

Item 1. Business

Overview

Jazz Pharmaceuticals plc is a global biopharmaceutical company dedicated to developing life-changing medicines for people with serious diseases – often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep medicine and movement disorders, and in oncology, including hematologic and solid tumors.

Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in both adult and pediatric patients with narcolepsy;
- **Sunosi® (solriamfetol)**, a product approved by the FDA and marketed in the U.S. to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea, or OSA, and also approved in Europe in January 2020 by the European Commission, or EC;
- **Defitelio® (defibrotide sodium)**, a product approved in the U.S. for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, or SOS, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Europe (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children undergoing HSCT therapy;
- **Erwinaze® (asparaginase *Erwinia chrysanthemi*)**, a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase; and
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or t-AML, or AML with myelodysplasia-related changes, or AML-MRC.

Over the last five years, we achieved multiple significant regulatory approvals, including most recently the European approval of Sunosi, and executed on five product launches. Over the next two years, we look forward to three additional potential regulatory approvals and related product launches (lurbinectedin, JZP-258 and JZP-458), as well as the

commencement of the rolling launch of Sunosi in Europe by mid-2020. In February 2020, the FDA accepted for filing with priority review the new drug application, or NDA, for lurbinectedin for the treatment of relapsed small cell lung cancer, or SCLC, a product candidate for which we recently acquired exclusive U.S. development and commercialization rights. In January 2020, we submitted an NDA to the FDA seeking marketing approval for JZP-258, an oxybate product candidate that contains 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem, for the treatment of cataplexy and EDS in narcolepsy patients seven years of age and older. We also have in development JZP-458, a recombinant *Erwinia* asparaginase product candidate, for the treatment of pediatric and adult patients with ALL or lymphoblastic lymphoma, or LBL, who are hypersensitive to *E. coli*-derived asparaginase products, and expect to submit a biologics license application, or BLA, to the FDA for JZP-458 as early as the fourth quarter of 2020.

Our strategy to create shareholder value is focused on:

- Strong financial execution through growth in sales of our current lead marketed products;
- Building a diversified product portfolio and development pipeline through a combination of our internal research and development efforts and obtaining rights to clinically meaningful and differentiated on- or near-market products and early- to late-stage product candidates through acquisitions, collaborations, licensing arrangements, partnerships and venture investments; and
- Maximizing the value of our products and product candidates by continuing to implement our comprehensive global development plans, including through generating additional clinical data and seeking regulatory approval for new indications and new geographies.

In 2019, consistent with our strategy, we continued to expand and advance our research and development pipeline in our sleep/neuroscience and hematology/oncology therapeutic areas, both by conducting activities internally and by leveraging partnerships with third parties. For a summary of our ongoing research and development activities, see "Business—Research and Development" in this Part I, Item 1.

Our Commercialized Products

Sleep Medicine and Neuroscience

Xyrem. Xyrem is the only product approved by the FDA and marketed in the U.S. for the treatment of both cataplexy and EDS in both adult and pediatric patients with narcolepsy. Sodium oxybate, the active pharmaceutical ingredient, or API, in Xyrem, is a formulation of the sodium salt of gamma-hydroxybutyrate, an endogenous neurotransmitter and metabolite of gamma-aminobutyric acid.

Narcolepsy is a chronic, debilitating neurological disorder characterized by EDS and the inability to regulate sleep-wake cycles normally. It affects an estimated one in 2,000 people in the U.S., with symptoms typically appearing in childhood. There are five primary symptoms of narcolepsy, including EDS, cataplexy, disrupted nighttime sleep, sleep-related hallucinations, and sleep paralysis. While patients with narcolepsy may not experience all five symptoms, EDS is an essential symptom of narcolepsy, is present in all narcolepsy patients and is characterized by chronic, pervasive sleepiness as well as sudden irresistible and overwhelming urges to sleep (inadvertent naps and sleep attacks). Narcolepsy may affect many areas of life, including limiting a patient's education and employment opportunities, and may lead to difficulties at work, school, or in daily life activities like driving, operating machinery or caring for children. Patients with narcolepsy may also suffer from significant medical comorbidities, including cardiac disorders, depression, suicide risk, anxiety, diseases of the digestive system and respiratory diseases.

Cataplexy, the sudden loss of muscle tone with retained consciousness, can be one of the most debilitating symptoms of narcolepsy. Cataplexy is present in approximately 70% of patients with narcolepsy. Cataplexy can range from slight weakness or a drooping of facial muscles to the complete loss of muscle tone resulting in postural collapse. It may also impair a patient's vision or speech. Cataplexy is often triggered by strong emotions such as laughter, anger or surprise. Cataplexy can severely impair a patient's quality of life and ability to function.

Xyrem was approved in the U.S. for the treatment of cataplexy in adult patients with narcolepsy in 2002 and was approved for EDS in adult patients with narcolepsy in 2005. In October 2018, Xyrem was also approved in the U.S. for the treatment of cataplexy or EDS in pediatric narcolepsy patients ages seven and older. The American Academy of Sleep Medicine recommends Xyrem as a standard of care for the treatment of both cataplexy and EDS associated with narcolepsy.

In the fourth quarter of 2019, the average number of active Xyrem patients in the U.S. was approximately 14,950, and we believe that there are significantly more patients with narcolepsy who might benefit from treatment with Xyrem. In an effort to reach more patients who might benefit from our medicine, we continue to implement initiatives such as outreach to prescribers

who treat narcolepsy, physician/healthcare provider education, enhanced patient and physician support services and unbranded disease awareness programs for the public.

Our marketing, sales and distribution of Xyrem in the U.S. are subject to a risk evaluation and mitigation strategy, or REMS, which is required by the FDA to mitigate the risks of serious adverse outcomes resulting from inappropriate prescribing, abuse, misuse and diversion of Xyrem. Under the Xyrem REMS, all of the Xyrem sold in the U.S. must be dispensed and shipped directly to patients or caregivers through a central pharmacy. Xyrem may not be stocked in retail pharmacies. Physicians and patients must complete an enrollment process prior to fulfillment of Xyrem prescriptions, and each physician and patient must receive materials concerning the serious risks associated with Xyrem before the physician can prescribe, or a patient can receive, the product. The central certified pharmacy must monitor and report instances of patient or prescriber behavior giving rise to a reasonable suspicion of abuse, misuse or diversion of Xyrem, and maintains enrollment and prescription monitoring information in a central database. The central pharmacy ships the product directly to the patient (or caregiver) by a courier service.

We have had exclusive agreements with Express Scripts Specialty Distribution Services, Inc., or ESSDS, the central pharmacy for Xyrem, to distribute Xyrem in the U.S. and provide patient support services related to Xyrem since 2002. Our current agreement with ESSDS, which expires on July 1, 2020, may be terminated by either party at any time without cause on 180 days' prior written notice to the other party. We are actively engaged in a selection process to identify the best provider of central pharmacy services, at the conclusion of which we expect to enter into a new agreement with ESSDS or another comparable service provider that we have selected. We own certain intellectual property rights relating to the Xyrem REMS and patient support programs, such as standard operating procedures and business rules. Should we decide to select a different service provider, 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 engage. Any new agreement will include standard terms and conditions, including terms around use of intellectual property.

In 2019, net product sales of Xyrem were $1.6 billion, which represented 77% of our total net product sales.

Sunosi. Sunosi received FDA approval in March 2019 and was launched in the U.S. in July 2019 to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA. Sunosi was also approved in January 2020 by the EC to improve wakefulness and reduce EDS in adults with narcolepsy (with or without cataplexy) or OSA, and we expect to commence a rolling launch of Sunosi in Europe by mid-2020 as we make pricing and reimbursement submissions in European countries.

OSA, commonly referred to as sleep apnea, is a highly prevalent disease, and EDS, a major symptom of OSA, is characterized by the inability to stay awake and alert during the day resulting in unplanned lapses into sleep or drowsiness. Although positive airway pressure therapy, with its most common form being continuous positive airway pressure, or CPAP, has been shown to be an effective therapy for sleep apnea that frequently results in improvement in EDS in many patients, not all patients tolerate CPAP therapy and among those who tolerate CPAP, usage is highly variable. EDS may persist in people with OSA despite using CPAP.

In 2019, net product sales of Sunosi were $3.7 million.

Hematology and Oncology

Defitelio. Defibrotide, the API in Defitelio, has been approved for the treatment of VOD, a potentially life-threatening complication of HSCT, and is in development for other complications following HSCT, including prevention of VOD, prevention of acute Graft versus Host Disease, or aGvHD, as well as complications following anti-cancer treatment, including prevention of chimeric antigen receptor T-cell, or CAR T-cell, therapy-associated neurotoxicity. Defibrotide is the sodium salt of a complex mixture of single-stranded oligodeoxyribonucleotides derived from porcine DNA. Defibrotide mediates its effects via interaction with endothelial cells. Non-clinical data suggest that defibrotide stabilizes endothelial cells by reducing endothelial cell activation and by protecting them from further damage.

Stem cell transplantation is a frequently used treatment modality for hematologic cancers and other conditions in both adults and children. Certain conditioning regimens used as part of HSCT can damage the cells that line the hepatic vessels, which is thought to lead to the development of VOD, also referred to as SOS, a blockage of the small vessels in the liver, that can lead to liver failure and potentially result in significant dysfunction in other organs such as the kidneys and lungs. Severe VOD is the most extreme form of VOD and is associated with multi-organ failure and high rates of morbidity and mortality. An analysis of retrospective data, prospective cohort studies and clinical trials published between 1979 and 2007 found that the 100-day mortality rate in severe VOD cases is greater than 80%.

The EC granted marketing authorization under exceptional circumstances for Defitelio for the treatment of severe VOD in adults and children undergoing HSCT in 2013. We commenced a rolling launch of Defitelio in European countries in 2014. In countries where we currently commercialize Defitelio, we are working to maintain current levels of market access.

In 2016, the FDA approved our NDA for Defitelio for the treatment of adult and pediatric patients with VOD with renal or pulmonary dysfunction following HSCT. We launched Defitelio in the U.S. shortly after FDA approval. We also launched defibrotide in Canada in 2017. In June 2019, Nippon Shinyaku Co., Ltd., the partner to whom we have granted exclusive rights to develop and commercialize defibrotide in Japan, received marketing authorization from Japan's Ministry of Health, Labour and Welfare and launched defibrotide in Japan in September 2019.

In 2019, Defitelio/defibrotide product sales were $172.9 million, which represented 8% of our total net product sales.

Erwinaze. Erwinaze (called Erwinase in markets outside the U.S.) is a biologic product used in conjunction with chemotherapy to treat patients with ALL who have developed hypersensitivity to *E. coli*-derived asparaginase. Originally developed by Public Health England, a national executive agency of the United Kingdom, or UK, 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 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 can be a crucial component of their therapeutic regimen. 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 clinically meaningful, indicating that the hypersensitivity reaction has resulted in an intervention or interruption in infusion occurring in the patient's treatment regimen. While treatment protocols for pediatric, adolescent and young adult (up to age 39) patients commonly include asparaginase, adult protocols do not.

First approved by the FDA under a BLA for administration via intramuscular injection in conjunction with chemotherapy, Erwinaze was launched in the U.S. in 2011. In 2014, the FDA approved a supplemental BLA for administration of Erwinaze via intravenous infusion in conjunction with chemotherapy.

Erwinaze is exclusively licensed to us for worldwide marketing, sales and distribution by Porton Biopharma Limited, or PBL, a company that is wholly owned by the UK Department of Health and Social Care. PBL also manufactures the product for us and is our sole supplier for Erwinaze. We are obligated to make tiered royalty payments to PBL based on worldwide net sales of Erwinaze. Our license and supply agreement with PBL, which includes our license to Erwinaze trademarks and manufacturing know-how, expires on December 31, 2020. Unless we and PBL enter into a new agreement, we will lose our rights to exclusively market Erwinaze effective December 31, 2020, other than our right to sell certain Erwinaze inventory for a post-termination sales period of 12 months and certain other post-termination rights, including but not limited to intellectual property and data ownership. Either party also has the right to terminate the agreement prior to December 31, 2020 in the event of the other party's uncured material breach or insolvency.

In 2019, net product sales of Erwinaze were $177.5 million, which represented 8% of our total net product sales.

Vyxeos. Vyxeos is a liposomal formulation of a fixed ratio combination of daunorubicin and cytarabine for intravenous infusion that is indicated for the treatment of adults with newly-diagnosed t-AML or AML-MRC and has been shown to have synergistic effects at killing leukemia cells in vitro and in animal models. Vyxeos is the first drug delivery combination product based on our CombiPlex technology platform to be approved by the FDA and the EC.

AML is a rapidly progressing and life-threatening blood cancer that begins in the bone marrow, which produces most of the body's new blood cells. AML cells crowd out healthy cells and move aggressively into the bloodstream to spread cancer to other parts of the body. AML is a relatively rare disease representing about 1% of all new cancer cases and has the lowest survival rate of any form of leukemia. Patients with newly diagnosed t-AML or AML-MRC may have a particularly poor prognosis.

In 2017, we launched Vyxeos in the U.S. after the FDA approved our NDA for the treatment of adults with newly-diagnosed t-AML or AML-MRC. In August 2018, the EC granted marketing authorization for Vyxeos, and, as part of our rolling launch of Vyxeos in Europe, we are continuing to make pricing and reimbursement submissions in European countries.

In 2019, Vyxeos product sales were $121.4 million, which represented 6% of our total net product sales.

Research and Development

A key aspect of our growth strategy is our continued investment in our evolving and expanding research and development activities. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies. While we are focused on opportunities within our sleep/neuroscience and hematology/oncology therapeutic areas, such as our recent expansion into movement disorders and solid tumors, we are also exploring and investing in adjacent therapeutic areas that could further diversify our portfolio.

Our development activities encompass all stages of development and currently include clinical testing of new product candidates and activities related to clinical improvements of, or additional indications or new clinical data for, our existing marketed products. We have also expanded into preclinical exploration of novel therapies, including precision medicines in hematology and oncology. We conduct most of these activities by leveraging our growing internal research and development function, but we have also entered into collaborations with third parties for the research and development of innovative early-stage product candidates and have supported third parties seeking to perform clinical studies that will generate additional data related to our products. We also seek out investment opportunities in support of development of early-stage technologies in our therapeutic areas and adjacencies.

Our current and planned development activities in our sleep and neuroscience therapeutic area are focused on JZP-258, JZP-324 and JZP-385, as well as exploring additional indications for Sunosi, including major depressive disorder.

JZP-258. JZP-258 is an oxybate product candidate with a unique composition of cations resulting in 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem. In January 2020, we submitted an NDA for JZP-258 for the treatment of both cataplexy and EDS in patients with narcolepsy and in connection with this submission, redeemed the priority review voucher, or PRV, we acquired in May 2018. Given the well-accepted relationship between dietary sodium and blood pressure as well as published hypertension guidelines underscoring that excessive consumption of sodium is independently associated with an increased risk of stroke, cardiovascular disease and other adverse outcomes, we believe that the lower sodium content of JZP-258 has the potential to offer a clinically meaningful benefit to patients compared to Xyrem. We are also conducting a Phase 3 clinical trial of JZP-258 for the treatment of idiopathic hypersomnia, a chronic neurological disorder that is primarily characterized by EDS and which currently has no approved therapies in the U.S.

JZP-324. We are also pursuing early-stage activities related to the development of JZP-324, a low sodium, oxybate formulation with the potential for once-nightly dosing that we believe could provide a clinically meaningful option for some narcolepsy patients.

JZP-385. JZP-385 is a T-type calcium channel modulator that is a small molecule currently in development for the treatment of essential tremor. We acquired JZP-385 in our acquisition of Cavion, Inc., or Cavion, a clinical-stage biotechnology company, in August 2019. We expect to initiate a Phase 2b study of JZP-385 in the fourth quarter of 2020.

Our current and planned development activities in our hematology and oncology therapeutic area are focused on JZP-458, lurbinectedin and exploring additional indications for Defitelio and Vyxeos, generating additional clinical data for Vyxeos, including in combination with other therapeutic agents, and the research and development of new product candidates.

JZP-458. JZP-458 is a recombinant *Erwinia* asparaginase that uses a novel *Pseudomonas fluorescens* expression platform, which is being developed for use as a component of a multi-agent chemotherapeutic regimen in the treatment of pediatric and adult patients with ALL or LBL, who are hypersensitive to *E. coli*-derived asparaginase products. JZP-458 was granted Fast Track designation by the FDA in October 2019 for the treatment of this patient population, and in December 2019, the first patient was enrolled in the pivotal Phase 2/3 clinical study for JZP-458 conducted in collaboration with the Children's Oncology Group. We expect to submit a BLA to the FDA for JZP-458 as early as the fourth quarter of 2020.

Lurbinectedin. In furtherance of our interest in and efforts to expand our oncology therapeutic area, in December 2019, we entered into an exclusive license agreement with Pharma Mar, S.A., or PharmaMar, pursuant to which we obtained exclusive U.S. development and commercialization rights to lurbinectedin, a product candidate under clinical investigation for the treatment of patients with relapsed SCLC. Lurbinectedin was granted orphan drug designation for SCLC by the FDA in August 2018, and PharmaMar submitted an NDA to the FDA in December 2019 for accelerated approval of lurbinectedin for relapsed SCLC based on data from a Phase 2 trial. In February 2020, the FDA accepted the NDA for filing with priority review with a Prescription Drug User Fee Act, or PDUFA, date of August 16, 2020. The term of our license agreement with PharmaMar extends until the latest of: (i) expiration of the last PharmaMar patent covering lurbinectedin in the U.S. (subject to certain exclusions), (ii) expiration of regulatory exclusivity for lurbinectedin in the U.S. and (iii) 12 years after the first commercial sale of lurbinectedin in the U.S. We also have the right to terminate the agreement at will upon a specified notice period, provided that the effective date of such termination is not within one year of the signing of the agreement. Either party can terminate the agreement for the other party's uncured material breach or bankruptcy.

Defitelio. Our Defitelio clinical development strategy generally focuses on the prevention and treatment of serious diseases associated with stem cell transplantation and endothelial cell damage. In addition to clinical trials we are sponsoring, there are more than 20 investigator-sponsored trials ongoing in the U.S. and EU evaluating defibrotide in multiple conditions.

Vyxeos. Our Vyxeos clinical development strategy is designed to target potential new patient segments across the AML landscape and to generate clinical data on Vyxeos when used in combination with other therapeutic agents. As reflected in the table below, we are pursuing this strategy by sponsoring clinical trials, working with cooperative groups who are conducting clinical trials, and partnering with The University of Texas MD Anderson Cancer Center, or MD Anderson. In August 2018, we announced a five-year collaboration with MD Anderson to evaluate potential treatment options for hematologic malignancies,

with a near-term focus on Vyxeos, and shortly thereafter, commenced development activities under this collaboration. In addition, there are multiple ongoing investigator-sponsored trials studying Vyxeos.

CombiPlex Platform. We are also evaluating the use of our CombiPlex delivery technology platform in a number of therapeutic combinations in oncology as part of our internal oncology research and development activities. CombiPlex enables the design and rapid evaluation of various combinations of therapies to deliver enhanced anti-cancer activity by identifying an optimal synergistic ratio of drugs in vitro and fixing this ratio in a nanoscale delivery complex that maintains and then coordinates the release of the synergistic combination after administration. CombiPlex utilizes two proprietary nanoscale delivery platforms: liposomes to control the release and distribution of water-soluble drugs and drugs that are both water- and fat-soluble (amphipathic), and nanoparticles to control the release and distribution of non-water-soluble (hydrophobic) drugs.

Through third parties, we are also pursuing preclinical and clinical research and development activities in hematology and in precision oncology under a number of licensing and collaboration agreements, including with:

- ImmunoGen, Inc., or ImmunoGen, for opt-in rights to license a hematology-related antibody-drug conjugate product candidate granted orphan drug designation by the FDA;
- Codiak BioSciences, Inc., or Codiak, for an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize potential therapeutic candidates directed at five targets to be developed using Codiak's engEx™ precision engineering platform for exosome therapeutics;
- Pfenex, Inc., or Pfenex, for rights to an early-stage long-acting *Erwinia* asparaginase and an option to negotiate a license for a recombinant pegaspargase product candidate;
- XL-protein GmbH, or XLp, for rights to use XLp's PASylation® technology to extend the plasma half-life of selected asparaginase product candidates; and
- Redx Pharma, or Redx, for pre-clinical collaboration activities related to the pan-RAF inhibitor program that we purchased from Redx for the potential treatment of RAF and RAS mutant tumors.

Below is a summary of our key ongoing and planned development projects related to our products and pipeline and their corresponding current stages of development:

Sleep and Neuroscience

Product Candidates	Description
Submitted for Regulatory Approval	
JZP-258 (oxybate; 92% sodium reduction)	Cataplexy and EDS in narcolepsy
Phase 3	
JZP-258 (oxybate; 92% sodium reduction)	Idiopathic hypersomnia
Sunosi	EDS in major depressive disorder (planned study)
Phase 2b	
JZP-385	Essential tremor (planned study)
Preclinical	
JZP-324	Oxybate once-nightly formulation

Hematology and Oncology

Product Candidates	Description
Submitted for Regulatory Approval	
Lurbinectedin	Relapsed SCLC (exclusive U.S. license)
Phase 3	
Defitelio	Prevention of VOD in high- and very high-risk patients following HSCT
Vyxeos	AML or high-risk Myelodysplastic Syndrome, or MDS (AML19 and AML 18) (cooperative group studies)
Vyxeos	Newly diagnosed adults with standard- and high-risk AML (AML Study Group cooperative group study)
Vyxeos	Newly diagnosed pediatric patients with AML (planned Children's Oncology Group cooperative group study)
Lurbinectedin	Relapsed SCLC (ATLANTIS) (exclusive U.S. license)

Product Candidates	Description
Phase 2/3	
JZP-458 (recombinant *Erwinia* asparaginase)	ALL/LBL
Phase 2	
Defitelio	Prevention of aGvHD following allogeneic HSCT
Defitelio	Prevention of CAR T-cell therapy-associated neurotoxicity
Vyxeos + venetoclax	De novo or relapsed/refractory, or R/R, AML (MD Anderson collaboration study)
Vyxeos	High-risk MDS (European Myelodysplastic Syndromes Cooperative Group cooperative group study)
Vyxeos	Newly diagnosed older adults with high-risk AML (planned cooperative group study)
Vyxeos + venetoclax	High-risk AML (planned cooperative group study)
Phase 1	
Vyxeos + gemtuzumab	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study)
Vyxeos + venetoclax	Low intensity Vyxeos therapy for first-line, unfit AML (Phase 1b study)
Vyxeos + other approved therapies	First-line, fit AML (Phase 1b study)
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study)
IMGN632	R/R CD123+ hematological malignancies (Jazz opt-in opportunity with ImmunoGen)
IMGN632 +/- venetoclax/azacitidine	CD123+ AML (Jazz opt-in opportunity with ImmunoGen; Phase 1b/2 study)
Preclinical	
CombiPlex	Solid tumors candidate
CombiPlex	Hematology/oncology exploratory activities
JZP-341 (long-acting *Erwinia* asparaginase)	ALL and other hematological malignancies (collaboration with Pfenex)
Recombinant pegaspargase	Hematological malignancies (Jazz opt-in opportunity with Pfenex)
Defitelio	Exploratory activities
Exosome NRAS candidate	Hematological malignancies (collaboration with Codiak)
Exosome STAT3 candidate	Hematological malignancies (collaboration with Codiak)
Exosome-based candidates	Solid tumors/hematological malignancies (collaboration with Codiak)
Pan-RAF inhibitor program	RAF and RAS mutant tumors (acquired from Redx, which is continuing development)

In 2020 and beyond, we expect that our research and development expenses will continue to increase from previous levels, particularly as we prepare for anticipated regulatory submissions and data read-outs from clinical trials, initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates.

Commercialization Activities

We have commercial operations primarily in the U.S., Europe and Canada. In the U.S., our products are commercialized through a number of teams, including a team of experienced, trained sales professionals who provide education and promote Xyrem, Sunosi, Defitelio, Erwinaze and Vyxeos to healthcare providers in the appropriate specialties for each product, a team that interacts with payors and institutions to ensure access and coverage for the products, and a team that distributes the products throughout the U.S. healthcare system (wholesalers, pharmacies, hospitals, and community and academic institutions) and provides patient services.

In Canada and in approved markets in Europe where we commercialize Defitelio, Erwinase and Vyxeos, we have a field force of hematology specialists. In markets where these products either are not approved or are unable to be promoted under local regulation, we have medical affairs personnel responsible for responding to medical information requests and for

providing information consistent with local treatment protocols with respect to such products. In certain European markets, we have a team of medical science liaisons in preparation for our rolling launch of Sunosi in Europe. We are currently in the process of recruiting a sales team in some of those markets. Outside the U.S., we directly market Xyrem in Canada for the treatment of cataplexy in patients with narcolepsy. We also utilize distributors in certain markets outside the U.S. where we do not market our products directly.

Our commercial activities include marketing related services, distribution services and commercial support services. We 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 also provide reimbursement support for our U.S. markets.

We believe that the size of our sales force is appropriate to effectively reach our target audience in the specialty markets in which we currently operate. We promote Defitelio, Erwinaze and Vyxeos to many hematology and oncology specialists who operate in the same hospitals, and we believe that we benefit from operational synergies from this overlap. Continued growth of our current marketed products and the launch of any future products, including potentially JZP-258, lurbinectedin and JZP-458, may require further expansion of our field force and support organization in and outside the U.S.

Competition

The biopharmaceutical industry is highly competitive. Our products compete, and our product candidates may in the future compete, with currently existing therapies, product candidates currently under development by us and others and/or future product candidates, including new chemical entities that may be safer, more effective or more convenient than our products. Any products that we develop may be commercialized in competitive markets, and our competitors, which include large global pharmaceutical companies and small research-based companies and institutions, may succeed in developing products that render our products obsolete or noncompetitive.

With respect to competition we face from generic drugs, certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. Generic competition often results in decreases in the prices at which branded products can be sold.

In particular, our products and most advanced product candidates face or may face competition as described below:

- *Xyrem*. While Xyrem is currently the only product approved by the FDA and marketed in the U.S. for the treatment of both cataplexy and EDS in both adult and pediatric patients with narcolepsy, we and others have launched products to treat EDS in narcolepsy and may in the future launch products to treat cataplexy in narcolepsy that are competitive with or disrupt the market for Xyrem. In the future, we expect Xyrem to face competition from authorized generic and generic versions of sodium oxybate. For a description of generic versions of sodium oxybate and/or new products for treatment of cataplexy and/or EDS that could compete with, or otherwise disrupt the market for, Xyrem, as well as a description of our settlement agreements with abbreviated new drug application, or ANDA, filers, see the risk factor under the heading "*The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products and product candidates would adversely affect sales of our oxybate products and product candidates"* in Part I, Item 1A of this Annual Report on Form 10-K.

  In addition to generic competition, Xyrem may face competition in the future from our JZP-258 product candidate, if approved, as well as from other new sodium oxybate formulations for treatment of narcolepsy. We are aware that Avadel Pharmaceuticals plc is conducting a Phase 3 clinical trial of a once-nightly formulation of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy, and that Avadel has indicated that it intends to seek approval using an NDA approval pathway under Section 505(b)(2) and referencing the safety and efficacy data for Xyrem. Xyrem may also face competition from new branded entrants to treat EDS in narcolepsy such as pitolisant. Other companies have announced that they have product candidates in various phases of development to treat the symptoms of narcolepsy, such as Axsome Therapeutics, Inc.'s reboxetine.

  In addition, we are also aware that prescribers often prescribe branded or generic medications for cataplexy before prescribing or instead of prescribing Xyrem and that payors often require patients to try such medications before they will cover Xyrem, even if they are not approved for this use. For example, prescribers often treat mild cataplexy with drugs that have not been approved by the FDA for this indication, including tricyclic antidepressants and selective serotonin reuptake inhibitors or selective norepinephrine reuptake inhibitors. We are also aware that branded or generic stimulants may be prescribed off label for treatment of EDS in narcolepsy. Wake-promoting agents Provigil® (modafinil) and Nuvigil® (armodafinil), and their generic equivalents are approved for the treatment of EDS in narcolepsy and other conditions, and may be used in conjunction with or instead of Xyrem.

- *Sunosi*. Sunosi faces competition from existing branded and generic products that treat EDS or improve wakefulness in adult patients with narcolepsy or OSA in a competitive retail pharmacy market. To successfully commercialize Sunosi, we need to differentiate Sunosi from other branded and generic products that treat EDS in patients with narcolepsy, including stimulants, wake-promoting agents, such as Provigil and Nuvigil, and generic versions of stimulants and wake-promoting agents. We are also aware that stimulants are prescribed off-label for patients to treat excessive sleepiness in OSA. Like Xyrem, Sunosi may face competition from new branded entrants such as pitolisant, a drug that was approved by the FDA in August 2019 for the treatment of EDS in adult patients with narcolepsy and became commercially available in the U.S. in the fourth quarter of 2019, and that has also been approved and marketed in Europe to treat adult patients with narcolepsy with or without cataplexy. Sunosi may also face competition from other products in development as potential treatments for EDS in patients with narcolepsy or OSA.
- *JZP-258.* We expect that, if approved, JZP-258 will face competition similar to that described above for Xyrem, including from new branded entrants in narcolepsy and/or from generic or authorized generic sodium oxybate products.
- *Defitelio*. While there is currently no direct competition to Defitelio to treat severe VOD, changes in the types of conditioning regimens used as part of HSCT may affect the incidence of VOD diagnosis and demand for Defitelio.
- *Erwinaze*. While there is currently no direct competition to Erwinaze to treat ALL patients with hypersensitivity to *E. coli*-derived asparaginase, we and other companies have developed or are developing new treatments for ALL. Some new asparaginase treatments could reduce the rate of hypersensitivity in patients with ALL, and new treatment protocols are being developed and approved for ALL that may not include asparaginase-containing regimens, including some for the treatment of relapsed or refractory ALL patients. We have experienced frequent intermittent shortages of the product that have impacted prescribing habits for Erwinaze, including prescribers' use of alternate methods to address hypersensitivity reactions. As a biologic product, Erwinaze also faces potential competition from biosimilar products.
- *Vyxeos*. With respect to Vyxeos, there are a number of alternative established therapies in AML. A key consideration in the treatment of AML patients is the patient's suitability for chemotherapy. The AML patient population studied in the Vyxeos Phase 3 clinical trial supporting our NDA included 60-75 year old fit patients, or those deemed able to tolerate intensive induction chemotherapy. Prior to Vyxeos, the most widely recognized option for the treatment of newly-diagnosed t-AML and AML-MRC in fit patients was cytarabine in combination with daunorubicin, known as 7+3, which is still used today in this population, along with other intensive chemotherapy regimens, particularly in patients under the age of 60. Also, since Vyxeos was approved, several other products have been approved by the FDA or are in development as treatment options for newly diagnosed AML patients eligible for intensive chemotherapy, such as targeted agents (e.g. midostaurin, enasidenib and ivosidenib), immunotherapies (e.g., gemtuzumab ozogamicin and CAR-T-cell therapy), and agents disrupting leukemia cell survival (e.g., glasdegib). We are also aware of the increasing use of venetoclax combined with either a hypomethylating agent or low-dose cytarabine, a treatment approved by the FDA in newly diagnosed AML patients who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
- *Lurbinectedin.* We expect that, if approved, lurbinectedin will face competition from topotecan, which is currently the only approved treatment in second line SCLC in the U.S., as well as other regimens for relapsed SCLC currently recommended in compendia guidelines. There are also a number of products and immunotherapies in development for the treatment of second line SCLC in various phases of development.

An important part of our corporate strategy is to build a diversified product pipeline, including by acquiring or in-licensing and developing, or partnering to license and develop, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. Our ability to continue to grow our product portfolio requires that we compete successfully with other pharmaceutical companies, many of which may have substantially greater financial sales and marketing resources, to acquire or in-license products and product candidates.

Customers

In the U.S., Xyrem is sold to one specialty pharmacy, ESSDS, which ships Xyrem directly to patients. Also in the U.S., Sunosi is distributed through a retail channel consisting of numerous distributors who sell Sunosi to retail pharmacies. Defitelio, Erwinaze and Vyxeos are sold to hospital customers through subsidiary specialty distributors of McKesson Corporation, or McKesson. We have distribution services agreements made in the ordinary course of business with McKesson and a pharmacy services agreement with ESSDS that provides for the distribution of Xyrem to patients. For more information

regarding our relationship with ESSDS, see "Business—Our Commercialized Products" in this Part I, Item 1. Purchases are made on a purchase order basis.

In certain countries in Europe, Defitelio, Erwinase and Vyxeos are sold pursuant to marketing authorizations. We distribute these products through Durbin PLC, a UK-based wholesaler and distributor, and O&M Movianto Nederland BV, our centralized European logistics services provider, to hospitals and local wholesalers in Europe where we market these products directly and, in other markets in Europe and elsewhere where we do not market these products directly, to local distributors and wholesalers. In countries where there is no marketing authorization, Defitelio, Erwinase and Vyxeos are sold pursuant to named patient programs, temporary use authorizations or similar authorizations.

We directly market Xyrem in Canada for the treatment of cataplexy in patients with narcolepsy. Xyrem is also sold in 22 countries by UCB Pharma Limited, or UCB (which has rights to market Xyrem in 54 countries).

Information on our total revenues by product and revenues attributed to customers who represented at least 10% of our total revenues in each of 2019, 2018 and 2017 is included in Note 18, Revenues, of the Notes to Consolidated Financial Statements included in Part IV of this Annual Report on Form 10-K.

Manufacturing

We have a manufacturing and development facility in Athlone, Ireland where we manufacture Xyrem and certain development-stage oxybate product candidates. We also have a manufacturing plant in Italy where we produce the defibrotide drug substance. Other than these two facilities, we currently do not have our own commercial manufacturing or packaging capability for our other products, product candidates or their APIs. As a result, our ability to develop and supply products in a timely and competitive manner depends primarily on our third party suppliers being able to meet our ongoing commercial and clinical trial needs for API, other raw materials, packaging materials and finished products.

Lead Marketed Products

Xyrem. Xyrem is manufactured by us in our Athlone facility and by Patheon Pharmaceuticals Inc., which we refer to together with its affiliates as Patheon, under a Master Manufacturing Services Agreement, or the Patheon Agreement, entered into with Patheon in 2015. We manufacture Xyrem in our Athlone facility for most of our U.S. commercial supply and rely on Patheon to supply Xyrem for other markets, though we are not required to purchase Xyrem exclusively from Patheon. The current term of the Patheon Agreement will expire on December 31, 2022, subject to further automatic two-yearly extensions if Patheon is then providing manufacturing services for any product, unless either party provides 18 months' prior notice of termination at least 18 months prior to the end of the then current term. In addition, we may terminate the Patheon Agreement for any reason upon 12 months' prior written notice, and each party has the right to terminate the agreement in the event of the other party's uncured material breach.

Siegfried USA, LLC and its European affiliates, or Siegfried, supply sodium oxybate, the API of Xyrem, to Patheon and our Athlone facility. Although Siegfried has been our only supplier of sodium oxybate since 2012, we have the right to purchase a portion of our worldwide requirements of sodium oxybate from other suppliers. The agreement with Siegfried expires in April 2024, 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. 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.

Xyrem is a Schedule III controlled substance in the U.S., and the API of Xyrem is the sodium salt of gamma-hydroxybutyric acid, which is a Schedule I controlled substance in the U.S. As a result, Xyrem is subject to regulation by the U.S. Drug Enforcement Administration, or DEA, under the Controlled Substances Act, or CSA, and its manufacturing and distribution are highly restricted. Quotas from the DEA are required in order to manufacture and package sodium oxybate and Xyrem in the U.S. For information related to DEA quota requirements, see "Business—Government Regulation—Other Post-Approval Pharmaceutical Product Regulation—Controlled Substance Regulations" in this Part I, Item 1.

Sunosi. Siegfried AG is our sole supplier of both the API and finished product for Sunosi for both commercial sale as well as development activities. Although Siegfried AG is currently our only manufacturer and supplier of Sunosi, we have the right to purchase a portion of our worldwide requirements of API and drug product from other suppliers. Under our agreement, we provide periodic rolling forecasts to Siegfried AG, and a portion of each rolling forecast is binding. The initial term of the agreement with Siegfried AG will expire on December 31, 2024 and will then be subject to automatic one-year extensions until either party provides notice to the other of its intent to terminate the agreement (either in whole or in part) at least 18 months before the end of the then-current term. Each party also has the right to terminate the agreement in the event of the other party's uncured material breach or insolvency. Solriamfetol, the API of Sunosi, was designated a Schedule IV controlled substance by the DEA under the CSA.

Defitelio. We are our sole supplier of, and we believe that we are currently the sole worldwide producer of, the defibrotide API. We manufacture the defibrotide API from porcine DNA in a single facility located in Villa Guardia, Italy. Patheon currently processes the defibrotide API into its finished vial form under a specific product agreement entered into under the Patheon Agreement. Patheon is the sole provider of our commercial and clinical supply of Defitelio; however, we are not required to purchase Defitelio exclusively from Patheon. If Patheon does not or is not able to supply us with Defitelio for any reason, it may take time and resources to implement and execute the necessary technology transfer to another processor, and such delay could negatively impact our anticipated revenues from Defitelio and could potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need.

Erwinaze. Erwinaze is exclusively licensed to us, and manufactured for us, by PBL, which is our sole supplier for Erwinaze. Our license and supply agreement with PBL, which includes an exclusive right to market, sell or distribute Erwinaze, an exclusive license to Erwinaze trademarks, and a non-exclusive license to PBL's manufacturing know-how, will expire on December 31, 2020. For information related to our agreement with PBL, see "Business—Our Commercialized Products—Erwinaze" in this Part I, Item 1.

A continuing and significant challenge to maintaining sales of Erwinaze and a barrier to increasing sales is PBL's inability to consistently supply product that meets specifications in quantities that are adequate to meet market demand. We experienced limited product availability of Erwinaze and supply disruptions globally in 2019 and may experience continued supply disruptions in 2020. Such supply instability will continue to adversely impact our ability to generate sales of and revenues from Erwinaze and our business, financial condition, results of operations and growth prospects could be materially adversely affected. For a more complete description of supply issues related to Erwinaze, see the risk factor under the heading "*Delays or problems in the supply of our products for sale or for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations could materially and adversely affect our business, financial condition, results of operations and growth prospects"* in Part I, Item 1A of this Annual Report on Form 10-K.

Vyxeos. Vyxeos is manufactured by Baxter Oncology GmbH, or Baxter, which is a sole source supplier from a single site location, using our CombiPlex technology platform. CombiPlex products represent formulations with increased manufacturing complexities associated with producing drug delivery vehicles encapsulating two or more drugs that are maintained at a fixed ratio and, in the case of Vyxeos, two drugs that are co-encapsulated in a freeze-dried format. There have been batch failures at Baxter due to mechanical, component and other issues, and batches have been produced that have otherwise not been in compliance with applicable specifications. We are continuing to work with Baxter to address manufacturing complexities. Our manufacturing agreement with Baxter expires in August 2022, subject to automatic three-year renewal terms, unless terminated by either party 24 months prior to the end of the initial term or any renewal term. Each party has the right to terminate the agreement for breach, subject to customary cure periods, and each party may terminate the agreement immediately in the event of the other party's insolvency. While other contract manufacturers may be able to produce Vyxeos, the proprietary technology that supports the manufacture of Vyxeos is not easily transferable. The marketing authorization in the European Union, or EU, for Vyxeos also requires us to comply with certain manufacturing-related post-approval commitments.

Product Candidates

JZP-258 is currently manufactured at our Athlone facility, and we expect to manufacture this product commercially at our Athlone facility should this candidate receive regulatory approval.

Clinical development supply of lurbinectedin is currently manufactured by Baxter and GP Pharm S.A., and its API is manufactured by PharmaMar. PharmaMar retains manufacturing rights for the API for potential future U.S. commercial supply of lurbinectedin. If lurbinectedin is approved by the FDA, launch quantities of lurbinectedin and ongoing supply of the API will be supplied to us by PharmaMar under a separate agreement to be entered into between us and PharmaMar. We also expect to enter into a manufacturing agreement for ongoing commercial supply of the drug product lurbinectedin with Baxter, GP Pharm S.A. and/or another comparable manufacturer.

JZP-458 is currently manufactured by Patheon, and the API of JZP-458 is manufactured by AGC Biologics A/S.

For further discussion of the challenges we face with respect to supply of our products and product candidates, see the risk factor under the heading "*Delays or problems in the supply of our products for sale or our for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations could materially and adversely affect our business, financial condition, results of operations and growth prospects"* in Part I, Item 1A of this Annual Report on Form 10-K.

Patents and Proprietary Rights

We actively seek to patent, or to acquire or obtain licenses to third party patents, to protect our products and product candidates and related 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 or relate to our products and product candidates, including certain formulations, used to treat particular conditions, distribution methods and methods of administration, drug delivery technologies and delivery profiles and methods of making and use. 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 patent laws of non-U.S. countries differ from those in U.S., and the degree of protection afforded by non-U.S. patents may be different from the protection offered by U.S. patents. In addition to patents, our products and product candidates are in some instances protected by various regulatory exclusivities. For a description of those exclusivities and their regulatory background, see "Business—Government Regulation—Marketing Exclusivity—The Hatch-Waxman Act" in this Part I, Item 1.

The patents, patent applications and regulatory exclusivities that relate to our marketed products include:

- *Xyrem.* We currently have nine issued, unexpired patents in the U.S. relating to Xyrem. All but two of these patents are listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Our patents relate to Xyrem's stable and microbially resistant formulation, its method of use, including its restricted distribution system, its method of administration, and a drug-drug interaction, or DDI, between Xyrem and divalproex sodium. In October 2018, as a result of the FDA's grant of pediatric exclusivity, an additional six months was added to the original expiration dates of all of our Orange Book-listed patents that existed at that time. As a result, our Orange Book-listed patents have periods of exclusivity between June 2020 and September 2033.

  Some of our Xyrem patents have been subject to patent litigation with the companies who filed ANDAs seeking to market a generic version of Xyrem, including challenge through the inter partes review, or IPR, procedures of the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO. Some IPR petitions were dismissed by the PTAB. However, in July 2018, the United States Court of Appeals for the Federal Circuit upheld on appeal PTAB decisions finding that six patents associated with the Xyrem REMS and three claims of a seventh REMS patent were unpatentable. As a result, we will not be able to enforce patents or claims that the PTAB found unpatentable. Although we have settled all patent litigation against the nine companies that filed ANDAs, it is possible that additional companies may challenge our U.S. patents for Xyrem in the future. For a description of our Xyrem settlements, see "Business—Competition" in this Part I, Item 1.

  A Xyrem formulation patent that had issued in multiple non-U.S. countries expired in December 2019. The European Patent Office has issued a method of administration patent relating to the DDI between Xyrem and divalproex sodium that will expire in February 2034. That patent is licensed to UCB as the marketing authorization holder outside of the U.S. and Canada, and UCB has the right to enforce it. In addition to our issued patents, we have patent applications relating to Xyrem pending in the U.S. and other countries.

- *Sunosi*. We acquired worldwide development, manufacturing and commercial rights to solriamfetol from Aerial BioPharma LLC, or Aerial, in 2014, including Aerial's patent rights relating to solriamfetol, other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd. retains rights. We have a portfolio of U.S. and non-U.S. patents and patent applications for solriamfetol relating to various compositions, formulations and methods of use. Four of our U.S. patents are method of use patents covering treatment of sleep-related conditions expiring between June 2026 and August 2027. Two other U.S. patents cover, respectively, the formulation of solriamfetol and the method of treating select conditions with formulations of solriamfetol (both expiring in September 2037). A request for a patent term extension for one of the above method of use patents has been filed. Sunosi has also been granted orphan drug exclusivity for narcolepsy in the U.S.

- *Defitelio*. The unique process of deriving defibrotide from porcine DNA is extensive and uses both chemical and biological processes that rely on complex characterization methods. We have U.S. and non-U.S. patents and patent applications relating to various compositions, methods of use and methods of characterization, expiring at various times between April 2021 and November 2035. None of these patents are listed in the Orange Book. Defibrotide has been granted orphan drug exclusivity by the FDA to treat and prevent VOD until March 2023. Defibrotide has also been granted orphan drug designation by the EC and the Korean Ministry of Food and Drug Safety to treat and prevent VOD, by the Commonwealth of Australia-Department of Health for the treatment of VOD and by the EC for the prevention of aGvHD. We acquired the rights to defibrotide for the treatment and prevention of VOD in North America, Central America and South America from Sigma-Tau Pharmaceuticals, Inc. in 2014.

- *Erwinaze*. Erwinaze has no patent protection. It had been granted orphan drug exclusivity by the FDA for the treatment of ALL in the U.S. until November 2018, and as a biological product approved under a BLA, we believe

that it is protected by exclusivity that prevents approval of a biosimilar in the U.S. through late 2023 under the U.S. Biologics Price Competition and Innovation Act, or BPCIA. In the EU, the regulatory data protection that provides an exclusivity period for Erwinase has lapsed. Any new marketing authorizations for Erwinase in other EU member states will not receive any regulatory data protection.

- *Vyxeos.* We have a portfolio of U.S. and non-U.S. patents and patent applications for Vyxeos and the CombiPlex technology platform relating to various compositions and methods of making and use. These include six U.S. patents covering Vyxeos compositions and methods of use expiring between April 2025 and September 2034 and two U.S. patents covering CombiPlex (which also cover Vyxeos) expiring in January 2027. These patents are listed in the Orange Book. Vyxeos has been granted orphan drug exclusivity by the FDA until August 2024, seven years from its FDA approval, for the treatment of adults with newly-diagnosed t-AML or AML-MRC. In addition, Vyxeos has been granted orphan drug designation by the EC until August 2028, ten years from its EC approval for the treatment of adults with newly-diagnosed t-AML or AML-MRC.

We also rely on trade secrets and other unpatented proprietary information to protect our products and commercial position, particularly with respect to our products with limited or no patent protection, such as Erwinaze.

The patents and/or patent applications that relate to our product candidates include:

- *JZP-258.* We have U.S. patents and patent applications that relate to our product candidate JZP-258. These patents expire December 2033.
- *JZP-385*. Through the acquisition of Cavion in 2019, we obtained a portfolio of U.S. and non-U.S. patents and patent applications, including rights relating to compositions and methods of using JZP-385. The portfolio includes a U.S. composition of matter patent relating to JZP-385, which expires in 2027.
- *JZP-458*. We obtained worldwide rights from Pfenex, including Pfenex's patent rights relating to JZP-458, in 2016 to develop and commercialize multiple early-stage hematology product candidates, including a license to a U.S. process patent relating to JZP-458, which expires in 2026.
- *Lurbinectedin*. In December of 2019, we entered into an exclusive license agreement with PharmaMar pursuant to which we obtained exclusive U.S. development and commercialization rights to lurbinectedin, including a license to a U.S. composition of matter patent, which expires in 2024.

In addition, we have rights to a number of trademarks and service marks, and pending trademark and service mark applications, in the U.S. and elsewhere in the world to further protect the proprietary position of our products. For a discussion of the challenges we face in obtaining or maintaining patent and/or trade secret protection, see the risk factors under the heading "Risks Related to Our Intellectual Property" in Part I, Item 1A of this Annual Report on Form 10-K.

Government Regulation

As a global pharmaceutical company, our activities are subject to extensive regulation in the U.S., the EU and other countries where we do business. Regulatory requirements encompass the entire life cycle of pharmaceutical products, from research and development activities to marketing approval, manufacturing, labeling, packaging, adverse event and safety reporting, storage, advertising, promotion, sale, pricing and reimbursement, recordkeeping, distribution, importing and exporting. Regulations differ from country to country and are constantly evolving.

Testing and Approval of Pharmaceutical Products

We are not permitted to market a product in a country until we receive approval from the relevant regulatory authority, such as the FDA in the U.S. and the EC or the competent authorities of the EU member states. An application for marketing approval must contain information generated by the applicant, also called a sponsor, demonstrating the quality, safety and efficacy of the product candidate, including data from preclinical and clinical trials, proposed product packaging and labeling and information pertaining to product formulation and the manufacture and analytical testing of the API and the finished product.

In the U.S., the FDA reviews and, if warranted, approves applications for marketing approval. The process for obtaining marketing approval in the U.S. for a drug or biologic product candidate generally includes:

- conducting preclinical laboratory and animal testing and submitting the results to the FDA in an investigational new drug, or IND, application requesting approval to test the product candidate in human clinical trials;
- conducting adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate in the desired indication;

- submitting an NDA, supplemental NDA, or sNDA, or BLA, as appropriate, to the FDA seeking approval for a specific indication; and
- completing inspections by the FDA of the facilities where the product candidate is manufactured, analyzed and stored to demonstrate compliance with current Good Manufacturing Practices, or cGMP, and any requested FDA audits of the clinical trial sites that generated the data supporting the application.

Human clinical trials conducted before approval of a product generally proceed in three sequential phases, although the phases may overlap. In Phase 1, the initial introduction of the product candidate in humans, the product candidate is typically tested to assess metabolism, pharmacokinetics, pharmacological actions and side effects associated with increasing doses. Phase 2 usually involves clinical trials in a limited patient population to determine the effectiveness of the product candidate for a particular indication or indications, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks. If a product candidate demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2, Phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients. Clinical trials must be conducted in accordance with specific protocols, as well as FDA requirements related to conducting the trials and recording and reporting the results, commonly referred to as good clinical practices, to ensure that the resulting data are credible and accurate and that the trial participants are adequately protected. The FDA enforces good clinical practices through periodic inspections of trial sponsors, clinical investigators and trial sites.

Once an NDA, sNDA or BLA has been compiled and submitted, the FDA performs an initial review before it accepts the application for filing. The FDA may refuse to file an application and/or request additional information before acceptance. Once accepted for filing, the FDA begins an in-depth review of the application. Under the current goals and policies agreed to by the FDA under PDUFA for a new molecular entity, the FDA has ten months from the filing decision 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 also has various programs, including Fast Track, Priority Review, Breakthrough Therapy and Accelerated Approval (Subpart H and E), that are intended to expedite the process for reviewing certain applications and/or provide for approval on the basis of surrogate endpoints or restricted distribution. Generally, products 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. For example, the FDA granted Vyxeos Breakthrough Therapy and Fast Track designations and also granted Priority Review with respect to our NDA for Vyxeos for the treatment of t-AML and AML-MRC that was approved in August 2017. In addition, a PRV may be used to obtain priority review by the FDA for one of our future regulatory submissions. We have used the PRV we acquired in May 2018 to obtain priority review for our JZP-258 NDA, which is under review by the FDA.

During its review of an application, the FDA evaluates whether the product demonstrates the required level of safety and efficacy for the indication for which approval is sought and also conducts the inspections and audits described above. The FDA may also refer an application to an advisory committee, typically a panel of clinicians, for review, evaluation and a non-binding recommendation as to whether the application should be approved. When the FDA completes its evaluation, it issues either an approval letter or a complete response letter. A complete response letter generally outlines what the FDA considers to be the deficiencies in the application and may indicate that substantial additional testing or information is required in order for the FDA to approve the product. If and when identified deficiencies have been addressed to the FDA's satisfaction after a review of the resubmission of the application, or if the decision is reversed through an administrative appeal, the FDA will issue an approval letter.

Even if a product is approved, the approval may be subject to limitations based on the FDA's interpretation of the data submitted in the application. For example, as a condition of approval, the FDA may require the sponsor to agree to certain post-marketing requirements, such as conducting Phase 4, or post-approval, clinical trials to gain additional safety data or to document a clinical benefit in the case of products approved under Accelerated Approval regulations. The FDA's approval of the BLA for Erwinaze includes a number of post-marketing commitments and requirements. Several post-marketing commitments and requirements were also mandated by the FDA in connection with its approval of Defitelio, including the requirement that we conduct a clinical trial to analyze the safety of defibrotide versus best supportive care in the prevention of VOD in adult and pediatric patients, and its approval of Vyxeos, including the requirement that we conduct a safety study to characterize infusion-related reactions in patients treated with Vyxeos and a clinical trial to determine dosing to minimize toxicity in patients with moderate and severe renal impairment.

In addition, if the FDA determines that a REMS is necessary to ensure that the benefits of the product outweigh the risks, a sponsor may be required to include a proposed REMS (either as part of the application or after approval), 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; or conditions on the product's prescribing or distribution referred to as elements to assure safe use. Xyrem is required to have a REMS. For more discussion regarding the Xyrem REMS, see the risk factors under the headings "*The distribution and sale of our oxybate products are subject to significant regulatory restrictions,*

including the requirements of a REMS, and these regulatory requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xyrem and if approved, JZP-258" and "Risks Related to Our Intellectual Property" in Part I, Item 1A of this Annual Report on Form 10-K.

The EU and many individual countries have regulatory structures similar to the U.S. for conducting preclinical and clinical testing and applying for marketing approval or authorization, although specifics may vary widely from country to country. Clinical trials in the EU must be conducted in accordance with the requirements of the EU Clinical Trials Directive, which may be replaced with the new EU Clinical Trials Regulation in 2022, and applicable good clinical practice standards. In the EU, there are several procedures for requesting marketing authorization which can be more efficient than applying for authorization on a country-by-country basis. There is a "centralized" procedure allowing submission of a single marketing authorization application to the European Medicines Agency, or EMA. If the EMA issues a positive opinion, the EC will grant a centralized marketing authorization that is valid in all EU member states and three of the four European Free Trade Association countries (Iceland, Liechtenstein and Norway). The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products and biotechnology-derived medicinal products, and optional for others. There is also a "decentralized" procedure allowing companies to file identical applications to several EU member states simultaneously for product candidates that have not yet been authorized in any EU member state and a "mutual recognition" procedure allowing companies that have a product already authorized in one EU member state to apply for that authorization to be recognized by the competent authorities in other EU member states. The UK's withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has, however, created significant uncertainty concerning the future relationship between the UK and the EU. The impact of Brexit on the on-going validity in the UK of current EU authorizations for medicinal products, whether granted through the centralized procedure, decentralized procedure, or mutual recognition, and on the future process for obtaining marketing authorization for pharmaceutical products manufactured or sold in the UK is unknown.

The maximum timeframe for the evaluation of an application in the EU under the centralized procedure is 210 days, subject to certain exceptions and clock stops. An initial marketing authorization granted in the EU is valid for five years, with renewal subject to re-evaluation of the risk-benefit profile of the product. Once renewed, the authorization is usually valid for an unlimited period unless the national competent authority or the EC decides on justified grounds to proceed with one additional five-year renewal.

In the EU, if an applicant can demonstrate that comprehensive data on the efficacy and safety of the product under normal conditions of use cannot be provided due to certain specified objective and verifiable reasons, products may be granted marketing authorization "under exceptional circumstances." A marketing authorization granted under exceptional circumstances is valid for five years, subject to an annual reassessment of conditions imposed by the EC. The marketing authorization in the EU for Defitelio was granted under exceptional circumstances because it was not possible to obtain complete information about the product due to the rarity of the disease and because ethical considerations prevented conducting a study directly comparing Defitelio with best supportive care or a placebo. As a result, the marketing authorization requires us to comply with a number of post-marketing obligations, including obligations relating to the manufacture of the drug substance and finished product, the submission of data concerning patients treated with the product collected through a third-party patient registry and the establishment of a multi-center, multinational and prospective observational patient registry to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use. We are in the process of conducting the post-authorization study in the EU to provide further data on long-term safety, health outcomes and patterns of utilization of Defitelio in normal use.

Similar to the use of REMS in the U.S. to ensure that the benefits of a product outweigh its risks, in the EU and other countries we are required and may, in the future in relation to new products, be required to agree to post-marketing obligations in the marketing authorization for our products, to include a patient package insert or a medication guide to provide information to consumers about the product's risks and benefits, to implement a plan for communication to healthcare providers, and to impose restrictions on the product's distribution. For example, the marketing authorization in the EU for Vyxeos requires us to comply with certain manufacturing-related post-approval commitments.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, modifying a REMS, or making certain additional labeling claims, are subject to further regulatory review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted to demonstrate that the product is safe and effective for the new intended use. Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

Manufacture of Pharmaceutical Products

The manufacturing process for pharmaceutical products is highly regulated, and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We and the third party suppliers of our products are subject to cGMP, which are extensive regulations governing manufacturing processes, stability testing, recordkeeping and quality

standards as defined by the FDA, the EC, the EMA, competent authorities of EU member states and other regulatory authorities. The FDA also periodically inspects manufacturing facilities and the sponsor's and manufacturer's records related to manufacturing, and assesses compliance with cGMP. Following such inspections, the FDA may issue notices on Form FDA 483 and warning letters. For example, the FDA issued a warning letter to PBL, the Erwinaze manufacturer, in January 2017 indicating that it was not satisfied with PBL's responses to a Form 483 issued to PBL and citing significant violations of cGMP for finished pharmaceuticals and significant deviations from cGMP for APIs. As recently as August 2018, the FDA conducted an inspection of the PBL manufacturing facility and issued an FDA Form 483 to PBL citing observations related to items referenced in the existing warning letter as well as other manufacturing practices, including data and records management. In addition to Form FDA 483 notices and warning letters, failure to comply with the statutory and regulatory requirements may result in suspension of manufacturing, product seizure, withdrawal of the product from the market, administrative, civil and criminal penalties, among other enforcement remedies both in the U.S. and in non-U.S. countries.

In the EU, a manufacturing authorization is required to manufacture medicinal products, and the manufacturing authorization holder must comply with various requirements set out in applicable EU laws, regulations and guidance. These requirements include compliance with EU cGMP standards when manufacturing products and their APIs, including APIs manufactured outside of the EU with the intention of importing them into the EU. In addition to inspection reports, manufacturers and marketing authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in cases of non-compliance with the EU or EU member states' requirements applicable to manufacturing.

Sales and Marketing of Pharmaceutical Products

Advertising and Promotional Activities

The FDA regulates advertising and promotional activities for products in the U.S., requiring advertising, promotional materials and labeling to be truthful and not misleading, and products to be marketed only for their approved indications and in accordance with the provisions of the approved label. The FDA actively investigates allegations of off-label promotion in order to enforce regulations prohibiting these types of activities. The FDA routinely issues informal and more formal communications such as untitled letters or warning letters interpreting its authority over these matters. While such communications may not be considered final agency decisions, many companies may decide not to contest the agency's interpretations so as to avoid disputes with the FDA, even if they believe the claims they were making to be truthful, not misleading and otherwise lawful.

In the EU, the advertising and promotion of our products are subject to laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with a marketing authorization approval. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Other applicable laws at the EU level and in the individual EU member states also apply to the advertising and promotion of medicinal products, including laws that prohibit the direct-to-consumer advertising of prescription-only medicinal products and further limit or restrict the advertising and promotion of our products to the general public and to health care professionals. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment.

Fraud and Abuse

We are also subject to numerous fraud and abuse laws and regulations globally. In the U.S., there are a variety of federal and state laws restricting certain marketing practices in the pharmaceutical industry pertaining to healthcare fraud and abuse, including anti-kickback laws and false claims laws. Our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws. The U.S. federal healthcare program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving anything of value to induce (or in return for) the referral of business, including the purchase, recommendation or prescription of a particular drug reimbursable under Medicare, Medicaid or other federally financed healthcare programs. The statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and patients, 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 and administrative sanction, the exemptions and safe harbors are drawn narrowly and are subject to regulatory revision or changes in interpretation by the U.S Department of Justice, or DOJ, and the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG. Practices or arrangements that involve remuneration may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Violations of the federal Anti-Kickback Statute may be established without providing specific intent to violate the statute, and may be punishable by civil,

criminal, and administrative fines and penalties, damages, imprisonment, and/or exclusion from participation in federal healthcare programs.

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false statement to get a false claim paid. A claim resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of themselves and the federal government alleging violations of the statute and to share in any monetary recovery. Violations of the False Claims Act may result in significant financial penalties (including mandatory penalties on a per claim or statement basis), treble damages and exclusion from participation in federal health care programs.

Pharmaceutical companies are subject to other federal false claim and statements laws, some of which extend to non-government health benefit programs. For example, the healthcare fraud provisions under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third party payors, or falsifying or covering up a material fact or making any materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of HIPAA fraud provisions may result in criminal, civil and administrative penalties, fines and damages, including exclusion from participation in federal healthcare programs.

The majority of individual states also have statutes or regulations similar to the federal anti-kickback law and the False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Other states restrict whether and when pharmaceutical companies may provide meals to health care professionals or engage in other marketing-related activities, and certain states and cities require identification or licensing of sales representatives.

Other Post-Approval Pharmaceutical Product Regulation

Safety Reporting/Pharmacovigilance

The FDA, the EMA and other governmental authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. We are required to file periodic safety update reports with the authorities concerning adverse events. If, upon review, an authority determines that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing, require post-approval safety studies, require a labor intensive collection of data regarding the risks and benefits of marketed products and ongoing assessments of those risks and benefits and/or require or conduct other actions, potentially including withdrawal or suspension of the product from the market. For example, if the EMA has concerns that the risk-benefit profile of a product has changed, it can, following an investigation procedure, adopt an opinion advising that the existing marketing authorization for the product be varied or suspended and requiring the marketing authorization holder to conduct post-authorization safety studies. The opinion is then submitted for approval by the EC. Also, from time to time, the FDA issues drug safety communications on its adverse event reporting system based on its review of reported adverse events.

The FDA and the competent authorities of the EU member states on behalf of the EMA also periodically inspect our records related to safety reporting. Following such inspections, the FDA may issue notices on FDA Form 483 and warning letters that could cause us to modify certain activities. An FDA Form 483 notice, if issued, can list conditions the FDA investigators believe may have violated relevant FDA regulations or guidance. Failure to adequately and promptly correct the observation(s) can result in a warning letter or other regulatory enforcement action. Similarly, the EMA's Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that the marketing authorization holder be required to take specific steps. Non-compliance can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

Sunshine Act and Transparency Laws

The Physician Payment Sunshine Act requires tracking of payments and transfers of value to physicians and teaching hospitals and ownership interests held by physicians and their families, and reporting to the federal government and public disclosure of these data. Beginning in 2022, reporting will also be required of information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. 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 healthcare providers in the states. Government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports.

Outside the U.S., interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. The provision of benefits

or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products, which is prohibited in the EU, is governed by the national anti-bribery laws of the EU member states, as described below in "Business—Government Regulation—Anti-Corruption Legislation" in this Part I, Item 1. Violation of these laws could result in substantial fines and imprisonment. Certain EU member states require that payments made to physicians be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Controlled Substance Regulations

A drug product approved by the FDA may be subject to scheduling as a controlled substance under the CSA depending on the drug's potential for abuse. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse. The API of Xyrem, sodium oxybate, is regulated by the DEA as a Schedule I controlled substance, and Xyrem is regulated as a Schedule III controlled substance. The API of Sunosi, solriamfetol, is regulated as a Schedule IV controlled substance. Individual states also impose similar requirements for controlled substances.

The DEA limits the quantity of certain Schedule I controlled substances that may be manufactured and procured in the U.S. in any given calendar year through a quota system and, as a result, quotas from the DEA are required in order to manufacture and package sodium oxybate and Xyrem in the U.S. Accordingly, we require DEA quotas for Siegfried, our U.S.-based sodium oxybate supplier, to procure sodium oxybate and for Patheon, our U.S.-based Xyrem supplier, to obtain the sodium oxybate from Siegfried in order to manufacture and supply us with Xyrem. Xyrem manufactured at our plant in Ireland enters the U.S. as a Schedule III drug and thus does not require a manufacturing quota.

As a Schedule III drug, Xyrem is also subject to DEA and state regulations relating to manufacturing, storage, distribution and physician prescription procedures, including limitations on prescription refills. In addition, 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.

Other Regulations

There are many other requirements and restrictions in the U.S. and elsewhere imposed on pharmaceutical companies and their activities, including those related to the posting of information relating to clinical studies and their outcomes, the export and importation of products, required authorizations for distributors, the identification or licensing of sales representatives, restrictions on the ability of manufacturers to offer co-pay support to patients for certain prescription drugs, implementation of required compliance programs or marketing codes of conduct, protection of the environment, taxation and work safety. Non-compliance with such requirements may result in civil, criminal or administrative sanctions.

Anti-Corruption Legislation

Our business activities outside of the U.S. are subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct or rules of other countries in which we operate, including the UK Bribery Act of 2010, or the UK Bribery Act. The FCPA and similar anti-corruption laws in other countries generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to U.S. or non-U.S. government officials in order to improperly influence any act or decision, secure an improper advantage, or 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 company and to devise and maintain an adequate system of internal accounting controls. The UK Bribery Act prohibits giving, offering, or promising bribes to any person, including UK and non-UK government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies that carry on a business or part of a business in the UK may be held liable for bribes given, offered or promised to any person, including UK and non-UK government officials and private persons in any country, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. As described above, our business is heavily regulated and therefore involves significant interaction with government officials in many countries. Additionally, in certain 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 may be subject to the FCPA, the UK Bribery Act and similar laws. Recently the Securities and Exchange Commission, or SEC, and the DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd-Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We engage in ongoing efforts designed to ensure our compliance with these laws, including due diligence, 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 our suppliers and other third party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits.

Data Protection and Privacy

We are also subject to data protection and privacy laws and regulations globally, which may place restrictions on our ability to transfer, access and use personal data across our business. The legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation, which went into effect on May 25, 2018 and imposes penalties up to 4% of annual global turnover. In addition, laws and regulations enacted in the United States, Europe, Asia and Latin America, including the new California Consumer Privacy Act of 2018, which went into effect January 1, 2020, increases potential enforcement and litigation activity. In order to manage these evolving risks, we have adopted a global privacy program including certification to the EU-U.S. and Swiss-U.S. Privacy Shield Programs.

Marketing Exclusivity

The Hatch-Waxman Act

The marketing approval process described above for the U.S. 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 United States Federal Food, Drug, and Cosmetic Act, or FDCA. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of preclinical and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information. As an alternative, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, provides two abbreviated approval pathways for certain drug products.

The first path, under Section 505(b)(2) of the FDCA, usually is used for the approval of a product that is similar, but not identical, to a previously-approved brand-name product, referred to as the reference listed drug, or RLD. Under this path, the applicant is permitted to rely to some degree on the FDA's finding that the RLD is safe and effective and must submit its own product-specific data on safety and effectiveness only to the extent necessary to bridge the differences between the products. The second abbreviated 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 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 RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This data and information are provided instead of data and information independently demonstrating the proposed generic product's safety and effectiveness.

The Hatch-Waxman Act requires an ANDA or a Section 505(b)(2) NDA applicant to certify that there are no patents listed for that product in the Orange Book, or that for each Orange Book-listed patent either the listed patent has expired, the listed patent 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 approval is sought after patent expiration is called a "Paragraph III Certification." A certification that the new product will not infringe the RLD's Orange Book-listed patents, or that such patents are invalid, is called a "Paragraph IV Certification." If a relevant patent covers an approved method of use, an ANDA or Section 505(b)(2) NDA applicant can also file a statement, called, in the case of an ANDA, a "section viii statement," that the application does not seek approval of the method of use covered by the listed patent. With such a statement, the applicant must "carve out" the protected method of use (typically an indication and related material) from the proposed product's labeling. If the applicant makes a Paragraph III Certification, the ANDA or the Section 505(b)(2) NDA will not be approved until the listed patents claiming the RLD have expired.

If the applicant has provided a Paragraph IV Certification to the FDA, the applicant must also send a notice of that certification to the NDA holder and the relevant patent holders once the FDA accepts the ANDA or the Section 505(b)(2) NDA for filing. The NDA and patent holders then have 45 days to initiate a patent infringement lawsuit. Filing the lawsuit triggers an automatic stay on FDA's approval of 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 Paragraph IV Certification, expiration of the patent, certain settlements of the lawsuit, or a

decision in the infringement case that is favorable to the applicant. The FDA may issue tentative approval of an application if the application meets all conditions for approval but cannot receive effective approval because the 30-month stay or another period of regulatory exclusivity has not expired. If an ANDA or Section 505(b)(2) NDA is approved before conclusion of any relevant patent litigation, the applicant can choose to launch the product, but does so "at risk" of being liable for damages, and potentially treble damages, if the RLD sponsor or patent holder ultimately prevails in patent litigation.

Under the Hatch-Waxman Act, newly approved drugs and indications may benefit from statutory periods of non-patent marketing exclusivity that can potentially delay review or approval of an ANDA or Section 505(b)(2) application. For example, 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 a drug containing an active moiety that the FDA has not previously approved. During this period, the FDA cannot accept for review an ANDA or a Section 505(b)(2) NDA for a product containing the same moiety, except that an application containing a Paragraph IV Certification may be submitted after four years, which may trigger the litigation and stay described above. The Hatch-Waxman Act also provides three years of marketing exclusivity with the approval of an NDA, including a Section 505(b)(2) NDA, for a product containing a previously-approved moiety but that incorporates a change (such as a new indication, dosage form or strength) from an approved product with the same moiety, if the change required clinical data from new investigations that were conducted or sponsored by the applicant. This three-year exclusivity does not preclude submission of the ANDA or Section 505(b)(2) NDA for such a product, but prevents the FDA from giving final approval to such product.

The Hatch-Waxman Act also permits a patent term extension of up to five years (but not beyond 14 years from the date of approval) for an NDA, including a Section 505(b)(2) NDA, that is approved for a product that contains an active ingredient that has not previously been approved. The extension, which compensates for patent term lost during product development and the FDA regulatory review process, is generally equal to the sum of one-half the time between the effective date of an IND application 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. It is available for only one patent for a given product, and it must be a patent that claims the product or a method of using or manufacturing the product. The USPTO, in consultation with the FDA, reviews and approves applications for patent term extension.

Orphan Drug and Other Exclusivities

Some jurisdictions, including the U.S., 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, which is one that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals, but for which there is no reasonable expectation that the cost of developing the product and making it available in the U.S. for the disease or condition will be recovered from U.S. sales of the product. Orphan drug designation does not shorten the duration of the regulatory review process or lower the approval standards, but can provide important benefits, including consultation with the FDA. If a product is approved for its orphan designated use, it may be entitled to orphan drug exclusivity, which blocks the FDA from approving for seven years any other application for a product that is the same drug for the same indication. If there is a previously-approved product that is the same drug for the same indication, orphan drug designation requires the sponsor to provide a plausible hypothesis of clinical superiority over the approved product, whereas orphan drug exclusivity requires the sponsor to actually demonstrate clinical superiority. Clinical superiority can be established by way of greater efficacy, greater safety, or making a major contribution to patient care. Additionally, a later product can be approved if the sponsor holding orphan drug exclusivity consents, or cannot adequately supply the market. Orphan drug exclusivity does not prevent approval of another sponsor's application for different indications or uses of the same drug, or for different drugs for the same indication. Defibrotide has been granted orphan drug exclusivity by the FDA to treat and prevent VOD until March 2023. Vyxeos has been granted orphan drug exclusivity by the FDA for the treatment of AML until August 2024.

Biologic products approved under a BLA are subject to the BPCIA, which authorizes an abbreviated approval pathway for a biological product that is "biosimilar" to an already approved biologic, or reference product. The BPCIA provides periods of exclusivity that protect a reference product from competition by biosimilars. The FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar cannot be licensed until 12 years after the reference product was first licensed. We believe that Erwinaze, which was approved under a BLA in November 2011, is subject to an exclusivity period that will prevent approval of a biosimilar in the U.S. into November 2023.

Under certain circumstances, the exclusivity periods applicable to drugs and biologics and the patent-related protections applicable to drugs may be eligible for a six-month extension if the sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. This exclusivity may be granted even if the data does not support a pediatric indication. We consider seeking pediatric exclusivity for our products whenever appropriate. For example, in response to a written request from the FDA, we conducted a Phase 3 clinical trial to assess the safety and efficacy of Xyrem in children and adolescents aged seven to 17 who have narcolepsy with cataplexy, and submitted study results in a supplement to the Xyrem NDA, seeking approval for this indication. In October 2018, FDA approved the sNDA and notified us that we had been

granted pediatric exclusivity, extending by six months the preclusive effect of our Orange Book-listed patents for Xyrem, as well as the three-year regulatory exclusivity period granted to the Xyrem pediatric indication because of the clinical studies that were necessary for approval of the sNDA.

In the EU, orphan drug designation may be granted to products that can be used to treat life-threatening diseases or chronically debilitating conditions with an incidence of no more than five in 10,000 people or that, for economic reasons, would be unlikely to be developed without incentives. Orphan designated medicinal products are entitled to a range of benefits during the development and regulatory review process and ten years of market exclusivity in all EU member states upon approval. As in the U.S., a similar medicinal product with the same orphan indication may be approved, notwithstanding orphan product exclusivity, if the exclusivity holder gives consent or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if the similar product is deemed safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity granted in relation to the original orphan medicinal product may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity. Defibrotide has been granted orphan drug designation by the EC and the Korean Ministry of Food and Drug Safety to treat and prevent VOD, by the Commonwealth of Australia-Department of Health for the treatment of VOD and by the EC for the prevention of aGvHD. Vyxeos has been granted orphan drug designation by the EC until August 2028.

Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access

Pricing and Reimbursement

Successful commercialization of our products depends in significant part on adequate financial coverage and reimbursement from third party payors, including governmental payors (such as the Medicaid and Medicare programs in the U.S.), managed care organizations and private health insurers. Third party payors decide which drugs will be reimbursed and establish reimbursement and co-pay levels and conditions for reimbursement. Third party payors are increasingly challenging the prices charged for medical products and services by examining their cost effectiveness, as demonstrated in pharmacoeconomic and/or clinical studies, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive products, when available, through their prescription benefits coverage and reimbursement, co-pay and prior authorization policies. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors may require prior approval before covering a specific product, or may require patients and health care providers to try other covered products first. Third party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. For certain categories of products, third party payors, principally through contracted pharmacy benefit managers, or PBMs, negotiate rebates with drug manufacturers for inclusion of products on their formularies in specific positions or coverage criteria. Beginning in the third quarter of 2019, we have been entering into agreements with certain PBMs to provide rebates for our products where coverage was provided and products were listed in certain formulary positions, among other conditions. We expect to enter into additional agreements in 2020.

Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Medicare is a federal program that is administered by the federal government covering individuals age 65 and over as well as those with certain disabilities. Medicare Part B pays physicians who administer our products. Under the Medicaid Drug Rebate program, as a condition of having federal funds made available to the states for our drugs under Medicare Part B, 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. Medicaid rebates are based on pricing data we report on a monthly and quarterly basis to the U.S. Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the Medicaid Drug Rebate program, several state Medicaid supplemental rebate programs and other governmental pricing programs. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. For the federal government to determine Medicare Part B payments to physicians, we are required to provide average sales price, or ASP, information for certain of our products to the CMS on a quarterly basis. The ASP is calculated based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. This information is used to compute Medicare payment rates, with rates for Medicare Part B drugs outside the hospital outpatient setting and in the hospital outpatient setting consisting of ASP plus a specified percentage. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B program, or the 340B program, in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration, or HRSA, requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered drugs used in an outpatient setting. 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 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 Drug Rebate program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. A new regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities became effective on January 1, 2019. We also are required to report our 340B ceiling prices to HRSA on a quarterly basis. 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 an inpatient setting.

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 and grantees, we also participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price to certain federal agencies 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 VA on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, 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 the annual Non-FAMP and FCP. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts, which can change and evolve time.

In addition, in the U.S., drug pricing by pharmaceutical companies is currently, and is expected to continue to be, under close scrutiny, including with respect to companies that have increased the price of products after acquiring those products from other companies. There are numerous ongoing efforts at the federal and state level seeking to indirectly or directly regulate drug prices to reduce overall healthcare costs using tools such as price ceilings, value-based pricing and increased transparency and disclosure obligations. Several states have passed or are considering legislation that purports to require companies to report proprietary pricing information. For example, in 2017, California adopted a prescription drug price transparency state bill requiring advance notice and an explanation for price increases of certain drugs that exceed a specified threshold. Similar bills have been previously introduced at the federal level and additional legislation could be introduced this year.

Similar to what is occurring in the U.S., political, economic and regulatory developments outside of the U.S. 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 EU member states 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. Health technology assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including countries representing major markets. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally compares attributes of individual medicinal products, as compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. On January 31, 2018, the EC adopted a proposal for an HTA regulation intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products. The proposal provides that EU member states will be able to use common HTA tools, methodologies, and procedures across the EU. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social and ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

In the EU, our products are marketed through various channels and within different legal frameworks. The making available or placing on the EU market of unauthorized medicinal products is generally prohibited. However, the competent authorities of the EU member states may exceptionally and temporarily allow and reimburse the supply of such unauthorized products, either on a named patient basis or through a compassionate use process, to individual patients or a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorized medicinal product. Such reimbursement may no longer be available if authorization for named patient or compassionate use programs expire or is terminated or if marketing authorization is granted for the product.

In some 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. After initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payors or authorities in other countries. In the EU, prices can be reduced further by parallel distribution and parallel trade, or arbitrage between low-priced and high-priced EU member states.

For more information, see the risk factors under the headings "*Adequate coverage and reimbursement from third party payors may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably,*" "*The pricing of pharmaceutical products has come under increasing scrutiny as part of a global trend toward healthcare cost containment and resulting changes in healthcare law and policy may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition*" and *"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"* in Part I, Item 1A of this Annual Report on Form 10-K.

Patient Assistance Programs

We have various patient assistance programs to help patients access our products, including co-pay coupons for certain products, services that help patients determine their insurance coverage for our products, and a free product program. We also make grants to independent charitable foundations that help financially needy patients with their premium, and co-pay and co-insurance obligations. There has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance, as well as reimbursement support offerings.

The OIG has established guidelines for pharmaceutical manufacturers who make donations to charitable organizations providing co-pay assistance to Medicare patients. Such donations are unlikely to run afoul of the anti-kickback laws provided that the organizations receiving donations, among other things, are *bona fide* charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. In 2016 and 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of charitable organizations that provide financial assistance to Medicare patients. In April 2019, we finalized our civil settlement agreement with the DOJ and OIG, and entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to implement or continue, as applicable, a set of defined corporate integrity activities to ensure compliance with OIG's policies around charitable contributions for a period of five years from the effective date of the corporate integrity agreement.

U.S. Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, which we refer to together as the Healthcare Reform Act, was intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges, and the expansion of the Medicaid program. This law has substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the 340B program, and fraud and abuse and enforcement. These changes have impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives.

Certain provisions of the Healthcare Reform Act have been subject to judicial challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. For example, the U.S. Tax Cuts and Jobs Act of 2017, signed into law in December 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment, commonly referred to as the "individual mandate," imposed by the Healthcare Reform Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year. Additional legislative changes, regulatory changes, and judicial challenges related to the Healthcare Reform Act remain possible. The nature and extent of any additional legislative changes, regulatory changes, or judicial challenges to the Healthcare Reform Act are uncertain at this time.

Employees

As of February 18, 2020, we had approximately 1,620 employees worldwide. We consider our employee relations to be good.

Environment, Health and Safety

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, in Italy and Ireland where we have manufacturing facilities. Our manufacturing activities involve the controlled storage, use and disposal of chemicals and solvents. Environmental and health and safety authorities in Italy and Ireland administer laws governing, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. In certain cases, such laws, directives and regulations may impose strict liability for pollution of the environment and contamination resulting from spills, disposals or other releases of hazardous substances or waste. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us or at off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination.

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc was formed under the laws of Ireland (registered number 399192) 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, or Azur Pharma, in October 2011. On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction, 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.

Our predecessor, Jazz Pharmaceuticals, Inc., was incorporated in California in March 2003 and was reincorporated in Delaware in January 2004.

Available Information

The mailing address of our headquarters is Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland, and our telephone number at that location is 353-1-634-7800. Our website is www.jazzpharmaceuticals.com.

We file or furnish pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as applicable, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, amendments to those reports, proxy statements and other information electronically with the SEC. Through a link on our website, we make copies of our periodic and current reports, amendments to those reports, proxy statements and other information available, free of charge, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. 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.

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 also refer to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and accompanying notes.

Risks Related to Our Lead Products and Product Candidates

Our inability to maintain or increase sales from our sleep therapeutic area would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our current business is substantially dependent on Xyrem® (sodium oxybate) oral solution, and our financial results are significantly influenced by sales of Xyrem. A significant decline in sales of Xyrem could cause us to reduce our operating expenses or seek to raise additional funds, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects, including on our ability to acquire, in-license or develop new products to grow our business. While our future plans assume that sales of Xyrem will increase, there is no guarantee that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. Our ability to maintain or increase Xyrem product

sales is subject to a number of risks and uncertainties as discussed in greater detail below, including those related to the introduction of authorized generic and generic versions of sodium oxybate and/or new products for treatment of cataplexy and/or excessive daytime sleepiness, or EDS, in narcolepsy in the U.S. market, increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, challenges to our intellectual property around Xyrem, and continued acceptance of Xyrem by physicians and patients.

As for other products and product candidates in our sleep and neuroscience therapeutic area, we obtained approval of Sunosi® (solriamfetol) in 2019 in the U.S. and in January 2020 in the European Union, or EU, for the treatment of EDS associated with narcolepsy or obstructive sleep apnea, or OSA. Our ability to realize the anticipated benefits from our investment in Sunosi is subject to a number of risks and uncertainties, including market acceptance of Sunosi; our ability, in a competitive retail pharmacy market, to differentiate Sunosi from other products that are prescribed to treat excessive sleepiness in patients with OSA or EDS in patients with narcolepsy; the availability of adequate formulary positions and pricing and adequate coverage and reimbursement by government programs and other third party payors, including the impact of future coverage decisions by payors; restrictions on permitted promotional activities based on any additional limitations on the labeling for the product that may be required by the FDA in the future and any such limitations that may be required by the European Commission, or the EC, or other regulatory authority on any approved labeling; and our ability to satisfy the FDA's post-marketing requirements.

We also submitted a new drug application, or NDA, in January 2020 for marketing approval of JZP-258, an oxybate product candidate that contains 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem, for the treatment of cataplexy and EDS in narcolepsy patients seven years of age and older. Our future plans assume that, if approved, JZP-258 may be prescribed to patients as a safer and clinically superior alternative to Xyrem as well as being prescribed to patients who may otherwise be ineligible to take Xyrem based on its high sodium content. Our ability to realize the anticipated benefits from our investment in JZP-258 is subject to a number of risks and uncertainties, including delay or failure in obtaining approval of JZP-258; our receipt of approval for narrower indications than sought or burdens in the approved label; obtaining FDA approval of a risk evaluation and mitigation strategy, or REMS; obtaining and maintaining adequate coverage and reimbursement for JZP-258; the introduction of new products in the U.S. market that compete with JZP-258 in the treatment of cataplexy and/or EDS in narcolepsy, including generic or authorized generic versions of sodium oxybate or new sodium oxybate products; and acceptance of JZP-258 by payors, physicians and patients.

If we are unable to successfully commercialize Sunosi and/or JZP-258 (if approved), or if sales of Sunosi and JZP-258 do not reach the levels we expect, our anticipated revenue from our sleep therapeutic area will be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products and product candidates would adversely affect sales of our oxybate products and product candidates.

While Xyrem is currently the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and EDS in both adult and pediatric patients with narcolepsy, we and others have launched and may in the future launch products that are competitive with or disrupt the market for Xyrem.

For example, in the future, we expect Xyrem to face competition from authorized generic and generic versions of sodium oxybate. Nine companies have sent us notices that they had filed abbreviated new drug applications, or ANDAs, seeking approval to market a generic version of Xyrem, and we have filed and settled patent lawsuits with all nine companies. To date, the FDA has approved or tentatively approved four of these ANDAs, and we believe that it is likely that the FDA will approve or tentatively approve some or all of the others. In our patent litigation settlement with the first filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC and now known as Hikma in the U.S.), or Hikma, we granted Hikma the right to sell an authorized generic product, or AG Product, with royalties back to us, in the U.S. beginning on January 1, 2023, or earlier under certain circumstances. Hikma has a right to elect to continue to sell the Hikma AG Product for a total of up to five years. We also granted Hikma a license to launch its own generic sodium oxybate product as early as six months after it has the right to sell the Hikma AG Product, but if it elects to launch its own generic product, Hikma will no longer have the right to sell the Hikma AG Product. In our settlements with Amneal Pharmaceuticals LLC, or Amneal, Lupin Inc., or Lupin, and Par Pharmaceutical, Inc., or Par, we granted each party the right to sell a limited volume of an AG Product in the U.S. beginning on July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025, with royalties back to us. AG Products will be distributed through the same REMS as Xyrem and, if approved, JZP 258. We also granted each of Amneal, Lupin and Par a license to launch its own generic sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including the circumstance where Hikma elects to launch its own generic product. If Amneal, Lupin or Par elects to launch its own generic product under such circumstance, it will no longer have the right to sell an AG Product. In our settlements with each of the other five ANDA filers, we granted each a license to launch its own generic sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including circumstances where Hikma launches its own generic sodium oxybate product. The actual timing of the launch of an AG Product or generic sodium oxybate product is uncertain because the launch dates of the AG

Products and generic sodium oxybate products under our settlement agreements are subject to acceleration under certain circumstances.

Any ANDA holder launching an AG Product or another generic sodium oxybate product will independently establish the price of the AG Product and/or its own generic sodium oxybate product. Generic competition often results in decreases in the prices at which branded products can be sold. After any introduction of a generic product, whether or not it is an AG Product, a significant percentage of the prescriptions written for Xyrem will likely be filled with the generic product. Certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. This would result in reduction in sales of, and revenue from, Xyrem, although we would continue to receive royalties and other revenue based on sales of an AG Product in accordance with the terms of our settlement agreements.

It is possible that additional companies may file ANDAs seeking to market a generic version of Xyrem which could lead to additional patent litigation or challenges with respect to Xyrem. Such patent litigation or challenges could potentially trigger acceleration of the launch dates in our settlement agreements if, for example, our patents covering Xyrem were all invalidated. Alternatively, the launch dates in our settlement agreements could be accelerated if a new ANDA filer were to obtain FDA approval for its sodium oxybate product, and launch its generic product through a generic sodium oxybate REMS before the entry dates specified in our settlement agreements. It is also possible that we could enter into a settlement agreement with a future ANDA filer that would permit such filer to enter the market on or prior to the launch date(s) in our settlement agreements. If a company launches a generic or authorized generic sodium oxybate product in any of these scenarios, except in limited circumstances related to an "at risk" launch, the launch date for Hikma's AG Product would be accelerated to a date on or prior to the date of such entry, which could lead to acceleration of the other settling ANDA filers' AG Product and generic sodium oxybate product launch dates as described above.

Another circumstance that could trigger acceleration of Hikma's launch date for an AG Product, which would also accelerate Amneal, Lupin and Par's launch dates for their AG Products and ultimately could lead to acceleration of the other settling ANDA filers' launch dates for their generic sodium oxybate products, is a substantial reduction in Xyrem net sales. Such a reduction could occur under various circumstances, including if we introduce, or a third party introduces, a product to treat EDS or cataplexy in narcolepsy that leads to a substantial decline in Xyrem net sales prior to January 1, 2023. Other companies may develop a sodium oxybate product for treatment of narcolepsy, using an alternative formulation or a different delivery technology, and seek approval in the U.S. using an NDA approval pathway under Section 505(b)(2) and referencing the safety and efficacy data for Xyrem. We are aware that Avadel Pharmaceuticals plc, or Avadel, is conducting a Phase 3 clinical trial of a once-nightly formulation of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy, and that Avadel has indicated that it intends to seek approval using the Section 505 (b)(2) approval pathway referencing the safety and efficacy data for Xyrem. Xyrem may also face competition from new branded entrants to treat EDS in narcolepsy such as pitolisant. Other companies have announced that they have product candidates in various phases of development to treat the symptoms of narcolepsy, such as Axsome Therapeutics, Inc.'s reboxetine.

We expect that, if approved, JZP-258, will face competition similar to that described above for Xyrem, including from generic or authorized generic sodium oxybate product or new branded entrants in narcolepsy such as Avadel. Avadel has announced that it has obtained an orphan drug designation from the FDA for its once-nightly sodium oxybate formulation. To obtain orphan drug exclusivity upon approval, Avadel will have to show clinical superiority to Xyrem and possibly to JZP-258, if approved. If the FDA approves Avadel's product and grants it orphan drug exclusivity before we obtain approval for JZP-258, there is a risk that JZP-258 will not be approvable for a narcolepsy indication for seven years unless it can establish clinical superiority to Avadel's product. We cannot predict the timing of Avadel's submission or how the FDA will evaluate any clinical superiority arguments that either company may make, but a delay in approval or inability to obtain approval for JZP-258 could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Moreover, non-oxybate products intended for the treatment of EDS or cataplexy in narcolepsy, including new market entrants, even if not directly competitive with Xyrem or JZP-258 (if approved), could have the effect of changing treatment regimens and payor or formulary coverage of Xyrem or JZP-258 in favor of other products, and indirectly materially and adversely affect sales of Xyrem (and if approved, JZP-258). Examples of such new market entrants include our product, Sunosi, and pitolisant, a drug that was approved by the FDA in August 2019 for the treatment of EDS in adult patients with narcolepsy and became commercially available in the U.S. in the fourth quarter of 2019, and that has also been approved and marketed in Europe to treat adult patients with narcolepsy with or without cataplexy. In addition, prescribers often prescribe stimulants or wake-promoting agents for treatment of EDS, and anti-depressants for cataplexy, before or instead of prescribing Xyrem, and payors often require patients to try such medications before they will cover Xyrem. Examples of such products are described in "Business—Competition" in Part I, Item 1 of this Annual Report on Form 10-K.

We expect that the approval and launch of an AG Product or other generic version of Xyrem could have a material adverse effect on our sales of and revenues from Xyrem and on our business, financial condition, results of operations and

growth prospects. We also expect that the approval and launch of any other sodium oxybate (including JZP-258 or Avadel's once-nightly sodium oxybate formulation) or alternative product that treats narcolepsy could have a material adverse effect on our sales of and revenues from Xyrem, which could have the additional impact of potentially triggering acceleration of market entry of AG Products or other generic sodium oxybate products under our ANDA litigation settlement agreements.

The distribution and sale of our oxybate products are subject to significant regulatory restrictions, including the requirements of a REMS, and these regulatory requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xyrem and if approved, JZP-258.

The active pharmaceutical ingredient, or API, of Xyrem, sodium oxybate, is the sodium salt of gamma-hydroxybutyric acid, or GHB, a central nervous system depressant known to be associated with facilitated sexual assault as well as with respiratory depression and other serious side effects. As a result, the FDA requires that we maintain a REMS with elements to assure safe use, or ETASU, for Xyrem to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the serious risks of the drug. The REMS imposes extensive controls and restrictions on the sales and marketing of Xyrem that we are responsible for implementing. Any failure to demonstrate our substantial compliance with our REMS obligations, or a determination by the FDA that the Xyrem REMS is not meeting its goals, could result in enforcement action by the FDA, lead to changes in our Xyrem REMS obligations, negatively affect sales of Xyrem, result in additional costs and expenses for us and/or require us to invest a significant amount of resources, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects. Similarly, we expect that the FDA will require approval of a REMS for JZP-258, and a delay in obtaining such approval could delay our anticipated launch of JZP-258, which could adversely affect our business, financial condition, results of operations and growth prospects.

The FDA has stated that it will evaluate the Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. We cannot predict whether the FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the Xyrem REMS, including in connection with the submission of applications for new oxybate products including JZP-258, new oxybate indications, the introduction of authorized generics, or to accommodate generics, or whether the FDA will approve modifications to the Xyrem REMS that we consider warranted in connection with the submission of applications for new oxybate products including JZP-258. Any modifications approved, required or rejected by the FDA could change the safety profile of Xyrem, and have a significant negative impact in terms of product liability, public acceptance of Xyrem as a treatment for cataplexy and EDS in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, any of which could have a material adverse effect on our Xyrem business. Modifications approved, required or rejected by the FDA could also make it more difficult or expensive for us to distribute Xyrem, make distribution easier for sodium oxybate competitors, disrupt continuity of care for Xyrem patients and/or negatively affect sales of Xyrem.

We depend on outside vendors, including the central certified pharmacy, to implement the requirements of the Xyrem REMS. If the central pharmacy fails to meet the requirements of the Xyrem REMS applicable to the central pharmacy or otherwise does not fulfill its contractual obligations to us, moves to terminate our agreement, refuses or fails to adequately serve patients, or fails to promptly and adequately address operational challenges or challenges in implementing REMS modifications, the fulfillment of Xyrem prescriptions and our sales would be adversely affected. If we change to a new central pharmacy, new contracts might be required with government payors 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 U.S. Drug Enforcement Administration, or DEA, and certified and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under the Xyrem REMS. Transitioning to a new pharmacy could result in product shortages, which would negatively affect sales of Xyrem, 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 its approval of Hikma's ANDA, the FDA waived the requirement of a single shared REMS between the brand drug and generic versions, approving Hikma's ANDA with a generic sodium oxybate REMS separate from the Xyrem REMS, except for the requirement that the generic sodium oxybate REMS program pharmacies contact the Xyrem REMS by phone to verify and report certain information. The generic sodium oxybate REMS was approved with the condition that it be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. A sodium oxybate distribution system that is less restrictive than the Xyrem REMS, such as the generic sodium oxybate REMS, which provides that generic sodium oxybate products and potentially new sodium oxybate products approved under a Section 505(b)(2) NDA approval pathway could be distributed through multiple pharmacies, could increase the risks associated with sodium oxybate distribution. Because patients, consumers and others may not differentiate generic sodium oxybate from Xyrem or differentiate between the different REMS programs, any negative outcomes, including risks to the public, caused by or otherwise related to a separate sodium oxybate REMS, could have a significant negative impact in terms of product liability, our reputation and good will, public acceptance of Xyrem as a treatment for cataplexy and EDS in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, any of which could have a material adverse effect on our Xyrem business.

We may face pressure to further modify the Xyrem REMS or to license or share intellectual property pertinent to the Xyrem REMS, including proprietary data required for the safe distribution of sodium oxybate, in connection with the FDA's approval of the generic sodium oxybate REMS or otherwise. Our settlement agreements with ANDA filers do not directly impact the FDA's waiver of the single shared system REMS requirement, any other ANDA or NDA filer's ability to develop and implement the generic sodium oxybate REMS for its sodium oxybate product, or our ability to take any action with respect to the safety of the generic sodium oxybate REMS. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the FDA's waiver of the single shared system REMS requirement, its approval and tentative approval of generic versions of sodium oxybate or the consequences of distribution of sodium oxybate through the generic sodium oxybate REMS approved by the FDA or another separate REMS.

REMS programs have increasingly drawn public scrutiny from the U.S. Congress, the Federal Trade Commission, or FTC, and the FDA, with allegations that such programs are used as a means of improperly blocking or delaying competition. In December 2019, as part of the Further Consolidated Appropriations Act of 2020, the U.S. Congress passed legislation known as the Creating and Restoring Equal Access To Equivalent Samples Act, or CREATES. CREATES is intended to prevent companies from using REMS and other restricted distribution programs as a means to deny potential competitors access to product samples that are reasonably necessary to conduct testing in support of an application that references a listed drug or biologic, and provides such potential competitors a potential private right of action if the innovator fails to timely provide samples upon request. CREATES also grants the FDA additional authority regarding approval of generic products with REMS.

It is possible that the FTC, the FDA, other governmental authorities or other third parties could claim that, or launch an investigation into whether, we are using our REMS programs in an anticompetitive manner or have engaged in other anticompetitive practices. The Federal Food, Drug and Cosmetic Act further states that a REMS ETASU shall not be used by an NDA holder to block or delay generic drugs or drugs covered by an application under Section 505(b)(2) from entering the market. In its 2015 letter approving the Xyrem REMS, the FDA expressed concern that we were aware that the Xyrem REMS could have the effect of blocking or delaying generic competition. We cannot predict whether we would face a government investigation or a complaint by a third party premised on a claim that the Xyrem REMS is blocking competition, or the outcome or impact of any such claim.

Pharmaceutical companies, including their agents and employees, are required to monitor adverse events occurring during the use of their products and report them to the FDA. The patient counseling and monitoring requirements of the Xyrem REMS provide more extensive information about adverse events experienced by patients taking Xyrem, including deaths, than is generally available for other products that are not subject to similar REMS requirements. 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 Xyrem labeling, including additional warnings or additional boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of Xyrem. As required by the FDA, Xyrem's current labeling includes a boxed warning regarding the risk of central nervous system depression and misuse and abuse.

Any failure to demonstrate our substantial compliance with the REMS or any other applicable regulatory requirements to the satisfaction of the FDA or another regulatory authority could result in such regulatory authorities taking actions in the future which could have a material adverse effect on Xyrem sales and therefore on our business, financial condition, results of operations and growth prospects.

While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize products outside our sleep and neuroscience therapeutic area.

In addition to Xyrem and our other sleep and neuroscience products and product candidates, we are commercializing a portfolio of products, including our other lead marketed products, Defitelio, Erwinaze and Vyxeos. An inability to effectively commercialize Defitelio and Vyxeos and to maximize their potential where possible through successful research and development activities, and an inability to retain marketing rights to Erwinaze after 2020, could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Defitelio

Our ability to maintain and grow sales and to realize the anticipated benefits from our investment in Defitelio® (defibrotide sodium) is subject to a number of risks and uncertainties, including continued acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries; the continued availability of favorable pricing and adequate coverage and reimbursement; the limited experience of, and need to educate, physicians in recognizing, diagnosing and treating hepatic veno-occlusive disease, or VOD, particularly in adults; the possibility that physicians recognizing VOD symptoms may not initiate or may delay initiation of treatment while waiting for those symptoms to improve, or may terminate treatment before the end of the recommended dosing schedule; and the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in hematopoietic stem cell transplantation treatment protocols reduce the incidence of VOD diagnosis and demand for Defitelio). If sales of Defitelio do not reach the levels we expect, our

anticipated revenue from the product will be negatively affected and our business, financial condition, results of operations and growth prospects could be materially adversely affected. In addition, because VOD is an ultra-rare disease, we have experienced inter-quarter variability in our Defitelio sales, which makes Defitelio sales difficult to predict from period to period. As a result, Defitelio sales results or trends in any period may not necessarily be indicative of future performance.

Erwinaze

Erwinaze® (asparaginase *Erwinia chrysanthemi*), which is approved to treat a limited population of patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase, is licensed from, and manufactured by, a single source, Porton Biopharma Limited, or PBL, a company that is wholly owned by the UK Department of Health and Social Care. Our license and supply agreement with PBL, which includes an exclusive right to market, sell or distribute Erwinaze, an exclusive license to Erwinaze trademarks, and a non-exclusive license to PBL's manufacturing know-how, will expire on December 31, 2020. Unless we and PBL enter into a new agreement, we will lose our licensed rights to exclusively market Erwinaze effective December 31, 2020, other than our right to sell certain Erwinaze inventory for a post-termination sales period of 12 months and certain other post-termination rights, including but not limited to intellectual property and data ownership. In such event, we may not be able to replace the product sales we would lose from Erwinaze, and our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, a continuing and significant challenge to maintaining sales of Erwinaze and a barrier to increasing sales is PBL's inability to consistently supply product that meets specifications in quantities that are adequate to meet market demand, as discussed elsewhere in these risk factors. Such supply instability will continue to adversely impact our ability to generate sales of and revenues from Erwinaze and our business, financial condition, results of operations and growth prospects could be materially adversely affected. Other challenges facing Erwinaze include the limited population of patients with ALL, and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that population; the development and/or approval of new asparaginase treatments or treatment protocols for ALL that may not include asparaginase-containing regimens and prescribers' use of alternate methods to address hypersensitivity reactions; difficulties with obtaining and maintaining favorable pricing and reimbursement arrangements; and potential competition from future biosimilar products.

Vyxeos

Our ability to realize the anticipated benefits from our investment in Vyxeos® (daunorubicin and cytarabine) liposome for injection by successfully and sustainably growing sales is subject to a number of risks and uncertainties, including our ability to differentiate Vyxeos from other liposomal chemotherapies and generically available chemotherapy combinations with which physicians and treatment centers are more familiar; acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries; the increasing complexity of the acute myeloid leukemia, or AML, landscape requiring changes in patient identification and treatment selection, including diagnostic tests and monitoring that clinicians may find challenging to incorporate; the use of new and novel compounds in AML that are either used off-label or are only approved for use in combination with other agents and that have not been tested in combination with Vyxeos; the limited size of the population of high-risk AML patients who may potentially be indicated for treatment with Vyxeos; the availability of adequate coverage, pricing and reimbursement approvals, competition from new and existing products and potential competition from products in development; and delays or problems in the supply or manufacture of Vyxeos. If sales of Vyxeos do not reach the levels we expect, our anticipated revenue from the product will be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We face substantial competition from other companies, including companies with larger sales organizations and more experience working with large and diverse product portfolios.

Our products compete, and our product candidates may in the future compete, with currently existing therapies, including generic drugs, product candidates currently under development by us and others and/or future product candidates, including new chemical entities that may be safer or more effective or more convenient than our products. Any products that we develop may be commercialized in competitive markets, and our competitors, which include large global pharmaceutical companies and small research-based companies and institutions, may succeed in developing products that render our products obsolete or noncompetitive. Many of our competitors, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through focused development programs and collaborative arrangements with large, established companies. In addition, many of our competitors deploy more personnel to market and sell their products than we do, and we compete with other companies to recruit, hire, train and retain pharmaceutical sales and marketing personnel. If our sales force and sales support organization are not appropriately resourced and sized to adequately promote our products, the commercial potential of our current and any future products may be diminished. In any event, the commercial potential of our current products and any 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, are more convenient or are less expensive than our products. For a description of the competition that our lead marketed products and most advanced product candidates face or may face, see the discussion in "Business—Competition" in Part I, Item 1 of this Annual Report on Form 10-K and the risk

factor under the heading "*The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products and product candidates would adversely affect sales of our oxybate products and product candidates"* in this Part I, Item 1A.

Adequate coverage and reimbursement from third party payors 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 successfully commercialize and achieve market acceptance of our products depends in significant part on adequate financial coverage and reimbursement from third party payors, including governmental payors (such as the Medicare and Medicaid programs in the U.S.), managed care organizations and private health insurers. Without third party payor reimbursement, patients may not be able to obtain or afford prescribed medications. In addition, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness and ability to prescribe our products. The demand for, and the profitability of, our products could be materially harmed if the Medicaid program, Medicare program, other federal healthcare program, or other third party commercial payors in the U.S. or elsewhere deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms.

As part of the overall trend toward cost containment, third party payors often require prior authorization for, and require reauthorization for continuation of, prescription products or impose step edits, which require prior use of another medication, usually a generic or preferred brand, prior to approving coverage for a new or more expensive product. Such restrictive conditions for reimbursement and an increase in reimbursement-related activities can extend the time required to fill prescriptions and may discourage patients from seeking treatment. We cannot predict actions that third party payors may take, or whether they will limit the access and level of reimbursement for our products or refuse to provide any approvals or coverage. From time to time, third party payors have refused to provide reimbursement for our products, and others may do so in the future.

Third party payors increasingly examine the cost-effectiveness of pharmaceutical products, in addition to their safety and efficacy, when making coverage and reimbursement decisions. We may need to conduct expensive pharmacoeconomic and/or clinical studies in order to demonstrate the cost-effectiveness of our products. If our competitors offer their products at prices that provide purportedly lower treatment costs than our products, or otherwise suggest that their products are safer, more effective or more cost-effective than our products, this may result in a greater level of access for their products relative to our products, which would reduce our sales and harm our results of operations. 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. Because some of our products compete in a market with both branded and generic products, obtaining and maintaining access and reimbursement coverage for our products may be more challenging than for products that are new chemical entities for which no therapeutic alternatives exist.

Third party pharmacy benefit managers, or PBMs, and payors can limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, and to exclude drugs from their formularies in favor of competitor drugs or alternative treatments, or place drugs on formulary tiers with higher patient co-pay obligations, and/or to mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments, make a complex and time-intensive request for medical exemptions, or pay 100% of the cost of a drug. In addition, in many instances, certain PBMs and third party payors may exert negotiating leverage by requiring incremental rebates, discounts or other concessions from manufacturers in order to maintain formulary positions, which could result in higher gross to net deductions for affected products. In this regard, we have started to enter into agreements with PBMs and payor accounts regarding formulary coverage for Xyrem and Sunosi, but we cannot guarantee that we will be able to agree to coverage terms with other PBMs and other third party payors.

Payors could decide to exclude Sunosi from formulary coverage lists, impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for Sunosi, limit the types of diagnoses for which coverage will be provided or impose a moratorium on coverage for products while the payor makes a coverage decision. An inability to obtain or maintain adequate formulary positions could increase patient cost-sharing for Sunosi and cause some patients to determine not to use Sunosi. Any delays or unforeseen difficulties in obtaining access or reimbursement approvals could limit patient access, depress therapy adherence rates, and adversely impact our ability to successfully launch Sunosi. If we are unsuccessful in obtaining broad coverage for Sunosi, our anticipated revenue from and growth prospects for Sunosi could be negatively affected. We anticipate similar payor coverage risks with respect to JZP-258, if approved.

In many countries outside the U.S., procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing approval. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the EU member states will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually

generic, products as an alternative to branded products, to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. If we are unable to maintain favorable pricing and reimbursement approvals in EU member states that represent significant markets, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. For example, the EC granted marketing authorization for Vyxeos in August 2018 and for Sunosi in January 2020, and, as part of our rolling launches of Vyxeos and Sunosi in Europe, we are making pricing and reimbursement submissions in European countries. If we experience setbacks or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected EU member states would be delayed, which could negatively impact anticipated revenue from and growth prospects for Vyxeos and/or Sunosi.

The pricing of pharmaceutical products has come under increasing scrutiny as part of a global trend toward healthcare cost containment and resulting changes in healthcare law and policy may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes, particularly given the current atmosphere of mounting criticism of prescription drug costs in the U.S. 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. For example, we anticipate that the U.S. Congress, state legislatures, and regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on government-funded reimbursement for drugs (including Medicare, Medicaid) and commercial health plans, new or increased requirements to pay prescription drug rebates and penalties to government health care programs, and additional pharmaceutical cost transparency bills that aim to require drug companies to justify their prices through required disclosures. Additionally, proposals made part of proposed legislation and executive rule-making seek to utilize an "international pricing index" as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B to more closely align with international drug prices. If the U.S. were to move to such a pricing system that were to apply to any of our products, our revenues from U.S. sales of such products could decrease.

Legislative and regulatory proposals that have recently been considered include the potential authorization of prescription drug importation from other countries, legislative proposals to limit the terms of patent litigation settlements with generic sponsors, and proposals to define certain conduct around patenting and new product development as unfair competition. All such considerations may adversely affect our business and industry in ways that we cannot accurately predict.

There is also ongoing activity related to the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, together, the Healthcare Reform Act. The Healthcare Reform Act has substantially changed the way healthcare is financed by both governmental and private insurers. These changes have impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment-for-performance initiatives. Some of the provisions of the Healthcare Reform Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the current presidential administration to repeal or replace certain aspects of the Healthcare Reform Act and to alter the implementation of the Healthcare Reform Act and related laws. We expect that the Healthcare Reform Act and its implementation, efforts to repeal or replace, or invalidate, the Healthcare Reform Act or portions thereof 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 sales of our products.

If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products, including Xyrem, may be affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. We have periodically increased the price of Xyrem, most recently in January 2020, and there is no guarantee that we will be able to make similar price adjustments in the future or that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes and revenues from Xyrem. We also have made and may in the future make similar price increases on our other products. There is no guarantee that such price increases will not negatively affect our reputation and our ability to secure and maintain reimbursement coverage for our products, which could limit the prices that we charge for our products, including Xyrem, limit the commercial opportunities for our products and/or negatively impact revenues from sales of our products.

If we become the subject of any future government investigation or U.S. Congressional hearing with respect to drug pricing or other business practices, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. Any such investigation or hearing could also result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We expect that legislators, policymakers and healthcare insurance funds in Europe will continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we will be able to charge for our products or the level of reimbursement available for these products from governmental authorities or third party payors. Further, an increasing number of European and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

In addition to access, coverage and reimbursement, the commercial success of our products depends upon their market acceptance by physicians, patients, third party payors and the medical community.

If physicians do not prescribe our products, we cannot generate the revenues we anticipate from product sales. Market acceptance of each of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved and any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and its diagnosis;
- the severity of side effects and other risks in relation to the benefits of our products;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- availability of sufficient product inventory to meet demand, particularly with respect to Erwinaze;
- physicians' decisions relating to treatment practices based on availability of product, particularly with respect to Erwinaze;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- with respect to Xyrem, physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the Xyrem REMS;
- the cost of treatment in relation to alternative treatments, including generic products; and
- the availability of financial or other assistance for patients who are uninsured or underinsured.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse events resulting from the use or misuse of any of our products or any similar products distributed by other companies, including generic versions of our products, 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 API in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. JZP-258 includes the same API as Xyrem, but uses a different mixture of salts. Patients, physicians and regulators may therefore view Xyrem or JZP 258, if approved, 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, and potentially other oxybate products generally because of their connection to GHB. Xyrem's label includes information about adverse events from GHB.

Delays or problems in the supply of our products for sale or for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations 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 API and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. We and our suppliers may 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. In addition, we and our suppliers are subject to the FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and equivalent rules and regulations prescribed by non-U.S. regulatory authorities. If we or any of our suppliers encounter manufacturing, quality or compliance difficulties with respect to any of our products, we may be unable to obtain or maintain regulatory approval or meet commercial demand for such products, which could adversely affect our business, financial condition, results of operations and growth prospects. In addition, we could be subject to enforcement action by regulatory authorities for our failure to comply with cGMP with respect to the products we manufacture in our facilities as well as for our failure to adequately oversee compliance with cGMP by any of our third party suppliers operating under contract. Moreover, failure to comply with applicable legal and regulatory requirements subjects us and our suppliers to possible regulatory action, including restrictions on supply or shutdown, which may adversely affect our or a supplier's ability to supply the ingredients or finished products we need.

We have a manufacturing and development facility in Ireland where we manufacture Xyrem and development-stage oxybate products, including JZP-258, and a manufacturing plant in Italy where we produce the defibrotide drug substance. We currently do not have our own commercial manufacturing or packaging capability for our other products, product candidates or

their APIs. As a result, our ability to develop and supply products in a timely and competitive manner depends primarily on third party suppliers being able to meet our ongoing commercial and clinical trial needs for API, other raw materials, packaging materials and finished products.

In part due to the limited market size for our products and product candidates, we have a single source of supply for most of our marketed products, product candidates and their APIs. Single sourcing puts us at risk of interruption in supply in the event of manufacturing, quality or compliance difficulties. If one of our suppliers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to implement and execute the necessary technology transfer to, and to qualify, a new supplier. The FDA and similar international or national 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 suppliers or facilities or a new supplier is unable to meet FDA's 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, which could negatively impact our anticipated revenues and could potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need.

Erwinaze is licensed from, and manufactured for us by, a single source, PBL. A continuing and significant challenge to maintaining sales of Erwinaze and a barrier to increasing sales is PBL's inability to consistently supply product that meets specifications in quantities that are adequate to meet market demand. All Erwinaze that PBL has been able to supply is currently completely absorbed by demand for the product, and erratic supply patterns have prevented us from meeting patient demand in some markets or from being able to expand to new markets or indications. As a consequence, there is no product inventory that can be used to absorb supply disruptions resulting from quality, manufacturing, regulatory or other issues. PBL has experienced and continues to experience product quality and manufacturing issues that have resulted, and continue to result, in disruptions in our ability to supply markets from time to time and have caused, and may in the future cause, us to implement batch-specific, modified product use instructions. We experienced limited product availability of Erwinaze and supply disruptions globally in 2019 and may experience continued supply disruptions in 2020. In addition, the FDA has issued a warning letter and FDA Forms 483 to PBL citing, among other things, significant violations of cGMP for finished pharmaceuticals and significant deviations from cGMP for APIs. We cannot predict whether the required remediation activities by PBL in connection with its prior warning letter and FDA Forms 483 will further strain PBL's manufacturing capacity or otherwise further adversely affect Erwinaze supply.

As capacity constraints and supply disruptions continue, whether as a result of continued quality or manufacturing challenges at PBL, regulatory issues or an inability to enforce our contractual rights, we will be unable to build product inventory, our ability to supply the market will continue to be compromised and physicians' decisions to use Erwinaze will continue to be negatively impacted. In addition, any inability to comply with regulatory requirements of the FDA, the UK Medicines and Healthcare Products Regulatory Agency, or MHRA, or other competent authorities in the EU member states in which Erwinaze is subject to marketing authorizations, including any failure by PBL to correct the violations and deviations referenced above to the satisfaction of the FDA, or failure to meet regulatory specifications for the product, could further adversely affect Erwinaze supply, particularly in light of the historical limitations on the supply of Erwinaze, and could result in enforcement actions by the FDA, the MHRA or other EU member states' competent authorities (including the issuance of the local equivalents of FDA Form 483s or warning letters), the approval of the FDA or other competent authorities being suspended, varied, or revoked, product release being delayed or suspended, including potentially the FDA refusing admission of Erwinaze in the U.S., or product being seized or recalled. Any of these actions could have a material adverse effect on our sales of, and revenues from, Erwinaze and further limit our future maintenance and potential growth of the market for this product.

Vyxeos is manufactured by Baxter Oncology GmbH, or Baxter, which is a sole source supplier from a single site location. Baxter has experienced batch failures due to mechanical, component and other issues in the production of Vyxeos, and batches have been produced that have otherwise not been in compliance with applicable specifications. We are continuing to work with Baxter to address manufacturing complexities related to Vyxeos. Moreover, the proprietary technology that supports the manufacture of Vyxeos is not easily transferable. Consequently, engaging an alternate manufacturer may be difficult, costly and time-consuming. If we fail to obtain a sufficient supply of Vyxeos in accordance with applicable specifications on a timely basis, our sales of and revenues from Vyxeos, our future maintenance and potential growth of the market for this product, our ability to conduct ongoing and future clinical trials of Vyxeos, and our business, financial condition, results of operations and growth prospects could be materially adversely affected. In addition, while the APIs in Vyxeos, daunorubicin and cytarabine, are available from a number of suppliers, certain suppliers have received warning letters from the FDA. As a result, we have qualified other suppliers for each API, and we provided the qualification data to the FDA. If the FDA restricts importation of API from either supplier, and we are unable to qualify API from additional suppliers in a timely manner, or at all, our ability to successfully commercialize Vyxeos and generate sales of this product at the level we expect and to conduct ongoing and future clinical trials of Vyxeos could be materially and adversely affected.

In addition, in order to conduct our ongoing and any future clinical trials of, complete marketing authorization submissions for, and potentially launch our other product candidates, we also need to have sufficient quantities of product manufactured. Moreover, to obtain approval from the FDA or a similar international or national regulatory body of any product candidate, we or our suppliers for that product must obtain approval by the applicable regulatory body to manufacture and supply product, in some cases based on qualification data provided to the applicable body as part of our regulatory submission. Any delay in generating, or failure to generate, data required in connection with submission of the chemistry, manufacturing and controls portions of any regulatory submission could negatively impact our ability to meet our anticipated submission dates, and therefore our anticipated timing for obtaining FDA or similar international or national regulatory body approval, or our ability to obtain regulatory approval at all. In addition, any failure of us or a supplier to obtain approval by the applicable regulatory body to manufacture and supply product or any delay in receiving, or failure to receive, adequate supplies of a product on a timely basis or in accordance with applicable specifications could negatively impact our ability to successfully launch and commercialize products and generate sales of products at the levels we expect.

Risks Related to Growth of Our Product Portfolio and Research and Development

Our future success depends on our ability to successfully develop and obtain and maintain regulatory approval in the U.S. and Europe for our late-stage product candidates and, if approved, to successfully launch and commercialize those product candidates.

The testing, manufacturing and marketing of our products require regulatory approvals, including approval from the FDA and similar bodies in Europe and other countries. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured. Our inability to obtain and maintain regulatory approval for our product candidates in the U.S. and Europe and to successfully commercialize new products that are approved would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In January 2020, we submitted to the FDA our NDA for JZP-258. Delay or failure in obtaining approval of JZP-258 could have a negative impact on our ability to recoup our research and development costs and to successfully commercialize JZP-258, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In December 2019, Pharma Mar, S.A., the company from whom we obtained exclusive U.S. development and commercialization rights to lurbinectedin, submitted an NDA to the FDA in December 2019 for accelerated approval of lurbinectedin for relapsed small cell lung cancer, and in February 2020, the FDA accepted the NDA for filing with priority review. Delay or failure in obtaining approval of lurbinectedin could have a negative impact on our ability to receive a return on our investment in that product candidate and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are pursuing activities related to the development of improved asparaginase products for patients with ALL or other hematological malignancies. Several of our external research and development collaborations are focused on these efforts, including our agreement with Pfenex, Inc., or Pfenex. Among the product candidates in collaboration with Pfenex is JZP-458, a recombinant *Erwinia* asparaginase product candidate, for the potential treatment of ALL and lymphoblastic lymphoma who have hypersensitivity to *E. coli*-derived asparaginase. We also have clinical development efforts focused on expanding the potential of Defitelio, Vyxeos and Sunosi, as well as clinical development efforts focused on JZP-385 for the treatment of essential tremor. Because combination regimens and the continual generation of new data have become particularly important in AML, if we are unable to initiate multiple combination studies, safely combine Vyxeos with novel agents, or if efficacy results do not meet clinicians' expectations, our growth prospects could be materially adversely affected. If we are not successful in the clinical development of our product candidates, if we are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our product candidates would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be able to successfully identify and acquire or in-license additional products or product candidates to grow our business, and, even if we are able to do so, we may otherwise fail to realize the anticipated benefits of these transactions.

In addition to continued investment in our research and development pipeline, we intend to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. However, we may be unable to identify or consummate suitable acquisition or in-licensing opportunities, and this inability could impair our ability to grow our business. Other companies, many of which may have substantially greater financial, sales and marketing resources, compete with us for these opportunities. 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.

Even if we are able to successfully identify and acquire, in-license or develop additional products or product candidates, we may not be able to successfully manage the risks associated with integrating any products or product candidates into our portfolio or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks, liabilities and uncertainties effectively, could have a material adverse effect on our business, results of operations and financial condition. In addition, product and product candidate acquisitions, particularly when the acquisition takes the form of a merger or other business consolidation, have required, and any similar future transactions will also require, significant efforts and expenditures, including with respect to transition and integration activities. We may encounter unexpected difficulties, or incur substantial costs, in connection with potential acquisitions and similar transactions, which include:

- the need to incur substantial debt or engage in dilutive issuances of equity securities to pay for acquisitions;
- the potential disruption of our historical core business;
- the strain on, and need to continue to expand, our existing operational, technical, financial and administrative infrastructure;
- the difficulties in integrating acquired products and product candidates into our portfolio;
- the difficulties in assimilating employees and corporate cultures;
- the failure to retain key managers and other personnel;
- the need to write down assets or recognize impairment charges;
- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures; and
- any unanticipated liabilities for activities of or related to the acquired business or its operations, products or product candidates.

As a result of these or other factors, products or product candidates we acquire, or obtain licenses to, may not produce the revenues, earnings or business synergies that we anticipated, acquired or in-licensed product candidates may not result in regulatory approvals, and acquired or licensed products may not perform as expected. Failure to manage effectively our growth through acquisitions or in-licensing transactions could adversely affect our growth prospects, business, results of operations and financial condition.

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, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.

As a condition to regulatory approval, each product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. If the FDA determines that the safety or efficacy data submitted for the NDAs for JZP-258 or lurbinectedin, or to be submitted in the planned biologics license application, or BLA, for JZP-458, do not warrant marketing approval, we may be required to conduct additional clinical trials, which could be costly and time-consuming. Even if we believe we have successfully completed testing, the FDA or any equivalent non-U.S. regulatory agency may determine our data is not sufficiently compelling to warrant marketing approval for the indications sought, if at all, and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. Any adverse events or other data generated during the course of clinical trials of our product candidates and/or clinical trials related to additional indications for our commercialized products could result in action by the FDA or a non-U.S. regulatory agency, which may restrict our ability to sell, or adversely affect sales of, currently marketed products, or such events or other data could otherwise have a material adverse effect on a related commercial product, including with respect to its safety profile. Any failure or delay in completing such clinical trials 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.

In addition to issues relating to the results generated in clinical trials, clinical trials can be delayed or halted for a variety of reasons, including:

- difficulty identifying, recruiting or enrolling eligible patients, often based on the number of clinical trials, particularly in hematology and oncology, with enrollment criteria targeting the same patient population;
- difficulty identifying a clinical development pathway, including viable indications and appropriate clinical trial protocol design, particularly where there is no applicable regulatory precedent;
- 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, known as an ethics committee in Europe, to conduct a clinical trial at a prospective study site;
- failure of our clinical trials and clinical investigators, including contract research organizations or other third parties assisting us with clinical trials, to satisfactorily perform their contractual duties, meet expected deadlines and comply with the FDA and other regulatory agencies' requirements, including good clinical practices;
- unforeseen safety issues;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites; or
- insufficient funds to complete the trials.

The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or our partners from obtaining and maintaining approvals for the commercialization of some or all of our product candidates.

We are not permitted to market a pharmaceutical product in the U.S. or in the EU member states until we receive approval from the FDA or a marketing authorization from the EC or the competent authorities of the EU member states, as applicable. If the FDA, the EC or the competent authorities of the EU member states determine that our quality, safety or efficacy data do not warrant marketing approval for a product candidate such as JZP-258, we could be required to conduct additional clinical trials as a condition to receiving approval, which could be costly and time-consuming and could delay or preclude the approval of our application. Any delay or failure in obtaining approval of a product candidate, our receipt of approval for narrower indications than sought, or burdens in an approved label such as a boxed warning, could have a negative impact on our ability to recoup our research and development costs and to successfully commercialize that product, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In May 2018, we purchased a rare pediatric disease priority review voucher for $110.0 million, which we redeemed in connection with the submission of our NDA for JZP-258 in January 2020. However, the redemption of our rare pediatric disease priority review voucher may not result in faster review or approval for JZP-258 compared to products considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval of JZP-258 by FDA. For example, the FDA could determine that our application is not sufficient to support approval with the label we have requested, and require amendments or additional data, which could delay or preclude the approval of our NDA.

Even if we receive approval of a product, regulatory authorities may impose significant labeling restrictions or requirements, including limitations on the dosing of the product, requirements around the naming or strength of a product, restrictions on indicated uses for which we may market the product, the imposition of a boxed warning or other warnings and precautions, and/or the requirement for a REMS to ensure that the benefits of the drug outweigh the risks. The FDA requires a REMS and a boxed warning for Xyrem, and similar restrictions could be imposed on other products in the future. For example, we expect that the FDA will require a REMS for approval of JZP-258. Regulatory authorities may also impose post-marketing obligations as part of their approval, which may lead to additional costs and burdens associated with commercialization of the drug, and may pose a risk to maintaining approval of the drug. We are subject to certain post-marketing requirements and commitments in connection with the approval of certain of our products, including Defitelio, Erwinaze, Vyxeos and Sunosi. These post-marketing requirements and commitments include satisfactorily conducting multiple post-marketing clinical trials and safety studies. In the event that we are unable to comply with our post-marketing obligations imposed as part of the marketing approvals in the U.S. or EU, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of and revenues from our products could be materially adversely affected.

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 depends in part on obtaining, maintaining and defending intellectual property protection for our products and product candidates, including protection of their use and methods of manufacturing and distribution. 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 adequately protected trade secrets that cover these activities.

The degree of 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:

- our patent applications, or those of our licensors or partners, may not result in issued patents;

- others may independently develop similar or therapeutically equivalent products without infringing our patents, or those of our licensors, such as products that are not covered by the claims of our patents, or for which we do not have adequate exclusive rights under our license agreements;
- our issued patents, or those of our licensors or partners, may be held invalid or unenforceable as a result of legal challenges by third parties or may be vulnerable to legal challenges as a result of changes in applicable law;
- we or our licensors or partners might not have been the first to invent or file, as appropriate, subject matters covered by our issued patents or pending patent applications or those of our licensors or partners;
- competitors may manufacture products in countries where we have not applied for patent protection or that have a different scope of patent protection or that do not respect our patents; or
- others may be issued patents that prevent the sale of our products or require licensing and the payment of significant fees or royalties.

Patent enforcement generally must be sought on a country-by-country basis, and issues of patent validity and infringement may be judged differently in different countries. For example, in the EU, approval of a generic pharmaceutical product can occur independently of whether the reference brand product is covered by patents, and enforcement of such patents generally must await approval and an indication that the generic product is being offered for sale.

Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property portfolio. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, and potentially invalidated or held unenforceable, including through patent litigation or through patent office procedures that permit challenges to patent validity. Patents can also be circumvented, potentially including by FDA approval of an ANDA or Section 505(b)(2) application that avoids infringement of our intellectual property.

We have settled patent litigation with nine companies seeking to introduce generic versions of Xyrem in the U.S. by granting those companies licenses to launch their generic products (and in certain cases, an authorized generic version of Xyrem) in advance of the expiration of the last of our patents. Notwithstanding our Xyrem patents and settlement agreements, additional third parties may also attempt to introduce generic versions of Xyrem or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy that design around our patents or assert that our patents are invalid or otherwise unenforceable. Such third parties could launch a generic or 505(b)(2) product referencing Xyrem before the dates provided in our patents or settlement agreements. For example, we have several method of use patents listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book, that expire in 2033 that cover treatment methods included in the Xyrem label related to a drug-drug interaction, or DDI, with divalproex sodium. Although the FDA has stated, in granting a Citizen Petition we submitted in 2016, that it would not approve any sodium oxybate ANDA referencing Xyrem that does not include the portions of the currently approved Xyrem label related to the DDI patents, we cannot predict whether a future ANDA filer, or a company that files a Section 505(b)(2) application for a drug referencing Xyrem, may pursue regulatory strategies to avoid infringing our DDI patents notwithstanding the FDA's response to the Citizen Petition, or whether any such strategy would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of these patents or will otherwise obtain a judicial determination that a generic or other sodium oxybate product, its package insert or the generic sodium oxybate REMS or another separate REMS will infringe any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents a future ANDA filer or other company introducing a different sodium oxybate product from marketing its product, or instead require that party to pay damages in the form of lost profits or a reasonable royalty.

Since Xyrem's regulatory exclusivity has expired in the EU, we are aware that generic or hybrid generic applications have been approved by various EU regulatory authorities, and additional generic or hybrid generic applications may be submitted and approved. We cannot predict whether our licensee in the EU will be able to enforce our existing European patents against generic or hybrid generic filers in the EU.

We also currently rely on trade secret protection for several of our products, including Erwinaze and Defitelio. Trade secret protection does not protect information or inventions if another party develops that information or invention independently, and establishing that a competitor developed a product through trade secret misappropriation rather than through legitimate means may be difficult to prove. Trade secret protection also requires that information be secret and subject to reasonable efforts to maintain secrecy, and this requirement may come into conflict with requirements to provide information to employees, consultants, business partners, and regulatory bodies. We seek to protect our trade secrets and other unpatented proprietary information in part through confidentiality and invention agreements with our employees, consultants, advisors and partners. Nevertheless, 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. Moreover, if a dispute arises with our employees, consultants, advisors or partners over the ownership of rights to inventions, including jointly developed intellectual property, we could lose patent protection or the confidentiality of our proprietary information, and possibly also lose the ability to pursue the development of certain new products or product candidates.

In some instances, we also rely on regulatory exclusivity to protect our commercial position. For example, Erwinaze was granted orphan drug exclusivity by the FDA for the treatment of ALL in the U.S. for a seven-year period from its FDA approval, which had precluded approval of another product with the same principal molecular structure for the same indication until November 2018. As a biologic product approved under a BLA, Erwinaze is also subject to the U.S. Biologics Price Competition and Innovation Act, or BPCIA, and accordingly should be protected by exclusivity that prevents approval of a biosimilar in the U.S. through late 2023 under the BPCIA. However, interpretation of regulatory exclusivity under the BPCIA may evolve over time based on FDA issuance of guidance documents, proposed regulations or decisions made by the FDA in the course of considering specific applications. In addition, the BPCIA exclusivity period does not prevent another company from independently developing a product that is highly similar to Erwinaze, generating all the data necessary for a full BLA and seeking approval. As a result, it is possible that a potential competing drug product might obtain FDA approval before the expected BPCIA exclusivity period has expired, which would adversely affect our sales of Erwinaze if we are able to maintain our marketing rights to that product. In the EU, the regulatory data protection that provides an exclusivity period for Erwinase has lapsed. Any new marketing authorizations for Erwinase in other EU member states will not receive any regulatory data protection. If a biosimilar product to Erwinaze is approved as interchangeable to Erwinaze in the U.S. or in other countries where Erwinaze is sold, a significant percentage of the prescriptions that could be filled by Erwinaze, if commercially available, 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.

We have incurred and may in the future incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, 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. If we choose to go to court to stop a third party from infringing our patents, our licensed patents or our partners' patents, that third party has the right to ask the court or an administrative agency to rule that these patents are invalid and/or should not be enforced. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, the inter partes review, or IPR, process under the Leahy-Smith America Invents Act permits any person, whether they are accused of infringing the patent at issue or not, to challenge the validity of certain patents through a proceeding before the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office.

There is a risk that a court or the PTAB could decide that our patents or certain claims in our patents are not valid or infringed, and that we do not have the right to stop a third party from using the inventions covered by those claims, as happened with six of our patents covering the Xyrem REMS, which were invalidated through the IPR process and delisted from the Orange Book. In addition, even if we prevail in establishing that another product infringes a valid claim of one of our patents, a court may determine that we can be compensated for the infringement in damages, and refuse to issue an injunction. As a result, we may not be entitled to stop another party from infringing our patents for their full term.

Litigation involving patent matters is frequently settled between the parties, rather than continuing to a court ruling, and we have settled patent litigation with all nine Xyrem ANDA filers. The FTC has publicly stated that, in its view, certain types of agreements between branded and generic pharmaceutical companies related to the settlement of patent litigation or the manufacture, marketing and sale of generic versions of branded drugs violate the antitrust laws and has commenced investigations and brought actions against some companies that have entered into such agreements. In particular, the FTC has expressed its intention to take aggressive action to challenge settlements that include an alleged transfer of value from the brand company to the generic company (so-called "pay for delay" patent litigation settlements). The U.S. Congress and state legislatures have also identified pharmaceutical patent settlements as potential impediments to generic competition and have introduced, and in states like California passed, legislation to regulate them. Third party payors have also challenged such settlements on the grounds that they increase drug prices. Because there is currently no precise legal standard with respect to the lawfulness of such settlements, there could be extensive litigation over whether any settlement that we have entered into or might enter into in the future constitutes a reasonable and lawful patent settlement. Parties to such settlement agreements in the U.S. are required by law to file the agreements with the FTC and the U.S. Department of Justice, or DOJ, for review. Accordingly, we have submitted our ANDA litigation settlement agreements to the FTC and the DOJ for review. We may receive formal or informal requests from the FTC regarding our ANDA litigation settlements, and there is a risk that the FTC may commence a formal investigation or action against us, or a third party may initiate civil litigation regarding such settlements, which could divert the attention of management and cause us to incur significant costs, regardless of the outcome. Any claim or finding that we or our business partners have failed to comply with applicable laws and regulations could be costly to us and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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. 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, which we may not be able to do.

Other Risks Related to Our Business and Industry

We have substantially expanded our international footprint and operations, and we may expand further in the future, which subjects us to a variety of risks and complexities which, if not effectively managed, could negatively affect our business.

We are headquartered in Dublin, Ireland and have multiple offices in the U.S., Canada, the UK, Italy and other countries in Europe. We may further expand our international operations into other countries in the future, either organically or by acquisition. Conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations, financial condition and growth prospects, including:

- the diverse regulatory, financial and legal requirements in the countries where we are located or do business, and any changes to those requirements;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and employment law and other regulations, as well as maintaining positive interactions with our unionized employees;
- costs of, and liabilities for, our international operations, products or product candidates; and
- public health risks, such as the recent spread in China of coronavirus in early 2020 and potential related effects on supply chain, travel and employee health and availability.

In addition, there can be no guarantee that we will effectively manage the increasing, global complexity of our business without experiencing operating inefficiencies or control deficiencies. Our failure to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The UK's withdrawal from the EU, commonly referred to as Brexit, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

Brexit will continue to create significant uncertainty concerning the future relationship between the UK and the EU, particularly if the recent UK withdrawal from the EU in January 2020 is followed by a failure to agree to a future trading relationship between the EU and the UK. Since a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. For example, there is a risk that the scope of a marketing authorization for a medicinal product granted by the EC or by the competent authorities of EU member states will not encompass the UK. In these circumstances, a separate authorization granted by the UK competent authorities will be required to place medicinal products on the UK market. In addition, our ability to rely on UK manufacturing sites for products intended for the EU market will depend on the terms of the trade agreements concluded between the EU and the UK in the coming months and, potentially, on the ability to obtain relevant exemptions under EU law to supply the EU market with products manufactured at UK-certified sites. There is also the risk that if batch release and quality control testing sites for our products are located only in the UK, manufacturers will need to use sites in other EU member states to manufacture products for supply to the EU market. All of these changes, if they occur, could increase our costs and otherwise adversely affect our business. In addition, currency exchange rates for the British Pound and the euro with respect to each other and to the U.S. dollar have already been, and may be continue to be, negatively affected by Brexit, which could cause volatility in our quarterly financial results.

We have an office in Oxford, England, which is focused on commercialization of our products outside of the U.S. We do not know to what extent, or when, the UK's recent withdrawal from the EU will impact our business, particularly our ability to conduct international business from a base of operations in the UK. The UK could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, possibly resulting in increased trade barriers, which could make doing business in Europe more difficult and/or costly. Moreover, in the U.S., tariffs on certain U.S. imports have recently been imposed, and the EU and other countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating global trade and political tensions. However, these tariffs and other trade restrictions, whether resulting from the UK's withdrawal from the EU or

otherwise, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

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, including our executive management team. We do not carry "key person" insurance. The loss of services and institutional knowledge of one or more additional members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities and may negatively impact our operations and future growth. In addition, changes in our organization as a result of executive management transition may have a disruptive impact on our ability to implement our strategy. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business. In any event, if we are unable to attract, retain and motivate quality individuals, or if there are delays, or if we do not successfully manage personnel and executive management transitions, our business, financial condition, results of operations and growth prospects could be adversely affected.

Significant disruptions of information technology systems or data security breaches could adversely affect our business.

In the ordinary course of our business, we collect, store, process and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. We have also outsourced some of our operations (including parts of our information technology infrastructure) to a number of third party vendors who may have, or could gain, access to our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties.

Our information technology systems, and those of our vendors, are large and complex and store large amounts of confidential information. The size and complexity of these systems make them potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third party vendors and/or business partners, or from cyber-attacks by malicious third parties. Attacks of this nature are increasing in frequency, persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of important information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our information. Although the aggregate impact on our operations and financial condition has not been material to date, we and our vendors have been the target of events of this nature and expect them to continue.

Significant disruptions of our, our third party vendors' and/or business partners' information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may further harm us. Moreover, the prevalent use of mobile devices to access confidential information increases the risk of security breaches. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

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.

FDA and Equivalent Non-U.S. Regulatory Authorities

Our activities are subject to extensive regulation encompassing the entire life cycle of our products, from research and development activities to marketing approval (including specific post-marketing obligations), manufacturing, labeling, packaging, adverse event and safety reporting, storage, advertising, promotion, sale, pricing and reimbursement, recordkeeping, distribution, importing and exporting. The failure by us or any of our third party partners, including our corporate development and collaboration partners, clinical trial sites, suppliers, 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, restrictions on our products, our suppliers, our other partners or us, the withdrawal, suspension or variation of product approval or manufacturing authorizations, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall, withdrawal 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 result in a significant drop in our revenues from the affected products and harm to our reputation and could have a significant impact on our sales, business and financial condition.

We monitor adverse events resulting from the use of our 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, potentially including variation, withdrawal or suspension of the marketing authorization, any of which could result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. The FDA and the competent authorities of the EU member states on behalf of the European Medicines Agency, or EMA, also periodically inspect our records related to safety reporting. The EMA's Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that the marketing authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended or revoked. Failure to adequately and promptly correct the observation(s) can result in further regulatory enforcement action, which could include the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

Erwinaze, defibrotide and Vyxeos are available on a named patient basis or through a compassionate use process in many countries where they are not commercially available. If any such country's regulatory authorities determine that we are promoting such products without proper authorization, we could be found to be in violation of pharmaceutical advertising laws or the regulations permitting sales under named patient programs. In that case, we may be subject to financial or other penalties. Any failure to maintain revenues from sales of Erwinaze, defibrotide and/or Vyxeos on a named patient basis and/or to generate revenues from commercial sales of these products exceeding historical sales on a named patient basis could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The FDA, the competent authorities of the EU member states and other governmental authorities require advertising and promotional materials to be truthful and not misleading, and products to be marketed only for their approved indications and in accordance with the provisions of the approved label. Regulatory authorities actively investigate allegations of off-label promotion in order to enforce regulations prohibiting these types of activities. A determination that we have promoted an approved product for off-label uses could subject us to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties, other sanctions and imprisonment. Even if we are not determined to have engaged in off-label promotion, an allegation that we have engaged in such activities could have a significant impact on our sales, business and financial condition. The U.S. 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. Failure to maintain a comprehensive and effective compliance program, and to integrate the operations of acquired businesses into a combined comprehensive and effective compliance program on a timely basis, could subject us to a range of regulatory actions and/or civil or criminal penalties 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.

Other Regulatory Authorities

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the DOJ, the FTC, the United States Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, and other regulatory bodies, as well as similar governmental authorities in those non-U.S. countries in which we commercialize our products.

We are subject to numerous fraud and abuse laws and regulations globally and our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws and regulations. These laws are described in "Business—Government Regulation" in Part I, Item 1 of this Annual Report on Form 10-K. While we maintain a comprehensive compliance program to try to ensure that our practices and the activities of our third-party contractors and employees fall within the scope of available statutory exceptions and regulatory safe harbors, regulators and enforcement agencies may disagree with our assessment or find fault with the conduct of our employees or contractors. In addition, existing regulations are subject to regulatory revision or changes in interpretation by the DOJ or OIG.

Many companies have faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities,

including providing free product to customers expecting 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 reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. If we become the subject of a government False Claims Act or other investigation or whistleblower suit, we could incur substantial legal costs (including settlement costs) and business disruption responding to such investigation or suit, regardless of the outcome.

Public reporting under the Physician Payment Sunshine Act, or Sunshine, provisions and other similar state laws, the requirements of which are discussed in "Business—Government Regulation" in Part I, Item 1 of this Annual Report on Form 10-K, has resulted in increased scrutiny of the financial relationships between industry, teaching hospitals, physicians and other healthcare providers. Such scrutiny may negatively impact our ability to engage with physicians on matters of importance to us. In addition, government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports. If the data reflected in our reports are found to be in violation of any of the Sunshine provisions or any other U.S. federal, state or local laws or regulations that may apply, or if we otherwise fail to comply with the Sunshine provisions or similar requirements of state or local regulators, we may be subject to significant civil, and administrative penalties, damages or fines.

We have various programs to help patients access our products, including patient assistance programs, which include co-pay coupons for certain of our products, assistance to help patients determine their insurance coverage for our products, and a free product program. Co-pay coupon programs for commercially insured patients, including our program for Xyrem, have received negative publicity related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. In the past, payors brought class action lawsuits challenging the legality of manufacturer co-pay programs under a variety of federal and state laws and insurers have taken actions through their network pharmacies and PBMs to restrict manufacturer co-pay programs. In September 2014, the OIG issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal Anti-Kickback Statute and other laws if they do not take appropriate steps to exclude Medicare Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, including Xyrem, and therefore could have a material adverse effect on our sales, business and financial condition.

We have established programs to consider grant applications submitted by independent charitable organizations, including organizations that provide co-pay support to patients who suffer from the diseases treated by our drugs. The OIG has issued guidance for how pharmaceutical manufacturers can lawfully make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are *bona fide* charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. Although we have structured our programs to follow available guidance, if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, such facts could be used as the basis for an enforcement action against us by the federal government or other enforcement agencies or private litigants.

In 2016 and 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of charitable organizations that provide financial assistance to Medicare patients. In April 2019, we finalized our civil settlement agreement with the DOJ and OIG, and entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to implement or continue, as applicable, a set of defined corporate integrity activities for a period of five years from the effective date of the corporate integrity agreement. In the event of a breach of the corporate integrity agreement, we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs, which would have a material adverse effect on our sales, business and financial condition.

We may also become subject to similar investigations by other state or federal governmental agencies or offices of our patient assistance programs or other business practices, which could result in damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions, as well as negative publicity, reduction in demand for, or patient access to, our products and/or reduce coverage of our products, including by federal and state health care programs. If any or all of these events occur, our business, financial condition, results of operations and stock price could be materially and adversely affected.

Our business activities outside of the U.S. are subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act of 2010, or the UK Bribery Act. In certain 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 may be subject to regulation under the FCPA and the UK Bribery Act. Recently the U.S. Securities and

Exchange Commission, or SEC, and the DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. Violation of these laws by us or our suppliers and other third party agents for which we may be liable may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

Outside the U.S., interactions between pharmaceutical companies and physicians are also governed by strict laws, such as national anti-bribery laws of European countries, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Xyrem and Sunosi are controlled substances under the Controlled Substances Act. Our suppliers, distributors, clinical sites and prescribers, as well as retail pharmacies for Sunosi and the central pharmacy for Xyrem, are subject to DEA and state regulations relating to manufacturing, storage, distribution and physician prescription procedures, including limitations on prescription refills, and are required to maintain DEA registration and state licenses, when handling these drugs and their APIs. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA, relevant state authorities or any comparable international requirements could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, could result in, among other things, additional operating costs to us or delays in shipments outside or into the U.S. and could have an adverse effect on our business and financial condition.

We are also subject to data protection and privacy laws and regulations governing the processing of personal data. If we or our third party partners fail to comply with applicable data protection and privacy laws and regulations, we could be subject to government enforcement actions and significant penalties against us, criminal and civil liability for us and our officers and directors, private litigation and/or adverse publicity. In addition, our business could be adversely impacted if our ability to transfer personal data outside of the European Economic Area or Switzerland is restricted, which could adversely impact our operating results. In addition, although we are not directly subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, other than with respect to providing certain employee benefits, we potentially could be subject to criminal penalties if we, our affiliates or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

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, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule, or FSS, pricing program, the Tricare Retail Pharmacy program, and have obligations to report the average sales price for certain of our drugs to the Medicare program. All of these programs are described in more detail under the heading "Business—Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access" in Part I, Item 1 of this Annual Report on Form 10-K.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts, which can change and evolve over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. Centers for Medicare and Medicaid Services, or CMS, could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively impact our financial results. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. The issuance of the final regulation, as well as any other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program, has increased and will continue to increase our costs and the complexity of

compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation.

The Health Resources and Services Administration, or HRSA, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our financial results. Further, any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act or otherwise could affect our 340B ceiling price calculations and negatively impact our results of operations.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pursuant to applicable law, knowing provision of false information in connection with price reporting under the U.S. Department of Veterans Affairs, FSS or Tricare Retail Pharmacy, or Tricare, programs can subject a manufacturer to civil monetary penalties. These program obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, 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 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.

Our business and operations could be negatively affected if we become subject to shareholder activism, which could cause us to incur significant expense, hinder execution of our business strategy and impact our stock price.

Shareholder activism, which takes many forms and arises in a variety of situations, has been increasingly prevalent. If we become the subject of certain forms of shareholder activism, such as proxy contests, the attention of our management and our board of directors may be diverted from execution of our strategy. Such shareholder activism could give rise to perceived uncertainties as to our future strategy, adversely affect our relationships with business partners and make it more difficult to attract and retain qualified personnel. Also, we may incur substantial costs, including significant legal fees and other expenses, related to activist shareholder matters. Our stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any shareholder activism.

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 or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairment or even death. This could result in product liability claims against us and/or recalls of one or more of our products. In many countries, including in EU member states, national laws provide for strict (no-fault) liability which applies even where damages are caused both by a defect in a product and by the act or omission of a third party.

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 investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, the EMA or the competent authorities of the EU member states. Such investigations could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the therapeutic indications for which they may be used, or suspension, variation, or withdrawal of approval. Any such regulatory action by the FDA, the EC or the competent authorities of the EU member states could lead to product liability lawsuits as well.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, or at all. 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. 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.

We use hazardous materials in our manufacturing facilities, and any claims relating to the improper handling, storage, release or disposal of these materials could be time-consuming and expensive.

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, in Italy and Ireland where we have manufacturing facilities. If an accident or contamination involving pollutants or hazardous substances occurs, an injured party could seek to hold us liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance with sufficient coverage on acceptable terms, or at all. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us or at off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination.

Risks Related to Our Financial Condition and Results

We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position, and our business would be adversely affected if we are unable to service our debt obligations.

As of December 31, 2019, we had total indebtedness of approximately $1.8 billion. Our substantial indebtedness 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 working capital, capital expenditures, acquisitions, investments 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, or our ability to take specified actions to take advantage of certain business opportunities that may be presented to us;
- result in dilution to our existing shareholders in the event exchanges of our exchangeable senior notes are settled in our ordinary shares;
- 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.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, seek additional capital or restructure or refinance our debt. These alternative measures may not be successful and may not permit us to meet our debt service obligations. In the absence of such cash flows and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. In addition, if we are unable to repay amounts under our secured credit agreement that we entered into in June 2015 and subsequently amended, which we refer to as the amended credit agreement, the lenders under the amended credit agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business.

Covenants in our amended 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.

The amended credit agreement contains various covenants that, among other things, limit our ability and/or our restricted subsidiaries' ability to:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- 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; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

The amended credit agreement also includes certain financial covenants that require us to maintain a maximum secured leverage ratio and a minimum interest coverage ratio. Our failure to comply with any of the covenants could result in a default under the amended 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. Moreover, our failure to repurchase our exchangeable senior notes at a time when the repurchase is required by the indentures governing our exchangeable senior notes or to pay any cash payable on future exchanges of our exchangeable senior notes as required by those indentures would constitute a default under those indentures. A default under those indentures could also lead to a default under other debt agreements or obligations, including the amended credit agreement. Likewise, a default under the amended

credit agreement could also lead to a default under other debt agreements or obligations, including the indentures governing our exchangeable senior notes.

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 and grow our business.

The scope of our business and operations has grown substantially since 2012, including through a series of business combinations and acquisitions. To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In the event of adverse capital and credit market conditions, we may not be able to borrow or raise additional capital on attractive terms, or at all, which could prevent us from expanding our business and otherwise could have a material adverse effect on our business and growth prospects. 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 have significant intangible assets and goodwill. Consequently, the future impairment of our intangible assets and goodwill may significantly impact our profitability.

Our intangible assets and goodwill are significant and 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. Our results of operations and financial position in future periods could be negatively impacted should future impairments of intangible assets or goodwill occur.

Our financial results have been and may continue to be adversely affected by foreign currency exchange rate fluctuations.

Because our financial results are reported in U.S. dollars, we are exposed to foreign currency exchange risk as the functional currency financial statements of non-U.S. subsidiaries are translated to U.S. dollars for reporting purposes. To the extent that revenue and expense transactions are not denominated in the functional currency, we are also subject to the risk of transaction losses. For example, because our Defitelio, Erwinase and Vyxeos product sales outside of the U.S. are primarily denominated in the euro, our sales of those products have been and may continue to be adversely affected by fluctuations in foreign currency exchange rates. Given the volatility of exchange rates, as well as our expanding operations, there is no guarantee that we will be able to effectively manage currency transaction and/or translation risks, which could adversely affect our operating results. Although we utilize foreign exchange forward contracts to manage currency risk primarily related to certain intercompany balances denominated in non-functional currencies, our efforts to manage currency risk may not be successful.

Changes in our effective tax rates could adversely affect our business and financial condition, results of operations and growth prospects.

We are incorporated in Ireland and maintain subsidiaries in North America and a number of other foreign jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various jurisdictions where we operate. Our effective tax rate may fluctuate depending on a number of factors, including, but not limited to, the distribution of our profits or losses between the jurisdictions where we operate and changes to or differences in interpretation of tax laws. We are subject to reviews and audits by the U.S. Internal Revenue Services, or IRS, and other taxing authorities from time to time, and the IRS or other taxing authority may challenge our structure, transfer pricing arrangements and tax positions through an audit or lawsuit. Responding to or defending against challenges from taxing authorities could be expensive and consume time and other resources. 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. Any of these actions 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 U.S. Internal Revenue Code, 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 we are 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, the IRS could assert that we should be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874. The IRS continues to scrutinize transactions that are potentially subject to Section 7874, and has issued several sets of final and temporary regulations under Section 7874 since 2012. We do not expect these regulations to affect the U.S. tax consequences of 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 prospective or retroactive application to us, our shareholders, Jazz Pharmaceuticals, Inc. and/or the Azur Merger.

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 is limited under Section 7874 of the Code and 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.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code can limit the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses, or NOLs, to offset U.S. taxable income resulting from certain transactions. Our U.S. affiliates have a significant amount of NOLs. As a result of Section 7874 of the Code, after the Azur Merger, our U.S. affiliates have not been able and will continue to be unable, for a period of time, to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions. While we expect to be able to fully utilize our U.S. affiliates' U.S. NOLs prior to their expiration, as a result of this limitation, it may take our U.S. affiliates longer to use their NOLs.

Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is also 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, the use 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.

Changes to tax laws relating to multinational corporations could adversely affect us.

The U.S. Congress, the EU, the Organization for Economic Co-operation and Development, or OECD, and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. One example is the OECD's initiative in the area of "base erosion and profit shifting," where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. Some countries are beginning to implement legislation and other guidance to align their international tax rules with the OECD's recommendation. As a result of the focus on the taxation of multinational corporations, the tax laws in Ireland, the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act, or U.S. Tax Act, was signed into law. The U.S. Tax Act made broad and complex changes to the U.S. tax code. The U.S. Department of Treasury has issued limited regulations and other interpretive guidance under the U.S. Tax Act, and is expected to issue additional guidance, the impact of which is uncertain but could change the financial impacts that were previously recorded or are expected to be recorded in future periods. Furthermore, the impact of this tax reform on certain holders of our ordinary shares could be adverse. Among other things, changes to the rules for determining a foreign corporation's status as a controlled foreign corporation could have an adverse effect on U.S. persons who are treated as owning (directly or indirectly) at least 10% of the value or voting power of our ordinary shares. Investors should consult their own advisers regarding the potential application of these rules to their investments.

A substantial portion of our indebtedness bears interest at variable interest rates based on USD LIBOR and certain of our financial contracts are also indexed to USD LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness and may otherwise adversely affect our financial condition and results of operations.

In July 2017, the Financial Conduct Authority, the authority that regulates the London Inter-bank Offered Rate, or LIBOR, announced that it intended to stop compelling banks to submit rates for the calculation of LIBOR after 2021. We have certain financial contracts, including the amended credit agreement and our interest rate swaps, that are indexed to USD LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness. Any transition process may involve, among other things, increased volatility or illiquidity in markets for instruments that rely on LIBOR, reductions in the value of certain instruments or the effectiveness of related transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent processes. The transition away from LIBOR may result in increased expenses, may impair our ability to refinance our indebtedness or hedge our exposure to floating rate instruments, or may result in

difficulties, complications or delays in connection with future financing efforts, any of which could adversely affect our financial condition and results of operations.

Risks Related 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.

The market price for our ordinary shares has fluctuated significantly from time to time and is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market, industry and other factors, including the risk factors described above. The stock market in general, including the market for life sciences companies, has experienced extreme price and trading volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors have harmed, and in the future 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. Our ability to meet analysts' forecasts, investors' expectations and our financial guidance is substantially dependent on our ability to maintain or increase sales of our marketed products.

In addition, the market price of our ordinary shares may decline if the effects of our strategic transactions on our financial or operating results are not consistent with the expectations of financial analysts or investors. The market price of our ordinary shares could also be affected by possible sales of our ordinary shares by holders of our exchangeable senior notes who may view our exchangeable senior notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity involving our ordinary shares by the holders of our exchangeable senior notes.

We are subject to Irish law, which differs from the laws in effect in the U.S. and may afford less protection to holders of our securities.

It may not be possible to enforce court judgments obtained in the U.S. 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 liability 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 U.S. 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 Act 2014, 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, mergers, amalgamations and acquisitions, takeovers and shareholder lawsuits. The duties of directors and officers of an Irish company are generally 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 U.S. jurisdiction.

Our articles of association, Irish law and the indentures governing our exchangeable senior notes contain provisions that 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. In addition to our articles of association, several mandatory provisions of Irish law could prevent or delay an acquisition of us. We are also subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our shares in certain circumstances. Furthermore, the indentures governing our exchangeable senior notes require us to repurchase our exchangeable senior notes for cash if we undergo certain fundamental changes and, in certain circumstances, to increase the exchange rate for a holder of our exchangeable senior notes. A takeover of us may trigger the requirement that we purchase our exchangeable senior notes and/or increase the exchange rate, which could make it more costly for a potential acquiror to engage in a business combination transaction with us.

These provisions, whether alone or together, 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, whether alone or together, could also discourage proxy contests and make it more difficult for our shareholders to elect directors other than the candidates nominated by our board.

Future sales and issuances of our ordinary shares, securities convertible into our ordinary shares or rights to purchase ordinary shares or convertible securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline.

We expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations or for general corporate purposes. To the extent we raise additional capital by issuing equity securities or securities convertible into or exchangeable for ordinary shares, our shareholders may experience substantial dilution. We may sell ordinary shares, and we may sell convertible or exchangeable securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell such ordinary shares, convertible or exchangeable securities or other equity securities in subsequent transactions, existing shareholders may be materially diluted.

We have never declared or paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.

We do not currently plan to pay cash dividends in the foreseeable future. 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 the amended credit agreement and other factors our board of directors deems relevant. Accordingly, 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. In addition, in the event that we pay a dividend on our ordinary shares, in certain circumstances, as an Irish tax resident company, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

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 2019 fiscal year relating to our periodic or current reports under the Securities Exchange Act of 1934, as amended.

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 Ewing, New Jersey.

We lease approximately 45,000 square feet of office space in Dublin, Ireland. This lease expires in December 2036, with an option to terminate in December 2024 with no less than one year's prior written notice and the payment of a termination fee, and a further option to terminate in December 2031 with no less than one year's prior written notice. We own approximately 58,000 square foot of manufacturing and development facility in Athlone, Ireland, which is primarily used for the manufacture of Xyrem and development-stage products.

In Palo Alto, California, we occupy a total of approximately 198,000 square feet of office space, 99,000 square feet of which is under a lease that expires in October 2029 and has an option to terminate in October 2027 with no less than one year's prior written notice and the payment of a termination fee. The remaining 99,000 square feet is under a lease that expires in July 2031 and an option to terminate in October 2027 with no less than one year's prior written notice and the payment of a termination fee. We have an option to extend the terms of both leases twice for a period of five years each.

We occupy approximately 60,000 square feet of office space in Philadelphia, Pennsylvania under a lease that expires in April 2029. We occupy approximately 26,000 square feet of office space in Oxford, United Kingdom under a lease that expires in April 2028. We own a manufacturing facility in Villa Guardia (Como), Italy, which is primarily used for the manufacture of Defitelio. The manufacturing facility is approximately 45,000 square feet. We also lease approximately 34,000 square feet of office and laboratory space in Villa Guardia (Como), Italy under a lease that expires in December 2023. In addition, we have offices in Canada, France and elsewhere in Europe.

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

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no 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 trade on The Nasdaq Global Select Market under the trading symbol "JAZZ."

Holders of Ordinary Shares

As of February 18, 2020, there were three holders of record of our ordinary shares. Because almost all 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

In 2019 and 2018, we did not declare or pay cash dividends on our common equity and we do not currently plan to pay cash dividends in the foreseeable future. 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 any current 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 and Current Reports on Form 8-K filed with the Securities and Exchange Commission, or SEC, during the year ended December 31, 2019, there were no unregistered sales of equity securities by us during the year ended December 31, 2019.

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, 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, Republic of Guinea-Bissau, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, countries that harbor certain terrorist groups and Ukraine 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

Irish 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 at the standard rate (currently 25%), unless an exemption applies.

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 subject 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 any tax consequences of holding our ordinary shares, including whether CAT is creditable or deductible in computing any domestic tax liabilities.

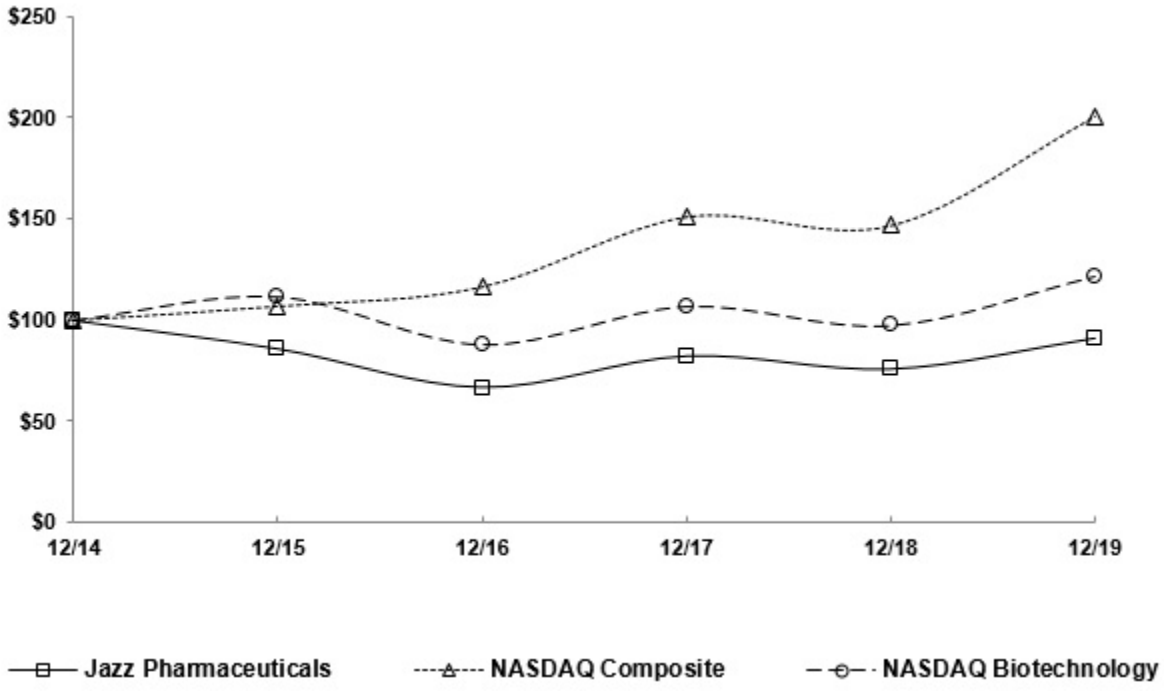
Stamp Duty. Irish stamp duty (if any) may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through Depository Trust Company, or DTC, to a buyer who holds the acquired shares through DTC will not be subject to Irish stamp 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 being contemplated 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.

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, 2014 in (i) our ordinary shares; (ii) the Nasdaq Composite Index; and (iii) the Nasdaq Biotechnology Index through December 31, 2019. 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)



(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, or Exchange Act, 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.

Issuer Purchases of Equity Securities

The following table summarizes purchases of our ordinary shares made by or on behalf of us or any of our "affiliated purchasers" as defined in Rule 10b-18(a)(3) under the Exchange Act during each fiscal month during the three-month period ended December 31, 2019:

	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (3)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (4)
October 1 - October 31, 2019	57,300	$ 122.96	57,300	$ 681,006,700
November 1 - November 30, 2019	555,852	$ 136.45	555,852	$ 605,174,166
December 1 - December 31, 2019	183,345	$ 149.49	183,345	$ 577,732,249
Total	796,497	$ 138.53	796,497	

(1) This column does not include ordinary shares that we withheld in order to satisfy minimum tax withholding requirements in connection with the vesting of restricted stock units.

(2) Average price paid per share includes brokerage commissions.

(3) The ordinary shares reported in this column above were purchased pursuant to our publicly announced share repurchase program. In November 2016, we announced that our board of directors authorized the use of up to $300 million to repurchase our ordinary shares. In November and December 2018, our board of directors increased the existing share repurchase program authorization by $320.0 million and $400.0 million, respectively. In October 2019, our board of

directors authorized the additional repurchase of shares having an aggregate purchase price of up to $500.0 million, exclusive of any brokerage commissions. This authorization has no expiration date.

(4) The dollar amount shown represents, as of the end of each fiscal month, the approximate dollar value of ordinary shares that may yet be purchased under our publicly announced share repurchase program, exclusive of any brokerage commissions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under our credit agreement, corporate and regulatory requirements and market conditions, and may be modified, suspended or otherwise discontinued at any time without prior notice.

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 income data for the years ended December 31, 2019, 2018 and 2017 and the selected consolidated balance sheet data as of December 31, 2019 and 2018 from the audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statements of income data for the years ended December 31, 2016 and 2015, and the selected consolidated balance sheet data as of December 31, 2017, 2016 and 2015 are derived from audited consolidated financial statements not included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2019	2018	2017	2016(1)	2015
	(In thousands, except per share amounts)				
Consolidated Statements of Income Data:					
Revenues:					
Product sales, net	$ 2,135,601	$ 1,869,473	$ 1,601,399	$ 1,477,261	$ 1,316,819
Royalties and contract revenues	26,160	21,449	17,294	10,712	7,984
Total revenues	2,161,761	1,890,922	1,618,693	1,487,973	1,324,803
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technologies)	127,930	121,544	110,188	105,386	102,526
Selling, general and administrative	736,942	683,530	544,156	502,892	449,119
Research and development	299,726	226,616	198,442	162,297	135,253
Intangible asset amortization	354,814	201,498	152,065	101,994	98,162
Impairment charges	—	42,896	—	—	31,523
Acquired in-process research and development	109,975	—	85,000	23,750	—
Total operating expenses	1,629,387	1,276,084	1,089,851	896,319	816,583
Income from operations	532,374	614,838	528,842	591,654	508,220
Interest expense, net	(72,261)	(77,075)	(77,756)	(61,942)	(56,917)
Foreign exchange gain (loss)	(5,811)	(6,875)	(9,969)	3,372	1,445
Loss on extinguishment and modification of debt	—	(1,425)	—	(638)	(16,815)
Income before income tax provision (benefit) and equity in loss of investees	454,302	529,463	441,117	532,446	435,933
Income tax provision (benefit)	(73,154)	80,162	(47,740)	135,236	106,399
Equity in loss of investees	4,089	2,203	1,009	379	—
Net income	523,367	447,098	487,848	396,831	329,534
Net loss attributable to noncontrolling interests	—	—	—	—	(1)
Net income attributable to Jazz Pharmaceuticals plc	$ 523,367	$ 447,098	$ 487,848	$ 396,831	$ 329,535
Net income attributable to Jazz Pharmaceuticals plc per ordinary share:					
Basic	$ 9.22	$ 7.45	$ 8.13	$ 6.56	$ 5.38
Diluted	$ 9.09	$ 7.30	$ 7.96	$ 6.41	$ 5.23
Weighted-average ordinary shares used in per share calculations - basic	56,749	59,976	60,018	60,500	61,232
Weighted-average ordinary shares used in per share calculations - diluted	57,550	61,221	61,317	61,870	63,036

	As of December 31,				
	2019	2018	2017	2016(1)	2015
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 1,077,344	$ 824,622	$ 601,035	$ 425,963	$ 988,785
Working capital	1,265,778	888,518	674,330	490,663	1,031,025
Total assets	5,538,897	5,203,491	5,123,672	4,800,227	3,332,612
Long-term debt, current and non-current (1)	1,607,257	1,596,412	1,581,038	2,029,625	1,188,444
Retained earnings	1,067,815	841,050	917,956	528,907	302,686
Total Jazz Pharmaceuticals plc shareholders' equity	3,110,981	2,757,422	2,713,097	1,877,339	1,598,646

(1) On July 12, 2016, we completed the acquisition of Celator Pharmaceuticals, Inc., or Celator, which acquisition we refer to in this report as the Celator Acquisition, for an aggregate cash consideration of $1.5 billion and the results of operations of the acquired Celator business, along with the estimated fair values of the assets acquired and liabilities assumed, have been included in our consolidated financial statements since the closing of the Celator Acquisition.

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 impact our business. In particular, we encourage you to review the risks and uncertainties described in "Risk Factors" in Part I, Item 1A in this Annual Report on Form 10-K. 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

Jazz Pharmaceuticals plc is a global biopharmaceutical company dedicated to developing life-changing medicines for people with serious diseases – often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep medicine and movement disorders, and in oncology, including hematologic and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies.

Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in both adult and pediatric patients with narcolepsy;
- **Sunosi® (solriamfetol)**, a product approved by the FDA and marketed in the U.S. to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea, or OSA, and also recently approved in Europe in January 2020 by the European Commission, or EC;
- **Defitelio® (defibrotide sodium)**, a product approved in the U.S. for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Europe (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children undergoing HSCT therapy;
- **Erwinaze® (asparaginase *Erwinia chrysanthemi*)**, a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase; and
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or t-AML, or AML with myelodysplasia-related changes.

Over the last five years, we achieved multiple significant regulatory approvals, including most recently the European approval of Sunosi, and executed on five product launches. Over the next two years, we look forward to three additional potential regulatory approvals and related product launches (lurbinectedin, JZP-258 and JZP-458), as well as the commencement of the rolling launch of Sunosi in Europe by mid-2020. In February 2020, the FDA accepted for filing with priority review the new drug application, or NDA, for lurbinectedin for the treatment of relapsed small cell lung cancer, or SCLC, a product candidate for which we recently acquired exclusive U.S. development and commercialization rights. In January 2020, we submitted an NDA to the FDA seeking marketing approval for JZP-258, an oxybate product candidate that contains 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem, for the treatment of cataplexy and EDS in narcolepsy patients seven years of age and older. We also have in development JZP-458, a recombinant *Erwinia* asparaginase product candidate, for the treatment of pediatric and adult patients with ALL or lymphoblastic lymphoma, or LBL, who are hypersensitive to *E. coli*-derived asparaginase products, and expect to submit a biologics license application to the FDA for JZP-458 as early as the fourth quarter of 2020.

Our strategy to create shareholder value is focused on:

- Strong financial execution through growth in sales of our current lead marketed products;
- Building a diversified product portfolio and development pipeline through a combination of our internal research and development efforts and obtaining rights to clinically meaningful and differentiated on- or near-market products and early- to late-stage product candidates through acquisitions, collaborations, licensing arrangements, partnerships and venture investments; and
- Maximizing the value of our products and product candidates by continuing to implement our comprehensive global development plans, including through generating additional clinical data and seeking regulatory approval for new indications and new geographies.

Our total net product sales increased by 14% in 2019 compared to 2018, primarily due to an increase in Xyrem net product sales. We expect total net product sales to increase in 2020 over 2019, primarily due to expected growth in sales of Xyrem and Sunosi.

In 2019, consistent with our strategy, we continued to expand and advance our research and development pipeline in our sleep/neuroscience and hematology/oncology therapeutic areas, both by conducting activities internally and by leveraging partnerships with third parties.

While we are focused on opportunities within our sleep/neuroscience and hematology/oncology therapeutic areas, such as our recent expansion into movement disorders and solid tumors, we are also exploring and investing in adjacent therapeutic areas that could further diversify our portfolio. Our development activities encompass all stages of development and currently include clinical testing of new product candidates and activities related to clinical improvements of, or additional indications or new clinical data for, our existing marketed products. We have also expanded into preclinical exploration of novel therapies, including precision medicines in hematology and oncology. A summary of our ongoing development activities is provided under “Business—Research and Development” in Part I, Item 1 of this Annual Report on Form 10-K. In 2020 and beyond, we expect that our research and development expenses will continue to increase from previous levels, particularly as we prepare for anticipated regulatory submissions and data read-outs from clinical trials, initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates.

2019 Highlights and Recent Developments

Regulatory Approvals and Launches

- In March 2019, we launched Xyrem for the treatment of cataplexy and EDS in pediatric patients with narcolepsy, after completing the implementation of the related approved risk evaluation and mitigation strategy, or REMS, modification. In May 2019, the FDA confirmed that as the first sponsor to obtain marketing approval for use of Xyrem to treat cataplexy and EDS in pediatric narcolepsy patients aged seven years and older, we are entitled to seven years of orphan drug exclusivity for the pediatric indication.
- In March 2019, the FDA approved our NDA for Sunosi as a treatment to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA, and recommended that solriamfetol be scheduled by the U.S. Drug Enforcement Administration, or DEA. In June 2019, the DEA designated solriamfetol as a Schedule IV controlled substance, and, in July 2019, we launched Sunosi in the U.S.
- In June 2019, our partner, Nippon Shinyaku Co., Ltd, announced that Japan's Ministry of Health, Labour and Welfare approved the marketing authorization of Defitelio® injection 200mg (defibrotide sodium) for the treatment of sinusoidal obstruction syndrome/hepatic VOD.

- In November 2019, the European Medicines Agency recommended the marketing authorization application for Sunosi in Europe, and in January 2020, the EC approved Sunosi to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA.

Regulatory Submissions

- In March 2019, we announced positive top-line results from our Phase 3 study evaluating the efficacy and safety of JZP-258 for the treatment of cataplexy and EDS in adult patients with narcolepsy and presented additional results from this study publicly at an international medical conference in September 2019. We submitted an NDA for this product in January 2020 and redeemed our priority review voucher, or PRV, in connection with this submission.
- In December 2019, we entered into an exclusive license agreement with Pharma Mar, S.A., or PharmaMar, pursuant to which we obtained exclusive U.S. development and commercialization rights to lurbinectedin, a product candidate under clinical investigation for the treatment of patients with relapsed SCLC. Lurbinectedin was granted orphan drug designation for SCLC by the FDA in August 2018. In December 2019, PharmaMar submitted an NDA to the FDA for accelerated approval of lurbinectedin for relapsed SCLC based on data from a Phase 2 trial, and in February 2020, the FDA accepted the NDA for filing with priority review with a Prescription Drug User Fee Act, or PDUFA, date of August 16, 2020.

Research & Development

- In July 2019, we announced that we are pursuing development activities for Sunosi for the potential treatment of EDS in patients with major depressive disorder. We expect to initiate a Phase 3 study in mid-2020.
- In October 2019, the FDA granted Fast Track designation to JZP-458, a recombinant *Erwinia* asparaginase product candidate, for the potential treatment of ALL and LBL and in December 2019, we announced enrollment of the first patient in this study.
- In October 2019, we announced enrollment of the first patient in an exploratory Phase 2 clinical trial evaluating the ability of defibrotide to prevent neurotoxicity in patients with relapsed or refractory diffuse large B-cell lymphoma receiving chimeric antigen receptor T-cell therapy.
- In October 2019, we completed enrollment in a Phase 2 study for defibrotide in the prevention of acute graft-vs-host disease.
- In December 2019, we activated sites for a Phase 1b master trial of Vyxeos in combination with various targeted agents in first-line, fit AML.

Other Significant Developments

- In January 2019, we entered into a strategic collaboration agreement with Codiak BioSciences, Inc. focused on the research, development and commercialization of exosome therapeutics to treat cancer.
- In February 2019, we received a contract termination notice from Porton Biopharma Limited, or PBL, the sole manufacturer of Erwinaze. As a result of our receipt of the contract termination notice, our license and supply agreement with PBL, which includes an exclusive right to market, sell or distribute Erwinaze, an exclusive license to Erwinaze trademarks, and a non-exclusive license to PBL's manufacturing know-how, will expire on December 31, 2020. Unless we and PBL enter into a new agreement, we will lose our licensed rights to exclusively market Erwinaze effective December 31, 2020, other than our right to sell certain Erwinaze inventory for a post-termination sales period of 12 months and certain other post-termination rights, including but not limited to intellectual property and data ownership.
- In April 2019, we finalized a settlement agreement with the U.S. Department of Justice, or DOJ, and the Office of Inspector General of the Department of Health and Human Services, or OIG, and we entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to implement or continue, as applicable, a set of defined corporate integrity activities for a period of five years from the effective date of the corporate integrity agreement.
- In June 2019, we received notice from ImmunoGen, Inc., or ImmunoGen, that, as a result of portfolio prioritization and restructuring initiatives, ImmunoGen will be discontinuing development of its IMGN779 antibody-drug conjugate, or ADC, product candidate, for which we possess opt-in rights, as well as the programs from which a third opt-in candidate was to be selected. IMGN632, a CD123-targeted ADC product candidate for which we possess opt-in rights, remains under development by ImmunoGen.
- In July 2019, we acquired from Redx Pharma plc, or Redx, a pan-RAF inhibitor program for the potential treatment of RAF and RAS mutant tumors. Under the terms of our agreement with Redx, we paid Redx $3.5 million at closing

and Redx is eligible to receive up to $203 million in development, regulatory and commercial milestone payments from us, as well as incremental tiered royalties in mid-single digit percentage based on any future net sales.

- In August 2019, we announced the acquisition of Cavion, Inc., a clinical-stage biotechnology company, or Cavion, for an upfront payment of $52.5 million with the potential for additional payments of up to $260.0 million upon the achievement of certain clinical, regulatory and commercial milestones, for a total potential consideration of $312.5 million. As a result of the acquisition, we added CX-8998, now named JZP-385, a modulator of T-type calcium channels, for the potential treatment of essential tremor, to our clinical pipeline.
- Beginning in the third quarter of 2019, we have been entering into agreements with commercial payor organizations, including pharmacy benefit managers, or PBMs, to ensure patient access for our products, Sunosi and Xyrem, and to support the long-term success of our sleep and neuroscience therapeutic area. These agreements include terms related to the payment of rebates and/or administrative fees on these products. We expect to enter into additional agreements in 2020 to continue to ensure patient access to and coverage for our products.
- In October 2019, our board of directors authorized the additional repurchase of our ordinary shares having an aggregate purchase price of up to $500.0 million, exclusive of any brokerage commissions, under our share repurchase program. During 2019, we repurchased an aggregate of $301.5 million of our ordinary shares under our share repurchase program at an average price of $133.97 per share.

Challenges, Risks and Trends Related to Our Business

Our business is substantially dependent on Xyrem. Our future plans assume that sales of Xyrem will increase, but there is no guarantee 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 January 2020, and there is no guarantee that we will be able to make similar price adjustments in the future or that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes and revenues from Xyrem. In the future, we expect Xyrem to face competition from generic and authorized generic versions of sodium oxybate pursuant to the settlement agreements we have entered into with multiple abbreviated new drug application filers. Generic competition can decrease the prices at which Xyrem is sold and the number of prescriptions written for Xyrem. Xyrem may also face competition from other branded sodium oxybate products and other new and existing branded market entrants.

As for other products and product candidates in our sleep and neuroscience therapeutic area, we obtained approval of Sunosi in the U.S. and EU, and in January 2020, we submitted an NDA for marketing approval of JZP-258. Our future plans assume that, if approved, JZP-258 may be prescribed to patients as a safer and clinically superior alternative to Xyrem as well as being prescribed to patients who may otherwise be ineligible to take Xyrem based on its high sodium content. We are aware that Avadel Pharmaceuticals plc, or Avadel, is conducting a Phase 3 clinical trial of a once-nightly formulation of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy, and that Avadel has indicated that it intends to seek approval using the Section 505(b)(2) approval pathway referencing the safety and efficacy data for Xyrem. If the FDA approves Avadel's product and grants it orphan drug exclusivity before we obtain approval for JZP-258, there is a risk that JZP-258 will not be approvable for a narcolepsy indication for seven years unless it can establish clinical superiority to Avadel's product. We cannot predict the timing of Avadel's submission or how the FDA will evaluate any clinical superiority arguments that either company may make, but a delay in approval or inability to obtain approval for JZP-258 could materially and adversely affect our business, financial condition, results of operations and growth prospects. For example, the FDA could determine that our application is not sufficient to support approval with the label we have requested, and require amendments or additional data, which could delay or preclude the approval of our NDA. If we are unable to successfully commercialize Sunosi and/or JZP-258 (if approved), or if sales of Sunosi and JZP-258 do not reach the levels we expect, our anticipated revenue from our sleep therapeutic area will be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to our sleep and neuroscience products and product candidates, we are commercializing a portfolio of hematology/oncology products, including Defitelio, Erwinaze and Vyxeos. An inability to effectively commercialize Defitelio and Vyxeos and to maximize their potential where possible through successful research and development activities could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Our license and supply agreement with PBL, which includes an exclusive right to market, sell or distribute Erwinaze, an exclusive license to Erwinaze trademarks, and a non-exclusive license to PBL's manufacturing know-how, will expire on December 31, 2020. If we are unable to enter into a new agreement with PBL for our marketing rights to Erwinaze and are unable to replace the product sales we would lose from Erwinaze, our business, financial condition, results of operations and growth prospects would be materially adversely affected.

A key aspect of our growth strategy is our continued investment in our evolving and expanding research and development activities. In neuroscience, we are developing JZP-385 for the treatment of essential tremor and expect to initiate a Phase 2b study of JZP-385 in the fourth quarter of 2020. In our hematology/oncology, we are developing JZP-458, a

recombinant *Erwinia* asparaginase, and we expect to submit a BLA to the FDA for JZP-458 as early as the fourth quarter of 2020. If we are not successful in the clinical development of these or other product candidates, if we are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our product candidates would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to continued investment in our research and development pipeline, we intend to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. For example, we entered into an exclusive license agreement for U.S. commercialization rights to lurbinectedin with PharmaMar, who had submitted an NDA to the FDA in December 2019 for accelerated approval of lurbinectedin, and the NDA was accepted for filing with priority review in February 2020 with a PDUFA date of August 16, 2020. Failure to identify and acquire, in-license or develop additional products or product candidates, successfully manage the risks associated with integrating any products or product candidates into our portfolio or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing, could have a material adverse effect on our business, results of operations and financial condition.

We are increasingly experiencing pressure from third party payors to agree to discounts, rebates or restrictive pricing terms for Xyrem. We also need to obtain adequate formulary positions and reimbursement coverage for newly-launched products such as Sunosi and future products, if approved, such as JZP-258, JZP-458 and lurbinectedin. Entering into agreements with payors or PBMs to ensure patient access has and will likely continue to result in higher gross to net deductions for future periods for these products. We cannot guarantee we will be able to agree to commercially reasonable terms with PBMs and other third party payors, or that we will be able to ensure patient access to our existing and future products. In addition to increasing pricing pressure from, and restrictions on reimbursement imposed by payors, healthcare cost containment has received global attention, and drug pricing by pharmaceutical companies is currently, and is expected to continue to be, subject to close scrutiny by both federal and state governments. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products may be affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

Finally, business practices by pharmaceutical companies, including product formulation improvements, patent settlements, REMS programs, have increasingly drawn public scrutiny from legislators and regulatory agencies, with allegations that such programs are used as a means of improperly blocking or delaying competition. If we become the subject of any future government investigation with respect to our business practices, including as they relate to the Xyrem REMS, the launch of JZP-258, our patent settlements or otherwise, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. Any of these risks and uncertainties could have a material adverse effect on our business, financial condition, results of operations and growth prospects. All of these risks are discussed in greater detail, along with other risks, in “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K.

Results of Operations

The following table presents revenues and expenses for the years ended December 31, 2019, 2018 and 2017 (in thousands except percentages):

	2019	Change	2018	Change	2017
Product sales, net	$ 2,135,601	14%	$ 1,869,473	17%	$ 1,601,399
Royalties and contract revenues	26,160	22%	21,449	24%	17,294
Cost of product sales (excluding amortization of acquired developed technologies)	127,930	5%	121,544	10%	110,188
Selling, general and administrative	736,942	8%	683,530	26%	544,156
Research and development	299,726	32%	226,616	14%	198,442
Intangible asset amortization	354,814	76%	201,498	33%	152,065
Impairment charges	—	N/A(1)	42,896	N/A(1)	—
Acquired in-process research and development	109,975	N/A(1)	—	N/A(1)	85,000
Interest expense, net	72,261	(6)%	77,075	(1)%	77,756
Foreign exchange loss	5,811	(15)%	6,875	(31)%	9,969
Loss on extinguishment and modification of debt	—	N/A(1)	1,425	N/A(1)	—
Income tax provision (benefit)	(73,154)	N/A(1)	80,162	N/A(1)	(47,740)
Equity in loss of investees	4,089	86%	2,203	118%	1,009

(1) Comparison to prior period is not meaningful.

Revenues

The following table presents product sales, royalties and contract revenues, and total revenues for the years ended December 31, 2019, 2018 and 2017 (in thousands except percentages):

	2019	Change	2018	Change	2017
Xyrem	$ 1,642,525	17%	$ 1,404,866	18%	$ 1,186,699
Erwinaze/Erwinase	177,465	2%	174,739	(11)%	197,340
Defitelio/defibrotide	172,938	16%	149,448	12%	133,650
Vyxeos	121,407	20%	100,835	N/A(1)	33,790
Sunosi	3,714	N/A(1)	—	N/A(1)	—
Other	17,552	(56)%	39,585	(21)%	49,920
Product sales, net	2,135,601	14%	1,869,473	17%	1,601,399
Royalties and contract revenues	26,160	22%	21,449	24%	17,294
Total revenues	$ 2,161,761	14%	$ 1,890,922	17%	$ 1,618,693

(1) Comparison to prior period is not meaningful.

Product Sales, Net

Xyrem product sales increased by 17% in 2019 compared to 2018 primarily due to a higher average net selling price and, to a lesser extent, an increase in sales volume. Price increases were instituted in January and July 2019, January 2018 and in January and July 2017. Xyrem product sales volume increased by 6% in 2019 compared to 2018 primarily driven by an increase in the average number of patients on Xyrem. Xyrem product sales increased by 18% in 2018 compared to 2017 primarily due to an increase in sales volume and, to a lesser extent, a higher average net selling price. Xyrem product sales volume increased by 9% in 2018 compared to 2017 primarily driven by an increase in the average number of patients on Xyrem. Erwinaze/Erwinase product sales increased in 2019 compared to 2018 primarily due to higher sales volume as a result of availability of supply from the manufacturer. Erwinaze/Erwinase product sales decreased in 2018 compared to 2017 primarily due to lower sales volume as a result of limited supply from the manufacturer. Ongoing supply challenges continue to negatively impact our ability to supply the market. We experienced limited product availability of Erwinaze and supply disruptions globally in 2019 and may experience continued supply disruptions in 2020. Defitelio/defibrotide product sales increased in 2019 compared to 2018, primarily due to higher sales volumes, partially offset by the negative impact of foreign exchange rates. Defitelio/defibrotide product sales increased in 2018 compared to 2017, primarily due to higher sales volumes

and, to a lesser extent, the positive impact of foreign exchange rates. Vyxeos product sales increased in 2019 compared to 2018 primarily due to volumes following the commercial launch in Europe in September 2018. Vyxeos product sales were $33.8 million in 2017 following its launch in the U.S. in August 2017. Other product sales decreased in 2019 and in 2018 compared to the immediately preceding years, primarily due to the sale of our rights to Prialt to TerSera Therapeutics LLC, or TerSera, in September 2018. We expect total product sales will increase in 2020 over 2019, primarily due to expected growth in sales of Xyrem and Sunosi.

Royalties and Contract Revenues

Royalties and contract revenues increased in 2019 and in 2018 compared to the immediately preceding years, primarily due to higher contract revenues from out-licensing agreements. We expect royalties and contract revenues to decrease in 2020 compared to 2019 primarily due to lower milestone revenues from out-licensing arrangements.

Cost of Product Sales

Cost of product sales increased in 2019 and in 2018 compared to the immediately preceding years, primarily due to changes in product mix and increases in net product sales. Gross margin as a percentage of net product sales was 94.0%, 93.5% and 93.1% in 2019, 2018 and 2017, respectively. The increase in the gross margin percentage in 2019 and in 2018 compared to the immediately preceding years was primarily due to changes in product mix. We expect that our gross margin as a percentage of net product sales will not change materially in 2020 compared to 2019.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased in 2019 compared to 2018 primarily due to higher expenses related to the launch of Sunosi in the U.S., an increase in compensation-related expenses driven by higher headcount, and an increase in other expenses related to the expansion and support of our business, partially offset by the recognition of a loss contingency including related interest of $58.2 million recorded in 2018 resulting from a settlement agreement with the U.S. Department of Justice and the Office of Inspector General. For a further description of this matter, see the risk factors under the heading “Other Risks Related to Our Business and Industry” in Part I, Item 1A of this Annual Report on Form 10-K. Selling, general and administrative expenses increased in 2018 compared to 2017 primarily due to the recognition of a loss contingency and related interest recorded in 2018, increased expenses related to the commercial launch of Sunosi in the U.S. and the rolling launch of Vyxeos in Europe, and an increase in compensation-related expenses driven by higher headcount compared to 2017. We expect selling, general and administrative expenses in 2020 to increase compared to 2019, primarily due to an increase in compensation-related expenses driven by higher headcount and other expenses related to the expansion and support of our business including an increase in expenses related to the continuation of the commercial launch of Sunosi in the U.S., the commercial launch of Sunosi in Europe and the planned commercial launch of both lurbinectedin and JZP-258 in the U.S.

Research and Development Expenses

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, milestone expenses and other research and development costs. Clinical study and outside services costs relate primarily to services performed by clinical research organizations, materials and supplies, and other third party fees. Personnel expenses relate primarily to salaries, benefits and share-based compensation. 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 which 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):

	Year Ended December 31,		
	2019	2018	2017
Clinical studies and outside services	$ 133,042	$ 117,903	$ 93,317
Personnel expenses	100,090	71,158	63,941
Milestone expense	26,000	11,000	19,500
Other	40,594	26,555	21,684
Total	$ 299,726	$ 226,616	$ 198,442

Research and development expenses increased by $73.1 million in 2019 compared to 2018. Clinical studies and outside services costs increased in 2019 compared to 2018 primarily due to an increase in expenses related to our ongoing preclinical and clinical development programs and support of partner programs. Personnel expenses increased by $28.9 million in 2019 compared to 2018, primarily due to increased headcount in support of our development programs. Milestone expense of $26.0 million in 2019 related to milestone payments made under our license and option agreement with Pfenex. Research and development expenses increased by $28.2 million in 2018 compared to 2017. Clinical studies and outside services costs increased in 2018 compared to 2017 primarily due to an increase in expenses related to our ongoing preclinical and clinical development programs and support of partner programs, partially offset by lower clinical trial costs following the completion of three Phase 3 clinical trials for Sunosi. Personnel expenses increased by $7.2 million in 2018 compared to 2017, primarily due to increased headcount in support of our development programs. Milestone expense of $11.0 million in 2018 related to milestone payments following FDA acceptance of our NDA for Sunosi in March 2018.

For 2020 and beyond, we expect that our research and development expenses will continue to increase from previous levels, particularly as we prepare for anticipated regulatory submissions and data read-outs from clinical trials, initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates. A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of and regulatory submissions for 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 Annual Report on Form 10-K.

Intangible Asset Amortization

Intangible asset amortization increased in 2019 compared to 2018 primarily due to the amortization of the cost of the PRV of $111.1 million in full following the notification to the FDA of our intention to redeem it in the NDA submission for JZP-258 and the reduction in the estimated remaining useful life of the Erwinaze intangible asset resulting from the contract termination notice we received from PBL in February 2019. Intangible asset amortization increased in 2018 compared to 2017 primarily due to the commencement of amortization of the Vyxeos intangible asset upon FDA approval in August 2017. Intangible asset amortization is expected to decrease in 2020 compared to 2019 as a result of the amortization in full of our PRV intangible asset in the fourth quarter of 2019.

Impairment Charges

In June 2018, we entered into an asset purchase agreement, or APA, with TerSera, pursuant to which TerSera agreed to purchase substantially all of the assets held by us related to Prialt. In connection with the entry into the APA, which was subsequently amended, we reclassified the Prialt assets to be transferred to TerSera as assets held for sale and recorded these assets at fair value, less estimated sales costs, resulting in the recognition of an impairment charge of $42.9 million in 2018. The transaction closed in September 2018.

Acquired In-Process Research and Development

In 2019, acquired in-process research and development, or IPR&D expense primarily related to an upfront payment of $56.0 million to Codiak in connection with our strategic collaboration agreement and the value attributed to JZP-385 in the acquisition of Cavion.

In 2017, IPR&D expense was primarily related to an upfront payment of $75.0 million in connection with our collaboration and option agreement with ImmunoGen.

Interest Expense, Net

Interest expense, net decreased by $4.8 million in 2019 compared to 2018, primarily due to higher interest income. Interest expense, net decreased by $0.7 million in 2018 compared to 2017, primarily due to higher interest income, partially offset by the interest expense on our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, which were issued in August 2017. We expect interest expense, net will not change materially in 2020 compared to 2019.

Foreign Exchange Loss

The foreign exchange loss is primarily related to the translation of euro-denominated net monetary liabilities, primarily intercompany balances, held by subsidiaries with a U.S. dollar functional currency and related foreign exchange forward contracts not designated as hedging instruments.

Loss on Extinguishment and Modification of Debt

In 2018, we recorded a loss of $1.4 million in connection with the second amendment of our 2015 credit agreement, related to unamortized debt issuance costs and original issue discount associated with extinguished debt and new third party fees associated with modified debt.

Income Tax Provision (Benefit)

Our income tax benefit was $73.2 million and $47.7 million in 2019 and 2017, respectively, and our income tax provision was $80.2 million in 2018. The income tax benefit for 2019 includes a discrete tax benefit of $112.3 million resulting from an intra-entity intellectual property asset transfer. The income tax benefit, which represents a deferred future benefit, was recorded as a deferred tax asset. The income tax benefit in 2017 included a benefit of $148.8 million relating to the enactment of the U.S. Tax Cuts and Jobs Act, or the U.S. Tax Act. The effective tax rates for 2019, 2018 and 2017 were (16.1)%, 15.1% and (10.8)%, respectively. The effective tax rate for 2019 was lower than the Irish statutory rate of 12.5% primarily due to the impact of the intra-entity intellectual property asset transfer. The effective tax rate for 2018 was higher than the Irish statutory rate of 12.5%, primarily due to income taxable at a rate higher than the Irish statutory rate and unrecognized tax benefits, partially offset by the release of reserves related to unrecognized tax benefits upon the expiration of a statute of limitation, originating tax credits and the release of a valuation allowance held primarily against certain foreign net operating losses or NOLs. The effective tax rate for 2017 was lower than the Irish statutory rate of 12.5%, primarily due to the impact of the enactment of the U.S. Tax Act. The decrease in the effective tax rate for 2019 compared to 2018 was primarily due to the impact of the intra-entity intellectual property asset transfer. Excluding this effect, the decrease in the effective tax rate for 2019 compared to 2018 was primarily due to the benefit from the application of the Italian patent box incentive regime. The increase in the effective tax rate for 2018 compared to 2017 was primarily due to the impact of the enactment of the U.S. Tax Act. Excluding this effect, the effective rate in 2018 would have decreased compared to 2017 primarily due to a decrease in the U.S. corporate income tax rate.

Equity in Loss of Investees

Equity in loss of investees relates to our share in the net loss of companies in which we have made investments accounted for under the equity method of accounting.

Liquidity and Capital Resources

As of December 31, 2019, we had cash, cash equivalents and investments of $1.1 billion, borrowing availability under our revolving credit facility of $1.6 billion and a long-term debt principal balance of $1.8 billion. Our long-term debt included $617.7 million aggregate principal amount term loan, $575.0 million principal amount of our 1.875% exchangeable senior notes due 2021 and $575.0 million principal amount of our 1.50% exchangeable senior notes due 2024. During 2019, 2018 and 2017, we generated cash flows from operations of $776.4 million, $798.9 million and $693.1 million, respectively, and we expect to continue to generate positive cash flow from operations.

We believe that our existing cash, cash equivalents and investments 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. 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 "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K under the headings "Risks Related to our Lead Products and Product Candidates" 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, and we may not be able to generate sufficient cash to service our debt obligations 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.

To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue new operations or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations or 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, and the consent of the lenders under the amended credit agreement could be required for certain financings.

In November 2016, our board of directors authorized a share repurchase program pursuant to which we were authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300 million, exclusive of any brokerage commissions. In November and December 2018, our board of directors increased the existing share repurchase

program authorization by $320.0 million and $400.0 million, respectively. In October 2019, our board of directors authorized the additional repurchase of shares having an aggregate purchase price of up to $500.0 million, exclusive of any brokerage commissions. Under this program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the amended credit agreement, corporate and regulatory requirements and market conditions. The repurchase program may be modified, suspended or discontinued at any time without prior notice. In 2019, we spent a total of $301.5 million to purchase 2.3 million of our ordinary shares under the share repurchase program at an average total purchase price, including brokerage commissions, of $133.97 per share. In 2018, we spent a total of $523.7 million to repurchase 3.5 million of our ordinary shares at an average total purchase price, including brokerage commissions, of $148.33 per share. All ordinary shares repurchased were canceled. As of December 31, 2019, the remaining amount authorized under the share repurchase program was $577.7 million.

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Net cash provided by operating activities	$ 776,401	$ 798,904	$ 693,087
Net cash used in investing activities	(155,300)	(394,487)	(268,950)
Net cash used in financing activities	(293,745)	(479,130)	(409,111)
Effect of exchange rates on cash and cash equivalents	366	(1,700)	5,046
Net increase (decrease) in cash and cash equivalents	$ 327,722	$ (76,413)	$ 20,072

Net cash provided by operating activities of $776.4 million in 2019 related to net income of $523.4 million, adjusted for acquired IPR&D expense of $110.0 million and non-cash items of $293.1 million primarily related to intangible asset amortization, share-based compensation expense, amortization of debt discount and deferred financing costs and deferred income taxes, partially offset by a net cash outflow of $150.1 million related to changes in operating assets and liabilities. Net cash provided by operating activities of $798.9 million in 2018 related to net income of $447.1 million, adjusted for non-cash items of $328.5 million primarily related to intangible asset amortization, share-based compensation expense, impairment charges, amortization of debt discount and deferred financing costs and deferred income taxes and a net cash inflow of $23.3 million related to changes in operating assets and liabilities. Net cash provided by operating activities of $693.1 million in 2017 related to net income of $487.8 million, adjusted for acquired IPR&D expense totaling $85.0 million and non-cash items of $93.5 million primarily related to intangible asset amortization, share-based compensation expense, amortization of debt discount and deferred financing costs and deferred income taxes and a net cash inflow of $26.8 million related to changes in operating assets and liabilities.

Net cash used in investing activities in 2019 related to milestone payments of $80.5 million triggered by FDA approval of Sunosi in March 2019 and subsequent U.S. Drug Enforcement Agency scheduling in June 2019, upfront payments for acquired IPR&D of $61.7 million primarily related to our strategic collaboration agreement with Codiak, consideration, net of cash acquired, of $55.1 million related to our acquisition of Cavion and purchases of property, plant and equipment of $40.1 million, partially offset by the net proceeds on maturity of investments of $67.9 million and net proceeds from the sale of assets of $14.2 million related to the sale of our rights to Prialt to TerSera in September 2018. Net cash used in investing activities in 2018 primarily related to the net acquisition of investments of $310.9 million, acquisition of intangible assets of $111.1 million, related to the purchase of a PRV, and purchases of property, plant and equipment of $20.4 million, partially offset by net proceeds of $47.9 million from the sale of our rights to Prialt to TerSera. Net cash used in investing activities in 2017 primarily related to the net acquisition of investments of $155.0 million, upfront payments for acquired IPR&D of $85.0 million primarily related to our collaboration and option agreement with ImmunoGen and purchases of property, plant and equipment of $29.0 million.

Net cash used in financing activities in 2019 primarily related to repurchase of ordinary shares under our share repurchase program of $301.5 million, repayment of our term loan principal of $33.4 million and payment of employee withholding taxes of $16.7 million related to share-based awards, partially offset by proceeds from employee equity incentive and purchase plans of $57.8 million. Net cash used in financing activities in 2018 primarily related to repurchase of ordinary shares under our share repurchase program of $523.7 million, repayment of our term loan principal of $25.7 million, payment of employee withholding taxes of $17.9 million related to share-based awards and payment of debt modification costs of $6.4 million, partially offset by proceeds from employee equity incentive and purchase plans of $93.3 million. Net cash used in financing activities in 2017 primarily related to repayment of borrowings under our revolving credit facility of $850.0 million, repurchase of ordinary shares under our share repurchase program of $98.8 million, repayment of our term loan principal of $36.1 million and payment of employee withholding taxes of $18.6 million related to share-based awards, partially offset by

net proceeds from issuance of debt of $559.4 million, proceeds from employee equity incentive and purchase plans of $31.8 million and proceeds from a tenant improvement allowance on a build-to-suit lease of $3.2 million.

Credit Agreement

On June 18, 2015, Jazz Pharmaceuticals plc, as guarantor, and certain of our wholly owned subsidiaries, as borrowers, entered into the 2015 credit agreement that provided for a $750.0 million principal amount term loan, which was drawn in full at closing, and a $750.0 million revolving credit facility, of which $160.0 million was drawn at closing and subsequently repaid. We used the proceeds from initial borrowings under the 2015 credit agreement to repay in full the $893.1 million principal amount of term loans outstanding under a previous credit agreement, and to pay related fees and expenses. The previous credit agreement was terminated upon repayment of the term loans outstanding thereunder.

On July 12, 2016, Jazz Pharmaceuticals plc, as guarantor, and certain of our wholly owned subsidiaries, as borrowers, entered into Amendment No. 1 to our 2015 credit agreement to provide for a revolving credit facility of $1.25 billion and a $750.0 million term loan facility. We used the proceeds of $1.0 billion of loans under the revolving credit facility, together with cash on hand, to fund the Celator Acquisition.

On June 7, 2018, we entered into the second amendment to the 2015 credit agreement to provide for a revolving credit facility of $1.6 billion, which replaced the existing revolving credit facility of $1.25 billion, and a new $667.7 million term loan facility, which replaced the $750.0 million term loan facility, of which $617.7 million principal amount was outstanding as of December 31, 2019. We refer to the 2015 credit agreement as amended by the first and second amendments as the amended credit agreement in this report. We expect to use the proceeds from future loans under the revolving credit facility, if any, for permitted capital expenditures and acquisitions, to provide for ongoing working capital requirements and for other general corporate purposes.

Under the amended credit agreement, the term loan matures on June 7, 2023 and the revolving credit facility terminates, and any loans outstanding thereunder become due and payable, on June 7, 2023.

Borrowings under the amended credit agreement bear interest, at our option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 1.375% to 1.750% per annum, based upon our secured leverage ratio, or (b) the prime lending rate, plus an applicable margin ranging from 0.375% to 0.750% per annum, based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio.

As of December 31, 2019, the interest rate on the term loan was 3.17% and the effective interest rate was 3.66%. As of December 31, 2019, we had undrawn amounts under our revolving credit facility totaling $1.6 billion.

Jazz Pharmaceuticals plc and certain of our wholly owned subsidiaries are borrowers under the amended credit agreement. The borrowers' obligations under the amended credit agreement and any hedging or cash management obligations entered into with a lender are guaranteed on a senior secured basis by Jazz Pharmaceuticals plc and certain of our subsidiaries (including the issuer of the 2021 Notes and the 2024 Notes, together referred to as the Exchangeable Senior Notes as described below) and are secured by substantially all of Jazz Pharmaceuticals plc's, the borrowers' and the guarantor subsidiaries' assets.

We may make voluntary prepayments of principal at any time without payment of a premium. We are required to make mandatory prepayments of the term loan (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), and (3) casualty proceeds and condemnation awards (subject to other exceptions).

Principal repayments of the term loan, which are due quarterly, are equal to 5.0% per annum of the principal amount outstanding on June 7, 2018 of $667.7 million, with any remaining balance payable on the maturity date.

The amended credit agreement contains financial covenants that require Jazz Pharmaceuticals plc and our restricted subsidiaries to not (a) exceed a maximum secured net leverage ratio or (b) fall below a cash interest coverage ratio. As of December 31, 2019, we were in compliance with these financial covenants.

Exchangeable Senior Notes

2024 Notes. In the third quarter of 2017, our wholly owned subsidiary Jazz Investments I Limited, completed a private placement of $575.0 million principal amount of 2024 Notes. We used the net proceeds from this offering to repay $500.0 million in outstanding loans under the revolving credit facility under the amended credit agreement and to pay related fees and expenses. We used the remainder of the net proceeds for general corporate purposes. The 2024 Notes are senior unsecured obligations of Jazz Investments I Limited and are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc and will rank pari passu in right of payment with the existing 2021 Notes. Interest on the 2024 Notes is payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2018,

at a rate of 1.50% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2024 Notes. The 2024 Notes mature on August 15, 2024, unless earlier exchanged, repurchased or redeemed.

The holders of the 2024 Notes have the ability to require us to repurchase all or a portion of their 2024 Notes for cash in the event we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from The Nasdaq Global Select Market. Prior to August 15, 2024, we may redeem the 2024 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2024 Notes additional amounts as a result of certain tax-related events. We also may redeem the 2024 Notes on or after August 20, 2021, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2024 Notes are exchangeable at an initial exchange rate of 4.5659 ordinary shares per $1,000 principal amount of 2024 Notes, which is equivalent to an initial exchange price of approximately $219.02 per ordinary share. Upon exchange, the 2024 Notes may be settled in cash, ordinary shares or a combination of cash and ordinary shares, at our election. Our intent and policy is to settle the principal amount of the 2024 Notes in cash upon exchange. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2024 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2024 Notes who elect to exchange their 2024 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to May 15, 2024, the 2024 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

2021 Notes. In August 2014, Jazz Investments I Limited completed a private placement of $575.0 million principal amount of the 2021 Notes. The 2021 Notes are senior unsecured obligations of Jazz Investments I Limited and are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. Interest on the 2021 Notes is payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2015, at a rate of 1.875% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2021 Notes. The 2021 Notes mature on August 15, 2021, unless earlier exchanged, repurchased or redeemed.

The holders of the 2021 Notes have the ability to require us to repurchase all or a portion of their 2021 Notes for cash in the event we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from The Nasdaq Global Select Market. Prior to August 15, 2021, we may redeem the 2021 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2021 Note additional amounts as a result of certain tax-related events. We also may redeem the 2021 Notes on or after August 20, 2018, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2021 Notes are exchangeable at an initial exchange rate of 5.0057 ordinary shares per $1,000 principal amount of 2021 Notes, which is equivalent to an initial exchange price of approximately $199.77 per ordinary share. Upon exchange, the 2021 Notes may be settled in cash, ordinary shares or a combination of cash and ordinary shares, at our election. Our intent and policy is to settle the principal amount of the 2021 Notes in cash upon exchange. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2021 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2021 Notes who elect to exchange their 2021 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to February 15, 2021, the 2021 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

Contractual Obligations

The table below presents a summary of our contractual obligations as of December 31, 2019 (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	$ 617,654	$ 33,387	$ 66,773	$ 517,494	$ —
Term loan - interest (2)	65,920	20,641	37,759	7,520	—
Exchangeable Senior Notes - principal	1,150,000	—	575,000	575,000	—
Exchangeable Senior Notes - interest (3)	64,688	19,406	28,031	17,251	—
Revolving credit facility - commitment fee (4)	13,922	4,067	8,111	1,744	—
Commitment to equity method investees	15,075	7,000	8,075	—	—
Purchase and other obligations (5)	98,034	74,488	17,551	5,908	87
Operating lease obligations (6)	213,578	21,315	42,243	45,365	104,655
Total	$ 2,238,871	$ 180,304	$ 783,543	$ 1,170,282	$ 104,742

(1) This table does not include potential future milestone payments or royalty obligations to third parties under asset purchase, product development, license and other 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. In December 2019, we entered into an exclusive license agreement with PharmaMar, for development and U.S. commercialization of lurbinectedin, a product candidate under clinical investigation for the treatment of patients with relapsed SCLC. The agreement became effective in January 2020 and we made an upfront payment of $200.0 million. PharmaMar is also eligible to receive milestone payments totaling up to $800.0 million based on regulatory and commercial milestones. PharmaMar is also eligible to receive incremental tiered royalties on future net sales of lurbinectedin ranging from the high teens up to 30 percent. In January 2019, we entered into a strategic collaboration agreement with Codiak for an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize potential therapeutic candidates directed at five targets to be developed using Codiak's engEx™ precision engineering platform for exosome therapeutics. Codiak is eligible to receive up to $20 million in preclinical development milestone payments. Codiak is also eligible to receive milestone payments totaling up to $200 million per target based on investigational NDA acceptance, clinical and regulatory milestones, including approvals in the U.S., the EU and Japan, and certain sales milestones. Codiak is also eligible to receive tiered royalties on net sales of each approved product. In August 2019, we announced the acquisition of Cavion, for an upfront payment of $52.5 million with the potential for additional payments of up to $260.0 million upon the achievement of certain clinical, regulatory and commercial milestones, for a total potential consideration of $312.5 million. In July 2019, we acquired a pan-RAF inhibitor program for the potential treatment of RAF and RAS mutant tumors from Redx. Redx is eligible to receive up to $203 million in development, regulatory and commercial milestone payments from us, as well as incremental tiered royalties in mid-single digit percentage based on any future net sales. In 2014, we acquired worldwide development, manufacturing and commercial rights to Sunosi from Aerial (other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights). In January 2020, we received approval of Sunosi by the EC, triggering regulatory milestones of $10.0 million and $3.0 million to Aerial and SK, respectively. Aerial and SK are currently eligible to receive milestone payments up to an aggregate of $165 million based on sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales of Sunosi. In July 2016, we entered into an agreement with Pfenex, which was subsequently amended in December 2017, that granted us worldwide rights to develop and commercialize multiple early-stage hematology product candidates and an option for us to negotiate a license for a recombinant pegaspargase product candidate with Pfenex. Under the amended agreement, Pfenex is eligible to receive future payments of up to $163 million based on the achievement of development, regulatory and sales milestones. Potential future milestone payments to other third parties under other agreements could be up to an aggregate of $123 million. These 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) Estimated interest for variable rate debt was calculated based on the interest rates in effect as of December 31, 2019. The interest rate for our term loan borrowing was 3.17% as of December 31, 2019. Interest that is fixed, associated with our interest rate swaps, is calculated based on the fixed interest swap rate as of December 31, 2019.

(3) We used the fixed interest rates of 1.875% on the 2021 Notes and 1.50% on the 2024 Notes to estimate interest owed as of December 31, 2019 until the respective final maturity dates of these notes.

(4) Our revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.25% and assumed undrawn amounts of $1.6 billion as of December 31, 2019 to estimate commitment fees owed.
(5) Consists primarily of non-cancelable commitments to our third party manufacturers and to ImmunoGen under our amended collaboration and option agreement.
(6) Consists primarily of the minimum lease payments for our office buildings and automobile lease payments for our sales force. Operating expenses associated with our leased office buildings are not included in table above.

We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries. Cumulative unremitted earnings of our foreign subsidiaries totaled approximately $1.6 billion at December 31, 2019. 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, 2019, it is not practicable to determine the amount of the income tax liability related to these undistributed earnings due to a variety of factors.

In addition, our liability for unrecognized tax benefits has been excluded from the above contractual obligations table as the nature and timing of future payments, if any, cannot be reasonably estimated. As of December 31, 2019, our liability for gross unrecognized tax benefits amounted to $124.3 million (excluding interest and penalties). We do not anticipate that the amount of our existing liability for unrecognized tax benefits will significantly change in the next twelve months.

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 described in more detail in Note 2, Summary of Significant Accounting Policies, of the Notes to Consolidated Financial Statements included in Part IV of this Annual Report on Form 10-K, we believe the following accounting estimates and policies to be critical.

Revenue Recognition

Revenues are recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services.

Product Sales, Net

Product sales revenue is recognized when control has transferred to the customer, which occurs at a point in time, 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 is derived from sales of Xyrem. We sell Xyrem in the U.S. to a single central pharmacy, Express Scripts Specialty Distribution Services, Inc., or ESSDS. In 2019, sales of Xyrem to Express Scripts accounted for 76% of our net product sales. We recognize revenues from sales of Xyrem within the U.S. when control has transferred to the customer, which occurs when ESSDS removes product from our consigned inventory location at its facility for shipment directly to a patient. We do not accept returns of Xyrem from ESSDS.

Items Deducted from Gross Product Sales. Revenues from sales of products are recorded net of government rebates and rebates under managed care plans and commercial payor contracts, estimated allowances for sales returns, government chargebacks, prompt payment discounts, patient coupon programs, and specialty distributor and wholesaler fees. 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 applicable regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates 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 a significant portion of our revenues from sales of Xyrem in the U.S. to one specialty pharmacy customer, ESSDS, 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 most of our other products. The most significant items deducted from gross product sales where we exercise judgment are rebates, sales returns and chargebacks.

The following table presents the activity and ending balances for our sales-related accruals and allowances (in thousands):

	Rebates Payable	Sales Returns Reserve	Chargebacks	Discounts and Distributor Fees	Total
Balance at December 31, 2016	$ 68,263	$ 4,366	$ 4,749	$ 4,199	$ 81,577
Provision, net	144,596	446	41,941	36,642	223,625
Payments/credits	(135,697)	(1,161)	(43,027)	(36,532)	(216,417)
Balance at December 31, 2017	77,162	3,651	3,663	4,309	88,785
Provision, net	160,648	1,203	41,387	42,956	246,194
Payments/credits	(156,696)	(2,344)	(44,642)	(41,808)	(245,490)
Balance at December 31, 2018	81,114	2,510	408	5,457	89,489
Provision, net	153,930	5,519	41,864	56,041	257,354
Payments/credits	(152,191)	(4,567)	(41,138)	(47,377)	(245,273)
Balance at December 31, 2019	$ 82,853	$ 3,462	$ 1,134	$ 14,121	$ 101,570

Total items deducted from gross product sales were $257.4 million, $246.2 million and $223.6 million, or 10.8%, 11.6% and 12.3% as a percentage of gross product sales, in 2019, 2018 and 2017, 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 years ended December 31, 2019, 2018 and 2017.

Rebates

We are subject to rebates on sales made under governmental and managed-care pricing programs and commercial payor contracts in the U.S. 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 under the terms of which discounts and rebates are provided to participating government entities. We offer rebates and discounts to managed health care organizations and commercial payors in the U.S. In estimating our provisions for rebates, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers, commercial payors and group purchasing organizations. We estimate the rebate provision based on historical utilization rates, historical payment experience, new information regarding changes in regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and channel inventory data obtained from our major U.S. wholesalers in accordance with our inventory management agreements. Estimating these rebates is complex, in part due to the time delay between the date of sale and the actual settlement of the liability. We believe that the methodology we use to estimate rebates on product sales made under governmental and managed-care pricing programs is reasonable and appropriate given current facts and circumstances. However, estimates may vary from actual experience.

Rebates were $153.9 million, $160.6 million and $144.6 million, or 6.5%, 7.6% and 7.9% as a percentage of gross product sales, in 2019, 2018 and 2017, respectively. Rebates as a percentage of gross product sales decreased in 2019 compared to 2018 primarily due to a decrease in the Tricare per unit rebate amount. Rebates as a percentage of gross product sales did not change materially in 2018 compared to 2017. We expect that rebates will continue to significantly impact our reported net sales. Rebates as a percentage of gross product sales are expected to increase in 2020 compared to 2019, primarily due to the entry into additional contracts with commercial payors.

Sales returns

For certain products, we allow customers to return product within a specified period before and after the applicable 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 market events including generic competition.

Sales returns were $5.5 million, $1.2 million and $0.4 million, or 0.2%, 0.1% and 0% as a percentage of gross product sales in 2019, 2018 and 2017, respectively. Sales returns as a percentage of gross product sales did not change materially in 2019 and 2018 compared to the immediately preceding years. Sales returns as a percentage of gross product sales are not expected to change materially in 2020 compared to 2019.

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, under which 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. We record the difference 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.

Chargebacks were $41.9 million, $41.4 million and $41.9 million, or 1.8%, 2.0% and 2.3% as a percentage of gross product sales in 2019, 2018 and 2017, respectively. Chargebacks as a percentage of gross product sales did not change materially in 2019 and 2018 compared to the immediately preceding years. We expect that chargebacks will continue to significantly impact our reported net product sales. Chargebacks as a percentage of gross product sales are not expected to change materially in 2020 compared to 2019.

Discounts and distributor fees

Discounts and distributor fees comprise prompt payment discounts, patient coupon programs and specialty distributor and wholesaler fees. We offer customers a cash discount on gross product sales as an incentive for prompt payment. We estimate provisions for prompt pay discounts based on contractual sales terms with customers and historical payment experience. To help patients afford our products, we have various programs to assist them, including patient assistance programs, a free product voucher program and co-pay coupon programs for certain products. We estimate provisions for these programs primarily based on expected program utilization, adjusted as necessary to reflect our actual experience on a product and program basis. Specialty distributor and wholesaler fees comprise fees for distribution of our products. We estimate provisions for distributor and wholesaler fees primarily based on sales volumes and contractual terms with our distributors.

Discounts and distributor fees were $56.0 million, $43.0 million and $36.6 million, or 2.4%, 2.0% and 2.0% as a percentage of gross product sales in 2019, 2018 and 2017, respectively. Discounts and distributor fees as a percentage of gross product sales did not change materially in 2019 and 2018 compared to the immediately preceding years. We expect that discounts and distributor fees as a whole will continue to significantly impact our reported net product sales. Discounts and distributor fees as a percentage of gross product sales are not expected to change materially in 2020 compared to 2019.

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 2019 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, 2019, we had $920.0 million of goodwill resulting from acquisitions accounted for as business combinations.

Intangible Assets

We have 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.

Finite-lived intangible assets consist primarily of purchased developed technology and are amortized on a straight-line basis over their estimated useful lives, which range from two to 18 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 is not expected to be recovered, the assets are written down to their estimated fair values.

As of December 31, 2019, we had $2.3 billion of finite-lived intangible assets and $0.1 billion of IPR&D assets. In relation to the sale of our rights to Prialt to TerSera in 2018, we adjusted the carrying value of the assets held for sale to fair value less costs to sell, which resulted in an impairment charge of $42.9 million in our consolidated statements of income in 2018, primarily related to the carrying balances of intangible assets. We did not recognize an impairment charge related to our intangible assets in 2019 and 2017.

Please refer to Note 9, Goodwill and Intangible assets, of the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for further information about our intangible assets and the remaining useful lives of our finite-lived intangible assets as of December 31, 2019.

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 and the U.S. 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 certain 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 certain 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.

We 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 allowance 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 provision in that period.

We have also provided for unrecognized tax benefits that we believe are not more-likely-than-not to be sustained upon examination by tax authorities. The evaluation of unrecognized tax benefits 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 unrecognized tax benefits 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 unrecognized tax benefits 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).

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:

	Year Ended December 31,		
	2019	2018	2017
Volatility	32%	35%	35%
Expected term (years)	4.5	4.5	4.3
Range of risk-free rates	1.3-2.5%	2.2-3.0%	1.6-2.1%
Expected dividend yield	—%	—%	—%

The two inputs which require the greatest judgment and have a large impact on fair values are volatility and expected term.

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. 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. We estimated the weighted-average expected term based on historical exercise data.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, please see Note 2, Summary of Significant Accounting Policies, of the Notes to Consolidated Financial Statements included in Part IV of this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. 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 states, agencies and municipalities in the U.S. Our cash equivalents and investments as of December 31, 2019 consisted of time deposits and money market funds which are not subject to significant interest rate risk.

We are exposed to risks associated with changes in interest rates in connection with our term loan borrowings. On June 7, 2018, we entered into the amended credit agreement to provide for a revolving credit facility of $1.6 billion, which

replaced the existing revolving credit facility of $1.25 billion, and a new $667.7 million term loan facility, which replaced the $750.0 million term loan facility, of which $617.7 million principal amount was outstanding as of December 31, 2019. There were no borrowings outstanding under the revolving credit facility as of December 31, 2019. To achieve a desired mix of floating and fixed interest rates on our term loan, we entered into interest rate swap agreements in March 2017 that are designated as cash flow hedges. These derivative instruments are utilized for risk management purposes, and we do not use these derivatives for speculative trading purposes. The interest rate swap agreements have a notional amount of $300.0 million and are effective from March 3, 2017 through July 12, 2021 and convert the floating rate on a portion of our term loan to a fixed rate of 1.895%, plus the borrowing spread. The impact of a hypothetical increase or decrease in interest rates on the fair value of our interest rate swap contracts would be offset by a change in the value of the underlying liability. If interest rates were to increase or decrease by 100 basis points, interest expense for 2020 would increase or decrease by approximately $2.8 million, based on the unhedged portion of our outstanding variable rate borrowings.

In August 2014, we completed a private placement of $575.0 million aggregate principal amount of the 2021 Notes. In the third quarter of 2017, we completed another private placement of $575.0 million aggregate principal amount of the 2024 Notes. The 2021 Notes and 2024 Notes have fixed annual interest rates of 1.875% and 1.50%, respectively, and we, therefore, do not have economic interest rate exposure on the Exchangeable Senior Notes. However, the fair values of the Exchangeable Senior Notes are exposed to interest rate risk. Generally, the fair values of the Exchangeable Senior Notes will increase as interest rates fall and decrease as interest rates rise. The fair values of the Exchangeable Senior Notes are also affected by volatility in our ordinary share price. As of December 31, 2019, the fair values of the 2021 Notes and the 2024 Notes were estimated to be $592 million and $579 million, respectively.

In July 2017, the Financial Conduct Authority, the authority that regulates LIBOR, announced it intended to stop compelling banks to submit rates for the calculation of LIBOR after 2021. The Alternative Reference Rates Committee, or ARRC, in the U.S. has proposed that the Secured Overnight Financing Rate, or SOFR, is the rate that represents best practice as the alternative to the U.S. dollar, or USD, LIBOR for use in derivatives and other financial contracts that are currently indexed to USD LIBOR. ARRC has proposed a paced market transition plan to SOFR from USD LIBOR and organizations are currently working on industry wide and company specific transition plans as it relates to derivatives and cash markets exposed to USD LIBOR. We have certain financial contracts, including the amended credit agreement and our interest rate swaps, that are indexed to USD LIBOR and are monitoring this activity and evaluating the related risks.

Foreign Exchange Risk. We have significant operations in Europe as well as in the U.S. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the functional 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 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 exposure is related to our subsidiaries that have functional currencies denominated in the euro. A hypothetical 10% strengthening or weakening in the rates used to translate the results of our foreign subsidiaries that have functional currencies denominated in euro would have increased or decreased net income for the year ended December 31, 2019 by approximately $14 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 foreign exchange gain (loss) in the consolidated statements of income. As of December 31, 2019, our primary exposure to transaction risk related to euro net monetary liabilities, including intercompany loans, held by subsidiaries with a U.S. dollar functional currency. We have entered into foreign exchange forward contracts to manage this currency risk. These foreign exchange forward contracts are not designated as hedges; gains and losses on these derivative instruments are designed to offset gains and losses on the underlying balance sheet exposures. As of December 31, 2019, we held foreign exchange forward contracts with notional amounts totaling $180.9 million. The net asset fair value of outstanding foreign exchange forward contracts was $2.3 million as of December 31, 2019. Based on our foreign currency exchange rate exposures as of December 31, 2019, a hypothetical 10% adverse fluctuation in exchange rates would decrease the fair value of our foreign exchange forward contracts by approximately $15 million as of December 31, 2019. The resulting loss on these forward contracts would be offset by a positive impact on the underlying monetary assets and liabilities.

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-44.

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 chief executive officer, who is both our principal executive officer and interim principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on his evaluation, our chief executive officer, who is both our principal executive officer and interim principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2019.

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 chief executive officer, who is both our principal executive officer and interim principal financial officer has concluded, based on his 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. During the quarter ended December 31, 2019, 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 Internal Control - Integrated Framework (2013), 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, 2019 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, 2019, 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

To the Shareholders and Board of Directors
Jazz Pharmaceuticals plc:

Opinion on Internal Control Over Financial Reporting

We have audited Jazz Pharmaceuticals plc's and subsidiaries' (the 'Company') internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ('PCAOB'), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, and the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes and financial statement schedule at Item 15(a)2 (collectively, the "consolidated financial statements"), and our report dated February 25, 2020 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company'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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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 of internal control over financial reporting 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.

Definition and Limitations of Internal Control Over Financial Reporting

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.

/s/ KPMG

Dublin, Ireland
February 25, 2020

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 2020 annual general meeting of shareholders, or our 2020 Proxy Statement, to be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, or Exchange Act. If our 2020 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 is to be included in our 2020 Proxy Statement as follows:

- The information relating to our directors and nominees for director is to be included in the section entitled "Proposal 1—Election of Directors;"
- The information relating to our executive officers is to be included in the section entitled "Executive Officers;"
- The information relating to our audit committee, audit committee financial expert and procedures by which shareholders may recommend nominees to our board of directors is to be included in the section entitled "Corporate Governance and Board Matters;" and
- The information regarding compliance with Section 16(a) of the Exchange Act is to be included in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance."

Such information is incorporated herein by reference to our 2020 Proxy Statement, provided that if the 2020 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.

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* under the section entitled "About" under "Corporate Ethics." 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 2020 Proxy Statement 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, provided that if the 2020 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 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 2020 Proxy Statement under the section entitled "Equity Compensation Plan Information" and the information required by this item with respect to security ownership of certain beneficial owners and management is to be included in our 2020 Proxy Statement under the section entitled "Security Ownership of Certain Beneficial Owners and Management" and in each case is incorporated herein by reference, provided that if the 2020 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 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is to be included in our 2020 Proxy Statement under the sections entitled "Certain Relationships and Related Party Transactions" and "Corporate Governance and Board Matters—Independence of the Board of Directors" and is incorporated herein by reference, provided that if the 2020 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 14. Principal Accountant Fees and Services

The information required by this item is to be included in our 2020 Proxy Statement under the section entitled "Proposal 2—On a Non-Binding Advisory Basis, Ratify Appointment of Independent Registered Accounting Firm and, On a Binding Basis, Authorize the Board of Directors, Acting Through the Audit Committee, to Determine the Independent Auditors' Remuneration" and is incorporated herein by reference, provided that if the 2020 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.

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-44 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:

Exhibit Number	Description of Document
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 herein 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	Tender Offer Agreement, dated December 19, 2013, by and among Jazz Pharmaceuticals Public Limited Company, Jazz Pharmaceuticals Italy S.r.l. and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K/A (File No. 001-33500), as filed with the SEC on December 20, 2013).

2.6†	Asset Purchase Agreement, dated January 13, 2014, by and among Jazz Pharmaceuticals International III Limited, Aerial BioPharma, LLC and Jazz Pharmaceuticals plc (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 January 13, 2014).
2.7†	Assignment Agreement, dated July 1, 2014, by and among Jazz Pharmaceuticals International II Limited, Sigma-Tau Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Gentium S.p.A. (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 August 5, 2014).
2.8	Amended and Restated Agreement for the Acquisition of the Topaz Portfolio Business of Jazz Pharmaceuticals plc, dated March 20, 2015, between Jazz Pharmaceuticals plc and Essex Bidco Limited (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 March 23, 2015).
2.9	Agreement and Plan of Merger, dated as of May 27, 2016, by and among Jazz Pharmaceuticals plc, Plex Merger Sub, Inc., and Celator Pharmaceuticals, 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 May 31, 2016).
3.1	Amended and Restated Memorandum and Articles of Association of Jazz Pharmaceuticals plc, as amended on August 4, 2016 (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2016, as filed with the SEC on August 9, 2016).
4.1	Reference is made to Exhibit 3.1.
4.3A	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).
4.3B	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).
4.4A	Indenture, dated as of August 13, 2014, by and among Jazz Pharmaceuticals plc, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.4B	Form of 1.875% Exchangeable Senior Note due 2021 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.5A	Indenture, dated as of August 23, 2017, among Jazz Pharmaceuticals Public Limited Company, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 23, 2017).
4.5B	Form of 1.50% Exchangeable Senior Note due 2024 (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 23, 2017).
4.6	Description of Share Capital
10.1	Settlement Agreement, dated as of April 5, 2017, by and between Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited, and Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Eurohealth (USA), Inc., and Hikma Pharmaceuticals PLC (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2017, as filed with the SEC on August 8, 2017).
10.2	Settlement Agreement, dated as of April 4, 2019, by and among United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Ltd. (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).
10.3	Corporate Integrity Agreement, dated as of April 3, 2019, by and between Jazz Pharmaceuticals plc and the Office of Inspector General of the United States Department of Health and Human Services (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).

10.4†	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).
10.5†	Royalty Bearing Licence Agreement and Supply Agreement Re Erwinia-Derived Asparaginase, dated July 22, 2005, between Public Health England (formerly 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) for the period ended June 30, 2012, as filed with the SEC on August 9, 2012).
10.6	Novation Agreement relating to Royalty Bearing Licence Agreement and Supply Agreement re Erwinia-Derived Asparaginase, dated as of May 13, 2015, by and among EUSA Pharma SAS, the Secretary of State for Health acting through Public Health England and Porton Biopharma Limited (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, 2015, as filed with the SEC on August 5, 2015).
10.7	Contract Variation Agreement by and between Porton Biopharma Limited and Jazz Pharmaceuticals France SAS, dated as of December 20, 2018 (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2018, as filed with the SEC on February 26, 2019).
10.8†	Master Manufacturing Services Agreement, dated as of October 1, 2015, by and between Jazz Pharmaceuticals Ireland Limited and Patheon Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2015, as filed with the SEC on February 23, 2016).
10.9A†	Clinical and Commercial Manufacturing and Supply Agreement, dated as of December 22, 2010, between Celator Pharmaceuticals, Inc. and Baxter Oncology GmbH (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the year ended December 31, 2017, as filed with the SEC on February 27, 2018).
10.9B†	Amendment No. 1 Clinical and Commercial Manufacturing and Supply Agreement, dated as of January 18, 2018, by and between Jazz Pharmaceuticals Ireland Limited and Baxter Oncology GmbH (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 March 31, 2018, as filed with the SEC on May 8, 2018).
10.10‡	Contract Manufacturing Agreement, dated as of January 20, 2020, by and between Jazz Pharmaceuticals Ireland Limited and Siegfried AG.
10.11A†	Pharmacy Master Services Agreement, dated as of July 1, 2017, by and between Jazz Pharmaceuticals, Inc. and Express Scripts Specialty Distribution Services, Inc. (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2017, as filed with the SEC on August 8, 2017).
10.11B	Amendment No. 1 to Pharmacy Master Services Agreement, effective as of June 30, 2019, by and between Jazz Pharmaceuticals, Inc. and Express Scripts Specialty Distribution Services, Inc. (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).
10.12‡	License Agreement, dated as of December 19, 2019, between Pharma Mar, S.A. and Jazz Pharmaceuticals Ireland Limited (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 January 22, 2020).
10.13A	Credit Agreement, dated as of June 18, 2015, among Jazz Pharmaceuticals plc, Jazz Securities Limited, Jazz Pharmaceuticals, Inc., Jazz Financing I Limited, Jazz Pharmaceuticals Ireland Limited, the lenders party thereto and Bank of America, N.A., as Collateral Agent, Administrative 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 18, 2015).
10.13B	Amendment No. 1, dated as of July 12, 2016, to Credit Agreement, dated as of June 18, 2015, among Jazz Pharmaceuticals plc, Jazz Securities Limited, Jazz Pharmaceuticals, Inc., Jazz Financing I Limited, Jazz Pharmaceuticals Ireland Limited, the lenders party thereto and Bank of America, N.A., as Collateral Agent, Administrative Agent, Swing Line Lender and L/C Issuer (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2016, as filed with the SEC on August 9, 2016).

10.13C	Amendment No. 2, dated as of June 7, 2018, to Credit Agreement, dated as of June 18, 2015 (as previously amended by Amendment No. 1, dated as of July 12, 2016), among Jazz Pharmaceuticals plc, Jazz Securities Designated Activity Company, Jazz Pharmaceuticals, Inc., Jazz Financing I Designated Activity Company, Jazz Pharmaceuticals Ireland Limited, the lenders party thereto and Bank of America, N.A., as Collateral Agent, Administrative Agent, Swing Line Lender and L/C Issuer (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2018, as filed with the SEC on August 7, 2018).
10.14A	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).
10.14B	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).
10.14C	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).
10.15	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.16A	Commercial Lease, dated as of January 7, 2015, by and between The Board of Trustees of the Leland Stanford Junior University and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.10 in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2014, as filed with the SEC on February 24, 2015).
10.16B	First Amendment, dated as of January 29, 2018, to Commercial Lease, dated as of January 7, 2015, by and between The Board of Trustees of the Leland Stanford Junior University and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2018, as filed with the SEC on August 7, 2018).
10.16C	Second Amendment, dated as of July 26, 2018, to Commercial Lease, dated as of January 7, 2015, by and between The Board of Trustees of the Leland Stanford Junior University and Jazz Pharmaceuticals, Inc., as previously amended by the First Amendment to Lease, dated as of January 29, 2018 (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2018, as filed with the SEC on November 6, 2018).
10.17A	Commercial Lease, dated as of September 22, 2017, by and between Jazz Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2017, as filed with the SEC on November 7, 2017).
10.17B	First Amendment, dated as of January 29, 2018, to Commercial Lease, dated as of September 22, 2017, by and between The Board of Trustees of the Leland Stanford Junior University and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2018, as filed with the SEC on August 7, 2018).
10.18+	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).
10.19+	Offer Letter from Jazz Pharmaceuticals, Inc. to Matthew Young (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 March 31, 2014, as filed with the SEC on May 8, 2014).
10.20+	Offer Letter from Jazz Pharmaceuticals, Inc. to Michael Miller (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2014, as filed with the SEC on November 4, 2014).
10.21+	Transition and Termination Agreement, dated as of November 2, 2019, by and between Jazz Pharmaceuticals, Inc. and Mike Miller (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).

10.22+	Compromise Agreement, dated as of October 5, 2019, by and between Jazz Pharmaceuticals Ireland Limited and Paul Treacy.
10.23+	Offer Letter from Jazz Pharmaceuticals, Inc. to Daniel N. Swisher, Jr. (incorporated herein by reference to Exhibit 10.21 in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the year ended December 31, 2017, as filed with the SEC on February 27, 2018).
10.24+	Offer Letter from Jazz Pharmaceuticals, Inc. to Robert Iannone dated as of April 11, 2019 (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2019, as filed with the SEC on August 6, 2019).
10.25A+	Employment Agreement, dated as of May 16, 2012 by and between Patricia Carr and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).
10.25B+	Change in Control Severance Terms, dated as of May 15, 2016, by and between Jazz Pharmaceuticals Ireland Ltd. and Patricia Carr (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).
10.25C+	Change in Control Stock Award Acceleration Agreement, dated as of May 15, 2016 by and between Jazz Pharmaceuticals plc and Patricia Carr (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 September 30, 2019, as filed with the SEC on November 5, 2019).
10.26+	Offer Letter, dated as of July 5, 2019 by and between Jazz Pharmaceuticals, Inc. and Neena M. Patil (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).
10.27+	Employment Contract, dated as of February 22, 2013, by and between Jazz Pharmaceuticals Ireland Limited and Finbar Larkin.
10.28A+	Employment Contract, dated as of December 14, 2019, by and between Jazz Pharmaceuticals UK Limited and Samantha Pearce.
10.28B+	Equity Award Letter, dated as of December 9, 2019, by and between Jazz Pharmaceuticals UK Limited and Samantha Pearce.
10.29A+	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).
10.29B+	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).
10.29C+	Form of Notice of Grant of Stock Options and Form of Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27C in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.29D+	Form of Notice of Grant of Stock Options and Form of Option Agreement (Irish) under Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27D in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.29E+	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 (incorporated herein by reference to Exhibit 10.27E in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.29F+	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 (incorporated herein by reference to Exhibit 10.27F in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.29G+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).

10.29H+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan - Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.30A+	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).
10.30B+	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).
10.30C+	Form of Stock Option Grant Notice and Form of 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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.30D+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.30E+	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 (incorporated herein by reference to Exhibit 10.28E in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.30F+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.30G+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.30H+	Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.28H in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.30I+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of U.S. Option Grant Notice and Form of U.S. Option Agreement (approved July 31, 2013) (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 September 30, 2013, as filed with the SEC on November 5, 2013).
10.30J+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of U.S. Restricted Stock Unit Award Grant Notice and Form of U.S. Restricted Stock Unit Award Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.30K+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.30L+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.30M+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2016, as filed with the SEC on May 10, 2016).

10.30N+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2016, as filed with the SEC on May 10, 2016).
10.30O+	Amended and Restated 2011 Equity Incentive Plan (approved August 4, 2016) (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2016, as filed with the SEC on August 9, 2016).
10.30P+	Amended and Restated 2011 Equity Incentive Plan (approved November 3, 2016) (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).
10.30Q+	Form of U.S. Restricted Stock Unit Award Grant Notice and Form of U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).
10.30R+	Form of U.S. Option Grant Notice and Form of U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 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) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).
10.30S+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 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) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).
10.30T+	Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2018, as filed with the SEC on August 7, 2018).
10.30U+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (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, 2018, as filed with the SEC on August 7, 2018).
10.30V+	Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).
10.30W+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).
10.31+	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).
10.32A+	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).
10.32B+	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 (incorporated herein by reference to Exhibit 10.30B in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.32C+	Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved August 1, 2013) (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).

10.32D+	Amended and Restated 2007 Non-Employee Directors Stock Award Plan (approved August 4, 2016) (incorporated herein by reference to Exhibit 10.9 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2016, as filed with the SEC on August 9, 2016).
10.32E+	Amended and Restated 2007 Non-Employee Directors Stock Award Plan (approved November 3, 2016) (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 September 30, 2016, as filed with the SEC on November 8, 2016).
10.32F+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).
10.32G+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated Non-Employee Directors 2007 Stock Award Plan (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).
10.32H+	Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2018, as filed with the SEC on November 6, 2018).
10.32I+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (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 September 30, 2018, as filed with the SEC on November 6, 2018).
10.32J+	Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).
10.32K+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (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 March 31, 2019, as filed with the SEC on May 7, 2019).
10.33A+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 10.31A in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.33B+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Sub-Plan Governing Purchase Rights to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.14C 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 May 8, 2012).
10.34A+	Jazz Pharmaceuticals plc Cash Bonus Plan for U.S. Affiliates (approved October 31, 2018) (incorporated herein by reference to Exhibit 10.26C in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2018, as filed with the SEC on February 26, 2019).
10.34B+	Jazz Pharmaceuticals Cash Bonus Plan (Ireland and Other Specified Affiliates) (Calendar Year 2019) (incorporated herein by reference to Exhibit 10.26D in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2018, as filed with the SEC on February 26, 2019).
10.34C+	Jazz Pharmaceuticals plc Cash Bonus Plan for U.S. Affiliates (approved October 30, 2019).
10.34D+	Jazz Pharmaceuticals Cash Bonus Plan (Ireland and Other Specified Affiliates) (Calendar Year 2020).
10.35+	Amended and Restated Executive Change in Control and Severance Benefit Plan, dated as of July 31, 2019 (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).

10.36A+	Amended and Restated Non-Employee Director Compensation Policy (approved May 5, 2016) (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2016, as filed with the SEC on August 9, 2016).
10.36B+	Amended and Restated Non-Employee Director Compensation Policy (approved May 3, 2018) (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2018, as filed with the SEC on August 7, 2018).
21.1	Subsidiaries of Jazz Pharmaceuticals plc.
23.1	Consent of KPMG, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page hereto).
31.1	Certification of Principal Executive Officer and Interim Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer and Interim Principal 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 - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+ 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.

‡ Pursuant to Item 601(b)(2) of Regulation S-K, certain portions of this agreement have been omitted because the omitted portions are both not material and would likely cause competitive harm to Jazz Pharmaceuticals if publicly disclosed.

* 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.

Item 16. Form 10-K Summary

None.

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 25, 2020

Jazz Pharmaceuticals public limited company
(Registrant)

/s/ BRUCE C. COZADD

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director
(Principal Executive Officer and Interim Principal Financial Officer)

/s/ PATRICIA CARR

Patricia Carr
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, Neena M. Patil and Patricia Carr, 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:

Signature	Title	Date
/s/ BRUCE C. COZADD **Bruce C. Cozadd**	Chairman, Chief Executive Officer and Director *(Duly Authorizer Officer, Principal Executive Officer and Interim Principal Financial Officer)*	February 25, 2020
/s/ PATRICIA CARR **Patricia Carr**	Vice President, Finance *(Principal Accounting Officer)*	February 25, 2020
/s/ PAUL L. BERNS **Paul L. Berns**	Director	February 25, 2020
/s/ PATRICK G. ENRIGHT **Patrick G. Enright**	Director	February 25, 2020
/s/ PETER GRAY **Peter Gray**	Director	February 25, 2020
/s/ HEATHER ANN MCSHARRY **Heather Ann McSharry**	Director	February 25, 2020
/s/ SEAMUS C. MULLIGAN **Seamus C. Mulligan**	Director	February 25, 2020
/s/ KENNETH W. O'KEEFE **Kenneth W. O'Keefe**	Director	February 25, 2020
/s/ ANNE O'RIORDAN **Anne O'Riordan**	Director	February 25, 2020
/s/ NORBERT G. RIEDEL, PH.D. **Norbert G. Riedel, Ph.D.**	Director	February 25, 2020
/s/ ELMAR SCHNEE **Elmar Schnee**	Director	February 25, 2020
/s/ CATHERINE A. SOHN, PHARM.D. **Catherine A. Sohn, Pharm.D.**	Director	February 25, 2020
/s/ RICK E WINNINGHAM **Rick E Winningham**	Director	February 25, 2020

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Jazz Pharmaceuticals plc:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Jazz Pharmaceuticals plc and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes and financial statement schedule at Item 15(a)2 (collectively, "the consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 25, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Assessment of the impairment analysis for the Vyxeos and Erwinaze/se intangible assets

As discussed in notes 2 and 9 to the consolidated financial statements, the finite-lived intangible assets balance as of December 31, 2019 was $2.3 billion, a substantial portion of which relates to finite-lived intangible assets in respect of Vyxeos and to a lesser extent, Erwinaze/se. The Company reviews finite-lived intangible assets for impairment when events or circumstances indicate that the carrying value of such assets may not be recoverable.

We identified the assessment of the impairment analysis for the Vyxeos and Erwinaze/se intangible assets as a critical audit matter. There was a high degree of subjectivity in assessing the significant assumptions upon which the revenue forecasts are dependent, specifically the Company's revenue growth rates for Vyxeos and supply forecasts for Erwinaze/se.

The primary procedures we performed to address this critical audit matter included the following:

- We tested certain internal controls over the Vyxeos and Erwinaze/se intangible asset impairment review processes, including controls related to the development of the revenue growth rate assumptions for Vyxeos and supply forecast assumptions for Erwinaze/se;
- We compared the Company's historical forecasted revenue growth rate assumptions for Vyxeos and historical supply forecast assumptions for Erwinaze/se to actual results to assess the Company's ability to accurately forecast;

- We evaluated the reasonableness of management's revenue growth rate assumptions for Vyxeos and supply forecast assumptions for Erwinaze/se by comparing those assumptions to (1) company-specific operational information and management's communications to the board of directors, (2) available third-party reports on expected market share, and (3) industry reports containing analyses of the Company's and its competitor's products; and
- We performed sensitivity analyses over the revenue growth rate assumptions for Vyxeos and supply forecast assumptions for Erwinaze/se to assess the impact of changes to those assumptions on the Company's determination of the carrying value of the Vyxeos and Erwinaze/se intangible assets.

Evaluation of the recoverability of U.S. and Irish deferred tax assets

As discussed in notes 2 and 21 to the consolidated financial statements, the Company had $642.1 million of deferred tax assets as of December 31, 2019, a substantial proportion of which relates to U.S. net operating losses (NOLs) and tax credits carried forward, and differences between the financial statement carrying amounts of Irish assets and liabilities and their respective tax basis.

We identified evaluation of the recoverability of U.S. and Irish deferred tax assets as a critical audit matter due to the subjectivity involved in assessing the Company's forecast of sufficient future taxable income in periods where losses or tax credits are available for use. In particular, evaluating the Company's revenue growth rate assumptions involved a high degree of auditor judgment.

The primary procedures we performed to address this critical audit matter included the following:

- We tested certain internal controls over the Company's deferred tax asset valuation allowance process including controls related to the development of revenue growth rate assumptions;
- We involved income tax professionals with specialized skills and knowledge, who assisted in performing a technical assessment of the Company's tax positions, application of the relevant tax regulations and utilization of NOLs and tax credits; and
- To assess the Company's ability to forecast, we compared the Company's previous forecasts to actual historic outcomes and compared current assumptions to underlying calculations. We assessed the integrity of underlying calculations and we checked certain information to third party sources, including expectations of performance of certain assets.

We have served as the Company's auditor since 2012.

/s/ KPMG

Dublin, Ireland

February 25, 2020

JAZZ PHARMACEUTICALS PLC

CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 637,344	$ 309,622
Investments	440,000	515,000
Accounts receivable, net of allowances of $1,296 and $534 at December 31, 2019 and 2018, respectively	355,987	263,838
Inventories	78,608	52,956
Prepaid expenses	39,434	25,017
Other current assets	78,895	67,572
Total current assets	1,630,268	1,234,005
Property, plant and equipment, net	131,506	200,358
Operating lease assets	139,385	—
Intangible assets, net	2,440,977	2,731,334
Goodwill	920,018	927,630
Deferred tax assets, net	221,403	57,879
Deferred financing costs	7,426	9,589
Other non-current assets	47,914	42,696
Total assets	$ 5,538,897	$ 5,203,491
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 47,545	$ 40,602
Accrued liabilities	267,873	264,887
Current portion of long-term debt	33,387	33,387
Income taxes payable	10,965	1,197
Deferred revenue	4,720	5,414
Total current liabilities	364,490	345,487
Deferred revenue, non-current	4,861	9,581
Long-term debt, less current portion	1,573,870	1,563,025
Operating lease liabilities, less current portion	151,226	—
Deferred tax liabilities, net	224,095	309,097
Other non-current liabilities	109,374	218,879
Commitments and contingencies (Note 13)		
Shareholders' equity:		
Ordinary shares, nominal value $0.0001 per share; 300,000 shares authorized; 56,140 and 57,504 shares issued and outstanding at December 31, 2019 and 2018, respectively	6	6
Non-voting euro deferred shares, €0.01 par value per share; 4,000 shares authorized, issued and outstanding at both December 31, 2019 and 2018	55	55
Capital redemption reserve	472	472
Additional paid-in capital	2,266,026	2,113,630
Accumulated other comprehensive loss	(223,393)	(197,791)
Retained earnings	1,067,815	841,050
Total shareholders' equity	3,110,981	2,757,422
Total liabilities and shareholders' equity	$ 5,538,897	$ 5,203,491

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,		
	2019	2018	2017
Revenues:			
Product sales, net	$ 2,135,601	$ 1,869,473	$ 1,601,399
Royalties and contract revenues	26,160	21,449	17,294
Total revenues	2,161,761	1,890,922	1,618,693
Operating expenses:			
Cost of product sales (excluding amortization of acquired developed technologies)	127,930	121,544	110,188
Selling, general and administrative	736,942	683,530	544,156
Research and development	299,726	226,616	198,442
Intangible asset amortization	354,814	201,498	152,065
Impairment charges	—	42,896	—
Acquired in-process research and development	109,975	—	85,000
Total operating expenses	1,629,387	1,276,084	1,089,851
Income from operations	532,374	614,838	528,842
Interest expense, net	(72,261)	(77,075)	(77,756)
Foreign exchange loss	(5,811)	(6,875)	(9,969)
Loss on extinguishment and modification of debt	—	(1,425)	—
Income before income tax provision (benefit) and equity in loss of investees	454,302	529,463	441,117
Income tax provision (benefit)	(73,154)	80,162	(47,740)
Equity in loss of investees	4,089	2,203	1,009
Net income	$ 523,367	$ 447,098	$ 487,848
Net income per ordinary share:			
Basic	$ 9.22	$ 7.45	$ 8.13
Diluted	$ 9.09	$ 7.30	$ 7.96
Weighted-average ordinary shares used in per share calculations - basic	56,749	59,976	60,018
Weighted-average ordinary shares used in per share calculations - diluted	57,550	61,221	61,317

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

JAZZ PHARMACEUTICALS PLC

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Net income	$ 523,367	$ 447,098	$ 487,848
Other comprehensive income (loss):			
Foreign currency translation adjustments	(20,720)	(58,988)	174,973
Unrealized gain (loss) on hedging activities, net of income tax provision (benefit) of ($697), $289 and $212, respectively	(4,882)	2,022	1,482
Other comprehensive income (loss)	(25,602)	(56,966)	176,455
Total comprehensive income	$ 497,765	$ 390,132	$ 664,303

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 (Loss)	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2016	59,820	$ 6	4,000	$ 55	$ 472	$ 1,665,232	$ (317,333)	$ 528,907	$1,877,339
Issuance of Exchangeable Senior Notes	—	—	—	—	—	149,767	—	—	149,767
Issuance of ordinary shares in conjunction with exercise of share options	428	—	—	—	—	22,683	—	—	22,683
Issuance of ordinary shares under employee stock purchase plan	104	—	—	—	—	9,141	—	—	9,141
Issuance of ordinary shares in conjunction with vesting of restricted stock units	250	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(18,589)	—	—	(18,589)
Share-based compensation	—	—	—	—	—	107,252	—	—	107,252
Shares repurchased	(704)	—	—	—	—	—	—	(98,799)	(98,799)
Other comprehensive income	—	—	—	—	—	—	176,455	—	176,455
Net income	—	—	—	—	—	—	—	487,848	487,848
Balance at December 31, 2017	59,898	6	4,000	55	472	1,935,486	(140,878)	917,956	2,713,097
Cumulative effect adjustment from adoption of new accounting standards	—	—	—	—	—	—	53	(332)	(279)
Issuance of ordinary shares in conjunction with exercise of share options	772	—	—	—	—	82,918	—	—	82,918
Issuance of ordinary shares under employee stock purchase plan	111	—	—	—	—	10,419	—	—	10,419
Issuance of ordinary shares in conjunction with vesting of restricted stock units	253	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(17,925)	—	—	(17,925)
Share-based compensation	—	—	—	—	—	102,732	—	—	102,732
Shares repurchased	(3,530)	—	—	—	—	—	—	(523,672)	(523,672)
Other comprehensive loss	—	—	—	—	—	—	(56,966)	—	(56,966)
Net income	—	—	—	—	—	—	—	447,098	447,098
Balance at December 31, 2018	57,504	$ 6	4,000	$ 55	$ 472	$ 2,113,630	$ (197,791)	$ 841,050	$2,757,422

JAZZ PHARMACEUTICALS PLC

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY—(Continued)
(In thousands)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2018	57,504	$ 6	4,000	$ 55	$ 472	$ 2,113,630	$ (197,791)	$ 841,050	$2,757,422
Cumulative effect adjustment from adoption of new accounting standards	—	—	—	—	—	—	—	4,848	4,848
Issuance of ordinary shares in conjunction with exercise of share options	515	—	—	—	—	46,477	—	—	46,477
Issuance of ordinary shares under employee stock purchase plan	106	—	—	—	—	11,354	—	—	11,354
Issuance of ordinary shares in conjunction with vesting of restricted stock units	265	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(16,739)	—	—	(16,739)
Share-based compensation	—	—	—	—	—	111,304	—	—	111,304
Shares repurchased	(2,250)	—	—	—	—	—	—	(301,450)	(301,450)
Other comprehensive loss	—	—	—	—	—	—	(25,602)	—	(25,602)
Net income	—	—	—	—	—	—	—	523,367	523,367
Balance at December 31, 2019	56,140	$ 6	4,000	$ 55	$ 472	$ 2,266,026	$ (223,393)	$1,067,815	$3,110,981

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,		
	2019	2018	2017
Operating activities			
Net income	$ 523,367	$ 447,098	$ 487,848
Adjustments to reconcile net income to net cash provided by operating activities:			
Intangible asset amortization	354,814	201,498	152,065
Share-based compensation	110,563	102,441	106,900
Impairment charges	—	42,896	—
Depreciation	15,342	15,233	13,089
Acquired in-process research and development	109,975	—	85,000
Loss on disposal of assets	21	655	473
Deferred tax benefit	(236,610)	(88,815)	(225,591)
Provision for losses on accounts receivable and inventory	6,668	4,728	2,190
Loss on extinguishment and modification of debt	—	1,425	—
Amortization of debt discount and deferred financing costs	46,396	43,960	30,026
Other non-cash transactions	(4,051)	4,499	14,321
Changes in assets and liabilities:			
Accounts receivable	(92,326)	(40,132)	12,278
Inventories	(32,790)	(18,512)	(8,667)
Prepaid expenses and other current assets	(25,650)	6,697	(26,874)
Other non-current assets	(14,830)	(320)	119
Operating lease assets	14,148	—	—
Accounts payable	4,770	17,040	214
Accrued liabilities	(5,565)	71,208	(6,578)
Income taxes payable	10,056	(19,735)	16,331
Deferred revenue	(5,414)	(7,497)	21,009
Other non-current liabilities	3,561	14,537	18,934
Operating lease liabilities, less current portion	(6,044)	—	—
Net cash provided by operating activities	776,401	798,904	693,087
Investing activities			
Acquisition of investments	(917,100)	(1,165,915)	(385,000)
Proceeds from maturity of investments	985,000	855,000	230,000
Acquired in-process research and development	(61,700)	—	(85,000)
Purchases of property, plant and equipment	(40,135)	(20,370)	(28,950)
Asset acquisition, net of cash acquired	(55,074)	—	—
Acquisition of intangible assets	(80,500)	(111,100)	—
Net proceeds from sale of assets	14,209	47,898	—
Net cash used in investing activities	(155,300)	(394,487)	(268,950)
Financing activities			
Proceeds from employee equity incentive and purchase plans	57,831	93,337	31,824
Share repurchases	(301,450)	(523,672)	(98,799)
Payment of employee withholding taxes related to share-based awards	(16,739)	(17,925)	(18,589)
Repayments of long-term debt	(33,387)	(25,717)	(36,094)
Payment of debt modification costs	—	(6,406)	—
Repayments under revolving credit facility	—	—	(850,000)
Proceeds from tenant improvement allowance on build-to-suit lease	—	1,253	3,154
Net proceeds from issuance of debt	—	—	559,393
Net cash used in financing activities	(293,745)	(479,130)	(409,111)
Effect of exchange rates on cash and cash equivalents	366	(1,700)	5,046
Net increase (decrease) in cash and cash equivalents	327,722	(76,413)	20,072
Cash and cash equivalents, at beginning of period	309,622	386,035	365,963
Cash and cash equivalents, at end of period	$ 637,344	$ 309,622	$ 386,035

JAZZ PHARMACEUTICALS PLC

CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)
(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 43,002	$ 42,706	$ 44,609
Cash paid for income taxes	183,610	164,217	174,124
Non-cash investing activities:			
Amounts capitalized in connection with facility lease obligations	—	27,747	40,970

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 is a global biopharmaceutical company dedicated to developing life-changing medicines for people with serious diseases – often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep medicine and movement disorders, and in oncology, including hematologic and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies.

Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in both adult and pediatric patients with narcolepsy;
- **Sunosi® (solriamfetol)**, a product approved by the FDA and marketed in the U.S. to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea and also approved in Europe in January 2020 by the European Commission;
- **Defitelio® (defibrotide sodium)**, a product approved in the U.S. for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Europe (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children undergoing HSCT therapy;
- **Erwinaze® (asparaginase *Erwinia chrysanthemi*)**, a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia who have developed hypersensitivity to *E. coli*-derived asparaginase; and
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or AML, or AML with myelodysplasia-related changes.

In February 2020, the FDA accepted for filing with priority review the new drug application, or NDA, for lurbinectedin for the treatment of relapsed small cell lung cancer, or SCLC, a product candidate for which we recently acquired exclusive U.S. development and commercialization rights. In January 2020, we submitted an NDA to the FDA seeking marketing approval for JZP-258, an oxybate product candidate that contains 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem, for the treatment of cataplexy and EDS in narcolepsy patients seven years of age and older. We also have in development JZP-458, a recombinant *Erwinia* asparaginase product candidate, for the treatment of pediatric and adult patients with ALL or lymphoblastic lymphoma, or LBL, who are hypersensitive to *E. coli*-derived asparaginase products.

Our strategy to create shareholder value is focused on:

- Strong financial execution through growth in sales of our current lead marketed products;
- Building a diversified product portfolio and development pipeline through a combination of our internal research and development efforts and obtaining rights to clinically meaningful and differentiated on- or near-market products and early- to late-stage product candidates through acquisitions, collaborations, licensing arrangements, partnerships and venture investments; and
- Maximizing the value of our products and product candidates by continuing to implement our comprehensive global development plans, including through generating additional clinical data and seeking regulatory approval for new indications and new geographies.

Throughout this report, unless otherwise indicated or the context otherwise requires, all references to "Jazz Pharmaceuticals," "the registrant," "we," "us," and "our" refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries. Throughout this report, all references to "ordinary shares" refer to Jazz Pharmaceuticals plc's ordinary shares.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and include the accounts of Jazz Pharmaceuticals plc and our subsidiaries and intercompany transactions and balances have been eliminated. Our consolidated financial statements include the results of operations of businesses we have acquired from the date of each acquisition for the applicable reporting periods.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures 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.

Adoption of New Accounting Standards

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02. Under the new guidance, lessees are required to recognize a right-of-use asset, which represents the lessee's right to use, or control the use of, a specified asset for the lease term, and a corresponding lease liability, which represents the lessee's obligation to make lease payments under a lease, measured on a discounted basis. We adopted ASU No. 2016-02 on a modified retrospective basis applied to leases existing as of, or entered into after, January 1, 2019. We elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification of those leases in place as of January 1, 2019.

The adoption of ASU No. 2016-02 resulted in the recognition of right-of-use assets and lease liabilities of $149.4 million and $162.9 million, respectively, on the consolidated balance sheet as of January 1, 2019, and the de-recognition of the build-to-suit assets and related financing obligations on the consolidated balance sheet as of December 31, 2018 of $95.4 million and $109.8 million, respectively, with the balance impacting retained earnings, deferred rent and deferred tax liabilities. The right-of-use assets and lease liabilities primarily relate to real estate leases. Refer to Note 12 for lease-related disclosures.

The cumulative effect of the changes made to our consolidated balance sheet as of January 1, 2019 for the adoption of the ASU No. 2016-02 was as follows (in thousands):

	Balance at December 31, 2018	Transition Adjustments	Balance at January 1, 2019
Assets:			
Property, plant and equipment, net	$ 200,358	$ (95,397)	$ 104,961
Operating lease assets	—	149,442	149,442
Liabilities:			
Accrued liabilities	264,887	8,165	273,052
Operating lease liabilities, less current portion	—	153,158	153,158
Deferred tax liabilities, net	309,097	1,489	310,586
Other non-current liabilities	218,879	(113,615)	105,264
Shareholders' Equity:			
Retained earnings	841,050	4,848	845,898

Significant Risks and Uncertainties

Our financial results are significantly influenced by sales of Xyrem. Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties including, without limitation, the introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, Xyrem in the treatment of cataplexy and/or EDS in narcolepsy, including generic or authorized generic versions of sodium oxybate; increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors; challenges to our intellectual property around Xyrem; and continued acceptance of Xyrem by physicians and patients.

In addition to risks related specifically to Xyrem, we are subject to other challenges and risks specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry

with development and commercial operations, including, without limitation, risks and uncertainties associated with: obtaining regulatory approval of our late-stage product candidates and effectively commercializing our approved products such as Sunosi and, if approved, JZP-258 and lurbinectedin; obtaining and maintaining adequate coverage and reimbursement for our products; increasing scrutiny of pharmaceutical product pricing and resulting changes in healthcare laws and policy; market acceptance; delays or problems in the supply of our products, loss of single source suppliers or failure to comply with manufacturing regulations; identifying, acquiring or in-licensing additional products or product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; the challenges of protecting and enhancing our intellectual property rights; complying with applicable regulatory requirements; and possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash, cash equivalents, investments and derivative contracts. 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 investments to the extent recorded on the balance sheet.

We manage our foreign currency transaction risk and interest rate risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of December 31, 2019 and 2018, we had foreign exchange forward contracts with notional amounts totaling $180.9 million and $271.5 million, respectively. As of December 31, 2019 and 2018, the outstanding foreign exchange forward contracts had a net asset fair value of $2.3 million and a net liability fair value of $0.3 million, respectively. As of December 31, 2019 and 2018, we had interest rate swap contracts with notional amounts totaling $300.0 million. These outstanding interest rate swap contracts had a net liability fair value of $1.5 million and a net asset fair value of $4.1 million as of December 31, 2019 and 2018, respectively. The counterparties to these contracts are large multinational commercial banks, and we believe the risk of nonperformance is not significant.

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 pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the U.S., and to other international distributors and hospitals. 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 as of December 31, 2019, allowances on receivables were not material. As of December 31, 2019, two customers accounted for 89% of gross accounts receivable, Express Scripts Specialty Distribution Services, Inc. and its affiliates, or ESSDS, which accounted for 77% of gross accounts receivable, and McKesson Corporation and affiliates, or McKesson, which accounted for 12% of gross accounts receivable. As of December 31, 2018, two customers accounted for 89% of gross accounts receivable, ESSDS, which accounted for 74% of gross accounts receivable, and McKesson, which accounted for 15% of gross accounts receivable.

We depend on single source suppliers for most of our products, product candidates and their APIs. With respect to Xyrem, the API is manufactured for us by a single source supplier and the finished product is manufactured both by us in our facility in Athlone, Ireland and by our U.S.-based Xyrem supplier.

Business Acquisitions

Our consolidated financial statements include the results of operations of an acquired business from the date of 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, liabilities assumed and any noncontrolling interests in the acquired business 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Cash Equivalents and Investments

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.

Investments consist of time deposits with initial maturities of greater than three months. Collectively, cash equivalents and investments are considered available-for-sale and are recorded at fair value. Unrealized gains and losses, net of tax, are recorded in accumulated other comprehensive 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 investments are included in interest expense, net in the consolidated statements of income.

Derivative Instruments and Hedging Activities

We record the fair value of derivative instruments as either assets or liabilities on the consolidated balance sheets. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction and, if it is, the type of hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, we formally document the nature and relationships between the hedging instruments and hedged item. We assess, both at inception and on an on-going basis, whether the derivative instruments that are used in cash flow hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. Gains or losses on cash flow hedges are reclassified from other comprehensive income (loss) to earnings when the hedged transaction occurs. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in current earnings. Derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings.

Inventories

Inventories are valued at the lower of cost or net realizable value. 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 product. If our estimate of future demand changes, we consider the impact on the reserve for excess inventory and adjust the reserve as required. Increases in the reserve are recorded as charges in cost of product sales.

We capitalize inventory costs associated with our products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval. We had no pre-approval inventory on our consolidated balance sheet as of December 31, 2019 or 2018.

Property, Plant and Equipment

Property, plant 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. Estimated useful lives are as follows:

Buildings	40 years
Manufacturing equipment and machinery	5-10 years
Computer software and equipment	3-7 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the noncancelable term of our leases or their economic useful lives. Maintenance and repairs are expensed as incurred.

Leases

We determine if an arrangement is a lease at inception. Operating leases are included in operating lease assets, other current liabilities, and operating lease liabilities on our consolidated balance sheets. Operating lease assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. In determining the net present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date. The operating lease asset also includes any lease payments made,

reduced by lease incentives and increased by initial direct costs incurred. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

We have lease agreements with lease and non-lease components, which are generally accounted for separately. For vehicle leases we account for the lease and non-lease components as a single lease component.

We have elected the short-term lease exemption and, therefore, do not recognize a right-of-use asset or corresponding liability for lease arrangements with an original term of 12 months or less. Rent expense under short-term leases is recognized on a straight-line basis over the lease term.

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.

Acquired In-Process Research and Development

The initial costs of rights to IPR&D projects acquired in an asset acquisition are expensed as IPR&D unless the project has an alternative future use. The fair value of IPR&D projects acquired in a business combination are capitalized and accounted for as indefinite-lived intangible assets until the underlying project receives regulatory approval, at which point the intangible asset will be accounted for as a finite-lived intangible asset, or discontinued, at which point the intangible asset will be written off. Development costs incurred after an acquisition are expensed as incurred.

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 18 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. Such assets 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 an asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying amount and the fair value of the impaired asset.

Revenue Recognition

Our revenue comprises product sales, net and royalty and contract revenues. Revenues are recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Product Sales, Net

Product sales revenue is recognized when control has transferred to the customer, which occurs at a point in time, 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.

Reserves for Variable Consideration

Revenues from sales of products are recorded at the net sales price, which includes estimates of variable consideration for which reserves are established and which relate to returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans and commercial payor contracts. Calculating certain of these reserves involves estimates and judgments and we determine their expected value 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. These reserves reflect our best estimates of the amount

of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. We reassess our reserves for variable consideration at each reporting date. Historically, adjustments to estimates for these reserves have not been material.

Reserves for returns, specialty distributor fees, wholesaler fees, government rebates, coupon programs and rebates under managed care plans and commercial payor contracts are included within current liabilities in our consolidated balance sheets. Reserves for government chargebacks and prompt payment discounts are shown as a reduction in accounts receivable.

Royalties and Contract Revenues

We enter into out-licensing agreements under which we license certain rights to our products or product candidates to third parties. If a licensing arrangement includes multiple goods or services, we consider whether the license is distinct. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. If the license to our intellectual property is determined not to be distinct, it is combined with other goods or services into a combined performance obligation. We consider whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting date and, if necessary, adjust the measure of performance and related revenue recognition.

At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or that of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price.

For arrangements that include sales-based royalties and milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties and sales-based milestones relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty or sales-based milestone has been allocated has been satisfied (or partially satisfied).

Cost of Product Sales

Cost of product sales includes 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. Excluded from cost of product sales shown on the consolidated statements of income is amortization of acquired developed technology of $243.7 million, $201.3 million and $149.1 million in 2019, 2018 and 2017, respectively.

Research and Development

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses and other research and development costs, including milestone payments incurred prior to regulatory approval of products. Clinical study and outside services costs relate primarily to services performed by clinical research organizations, clinical studies performed at clinical sites, materials and supplies, and other third party fees. Personnel expenses relate primarily to salaries, benefits and share-based compensation. 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. 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.

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $65.4 million, $37.4 million and $36.6 million in 2019, 2018 and 2017, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 recognize the benefits of a tax position if it is "more-likely-than-not" of being sustained. A recognized tax benefit is then measured as the largest amount of tax benefit that is greater than fifty percent likely of being realized upon settlement. Interest and penalties related to unrecognized tax benefits are included in the income tax provision 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 weighted 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 weighted average exchange rate for the reporting period. Any monetary assets and liabilities arising from these 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 exchange gain (loss) in our consolidated statements of income.

Deferred Financing Costs

Deferred financing costs are reported at cost, less accumulated amortization and are presented in the consolidated balance sheets as a direct deduction from the carrying value of the associated debt, with the exception of deferred financing costs associated with revolving-debt arrangements which are presented as assets. The related amortization expense is included in interest expense, net in our consolidated statements of income.

Contingencies

From time to time, we may become involved in claims and other legal matters arising in the ordinary course of business. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses.

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. 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 December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes", which simplifies the accounting for income taxes by removing certain exceptions to the general principles in the existing guidance for income taxes and making other minor improvements. The amendments are effective for annual reporting periods beginning after December 15, 2020 with early adoption permitted. We are currently evaluating the impact of adopting this new accounting guidance.

In August 2018, the FASB issued ASU No. 2018-15, "Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract", which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The standard is effective for us beginning January 1, 2020 and early adoption is permitted. The new guidance is not expected to have a material impact on our results of operations and financial position.

In January 2017, the FASB issued ASU No. 2017-04, "Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment" which simplifies the accounting for goodwill impairment by eliminating Step 2 of the current goodwill impairment test. Goodwill impairment will now be the amount by which the reporting unit's carrying value exceeds

its fair value, limited to the carrying value of the goodwill. The standard is effective for us beginning January 1, 2020. Early adoption is permitted for any impairment tests performed after January 1, 2017. The new guidance is not expected to have a material impact on our results of operations and financial position.

3. Asset Acquisition, Collaborations and Disposition

Asset Acquisition

On August 12, 2019, we announced the acquisition of Cavion, Inc., or Cavion, a clinical-stage biotechnology company, for an upfront payment of $52.5 million with the potential for additional payments of up to $260.0 million upon the achievement of certain clinical, regulatory and commercial milestones, for a total potential consideration of $312.5 million. As a result of the acquisition, we added JZP-385, a modulator of T-type calcium channels, for the potential treatment of essential tremor, to our clinical pipeline. The acquisition of Cavion was accounted for as an asset acquisition because it did not meet the definition of a business.

The following table summarizes the total consideration for the acquisition and the value of assets acquired and liabilities assumed (in thousands):

Consideration		
Upfront payment for acquisition of Cavion's outstanding shares	$	52,500
Cash acquired		397
Working capital adjustment		(255)
Transaction costs		2,829
Total consideration	$	55,471
Assets Acquired and Liabilities Assumed		
Cash	$	397
In-process research and development		48,275
Deferred tax assets		7,995
Other assets and liabilities		(1,196)
Total net assets acquired	$	55,471

The value attributed to in-process research and development relates to JZP-385 and was expensed as it was determined to have no alternative future use.

Collaboration and License Agreement

On January 2, 2019, we entered into a strategic collaboration agreement with Codiak BioSciences, Inc., or Codiak, focused on the research, development and commercialization of exosome therapeutics to treat cancer. Codiak granted us an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize therapeutic candidates directed at five targets to be developed using Codiak's engEx™ precision engineering platform for exosome therapeutics.

Under the terms of the agreement, Codiak is responsible for the execution of preclinical and early clinical development of therapeutic candidates directed at all five targets through Phase 1/2 proof of concept studies. Following the conclusion of the applicable Phase 1/2 study, we will be responsible for future development, potential regulatory submissions and commercialization for each product. Codiak has the option to participate in co-commercialization and cost/profit-sharing in the U.S. and Canada on up to two products.

As part of the agreement, we paid Codiak an upfront payment of $56.0 million in January 2019, which was recorded as acquired IPR&D expense in our consolidated statements of income for the year ended December 31, 2019. Codiak is eligible to receive up to $20 million in preclinical development milestone payments. Codiak is also eligible to receive milestone payments totaling up to $200 million per target based on investigational new drug application acceptance, clinical and regulatory milestones, including approvals in the U.S., the European Union and Japan, and certain sales milestones. Codiak is also eligible to receive tiered royalties on net sales of each approved product.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Collaboration and Option Agreement

In 2017, we entered into a collaboration and option agreement with ImmunoGen, Inc., or ImmunoGen, and we paid them a non-refundable upfront payment of $75.0 million, which was charged to acquired IPR&D expense upon closing of the transaction.

This agreement was amended in November 2019. Under the amended agreement we have the right to opt into an exclusive, worldwide license to develop and commercialize IMGN632, a CD123-targeted ADC for hematological malignancies, currently in Phase 1. ImmunoGen will be responsible for the development of IMGN632 prior to any potential opt-in by us. Following any opt-in, we would be responsible for any further development as well as for potential regulatory submissions and commercialization.

As part of the amended agreement, we will pay ImmunoGen up to $25 million in development funding. We may exercise our opt-in right at any time prior to a pivotal study or any time prior to a biologics license application upon payment of an option exercise fee. The option exercise fee depends on the timing of exercise and certain other conditions. If we elect to opt-in, ImmunoGen would be eligible to receive milestone payments based on receiving regulatory approval of the applicable product, plus tiered royalties as a percentage of commercial sales. After opt-in, we will share with ImmunoGen the costs associated with developing and obtaining regulatory approvals in the U.S. and the EU. ImmunoGen has the right to co-commercialize the product with us in the U.S. with U.S. profit-sharing in lieu of our payment of applicable U.S. milestone and royalties to ImmunoGen.

Disposition

On June 29, 2018, we entered into an asset purchase agreement, or APA, with TerSera Therapeutics LLC, or TerSera, pursuant to which TerSera agreed to purchase substantially all of our assets related to the manufacture, marketing and sale of Prialt, but excluding accounts receivable, and to assume certain related liabilities as set forth in the APA. We entered into an amendment to the APA, and the transaction closed, on September 27, 2018. The total sales price was $80.0 million, of which we received $50.0 million at closing and $15.0 million, less certain reimbursable expenses on December 30, 2019. We are entitled to receive a further $15.0 million, less certain reimbursable expenses payable on December 31, 2020, or earlier under certain conditions.

The related assets met the assets held for sale criteria and were reclassified to assets held for sale as of June 30, 2018. We adjusted the carrying value of the assets held for sale to fair value less costs to sell, which resulted in an impairment charge of $42.9 million in our consolidated statements of income in 2018, primarily related to the carrying balances of intangible assets. Upon closing, we recognized a loss on disposal of $0.5 million within selling, general and administrative expenses in our consolidated statements of income in 2018.

We determined that the disposal of these assets does not qualify for reporting as a discontinued operation since it does not represent a strategic shift that has or will have a major effect on our operations and financial results.

4. Cash and Available-for-Sale Securities

Cash and cash equivalents and investments consisted of the following (in thousands):

	December 31, 2019					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 333,172	$ —	$ —	$ 333,172	$ 333,172	$ —
Time deposits	460,000	—	—	460,000	20,000	440,000
Money market funds	284,172	—	—	284,172	284,172	—
Totals	$ 1,077,344	$ —	$ —	$ 1,077,344	$ 637,344	$ 440,000

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	December 31, 2018					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 215,606	$ —	$ —	$ 215,606	$ 215,606	$ —
Time deposits	515,000	—	—	515,000	—	515,000
Money market funds	94,016	—	—	94,016	94,016	—
Totals	$ 824,622	$ —	$ —	$ 824,622	$ 309,622	$ 515,000

Cash equivalents and investments are considered available-for-sale securities. 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. Our investment balances represent time deposits with original maturities of greater than three months and less than one year. Interest income from available-for-sale securities was $20.5 million, $16.9 million and $4.1 million in 2019, 2018 and 2017, respectively.

5. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	December 31, 2019			December 31, 2018		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Assets:						
Available-for-sale securities:						
Time deposits	$ —	$ 460,000	$ 460,000	$ —	$ 515,000	$ 515,000
Money market funds	284,172	—	284,172	94,016	—	94,016
Interest rate contracts	—	—	—	—	4,070	4,070
Foreign exchange forward contracts	—	2,508	2,508	—	1,194	1,194
Totals	$ 284,172	$ 462,508	$ 746,680	$ 94,016	$ 520,264	$ 614,280
Liabilities:						
Interest rate contracts	$ —	$ 1,515	$ 1,515	$ —	$ —	$ —
Foreign exchange forward contracts	—	182	182	—	1,460	1,460
Totals	$ —	$ 1,697	$ 1,697	$ —	$ 1,460	$ 1,460

As of December 31, 2019, our available-for-sale securities included time deposits and money market funds and their carrying values were approximately equal to their fair values. Time deposits were measured at fair value using Level 2 inputs and money market funds were measured using quoted prices in active markets, which represent Level 1 inputs. Level 2 inputs, obtained from various third party data 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.

Our derivative assets and liabilities include interest rate and foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk as well as an evaluation of our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the fair value hierarchy.

There were no transfers between the different levels of the fair value hierarchy in 2019 or in 2018.

As of December 31, 2019 and 2018, the carrying amount of investments measured using the measurement alternative for equity investments without a readily determinable fair value was $4.5 million. The carrying amount, which is recorded within other non-current assets, represents the purchase price paid in 2018.

As of December 31, 2019, the estimated fair values of our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, and our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, were approximately $592 million and $579 million, respectively. The fair values of the 2021 Notes and the 2024 Notes, which we refer to together as the Exchangeable Senior Notes, were estimated using quoted market prices obtained from brokers (Level 2). The estimated fair value of our borrowings under our term loan was approximately equal to its book value based on the borrowing rates currently available for variable rate loans (Level 2).

6. Derivative Instruments and Hedging Activities

We are exposed to certain risks arising from operating internationally, including fluctuations in interest rates on our outstanding term loan borrowings and fluctuations in foreign exchange rates primarily related to the translation of euro-denominated net monetary liabilities, including intercompany balances, held by subsidiaries with a U.S. dollar functional currency. We manage these exposures within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes.

To achieve a desired mix of floating and fixed interest rates on our variable rate debt, we entered into interest rate swap agreements in March 2017 which are effective until July 2021. These agreements hedge contractual term loan interest rates. As of December 31, 2019 and 2018, the interest rate swap agreements had a notional amount of $300.0 million. As a result of these agreements, the interest rate on a portion of our term loan borrowings was fixed at 1.895%, plus the borrowing spread, until July 2021.

The effective portion of changes in the fair value of derivatives designated as and that qualify as cash flow hedges is recorded in accumulated other comprehensive loss and is subsequently reclassified into earnings in the period that the hedged forecasted transaction affects earnings. The impact on accumulated other comprehensive loss and earnings from derivative instruments that qualified as cash flow hedges was as follows (in thousands):

	Year Ended December 31,		
Interest Rate Contracts:	**2019**	**2018**	**2017**
Gain (loss) recognized in accumulated other comprehensive loss, net of tax	$ (3,903)	$ 2,274	$ (213)
Loss (gain) reclassified from accumulated other comprehensive loss to interest expense, net of tax	$ (979)	$ (252)	$ 1,695

Assuming no change in LIBOR-based interest rates from market rates as of December 31, 2019, $0.8 million of losses recognized in accumulated other comprehensive loss will be reclassified to earnings over the next 12 months.

We enter into foreign exchange forward contracts, with durations of up to 12 months, designed to limit the exposure to fluctuations in foreign exchange rates related to the translation of certain non-U.S. dollar denominated liabilities, including intercompany balances. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of December 31, 2019 and 2018, the notional amount of foreign exchange contracts where hedge accounting was not applied was $180.9 million and $271.5 million, respectively.

The foreign exchange loss in our consolidated statements of income included the following gains and losses associated with foreign exchange contracts not designated as hedging instruments (in thousands):

	Year Ended December 31,		
Foreign Exchange Forward Contracts:	**2019**	**2018**	**2017**
Gain (loss) recognized in foreign exchange loss	$ (6,192)	$ (14,648)	$ 17,902

The cash flow effects of our derivative contracts are included within net cash provided by operating activities in the consolidated statements of cash flows.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table summarizes the fair value of outstanding derivatives (in thousands):

	December 31, 2019			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Interest rate contracts	Other current assets	$ —	Accrued liabilities	$ 855
			Other non-current liabilities	660
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	2,508	Accrued liabilities	182
Total fair value of derivative instruments		$ 2,508		$ 1,697

	December 31, 2018			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Interest rate contracts	Other current assets	$ 1,929	Accrued liabilities	$ —
	Other non-current assets	2,141		
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	1,194	Accrued liabilities	1,460
Total fair value of derivative instruments		$ 5,264		$ 1,460

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Although we do not offset derivative assets and liabilities within our consolidated balance sheets, our International Swap and Derivatives Association agreements provide for net settlement of transactions that are due to or from the same counterparty upon early termination of the agreement due to an event of default or other termination event. The following table summarizes the potential effect on our consolidated balance sheets of offsetting our interest rate contracts and foreign exchange forward contracts subject to such provisions (in thousands):

	December 31, 2019					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 2,508	$ —	$ 2,508	$ (596)	$ —	$ 1,912
Derivative liabilities	$ (1,697)	$ —	$ (1,697)	$ 596	$ —	$ (1,101)

	December 31, 2018					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 5,264	$ —	$ 5,264	$ (935)	$ —	$ 4,329
Derivative liabilities	$ (1,460)	$ —	$ (1,460)	$ 935	$ —	$ (525)

7. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2019	2018
Raw materials	$ 13,595	$ 10,895
Work in process	36,658	20,743
Finished goods	28,355	21,318
Total inventories	$ 78,608	$ 52,956

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

8. Property, Plant and Equipment

Property, plant and equipment consisted of the following (in thousands):

	December 31,	
	2019	2018
Leasehold improvements	$ 52,294	$ 33,273
Land and buildings	47,053	46,650
Manufacturing equipment and machinery	28,860	25,837
Computer software	25,680	19,062
Computer equipment	16,577	13,679
Furniture and fixtures	11,152	8,155
Construction-in-progress	5,147	51,243
Build-to-suit facility	—	52,067
Subtotal	186,763	249,966
Less accumulated depreciation and amortization	(55,257)	(49,608)
Property, plant and equipment, net	$ 131,506	$ 200,358

The decrease in the carrying amount of construction-in-progress and build-to-suit facility assets as of December 31, 2019 compared to December 31, 2018 primarily reflects the de-recognition of assets related to build-to-suit facility leases on adoption of ASU No. 2016-02.

Depreciation and amortization expense on property, plant and equipment amounted to $15.3 million, $15.2 million and $13.1 million for the years ended December 31, 2019, 2018 and 2017, respectively.

9. Goodwill and Intangible Assets

The gross carrying amount of goodwill was as follows (in thousands):

Balance at December 31, 2018	$ 927,630
Foreign exchange	(7,612)
Balance at December 31, 2019	$ 920,018

The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	December 31, 2019				December 31, 2018		
	Remaining Weighted-Average Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Acquired developed technologies	13.3	$ 3,166,485	$ (864,834)	$ 2,301,651	$ 3,110,641	$ (632,413)	$ 2,478,228
Priority review voucher (PRV)	—	111,101	(111,101)	—	111,101	—	111,101
Manufacturing contracts	—	12,025	(12,025)	—	12,256	(12,256)	—
Trademarks	—	2,890	(2,890)	—	2,896	(2,896)	—
Total finite-lived intangible assets		3,292,501	(990,850)	2,301,651	3,236,894	(647,565)	2,589,329
Acquired IPR&D assets		139,326	—	139,326	142,005	—	142,005
Total intangible assets		$ 3,431,827	$ (990,850)	$ 2,440,977	$ 3,378,899	$ (647,565)	$ 2,731,334

The increase in the gross carrying amount of intangible assets as of December 31, 2019 compared to December 31, 2018 reflects the capitalization of milestone payments triggered by FDA approval of Sunosi in March 2019 and subsequent U.S.

Drug Enforcement Agency scheduling in June 2019, partially offset by the negative impact of foreign currency translation adjustments due to the weakening of the euro against the U.S. dollar.

We amortized the cost of the priority review voucher, or PRV, of $111.1 million in full in the fourth quarter of 2019, following the notification to the FDA of our intention to redeem it in the NDA submission for JZP-258.

The assumptions and estimates used to determine future cash flows and remaining useful lives of our intangible and other long-lived assets are complex and subjective. They can be affected by various factors, including external factors, such as industry and economic trends, and internal factors such as changes in our business strategy and our forecasts for specific product lines. We reduced the estimated remaining useful life of the Erwinaze intangible asset due to the receipt of a contract termination notice from Porton Biopharma Limited in February 2019. The reduction in the estimated remaining useful life increased intangible asset amortization expense by $54.9 million, reduced net income by $37.3 million, reduced basic net income per ordinary share by $0.66, and reduced diluted net income per ordinary share by $0.65 during the year ended December 31, 2019. The carrying value of the Erwinaze intangible asset as of December 31, 2019 was $136.0 million.

Based on finite-lived intangible assets recorded as of December 31, 2019, and assuming the underlying assets will not be impaired and that we will not change the expected lives of any other assets, future amortization expenses were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2020	$ 251,032
2021	204,025
2022	159,038
2023	159,038
2024	159,038
Thereafter	1,369,480
Total	$ 2,301,651

10. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2019	2018
Rebates and other sales deductions	$ 96,860	$ 86,495
Employee compensation and benefits	80,290	58,543
Current portion of operating lease liabilities	12,728	—
Selling and marketing accruals	11,299	6,780
Inventory-related accruals	7,816	8,753
Accrued interest	7,386	7,407
Royalties	6,931	2,679
Professional fees	4,718	2,333
Sales returns reserve	3,462	2,510
Clinical trial accruals	2,551	5,904
Accrued construction-in-progress	1,564	1,065
Derivative instrument liabilities	1,037	1,460
Accrued loss contingency	—	58,154
Other	31,231	22,804
Total accrued liabilities	$ 267,873	$ 264,887

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

11. Debt

The following table summarizes the carrying amount of our indebtedness (in thousands):

	December 31,	
	2019	2018
2021 Notes	$ 575,000	$ 575,000
Unamortized discount and debt issuance costs on 2021 Notes	(38,865)	(60,910)
2021 Notes, net	536,135	514,090
2024 Notes	575,000	575,000
Unamortized discount and debt issuance costs on 2024 Notes	(117,859)	(138,914)
2024 Notes, net	457,141	436,086
Term loan	613,981	646,236
Total debt	1,607,257	1,596,412
Less current portion	33,387	33,387
Total long-term debt	$ 1,573,870	$ 1,563,025

Credit Agreement

On June 18, 2015, Jazz Pharmaceuticals plc, as guarantor, and certain of our wholly owned subsidiaries, as borrowers, entered into a credit agreement, or the 2015 credit agreement, that provided for a $750.0 million principal amount term loan, which was drawn in full at closing, and a $750.0 million revolving credit facility, of which $160.0 million was drawn at closing and subsequently repaid. We used the proceeds from initial borrowings under the 2015 credit agreement to repay in full the $893.1 million principal amount of term loans outstanding under the credit agreement that we entered into in June 2012, as subsequently amended, which we refer to as the previous credit agreement, and to pay related fees and expenses. The previous credit agreement was terminated upon repayment of the term loans outstanding thereunder.

On July 12, 2016, we amended the 2015 credit agreement to provide for a revolving credit facility of $1.25 billion and a $750.0 million term loan facility. We used the proceeds of $1.0 billion of loans under the revolving credit facility, together with cash on hand, to fund the acquisition of Celator Pharmaceuticals, Inc., or the Celator Acquisition.

On June 7, 2018, we entered into the second amendment to the 2015 credit agreement to provide for a revolving credit facility of $1.6 billion, which replaced the existing revolving credit facility of $1.25 billion, and a new $667.7 million term loan facility, which replaced the $750.0 million term loan facility, of which $617.7 million principal amount was outstanding as of December 31, 2019. We refer to the 2015 credit agreement as amended by the first and second amendments as the amended credit agreement. We expect to use the proceeds from future loans under the revolving credit facility, if any, for permitted capital expenditures, permitted acquisitions, to provide for ongoing working capital requirements and for other general corporate purposes.

Under the amended credit agreement, the term loan matures on June 7, 2023 and the revolving credit facility terminates, and any loans outstanding thereunder become due and payable, on June 7, 2023.

Borrowings under the amended credit agreement bear interest, at our option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 1.375% to 1.750% per annum, based upon our secured leverage ratio, or (b) the prime lending rate, plus an applicable margin ranging from 0.375% to 0.750% per annum, based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio.

As of December 31, 2019, the interest rate on the term loan was 3.17% and the effective interest rate was 3.66%. As of December 31, 2019, we had undrawn revolving credit facilities totaling $1.6 billion.

Jazz Pharmaceuticals plc and certain of our wholly owned subsidiaries are borrowers under the amended credit agreement. The borrowers' obligations under the amended credit agreement and any hedging or cash management obligations entered into with a lender are guaranteed on a senior secured basis by Jazz Pharmaceuticals plc and certain of our subsidiaries (including the issuer of the Exchangeable Senior Notes as described below) and are secured by substantially all of Jazz Pharmaceuticals plc's, the borrowers' and the guarantor subsidiaries' assets.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

We may make voluntary prepayments of principal at any time without payment of a premium. We are required to make mandatory prepayments of the term loan (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), and (3) casualty proceeds and condemnation awards (subject to other exceptions).

Principal repayments of the term loan, which are due quarterly, are equal to 5.0% per annum of the principal amount outstanding on June 7, 2018 of $667.7 million, with any remaining balance payable on the maturity date.

The amended credit agreement contains financial covenants that require Jazz Pharmaceuticals plc and our restricted subsidiaries to not (a) exceed a maximum secured net leverage ratio or (b) fall below a cash interest coverage ratio. As of December 31, 2019, we were in compliance with these financial covenants.

In connection with our entry into the amendments to the 2015 credit agreement, we recorded a loss on extinguishment and modification of debt of $1.4 million in 2018.

Exchangeable Senior Notes Due 2024

In the third quarter of 2017, we completed a private placement of $575.0 million principal amount of 2024 Notes. We used the net proceeds from this offering to repay $500.0 million in outstanding loans under the revolving credit facility and to pay related fees and expenses. We used the remainder of the net proceeds for general corporate purposes. Interest on the 2024 Notes is payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2018, at a rate of 1.50% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2024 Notes. The 2024 Notes mature on August 15, 2024, unless earlier exchanged, repurchased or redeemed.

The holders of the 2024 Notes have the ability to require us to repurchase all or a portion of their 2024 Notes for cash in the event we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from The Nasdaq Global Select Market. Prior to August 15, 2024, we may redeem the 2024 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2024 Notes additional amounts as a result of certain tax-related events. We also may redeem the 2024 Notes on or after August 20, 2021, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2024 Notes are exchangeable at an initial exchange rate of 4.5659 ordinary shares per $1,000 principal amount of 2024 Notes, which is equivalent to an initial exchange price of approximately $219.02 per ordinary share. Upon exchange, the 2024 Notes may be settled in cash, ordinary shares or a combination of cash and ordinary shares, at our election. Our intent and policy is to settle the principal amount of the 2024 Notes in cash upon exchange. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2024 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2024 Notes who elect to exchange their 2024 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to May 15, 2024, the 2024 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

In accounting for the issuance of the 2024 Notes, we separated the 2024 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the estimated fair value of a similar liability that does not have an associated exchange feature. The carrying amount of the equity component representing the exchange option was determined by deducting the fair value of the liability component from the face value of the 2024 Notes as a whole. The excess of the principal amount of the liability component over its carrying amount will be amortized to interest expense over the expected life of the 2024 Notes using the effective interest method with an effective interest rate of 6.8% per annum. We have determined the expected life of the 2024 Notes to be equal to the original seven-year term. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. As of December 31, 2019 and 2018, the "if-converted value" did not exceed the principal amount of the 2024 Notes.

We allocated the total issuance costs incurred of $15.6 million to the liability and equity components based on their relative values. Issuance costs attributable to the liability component will be amortized to expense over the term of the 2024 Notes, and issuance costs attributable to the equity component were included with the equity component in our shareholders' equity.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

As of December 31, 2019 and 2018, the carrying value of the equity component of the 2024 Notes, net of equity issuance costs, was $149.8 million.

Exchangeable Senior Notes Due 2021

In August 2014, we completed a private placement of the 2021 Notes. Interest on the 2021 Notes is payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2015, at a rate of 1.875% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2021 Notes. The 2021 Notes mature on August 15, 2021, unless earlier exchanged, repurchased or redeemed.

The holders of the 2021 Notes have the ability to require us to repurchase all or a portion of their 2021 Notes for cash in the event Jazz Pharmaceuticals plc undergoes certain fundamental changes. Prior to August 15, 2021, we may redeem the 2021 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2021 Note additional amounts as a result of certain tax-related events. We also may redeem the 2021 Notes on or after August 20, 2018, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2021 Notes are exchangeable at an initial exchange rate of 5.0057 ordinary shares per $1,000 principal amount of 2021 Notes, which is equivalent to an initial exchange price of approximately $199.77 per ordinary share. Upon exchange, the 2021 Notes may be settled in cash, ordinary shares or a combination of cash and ordinary shares, at our election. Our intent and policy is to settle the principal amount of the 2021 Notes in cash upon exchange. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2021 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2021 Notes who elect to exchange their 2021 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to February 15, 2021, the 2021 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

In accounting for the issuance of the 2021 Notes, we separated the 2021 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the estimated fair value of a similar liability that does not have an associated exchange feature. The carrying amount of the equity component representing the exchange option was determined by deducting the fair value of the liability component from the face value of the 2021 Notes as a whole. The excess of the principal amount of the liability component over its carrying amount will be amortized to interest expense over the expected life of the 2021 Notes using the effective interest method with an effective interest rate of 6.4% per annum. We have determined the expected life of the 2021 Notes to be equal to the original seven-year term. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. As of December 31, 2019 and 2018, the "if-converted value" did not exceed the principal amount of the 2021 Notes.

We allocated the total issuance costs incurred of $16.1 million to the liability and equity components based on their relative values. Issuance costs attributable to the liability component will be amortized to expense over the term of the 2021 Notes, and issuance costs attributable to the equity component were included with the equity component in our shareholders' equity.

As of December 31, 2019 and 2018, the carrying value of the equity component of the 2021 Notes, net of equity issuance costs, was $126.9 million.

The Exchangeable Senior Notes were issued by Jazz Investments I Limited, or the Issuer, a 100%-owned finance subsidiary of Jazz Pharmaceuticals plc. The Exchangeable Senior Notes are senior unsecured obligations of the Issuer and are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. No subsidiary of Jazz Pharmaceuticals plc guaranteed the Exchangeable Senior Notes. Subject to certain local law restrictions on payment of dividends, among other things, and potential negative tax consequences, we are not aware of any significant restrictions on the ability of Jazz Pharmaceuticals plc to obtain funds from the Issuer or Jazz Pharmaceuticals plc's other subsidiaries by dividend or loan, or any legal or economic restrictions on the ability of the Issuer or Jazz Pharmaceuticals plc's other subsidiaries to transfer funds to Jazz Pharmaceuticals plc in the form of cash dividends, loans or advances. There is no assurance that in the future such restrictions will not be adopted.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

For the years ended December 31, 2019, 2018 and 2017, we recognized $59.1 million, $56.7 million and $37.8 million, respectively, in interest expense, net related to the contractual coupon rate and amortization of the debt discount on the Exchangeable Senior Notes.

Scheduled maturities with respect to our long-term debt are as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2020	$ 33,387
2021	608,387
2022	33,387
2023	517,493
2024	575,000
Total	$ 1,767,654

12. Leases

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.

The components of the lease expense for the year ended December 31, 2019 were as follows (in thousands):

Lease Cost	Year Ended December 31, 2019
Operating lease cost	$ 23,087
Short-term lease cost	2,465
Variable lease cost	5
Sublease income	(634)
Net lease cost	$ 24,923

Supplemental balance sheet information related to operating leases was as follows (in thousands):

Leases	Classification	December 31, 2019
Assets		
Operating lease assets	Operating lease assets	$ 139,385
Liabilities		
Current		
Operating lease liabilities	Accrued liabilities	12,728
Non-current		
Operating lease liabilities	Operating lease liabilities, less current portion	151,226
Total operating lease liabilities		$ 163,954

Lease Term and Discount Rate	December 31, 2019
Weighted-average remaining lease term - operating leases (years)	9.7
Weighted-average discount rate - operating leases	5.3%

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Supplemental cash flow information related to operating leases was as follows (in thousands):

	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash outflows from operating leases	$ 17,066
Non-cash operating activities:	
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	$ 153,448

(1) Includes the balances recognized on January 1, 2019 on adoption of ASU No. 2016-02.

Maturities of operating lease liabilities were as follows (in thousands):

Year Ending December 31,	Operating leases
2020	$ 21,315
2021	21,104
2022	21,139
2023	21,508
2024	23,857
Thereafter	104,655
Total lease payments	$ 213,578
Less imputed interest	(49,624)
Present value of lease liabilities	$ 163,954

13. 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 executive 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 policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we did not recognize any liabilities relating to these obligations as of December 31, 2019 and December 31, 2018. 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.

Other Commitments

As of December 31, 2019, we had $74.5 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

14. Shareholders' Equity

Share Repurchase Program

In November 2016, our board of directors authorized a share repurchase program pursuant to which we were authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300.0 million, exclusive of any brokerage commissions. In November and December 2018, our board of directors increased the existing share repurchase program authorization by $320.0 million and $400.0 million. In October 2019, our board of directors authorized the additional repurchase of shares having an aggregate purchase price of up to $500.0 million, exclusive of any brokerage commissions. Under this program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the amended credit agreement, corporate and regulatory requirements and market conditions. The share repurchase program may be modified, suspended or discontinued at any time without prior notice. In 2019, we spent a total of $301.5 million to repurchase 2.3 million of our ordinary shares at an average total purchase price, including brokerage commissions, of $133.97 per share. In 2018, we spent a total of $523.7 million to repurchase 3.5 million of our ordinary shares at an average total purchase price, including brokerage commissions, of $148.33 per share. All ordinary shares repurchased were canceled. As of December 31, 2019, the remaining amount authorized under the share repurchase program was $577.7 million.

Authorized But Unissued Ordinary Shares

We had reserved the following shares of authorized but unissued ordinary shares (in thousands):

	December 31,	
	2019	2018
2011 Equity Incentive Plan	19,552	17,729
2007 Employee Stock Purchase Plan	1,883	1,126
Amended and Restated 2007 Non-Employee Directors Stock Award Plan	438	453
Amended and Restated Directors Deferred Compensation Plan	178	178
2007 Equity Incentive Plan	13	13
Total	22,064	19,499

Dividends

In 2019 and 2018, we did not declare or pay cash dividends on our common equity. 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 credit agreement restrict our ability to make certain restricted payments, including dividends and other distributions by us in respect of our ordinary shares, subject to, among other exceptions, (1) a general exception for dividends and restricted payments up to $30 million in the aggregate and (2) an exception that allows for restricted payments, subject to a cap equal to the sum of (i) $100 million plus (ii) so long as our secured leverage ratio (as defined in our credit agreement) does not exceed 3:1 after giving pro forma effect to the restricted payment, a formula-based amount tied to our consolidated net income; provided that such cap applies only if our total leverage ratio (as defined in our credit agreement) exceeds 2:1 after giving pro forma effect to the restricted payment.

15. Comprehensive Income (Loss)

Comprehensive income (loss) includes net income and all changes in shareholders' equity during a period, except for those changes resulting from investments by shareholders or distributions to shareholders.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of December 31, 2019 and 2018 were as follows (in thousands):

	Net Unrealized Gain (Loss) From Hedging Activities	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2018	$ 3,557	$ (201,348)	$ (197,791)
Other comprehensive loss before reclassifications	(3,903)	(20,720)	(24,623)
Amounts reclassified from accumulated other comprehensive loss	(979)	—	(979)
Other comprehensive loss, net	(4,882)	(20,720)	(25,602)
Balance at December 31, 2019	$ (1,325)	$ (222,068)	$ (223,393)

In 2019, other comprehensive loss reflects foreign currency translation adjustments, primarily due to the weakening of the euro against the U.S. dollar, and the net unrealized loss on derivatives that qualify as cash flow hedges.

16. Net Income per Ordinary Share

Basic net income per ordinary share attributable to Jazz Pharmaceuticals plc is based on the weighted-average number of ordinary shares outstanding. Diluted net income per ordinary share attributable to Jazz Pharmaceuticals plc 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 attributable to Jazz Pharmaceuticals plc were computed as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2019	2018	2017
Numerator:			
Net income	$ 523,367	$ 447,098	$ 487,848
Denominator:			
Weighted-average ordinary shares used in per share calculations - basic	56,749	59,976	60,018
Dilutive effect of employee equity incentive and purchase plans	801	1,245	1,299
Weighted-average ordinary shares used in per share calculations - diluted	57,550	61,221	61,317
Net income per ordinary share :			
Basic	$ 9.22	$ 7.45	$ 8.13
Diluted	$ 9.09	$ 7.30	$ 7.96

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans and the Exchangeable Senior Notes are determined by applying the treasury stock method to the assumed exercise of share options, the assumed vesting of outstanding restricted stock units, or RSUs, the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP, and the assumed issuance of ordinary shares upon exchange of the Exchangeable Senior Notes. The potential issue of ordinary shares issuable upon exchange of the Exchangeable Senior Notes had no effect on diluted net income per ordinary share because the average price of our ordinary shares in 2019, 2018 and 2017 did not exceed the effective exchange prices per ordinary share of the Exchangeable Senior Notes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table represents the weighted-average ordinary shares that were excluded from the computation of diluted net income attributable to Jazz Pharmaceuticals plc per ordinary share for the years presented because including them would have an anti-dilutive effect (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Exchangeable Senior Notes	5,504	5,504	3,805
Options, RSUs and ESPP	5,000	3,113	3,333

17. 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 identification, development and commercialization of meaningful pharmaceutical products that address unmet medical needs.

The following table presents total long-lived assets by location (in thousands):

	December 31,	
	2019	2018
Ireland	$ 77,237	$ 61,290
United States	171,079	126,941
Italy	12,959	8,760
Other	9,616	3,367
Total long-lived assets (1)	$ 270,891	$ 200,358

(1) Long-lived assets consist of property, plant and equipment and operating lease assets.

18. Revenues

The following table presents a summary of total revenues (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Xyrem	$ 1,642,525	$ 1,404,866	$ 1,186,699
Erwinaze/Erwinase	177,465	174,739	197,340
Defitelio/defibrotide	172,938	149,448	133,650
Vyxeos	121,407	100,835	33,790
Sunosi	3,714	—	—
Other	17,552	39,585	49,920
Product sales, net	2,135,601	1,869,473	1,601,399
Royalties and contract revenues	26,160	21,449	17,294
Total revenues	$ 2,161,761	$ 1,890,922	$ 1,618,693

The following table presents a summary of total revenues attributed to geographic sources (in thousands):

	Year Ended December 31,		
	2019	2018	2017
United States	$ 1,965,318	$ 1,727,576	$ 1,463,457
Europe	150,201	125,911	125,624
All other	46,242	37,435	29,612
Total revenues	$ 2,161,761	$ 1,890,922	$ 1,618,693

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table presents a summary of the percentage of total revenues from customers that represented more than 10% of our total revenues:

	Year Ended December 31,		
	2019	2018	2017
ESSDS	76%	74%	73%
McKesson	14%	17%	16%

Financing and payment

Our payment terms vary by the type and location of our customer but payment is generally required in a term ranging from 30 to 45 days.

Contract Liabilities - Deferred Revenue

The deferred revenue balance as of December 31, 2019 primarily related to deferred upfront fees received from Nippon Shinyaku Co., Ltd., or Nippon Shinyaku, in connection with two license, development and commercialization agreements granting Nippon Shinyaku exclusive rights to develop and commercialize each of Defitelio and Vyxeos in Japan. We recognized contract revenues of $5.4 million in 2019 relating to these upfront payments. The deferred revenue balances are being recognized over an average of four years representing the period we expect to perform our research and developments obligations under each agreement.

The following table presents a reconciliation of our beginning and ending balances in contract liabilities from contracts with customers for the year ended December 31, 2019 (in thousands):

	Contract Liabilities
Balance as of December 31, 2018	$ 14,995
Amount recognized within royalties and contract revenues	(5,414)
Balance as of December 31, 2019	$ 9,581

19. Share-Based Compensation

2011 Equity Incentive Plan

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction, or the Azur Merger. 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, RSUs, other stock awards, and performance awards that may be settled in cash, shares, or other property. All outstanding 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, 2019, a total of 27,012,330 of our ordinary shares had been authorized for issuance under the 2011 Plan. In addition, the share reserve under the 2011 Plan will automatically increase on January 1 of each year 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, 2020, the share reserve under the 2011 Plan automatically increased by 2,526,341 ordinary shares pursuant to this provision.

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 stock options, 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. The share reserve under the 2007 Plan will not automatically increase. Since the Azur Merger, all of the new grants under the 2007 Plan were granted to non-employee directors, vest ratably over service periods of one to three years and expire no more than 10 years after the date of grant. The 2007 Plan expired in April 2017, and accordingly, no new grants can be awarded under the 2007 Plan. As of December 31, 2019, the number of shares reserved represents issuable shares from options granted but not yet exercised under the 2007 Plan.

2007 Employee Stock Purchase Plan

In 2007, Jazz Pharmaceuticals, Inc.'s employees became eligible to participate in the 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 and restated 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 amended and restated 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, 2019, a total of 4,421,024 of our ordinary shares had been authorized for issuance under the ESPP. The share reserve under the ESPP will automatically increase on January 1 of each year through January 1, 2022, by the least of (a) 1.5% of the total number of ordinary shares outstanding on December 31 of the preceding calendar year, (b) 1,000,000 shares, and (c) such lesser number of ordinary shares as determined by our board of directors or a duly-authorized committee thereof. On January 1, 2020, the share reserve under the ESPP automatically increased by 842,113 ordinary shares pursuant to this provision.

Amended and Restated 2007 Non-Employee Directors Stock Award Plan

The Amended and Restated 2007 Non-Employee Directors Stock Award Plan, or the 2007 Directors Award 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 Award Plan provided for the automatic grant of 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 Award 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, or the Internal Revenue Code, in connection with the Azur Merger. Accordingly, all future stock option grants under the 2007 Directors Award Plan will be at the discretion of our board of directors. Since the Azur Merger, all of the new grants under the 2007 Directors Award 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. In addition, the 2007 Directors Award Plan provides the source of shares to fund distributions made prior to August 15, 2010 under the Directors Deferred Compensation Plan described below. In August 2016, our shareholders approved our proposal to expand the types of stock awards that may be granted to our non-employee directors under the 2007 Directors Award Plan and eliminate the final automatic share reserve increase under the 2007 Directors Award Plan that was scheduled to occur on January 1, 2017. As of December 31, 2019, a total of 903,938 of our ordinary shares had been authorized for issuance under the 2007 Directors Award Plan.

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 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.

Since the consummation of the Azur Merger we have not permitted non-employee directors to defer any annual retainer fees under the Directors Deferred Plan. On October 31, 2019, our board of directors approved the termination of the Directors Deferred Plan, and all outstanding phantom stock will be distributed to each applicable non-employee director in November 2020. We recorded no expense in 2019, 2018 and 2017 related to retainer fees earned and deferred. As of December 31, 2019, 14,499 of our ordinary shares that 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,		
	2019	2018	2017
Grant date fair value	$ 42.09	$ 47.17	$ 42.72
Volatility	32%	35%	35%
Expected term (years)	4.5	4.5	4.3
Range of risk-free rates	1.3-2.5%	2.2-3.0%	1.6-2.1%
Expected dividend yield	—%	—%	—%

We rely on a blend of the historical and implied volatilities of our own ordinary shares to determine expected volatility for share option grants. 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 and our estimates were based on historical exercise data. 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 related to share options, RSUs and grants under our ESPP was as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Selling, general and administrative	$ 78,697	$ 76,770	$ 83,218
Research and development	25,229	19,037	17,870
Cost of product sales	6,637	6,634	5,812
Total share-based compensation expense, pre-tax	110,563	102,441	106,900
Income tax benefit from share-based compensation expense	(15,712)	(17,230)	(21,792)
Total share-based compensation expense, net of tax	$ 94,851	$ 85,211	$ 85,108

We recognized income tax benefits related to share option exercises of $5.1 million, $7.7 million and $8.9 million in 2019, 2018 and 2017, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Share Options

The following table summarizes information as of December 31, 2019 and activity during 2019 related to our share option plans:

	Shares Subject to Outstanding Options (In thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2019	5,280	$ 127.08		
Options granted	1,691	138.14		
Options exercised	(515)	90.27		
Options forfeited	(436)	139.56		
Options expired	(186)	159.59		
Outstanding at December 31, 2019	5,834	$ 131.57	6.6	$ 127,778
Vested and expected to vest at December 31, 2019	5,553	$ 131.15	6.5	$ 124,884
Exercisable at December 31, 2019	3,402	$ 125.81	5.1	$ 102,366

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 $26.2 million, $43.4 million and $38.9 million during 2019, 2018 and 2017, respectively. We issued new ordinary shares upon exercise of share options.

As of December 31, 2019, total compensation cost not yet recognized related to unvested share options was $80.1 million, which is expected to be recognized over a weighted-average period of 2.6 years.

As of December 31, 2019, total compensation cost not yet recognized related to grants under the ESPP was $4.6 million, which is expected to be recognized over a weighted-average period of 1.0 years.

Restricted Stock Units

In 2019, we granted RSUs covering an equal number of our ordinary shares to employees with a weighted-average grant date fair value of $138.11. 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 an expense ratably over the vesting period of four years. In 2019, 391,000 RSUs were released with 265,000 ordinary shares issued and 126,000 ordinary shares withheld for tax purposes. The total fair value of shares vested was $52.0 million, $55.8 million and $53.2 million during 2019, 2018 and 2017, respectively.

As of December 31, 2019, total compensation cost not yet recognized related to unvested RSUs was $101.0 million, which is expected to be recognized over a weighted-average period of 2.5 years.

The following table summarizes information as of December 31, 2019 and activity during 2019 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, 2019	1,102	$ 142.13		
RSUs granted	682	138.11		
RSUs released	(391)	144.34		
RSUs forfeited	(212)	140.76		
Outstanding at December 31, 2019	1,181	$ 139.32	1.4	$ 176,158

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

20. Employee Benefit Plans

We operate a number of defined contribution retirement plans. The costs of these plans are charged to the consolidated statements of income in the period they are incurred. We recorded expense related to our defined contribution plans of $8.2 million, $6.4 million and $5.5 million in 2019, 2018 and 2017, respectively. In Ireland, we operate a defined contribution plan in which we contribute up to 8% of an employee's eligible earnings. We recorded expense of $1.3 million, $1.2 million and $1.0 million in 2019, 2018 and 2017, respectively, in connection with the contributions we made under the Irish defined contribution plan. In the U.S., 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. We match certain employee contributions under the 401(k) savings plan. We recorded expense of $5.0 million, $4.2 million and $3.7 million in 2019, 2018 and 2017, respectively. In the United Kingdom, or UK, we operate a defined contribution plan in which we contribute up to 12% of an employee's eligible earnings. We recorded expense of $1.1 million, $0.8 million and $0.7 million in 2019, 2018 and 2017, respectively, in connection with contributions we made under the UK defined contribution plan. In France, we operate a defined contribution plan in which we contribute up to 14% of an employee's eligible earnings. We recorded expense of $0.6 million, $0.4 million and $0.3 million in 2019, 2018 and 2017, respectively, in connection with the contributions we made under the French defined contribution plan. In France, we also accrue for a potential liability which is payable if an employee leaves employment. The accrued liability for France was $0.6 million as of December 31, 2019 and $0.4 million as of December 31, 2018. In Italy, we accrue for a potential liability which is payable if an employee leaves employment. The accrued liability for Italy was $0.3 million as of December 31, 2019 and 2018.

21. Income Taxes

The components of income before the income tax provision (benefit) and equity in loss of investees were as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Ireland	$ (6,451)	$ 170,666	$ 77,476
United States	317,728	294,621	271,440
Other	143,025	64,176	92,201
Total	$ 454,302	$ 529,463	$ 441,117

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table sets forth the details of the income tax provision (benefit) (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Current			
Ireland	$ 51,696	$ 33,431	$ 28,045
United States	109,495	95,143	135,608
Other	2,265	40,403	14,198
Total current tax expense	163,456	168,977	177,851
Deferred, exclusive of other components below			
Ireland	(163,626)	(12,408)	(19,709)
United States	(41,297)	(41,337)	(27,559)
Other	(37,244)	(34,545)	(19,108)
Total deferred, exclusive of other components	(242,167)	(88,290)	(66,376)
Deferred, change in tax rates			
United States	203	(538)	(155,679)
Other	5,354	13	(3,536)
Total deferred, change in tax rates	5,557	(525)	(159,215)
Total deferred tax benefit	(236,610)	(88,815)	(225,591)
Total income tax provision (benefit)	$ (73,154)	$ 80,162	$ (47,740)

On December 22, 2017, the U.S. Tax Cuts and Jobs Act, or U.S. Tax Act, was signed into law. The legislation significantly changed U.S. tax law by, among other things, lowering corporate income tax rates, implementing a modified territorial tax system, imposing a one-time transition tax on deemed repatriated earnings of foreign subsidiaries and changing the rules which determine whether a U.S. person is a U.S. shareholder of a controlled foreign corporation, for 2017 and onwards. The U.S. Tax Act reduced the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. It also included two new U.S. tax base erosion provisions, the global intangible low-taxed income, or GILTI, provisions and the base-erosion and anti-abuse tax, or BEAT, provisions. The GILTI provisions require us to include in our U.S. income tax return foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets. The GILTI tax expenses recognized in our consolidated statements of income in 2019 and 2018 were not significant. The Company elects to account for tax expenses associated with the GILTI provisions in the period they are incurred. The BEAT provisions in the U.S. Tax Act eliminate the deduction of certain base-erosion payments made to related foreign corporations, and impose a minimum tax if greater than regular tax. The Company was not subject to BEAT in 2019 or 2018.

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. federal income tax rate from 35% to 21% under the U.S. Tax Act, we remeasured our net deferred tax liabilities as of December 22, 2017 and recognized a $155.1 million income tax benefit in our consolidated statement of income in 2017.

Our income tax benefit of $73.2 million and $47.7 million in 2019 and 2017, respectively, and our income tax provision of $80.2 million in 2018 related to tax arising on income in Ireland, the U.S. and certain other foreign jurisdictions, certain unrecognized tax benefits and various expenses not deductible for income tax purposes. The income tax benefit in 2019 includes a discrete tax benefit of $112.3 million resulting from an intra-entity intellectual property asset transfer. The tax benefit, which represents a deferred future benefit, was recorded as a deferred tax asset. The income tax benefit in 2017 included a provisional benefit of $148.8 million relating to the impact of the enactment of the U.S Tax Act.

The effective tax rates for 2019, 2018 and 2017 were (16.1)%, 15.1% and (10.8)%, respectively. The effective tax rate for 2019 was lower than the Irish statutory rate of 12.5% primarily due to the impact of the intra-entity intellectual property asset transfer. The effective tax rates for 2018 was higher than the Irish statutory rate of 12.5%, primarily due to income taxable at a rate higher than the Irish statutory rate and unrecognized tax benefits, partially offset by the release of reserves related to unrecognized tax benefits from the expiration of a statute of limitation, originating tax credits and the release of a valuation

allowance held against certain foreign net operating losses, or NOLs. The effective tax rate for 2017 was lower than the Irish statutory rate of 12.5%, primarily due to the impact of the enactment of the U.S. Tax Act. The decrease in the effective tax rate in 2019 compared to 2018 was primarily due to the impact of the intra-entity intellectual property asset transfer. Excluding this effect, the decrease in the effective tax rate in 2019 compared to 2018 was primarily due to the benefit from the application of the Italian patent box incentive regime for 2015 through 2019. The increase in the effective tax rate in 2018 compared to 2017 was primarily due to the impact of the enactment of the U.S. Tax Act in 2017. Excluding this effect, the effective tax rate in 2018 decreased compared to 2017, primarily due to a decrease in the U.S. corporate income tax rate.

The reconciliation between the statutory income tax rate applied to income before the income tax provision (benefit) and equity in loss of investees and our effective income tax rate was as follows:

	Year Ended December 31,		
	2019	2018	2017
Statutory income tax rate	12.5 %	12.5 %	12.5 %
Intra-entity transfer of intellectual property assets	(24.7)%	— %	— %
Foreign income tax rate differential	8.7 %	11.9 %	20.3 %
Research and other tax credits	(8.7)%	(3.0)%	(2.6)%
Patent box incentive benefit	(7.0)%	— %	— %
Deduction on subsidiary equity	(5.2)%	(0.5)%	(0.7)%
Change in valuation allowance	3.3 %	3.2 %	(2.8)%
Non-deductible acquired IPR&D	2.5 %	— %	— %
Non-deductible compensation	1.8 %	1.2 %	2.6 %
Financing costs	(1.7)%	(4.3)%	(5.6)%
Change in tax rate	1.5 %	(0.1)%	(0.4)%
Change in estimates	0.3 %	(1.1)%	(2.1)%
Change in unrecognized tax benefits	0.1 %	1.1 %	2.8 %
Excess tax benefits from share-based compensation	(0.1)%	(0.4)%	(1.5)%
Non-deductible loss contingency	— %	0.8 %	— %
Impact of U.S. Tax Act	— %	(1.4)%	(33.7)%
Investment in subsidiaries	— %	(4.8)%	— %
Other	0.6 %	— %	0.4 %
Effective income tax rate	(16.1)%	15.1 %	(10.8)%

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Significant components of our net deferred tax assets/(liabilities) were as follows (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 90,670	$ 106,128
Tax credit carryforwards	230,447	156,242
Intangible assets	154,844	23,469
Share-based compensation	26,091	24,592
Accruals	49,063	57,575
Indirect effects of unrecognized tax benefits	39,432	34,349
Investment in subsidiaries	—	25,585
Lease liabilities	33,847	—
Other	48,630	51,175
Total deferred tax assets	673,024	479,115
Valuation allowance	(66,307)	(61,237)
Net deferred tax assets	606,717	417,878
Deferred tax liabilities:		
Intangible assets	(537,520)	(595,746)
Operating lease assets	(28,442)	—
Other	(43,447)	(73,350)
Total deferred tax liabilities	(609,409)	(669,096)
Net deferred tax liabilities	$ (2,692)	$ (251,218)

The net change in valuation allowance was an increase of $5.1 million and $9.1 million in 2019 and 2018, respectively, and a decrease of $1.0 million in 2017.

The following table summarizes the presentation of deferred tax assets and liabilities (in thousands):

	December 31,	
	2019	2018
Deferred tax assets	$ 221,403	$ 57,879
Deferred tax liabilities	(224,095)	(309,097)
Net deferred tax liabilities	$ (2,692)	$ (251,218)

As of December 31, 2019, we had NOL carryforwards and tax credit carryforwards for U.S. federal income tax purposes of approximately $273.0 million and $173.1 million, respectively, available to reduce future income subject to income taxes. These NOL carryforwards are inclusive of $204.7 million from the Celator Acquisition in 2016 and $18.7 million from the Cavion acquisition in 2019. The U.S. federal NOL carryforwards will expire, if not utilized, in the tax years 2020 to 2036, and the U.S. federal tax credits will expire, if not utilized, in the tax years 2020 to 2039. In addition, we had approximately $94.0 million of NOL carryforwards and $11.3 million of tax credit carryforwards as of December 31, 2019 available to reduce future taxable income for U.S. state income tax purposes. The U.S. state NOL carryforwards will expire, if not utilized, in the tax years 2020 to 2038. As of December 31, 2019, there were NOL and other carryforwards for income tax purposes of approximately $78.4 million, $46.2 million, $45.2 million and $24.6 million available to reduce future income subject to income taxes in Ireland, United Kingdom, Luxembourg and Malta, respectively. The NOLs and other deductions generated in Ireland, the United Kingdom, Luxembourg and Malta have no expiration date. We also had foreign tax credit carryforwards in Ireland, as of December 31, 2019, of $41.7 million, which may only be utilized against certain sources of income. The foreign tax credit carryforwards have no expiration date.

Utilization of certain of our NOL and tax credit carryforwards in the U.S. is subject to an 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. In addition, as a result of the Azur Merger, until 2022 we are subject to certain limitations under the Internal Revenue Code in relation to the utilization of U.S. NOLs to offset U.S. taxable income resulting from certain transactions.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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. Our valuation allowance was $66.3 million and $61.2 million as of December 31, 2019 and 2018, respectively, for certain Irish, U.S. (federal and state) and foreign deferred tax assets which we maintain until sufficient positive evidence exists to support reversal. During 2019, as part of the overall change in valuation allowance, we recognized a net income tax provision of $6.3 million relating primarily to the creation of a valuation allowance of $15.7 million against certain deferred tax assets primarily associated with foreign tax credits and temporary differences related to foreign subsidiaries, partially offset by the net release of valuation allowances against certain deferred tax assets primarily associated with NOLs. During 2018, as part of the overall change in valuation allowance, we recognized a net income tax provision of $11.2 million relating primarily to the creation of a valuation allowance of $25.7 million against certain deferred tax assets primarily associated with temporary differences related to foreign subsidiaries, partially offset by the net release of valuation allowances against certain deferred tax assets primarily associated with NOLs and foreign tax credits. The $11.2 million net income tax provision included a benefit of $10.9 million relating to a change in judgment leading to the reversal of a valuation allowance against certain deferred tax assets, primarily related to NOLs in the United Kingdom and a benefit of $5.9 million relating to the reversal of a valuation allowance upon completing our analysis of our ability to utilize certain foreign tax credits generated by the one-time transition tax in the U.S. Management determined that valuation allowances were 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, 2018, 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. During 2017, as part of the overall change in valuation allowance, we recognized a net income tax benefit of $6.6 million relating to the net release of a valuation allowance against certain deferred tax assets primarily associated with NOLs, partially offset by the creation of a provisional valuation allowance of $5.9 million against certain deferred tax assets primarily associated with excess foreign tax credits generated during the year as a result of the U.S. Tax Act. The $6.6 million net income tax benefit included a benefit of $9.1 million relating to the utilization of NOL carryforwards against which a valuation allowance was carried. 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. Realization of substantially all the deferred tax assets is dependent on future book income.

Temporary differences related to foreign subsidiaries that are considered indefinitely reinvested totaled approximately $1.6 billion and $1.2 billion as of December 31, 2019 and 2018, respectively. In the event of the distribution of those earnings in the form of dividends, a sale of the subsidiaries, or certain other transactions, 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, 2019, it was not practicable to determine the amount of the unrecognized deferred tax liability related to these earnings.

We only 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 recorded an unrecognized tax benefit for certain tax benefits which we judge may not be sustained upon examination.

A reconciliation of our gross unrecognized tax benefits follows (in thousands):

	December 31,		
	2019	2018	2017
Balance at the beginning of the year	$ 118,213	$ 106,162	$ 90,910
Increases related to current year tax positions	27,552	22,649	27,875
Increases related to prior year tax positions	761	7,584	1,620
Decreases related to prior year tax positions	(91)	—	(1,075)
Lapse of the applicable statute of limitations	(22,116)	(18,182)	(13,168)
Balance at the end of the year	$ 124,319	$ 118,213	$ 106,162

The unrecognized tax benefits were included in other non-current liabilities and deferred tax assets, net, in our consolidated balance sheets. Interest related to our unrecognized tax benefits is recorded in the income tax provision in our consolidated statements of income. As of December 31, 2019 and 2018, our accrued interest and penalties related to unrecognized tax benefits was $7.4 million and $6.3 million, respectively. Interest and penalties related to unrecognized tax benefits recognized in the statements of income were not significant. Included in the balance of unrecognized tax benefits were

potential benefits of $78.8 million and $78.5 million at December 31, 2019 and 2018, respectively, that, if recognized, would affect the effective tax rate on income.

We file income tax returns in multiple tax jurisdictions, the most significant of which are Ireland and the U.S. (both at the federal level and in various state jurisdictions). For Ireland we are no longer subject to income tax audits by taxing authorities for the years prior to 2014. The U.S. jurisdictions generally have statute of limitations three to four years from the later of the return due date or the date when the return was filed. However, in the U.S. (at the federal level and in most states), carryforward tax attributes that were generated in 2015 and earlier may still be adjusted upon examination by the tax authorities. Certain of our subsidiaries are currently under examination by the French tax authorities for the years ended December 31, 2012, 2013, 2015, 2016 and 2017. These examinations may lead to ordinary course adjustments or proposed adjustments to our taxes. In December 2015, we received proposed tax assessment notices, and, in October 2018 and December 2019, we received revised tax assessment notices from the French tax authorities for 2012 and 2013 and in December 2018 and September 2019, we received a proposed tax assessment notice for 2015, 2016 and 2017, relating to certain transfer pricing adjustments. The notices propose additional French tax of approximately $42 million for 2012 and 2013 and approximately $12 million for 2015, 2016 and 2017 including interest and penalties through the respective dates of the proposed assessments, translated at the foreign exchange rate at December 31, 2019. We disagree with the proposed assessments and are contesting them vigorously. Certain of our Italian subsidiaries are currently under examination by the Italian tax authorities for the year ended December 31, 2017.

22. Subsequent Event

License Agreement

On December 19, 2019, we entered into an exclusive license agreement with Pharma Mar, S.A., or PharmaMar, for development and U.S. commercialization of lurbinectedin, a product candidate under clinical investigation for the treatment of patients with relapsed SCLC. Lurbinectedin was granted orphan drug designation for SCLC by the FDA in August 2018. In December 2019, PharmaMar submitted an NDA to the FDA for accelerated approval of lurbinectedin for relapsed SCLC based on data from a Phase 2 trial, and in February 2020, the FDA accepted the NDA for filing with priority review.

Under the terms of this agreement, which become effective in January 2020 upon expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, we paid PharmaMar an upfront payment of $200 million, which will be recorded as acquired IPR&D expense in our consolidated statements of income in the first quarter of 2020.

PharmaMar is eligible to receive potential regulatory milestone payments of up to $250 million upon the achievement of accelerated and/or full regulatory approval of lurbinectedin by FDA within certain timelines. PharmaMar is also eligible to receive up to $550 million in potential commercial milestone payments, as well as incremental tiered royalties on future net sales of lurbinectedin ranging from the high teens up to 30 percent. PharmaMar may receive additional payments on approval of other indications, with any such payments creditable against commercial milestone payment obligations. PharmaMar retains production rights for lurbinectedin and will supply the product to Jazz.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

23. Quarterly Financial Data (Unaudited)

The following interim financial information presents our 2019 and 2018 results of operations on a quarterly basis (in thousands, except per share amounts):

	2019			
	March 31	June 30	September 30	December 31
Revenues	$ 508,186	$ 534,133	$ 537,702	$ 581,740
Gross margin (1)	469,825	495,747	500,921	541,178
Net income	85,201	261,898	102,276	73,992
Net income per ordinary share, basic	1.49	4.62	1.80	1.31
Net income per ordinary share, diluted	1.47	4.56	1.78	1.29

	2018			
	March 31	June 30	September 30	December 31
Revenues	$ 444,613	$ 500,479	$ 469,373	$ 476,457
Gross margin (1)	406,928	461,381	438,623	440,997
Net income	45,991	92,321	149,316	159,470
Net income per ordinary share, basic	0.77	1.53	2.47	2.69
Net income per ordinary share, diluted	0.75	1.50	2.41	2.64

(1) Gross margin is computed by subtracting cost of product sales (excluding amortization of acquired developed technologies) from product sales, net.

The interim financial information above includes the following items:

- Estimated loss contingency of $57.0 million in the first quarter of 2018;
- Impairment charges and disposal costs of $44.0 million in the second quarter of 2018;
- Upfront and milestone payments of $56.0 million and $48.3 million in the first and third quarters of 2019, respectively, and $11.0 million in the first quarter of 2018;
- A one-time tax benefit of $112.3 million resulting from an intra-entity intellectual property asset transfer in the second quarter of 2019; and
- Amortization costs of $111.1 million in the fourth quarter of 2019 in respect of the PRV.

Schedule II

Valuation and Qualifying Accounts
(In thousands)

		Balance at beginning of period	Additions charged to costs and expenses	Other Additions	Deductions	Balance at end of period
For the year ended December 31, 2019						
Allowance for doubtful accounts	(1)	$ 50	$ 9	$ —	$ (9)	$ 50
Allowance for sales discounts	(1)	76	782	—	(745)	113
Allowance for chargebacks	(1)	408	41,864	—	(41,139)	1,133
Deferred tax asset valuation allowance	(2)(3)(4)	61,237	20,086	357	(15,373)	66,307
For the year ended December 31, 2018						
Allowance for doubtful accounts	(1)	$ 396	$ 20	$ —	$ (366)	$ 50
Allowance for sales discounts	(1)	103	811	—	(838)	76
Allowance for chargebacks	(1)	3,663	41,387	—	(44,642)	408
Deferred tax asset valuation allowance	(2)(3)	52,144	35,500	—	(26,407)	61,237
For the year ended December 31, 2017						
Allowance for doubtful accounts	(1)	$ 287	$ 231	$ —	$ (122)	$ 396
Allowance for sales discounts	(1)	118	1,087	—	(1,102)	103
Allowance for chargebacks	(1)	4,749	41,941	—	(43,027)	3,663
Deferred tax asset valuation allowance	(2)(3)(4)	53,184	7,509	5,581	(14,130)	52,144

(1) Shown as a reduction of accounts receivable. Charges related to sales discounts and chargebacks are reflected as a reduction of revenue.

(2) Additions to the deferred tax asset valuation allowance charged to costs and expenses relate to movements on certain Irish, U.S. (federal and state) and other foreign deferred tax assets where we continue to maintain a valuation allowance until sufficient positive evidence exists to support reversal.

(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.

(4) Other additions to the deferred tax asset valuation allowance relate to currency translation adjustments recorded directly in other comprehensive income and, in 2019, additions resulting from the Cavion asset acquisition.

Exhibit 21.1

Subsidiaries of the Registrant

Name	**State/Jurisdiction of Incorporation**
Jazz Pharmaceuticals Ireland Limited	Ireland
Jazz Financing I DAC	Ireland
Jazz Capital Ltd	Ireland
Jazz Pharmaceuticals, Inc.	Delaware
Celator Pharmaceuticals, Inc	Delaware
Jazz Pharmaceuticals Europe Holdings Limited	Gibraltar
Jazz Pharmaceuticals France SAS	France
Jazz Pharmaceuticals Lux S.à r.l.	Luxembourg
Gentium S.r.L.	Italy
Jazz Investments I Limited	Bermuda
Jazz Pharmaceuticals International Limited	Bermuda

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Jazz Pharmaceuticals plc

We consent to the incorporation by reference in the registration statements (No. 333-229889, No. 333-224757, No. 333-216338, No. 333-209767, No. 333-202269, No. 333-194131, No. 333-186886 and No. 333-179075) on Form S-8 of Jazz Pharmaceuticals plc of our reports dated February 25, 2020, with respect to the consolidated balance sheets of Jazz Pharmaceuticals plc as of December 31, 2019 and 2018, the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes and financial statement schedule at Item 15(a)2, and the effectiveness of internal control over financial reporting as of December 31, 2019, which reports appear in the December 31, 2019 annual report on Form 10-K of Jazz Pharmaceuticals plc.

/s/ KPMG

KPMG
Dublin, Ireland
February 25, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

AND INTERIM PRINICIPAL FINANCIAL OFFICER

I, Bruce C. Cozadd, 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 25, 2020

By: /s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman, Chief Executive Officer and Director
(Principal Executive Officer and
Interim Principal Financial Officer)

Exhibit 32.1

CERTIFICATION[(1)]

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, Principal Executive Officer and Interim Principal Financial Officer of Jazz Pharmaceuticals public limited company (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2019, 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 Exchange Act; 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 25, 2020

/s/ Bruce C. Cozadd

Bruce C. Cozadd

Chairman, Chief Executive Officer and Director
(Principal Executive Officer and
Interim Principal 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.

Exhibit 4.6

DESCRIPTION OF SHARE CAPITAL

The following description of the share capital of Jazz Pharmaceuticals plc, or the Company, is a summary. This summary does not purport to be complete and is qualified in its entirety by reference to the Irish Companies Act 2014 (as amended), or the Companies Act, and the complete text of the Company's amended and restated memorandum and articles of association, which amended and restated memorandum and articles of association, or the Company's Constitution, are filed as Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission, or SEC, on August 9, 2016. You should read those laws and documents carefully.

Capital Structure

Authorized Share Capital

The authorized share capital of the Company is €40,000 and $30,000, divided into 4,000,000 non-voting euro deferred shares with nominal value of €0.01 per share and 300,000,000 ordinary shares with nominal value of $0.0001 per share.

The Company may issue shares subject to the maximum authorized share capital contained in the Company's Constitution. The authorized share capital may be increased or reduced (but not below the number of shares then issued and outstanding) by a resolution approved by a simple majority of the votes cast at a general meeting, in person or by proxy, of the Company's shareholders (referred to under Irish law as an "ordinary resolution"). The shares comprising the Company's authorized share capital may be divided into shares of such nominal value as the resolution shall prescribe. As a matter of Irish law, the directors of a company may issue new ordinary or preferred shares for cash without shareholder approval once authorized to do so by the memorandum and articles of association or by an ordinary resolution adopted by the shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it must be renewed by the shareholders by an ordinary resolution.

The Company's board of directors is authorized pursuant to shareholder resolutions passed on August 4, 2016 to issue new ordinary or preferred shares for cash without shareholder approval for a period of five years from the date of the passing of the resolutions.

The rights and restrictions to which ordinary shares are subject are prescribed in the Company's Constitution. The Company's Constitution permits it to issue preferred shares once authorized to do so by ordinary resolution. The Company may, by ordinary resolution and without obtaining any vote or consent of the holders of any class or series of shares, unless expressly provided by the terms of that class or series of shares, provide from time to time for the issuance of other classes or series of shares and to establish the characteristics of each class or series, including the number of shares, designations, relative voting rights, dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

Irish law does not recognize fractional shares held of record. Accordingly, the Company's Constitution does not provide for the issuance of fractional shares, and the official Irish register of the Company will not reflect any fractional shares. Whenever an alteration or reorganization of the Company's share capital would result in any shareholder becoming entitled to fractions of a share, the Company's board of directors may, on behalf of those shareholders that would become entitled to fractions of a share, sell the shares representing the fractions for the best price reasonably obtainable, to any person and distribute the proceeds of the sale in due proportion among those members.

Issued Share Capital

As of December 31, 2019, 56,140,917 ordinary shares were issued and outstanding. In addition, as of December 31, 2019, 4,000,000 non-voting euro deferred shares were issued and outstanding at that time, which shares are held by nominees in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro. The euro deferred shares, which are not listed on any stock exchange and are not the subject of any registration, carry no voting rights and are not entitled to receive any dividend or distribution. On a return of assets, whether on liquidation or otherwise, the euro deferred shares will entitle the

holder thereof only to the repayment of the amounts paid up on such shares after repayment of the capital paid up on ordinary shares plus the payment of $5,000,000 on each of the ordinary shares and the holders of the euro deferred shares (as such) will not be entitled to any further participation in the assets or profits of the Company.

Preemption Rights, Share Warrants and Share Options

Under Irish law, certain statutory preemption rights apply automatically in favor of shareholders where shares are to be issued for cash. However, the Company has opted out of these preemption rights by way of shareholder resolution as permitted under Irish law. Irish law provides that this opt-out expires every five years unless renewed by a resolution approved by not less than 75% of the votes cast at a general meeting, in person or by proxy, of the Company's shareholders (referred to under Irish law as a "special resolution") and Parent's current opt-out will expire on August 4, 2021. If the opt-out is not renewed before then, shares issued for cash must be offered to existing shareholders on a pro rata basis to their existing shareholding before the shares may be issued to any new shareholders. The statutory preemption rights do not apply (i) where shares are issued for non-cash consideration (such as in a stock-for-stock acquisition), (ii) to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution) or (iii) where shares are issued pursuant to an employee stock option or similar equity plan.

The Company's Constitution provides that, subject to any shareholder approval requirement under any laws, regulations or the rules of any stock exchange to which it is subject, the Company's board of directors is authorized, from time to time, in its discretion, to grant such persons, for such periods and upon such terms as it deems advisable, options to purchase such number of shares of any class or classes or of any series of any class as the Company's board of directors may deem advisable, and to cause warrants or other appropriate instruments evidencing such options to be issued. The Companies Act provides that, save to the extent the constitution of a company provides otherwise, the directors of a company may issue options. The Company is subject to the rules of The NASDAQ Stock Market LLC and the U.S. Internal Revenue Code of 1986, or the Code, which require shareholder approval of certain equity plan and share issuances. The Company's board of directors may issue shares upon exercise of validly issued warrants or options without shareholder approval or authorization, except as described above (up to the relevant authorized share capital limit).

Dividends

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits less accumulated realized losses and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless the Company's net assets are equal to, or in excess of, the aggregate of its called up share capital plus undistributable reserves and the distribution does not reduce its net assets below such aggregate. Undistributable reserves include the share premium account, the par value of shares acquired by Parent and the amount by which Parent's accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed Parent's accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital.

The determination as to whether or not the Company has sufficient distributable reserves to fund a dividend must be made by reference to its "relevant financial statements." The "relevant financial statements" are either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Companies Act, which give a "true and fair view" of the Company's unconsolidated financial position and accord with accepted accounting practice. The relevant financial statements must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

The Company's Constitution authorizes the directors to declare dividends without shareholder approval to the extent they appear justified by profits lawfully available for distribution. The Company's board of directors may also recommend a dividend to be approved and declared by the shareholders at a general meeting. The Company's board of directors may direct that the payment be made by distribution of assets, shares or cash, and no dividend issued may exceed the amount recommended by the directors. The dividends declared by the directors or shareholders may be paid in the form of cash or non-cash assets and may be paid in dollars or any other currency.

The Company's board of directors may deduct from any dividend payable to any shareholder any amounts payable by such shareholder to the Company in relation to its shares.

The Company may issue shares with preferred rights to participate in dividends declared by the Company from time to time, as determined by ordinary resolution. The holders of preferred shares may, depending on their terms,

rank senior to ordinary shares in terms of dividend rights and/or be entitled to claim arrears of a declared dividend out of subsequently declared dividends in priority to ordinary shareholders.

Share Repurchases, Redemptions and Conversions

Overview

The Company's Constitution provides that, unless the board specifically determines otherwise, any ordinary share that it has agreed to acquire shall be deemed to be a redeemable share. Accordingly, for Irish law purposes, the repurchase of ordinary shares by the Company may technically be effected as a redemption of those shares as described below under "*—Repurchases and Redemptions*." If the Company's Constitution did not contain such provision, repurchases by the Company would be subject to many of the same rules that apply to purchases of its ordinary shares by subsidiaries described below under "*—Purchases by the Company's Subsidiaries*," including the shareholder approval requirements described below, and the requirement that any purchases on market be effected on a "recognized stock exchange," which, for purposes of the Companies Act, includes The NASDAQ Global Select Market. Neither Irish law nor any of the Company's constituent documents places limitations on the right of nonresident or foreign owners to vote or hold its ordinary shares. Except where otherwise noted, references herein to repurchasing or buying back ordinary shares refer to the redemption of ordinary shares by the Company or the purchase of ordinary shares by one of its subsidiaries, in each case in accordance with the Company's Constitution and Irish law as described below.

Repurchases and Redemptions

Under Irish law, a company may issue redeemable shares and redeem them out of distributable reserves or the proceeds of a new issue of shares for that purpose. Please see also "*—Dividends*." The Company may not purchase any of its shares if, as a result of such purchase, the nominal value of its issued share capital which is not redeemable would be less than 10% of the nominal value of its total issued share capital. All redeemable shares must also be fully-paid. Redeemable shares may, upon redemption, be cancelled or held in treasury. Based on the provisions of the Company's Constitution, shareholder approval will not be required to redeem its shares.

The Company may also be given an additional general authority to purchase its ordinary shares on market by way of ordinary resolution, which would take effect on the same terms and be subject to the same conditions as applicable to purchases by the Company's subsidiaries as described below.

Repurchased and redeemed shares may be cancelled or held as treasury shares. The nominal value of treasury shares held by the Company at any time must not exceed 10% of the aggregate of the par value and share premium received in respect of the allotment of Parent shares together with the par value of any shares acquired by Parent. The Company may not exercise any voting rights in respect of any shares held as treasury shares.

Treasury shares may be canceled by the Company or re-issued subject to certain conditions.

Purchases by the Company's Subsidiaries

Under Irish law, an Irish or non-Irish subsidiary of the Company may purchase the Company's shares either on market or off market. For a subsidiary of the Company to make purchases on market of ordinary shares, the Company's shareholders must provide general authorization for such purchase by way of ordinary resolution. However, as long as this general authority has been granted, no specific shareholder authority for a particular on market purchase by a subsidiary of ordinary shares is required. For a purchase of ordinary shares by a subsidiary of the Company off market, the proposed purchase contract must be authorized by special resolution of the Company's shareholders before the contract is entered into. The person whose ordinary shares are to be bought back cannot vote in favor of the special resolution and, from the date of the notice of the meeting at which the resolution approving the contract is proposed, the purchase contract must be on display or must be available for inspection by Parent's shareholders at the registered office of Parent.

In order for one of the Company's subsidiaries to make an on market purchase of its shares, such shares must be purchased on a "recognized stock exchange." The NASDAQ Global Select Market, on which ordinary shares are currently listed, is specified as a recognized stock exchange for this purpose by Irish law.

The number of shares held by the Company's subsidiaries at any time will count as treasury shares and will be included in any calculation of the permitted treasury share threshold of 10% of the aggregate of the par value and

share premium received in respect of the allotment of Parent shares together with the par value of any shares acquired by Parent. While a subsidiary holds the Company's shares, it cannot exercise any voting rights in respect of those shares and no dividend or other payment (including any payment in a winding up of the Company) shall be payable in respect of those shares. The acquisition of ordinary shares by a subsidiary must be funded out of distributable reserves of the subsidiary.

Lien on Shares, Calls on Shares and Forfeiture of Shares

The Company's Constitution provides that it has a first and paramount lien on every share that is not a fully paid up share for all amounts payable at a fixed time or called in respect of that share. Subject to the terms of their allotment, directors may call for any unpaid amounts in respect of any shares to be paid, and if payment is not made, the shares may be forfeited. These provisions are standard inclusions in the memorandum and articles of association of an Irish public company limited by shares such as the Company's and are only applicable to ordinary shares that have not been fully paid up.

Bonus Shares

Under the Company's Constitution, the Company's board of directors may resolve to capitalize any amount for the time being standing to the credit of any of Parent's reserve accounts or to the credit of the profit and loss account which is not available for distribution through the issuance of fully paid up bonus shares on the same basis of entitlement as would apply in respect of a dividend distribution.

Consolidation and Division; Subdivision

Under the Company's Constitution, the Company may, by ordinary resolution, consolidate and divide all or any of its share capital into shares of larger nominal value than its existing shares or subdivide its shares into smaller amounts than are fixed by the Company's Constitution.

Reduction of Share Capital

The Company may, by ordinary resolution, reduce its authorized share capital in any way. The Company also may, by special resolution and subject to confirmation by the Irish High Court, reduce or cancel its issued share capital (which includes share premium) in any manner permitted by the Companies Act.

Annual Meetings of Shareholders

The Company is required to hold an annual general meeting at intervals of no more than 15 months from the previous annual general meeting, provided that an annual general meeting is held in each calendar year following the first annual general meeting and no more than nine months after the Company's fiscal year-end. Parent's articles of association provide that shareholder meetings may be held outside of Ireland (subject to compliance with the Companies Act). Where a company holds its annual general meeting or extraordinary general meeting outside of Ireland, the Companies Act requires that the company, at its own expense, make all necessary arrangements to ensure that members can by technological means participate in the meeting without leaving Ireland (unless all of the members entitled to attend and vote at the meeting consent in writing to the meeting being held outside of Ireland).

Notice of an annual general meeting must be given to all of the Company's shareholders and to its auditors. The Company's Constitution provides for a minimum notice period of 21 clear days, which is the minimum permitted under Irish law.

The only matters which must, as a matter of Irish law, be transacted at an annual general meeting are the presentation of the annual financial statements and reports of the directors and auditors, a review by the shareholders of the company's affairs, the appointment of new auditors and the fixing of the auditor's remuneration (or delegation of same). If no resolution is made in respect of the reappointment of an existing auditor at an annual general meeting, the existing auditor will be deemed to have continued in office.

Extraordinary General Meetings of Shareholders

Extraordinary general meetings may be convened by (i) the Company's board of directors, (ii) on requisition of the Company's shareholders holding not less than 10% of its paid up share capital carrying voting rights, (iii) on requisition of the Company's auditors or (iv) in exceptional cases, by order of the court. Extraordinary general meetings are generally held for the purpose of approving shareholder resolutions as may be required from time to

time. At any extraordinary general meeting only such business shall be conducted as is set forth in the notice thereof.

Notice of an extraordinary general meeting must be given to all of the Company's shareholders and to its auditors. Under Irish law and the Company's Constitution, the minimum notice periods are 21 clear days' notice in writing for an extraordinary general meeting to approve a special resolution and 14 clear days' notice in writing for any other extraordinary general meeting.

In the case of an extraordinary general meeting convened by the Company's shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of any such valid requisition notice, the Company's board of directors has 21 days to convene a meeting of its shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If the Company's board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the Company's receipt of the requisition notice.

If the Company's board of directors becomes aware that its net assets are not greater than half of the amount of the Company's called-up share capital, it must convene an extraordinary general meeting of its shareholders not later than 28 days from the date that they learn of this fact to consider how to address the situation.

Quorum for General Meetings

The Company's Constitution provides that no business shall be transacted at any general meeting unless a quorum is present. One or more of the Company's shareholders present in person or by proxy holding not less than a majority of the Company's issued and outstanding shares entitled to vote at the meeting in question constitute a quorum.

Voting

At general meetings of the Company, a resolution put to the vote of the meeting is decided on a poll. The Company's Constitution provides that its board of directors or its chairman may determine the manner in which the poll is to be taken and the manner in which the votes are to be counted.

Each shareholder is entitled to one vote for each ordinary share that he or she holds as of the record date for the meeting. Voting rights may be exercised by shareholders registered in the Company's share register as of the record date for the meeting or by a duly appointed proxy, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, such company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in the manner prescribed by the Company's Constitution, which permits shareholders to notify the Company of their proxy appointments electronically in such manner as may be approved by the Company's board of directors.

In accordance with the Company's Constitution, it may from time to time be authorized by ordinary resolution to issue preferred shares. These preferred shares may have such voting rights as may be specified in the terms of such preferred shares (e.g., they may carry more votes per share than ordinary shares or may entitle their holders to a class vote on such matters as may be specified in the terms of the preferred shares). Treasury shares or the Company's shares that are held by its subsidiaries are not entitled to be voted at general meetings of shareholders.

Irish law requires special resolutions of the Company's shareholders at a general meeting to approve certain matters. Examples of matters requiring special resolutions include:

- amending the objects or memorandum of association of the Company;
- amending the articles of association of the Company;
- approving a change of name of the Company;
- authorizing the entering into of a guarantee or provision of security in connection with a loan, quasi- loan or credit transaction to a director or a person who is deemed to be "connected" to a director for the purposes of the Companies Act;

- opting out of preemption rights on the issuance of new shares;
- re-registration of the Company from a public limited company to a private company;
- variation of class rights attaching to classes of shares (where the articles of association do not provide otherwise);
- purchase of the Company's shares off market;
- reduction of issued share capital;
- sanctioning a compromise/scheme of arrangement with creditors or shareholders;
- resolving that the Company be wound up by the Irish courts;
- resolving in favor of a shareholders' voluntary winding-up; and
- setting the re-issue price of treasury shares.

Unanimous Shareholder Consent to Action Without Meeting

The Companies Act provides that shareholders may approve an ordinary or special resolution of shareholders without a meeting only if (i) all shareholders sign the written resolution and (ii) the company's articles of association permit written resolutions of shareholders (the Company's articles of association contain the appropriate authorizations for this purpose).

Variation of Rights Attaching to a Class or Series of Shares

Under the Company's Constitution and the Companies Act, any variation of class rights attaching to its issued shares must be approved by a special resolution of the Company's shareholders of the affected class or with the consent in writing of the holders of three-quarters of all the votes of that class of shares.

The provisions of the Company's Constitution relating to general meetings apply to general meetings of the holders of any class of the Company's shares except that the necessary quorum is determined in reference to the shares of the holders of the class. Accordingly, for general meetings of holders of a particular class of the Company's shares, a quorum consists of the holders present in person or by proxy representing at least one half of the issued shares of the class.

Inspection of Books and Records

Under Irish law, shareholders have the right to: (i) receive a copy of the Company's Constitution and any act of the Irish Government which alters its memorandum; (ii) inspect and obtain copies of the minutes of general meetings and the Company's resolutions; (iii) inspect and receive a copy of the register of shareholders, register of directors and secretaries, register of directors' interests and other statutory registers maintained in respect of the ordinary shares; (iv) receive copies of financial statements and directors' and auditors' reports which have previously been sent to shareholders prior to an annual general meeting; and (v) receive financial statements of any of the Company's subsidiaries that have previously been sent to shareholders prior to an annual general meeting for the preceding ten years. The Company's auditors also have the right to inspect all of the Company's books, records and vouchers. The auditors' report must be circulated to the shareholders with the Company's financial statements prepared in accordance with Irish law 21 clear days before the annual general meeting and must be read to the shareholders at the Company's annual general meeting.

Acquisitions

An Irish public limited company may be acquired in a number of ways, including:

- a court-approved scheme of arrangement under the Companies Act. A scheme of arrangement with shareholders requires a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve the scheme;

- through a tender or takeover offer by a third party for all of the Company's shares. Where the holders of 80% or more of the Company's shares have accepted an offer for their shares, the remaining shareholders may also be statutorily required to transfer their shares, and if the bidder does not exercise its "squeeze out" right, then the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms. If the Company's shares were to be listed on the main securities market of Euronext Dublin or another main securities market or regulated stock exchange in the European Union, this threshold would be increased to 90%; and
- by way of a merger with an EU-incorporated company under the EU Cross-Border Mergers Directive 2005/56/EC. Such a merger must be approved by a special resolution.

Irish law does not generally require shareholder approval for a sale, lease or exchange of all or substantially all of a company's property and assets, unless the company is listed on a regulated stock exchange in the European Union.

Appraisal Rights

Generally, under Irish law, shareholders of an Irish company do not have dissenters' or appraisal rights. Under the European Communities (Cross-Border Mergers) Regulations 2008 governing the merger of an Irish company limited by shares such as the Company and a company incorporated in the European Economic Area (the European Economic Area includes all member states of the European Union and Norway, Iceland and Liechtenstein), a shareholder (i) who voted against the special resolution approving the merger or (ii) of a company in which 90% of the shares are held by the other party to the merger, has the right to request that the company acquire its shares for cash at a price determined in accordance with the share exchange ratio set out in the merger agreement.

Disclosure of Interests in Shares

Under the Companies Act, subject to certain limited exceptions, a person must notify the Company (but not the public) if, as a result of a transaction, such person will become interested in three percent or more of the Company's voting shares, or if as a result of a transaction a shareholder who was interested in more than three percent of its voting shares ceases to be so interested. Where any person is interested in more than three percent of the Company's voting shares, such person must notify the Company of any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the voting shares in which the person is interested as a proportion of the entire nominal value of the Company's issued share capital (or any such class of share capital in issue). Where the percentage level of the person's interest does not amount to a whole percentage, this figure may be rounded down to the next whole number. The Company must be notified within five business days of the transaction or alteration of the person's interests that gave rise to the notification requirement. If a person fails to comply with these notification requirements, such person's rights in respect of any of the Company's shares he or she holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

In addition to these disclosure requirements, the Company, under the Companies Act, may, by notice in writing, require a person whom the Company knows or has reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in the Company's relevant share capital to: (i) indicate whether or not it is the case; and (ii) where such person holds or has during that time held an interest in the Company's shares, to provide additional information, including the person's own past or present interests in the Company's shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, the Company may apply to a court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Companies Act, as follows:

- any transfer of those shares or, in the case of unissued shares, any transfer of the right to be issued with shares and any issue of shares, shall be void;
- no voting rights shall be exercisable in respect of those shares;
- no further shares shall be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and

- no payment shall be made of any sums due from the Company on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event the Company is in an offer period pursuant to the Irish takeover rules, as defined below, accelerated disclosure provisions apply for persons holding an interest in the Company's securities of one percent or more.

Anti-Takeover Provisions

Irish Takeover Rules and Substantial Acquisition Rules

A transaction in which a third party seeks to acquire 30% or more of the voting rights of the Company and certain other acquisitions of the Company's securities are governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder, which are referred to herein as the "Irish takeover rules," and are regulated by the Irish Takeover Panel. The "General Principles" of the Irish takeover rules and certain important aspects of the Irish takeover rules are described below.

General Principles

The Irish takeover rules are built on the following General Principles which will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all holders of securities of the target company must be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of securities in the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer; where it advises the holders of securities, the board of directors of the target company must give its views on the effects of the implementation of the offer on employment, employment conditions and the locations of the target company's place of business;
- a target company's board of directors must act in the interests of the company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets must not be created in the securities of the target company, the bidder or any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;
- a bidder can only announce an offer after ensuring that he or she can pay in full the consideration offered, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company may not be hindered in the conduct of its affairs longer than is reasonable by an offer for its securities (this is a recognition that an offer will disrupt the day-to-day running of a target company, particularly if the offer is hostile and the board of directors of the target company must direct its attention to resisting the offer); and
- an acquisition of securities (whether such acquisition is to be effected by one transaction or a series of transactions) shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure. Specifically, the acquisition of 10% or more of the issued voting shares within a seven day period that would take a shareholder's holding to or above 15% of the issued voting shares (but less than 30%) is prohibited, subject to certain exemptions.

Mandatory Bid

Under certain circumstances, a person who acquires ordinary shares, or other of the Company's voting securities, may be required under the Irish takeover rules to make a mandatory cash offer for the remaining issued

and outstanding voting securities at a price not less than the highest price paid for the securities by the acquiror, or any parties acting in concert with the acquiror, during the previous 12 months. This mandatory bid requirement is triggered if an acquisition of securities would increase the aggregate holding of an acquiror, including the holdings of any parties acting in concert with the acquiror, to securities representing 30% or more of the voting rights in the Company, unless the Irish Takeover Panel otherwise consents. An acquisition of securities by a person holding, together with its concert parties, securities representing between 30% and 50% of the voting rights in the Company would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person (together with its concert parties) would increase by 0.05% within a 12-month period. Any person (excluding any parties acting in concert with the holder) holding securities representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements in purchasing additional securities.

Voluntary bid; Requirements to Make a Cash Offer and Minimum Price Requirements

If a person makes a voluntary offer to acquire the issued and outstanding ordinary shares of the Company and the bidder acquired ordinary shares in the three-month period prior to the commencement of the offer period, the offer price must not be less than the highest price paid for ordinary shares by the bidder or its concert parties during that period. The Irish Takeover Panel has the power to extend the "look back" period to 12 months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired more than 10% of the issued and outstanding ordinary shares (i) during the period of 12 months prior to the commencement of the offer period or (ii) at any time after the commencement of the offer period, the offer must be in cash (or accompanied by a full cash alternative) and the price per ordinary share must not be less than the highest price paid by the bidder or its concert parties during, in the case of (i), the 12-month period prior to the commencement of the offer period or, in the case of (ii), the offer period. The Irish Takeover Panel may apply this rule to a bidder who, together with its concert parties, has acquired less than 10% of the total ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence on the date of the first announcement of the offer or proposed offer.

Substantial Acquisition Rules

The Irish takeover rules also contain rules governing substantial acquisitions of shares and other voting securities which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of the voting rights of the Company. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of the voting rights of the Company is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of the voting rights of the Company and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

Frustrating Action

Under the Irish takeover rules, the Company's board of directors is not permitted to take any action that might frustrate an offer for its shares once the Company's board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which the Company's board of directors has reason to believe an offer is or may be imminent. Exceptions to this prohibition are available where:

- the action is approved by the Company's shareholders at a general meeting; or
- the Irish Takeover Panel has given its consent, where:
- it is satisfied the action would not constitute frustrating action;
- the Company's shareholders holding more than 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;

- the action is taken in accordance with a contract entered into prior to the announcement of the offer (or any earlier time at which the Company's board of directors considered the offer to be imminent); or
- the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

Other Provisions

Certain other provisions of Irish law or the Company's Constitution may be considered to have anti-takeover effects, including advance notice requirements for director nominations and other shareholder proposals, as well those described under the following captions: "*—Capital Structure—Authorized Share Capital*" (regarding issuance of preferred shares), "*—Preemption Rights, Share Warrants and Share Options*," "*—Disclosure of Interests in Shares*" and "*—Corporate Governance*."

Corporate Governance

The Company's Constitution delegates the day-to-day management of the Company to the board of directors. The Company's board of directors may then delegate the management of the Company to committees of the board of directors (consisting of one or more members of the board of directors) or executives; regardless, the Company's board of directors remains responsible, as a matter of Irish law, for the proper management of the affairs of the company. Committees may meet and adjourn as they determine proper. A vote at any committee meeting will be determined by a majority of votes of the members present.

The Company's board of directors has a standing audit committee, a compensation committee and a nominating and corporate governance committee, with each committee comprised solely of independent directors, as prescribed by The NASDAQ Global Select Market listing standards and SEC rules and regulations. The Company has adopted corporate governance policies, including a code of conduct and an insider trading policy, as well as an open door reporting policy and a comprehensive compliance program.

The Companies Act require a minimum of two directors. The Company's Constitution provides that the board may determine the size of the board from time to time.

The Company's board of directors is divided into three classes, designated Class I, Class II and Class III. The term of the Class I directors will expire on the date of the 2021 annual general meeting; the term of the Class II directors will expire on the date of the 2022 annual general meeting; and the term of the Class III directors will expire on the date of the 2020 annual general meeting. 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. In no case will any decrease in the number of directors shorten the term of any incumbent director. A director may hold office until the annual general meeting of the year in which his or her term expires and until his or her successor is elected and duly qualified, subject to his or her prior death, resignation, retirement, disqualification or removal from office.

Directors are elected by ordinary resolution at a general meeting. Irish law requires majority voting for the election of directors, which could result in the number of directors falling below the prescribed minimum number of directors due to the failure of nominees to be elected. Accordingly, the Company's Constitution provides that if, at any general meeting of shareholders, the number of directors is reduced below the minimum prescribed by the Constitution due to the failure of any person nominated to be a director to be elected, then, in such circumstances, the nominee or nominees who receive the highest number of votes in favor of election will be elected in order to maintain such prescribed minimum number of directors. Each director elected in this manner will remain a director (subject to the provisions of the Companies Act and the articles of association) only until the conclusion of the next annual general meeting unless he or she is reelected.

Under the Companies Act and notwithstanding anything contained in the Constitution or in any agreement between the Company and a director, the Company's shareholders may, by an ordinary resolution, remove a director from office before the expiration of his or her term at a meeting held on no less than 28 days' notice and at which the director is entitled to be heard. The power of removal is without prejudice to any claim for damages for breach of contract (e.g. employment contract) that the director may have against the Company in respect of his removal.

The Company's Constitution provides that the board of directors may fill any vacancy occurring on the board of directors. If the Company's board of directors fills a vacancy, the director's term expires at the next annual

general meeting. A vacancy on the board of directors created by the removal of a director may be filled by the shareholders at the meeting at which such director is removed and, in the absence of such election or appointment, the remaining directors may fill the vacancy.

Legal Name; Formation; Fiscal Year; Registered Office

Jazz Pharmaceuticals Public Limited Company is the Company's current legal and commercial name. The Company was incorporated in Ireland on March 15, 2005 as a private limited company (registration number 399192) under the name Azur Pharma Limited. Azur Pharma Limited was re-registered as a public limited company named Azur Pharma Public Limited Company effective October 20, 2011, and was subsequently renamed Jazz Pharmaceuticals Public Limited Company on January 16, 2012. The Company's fiscal year ends on December 31st and its registered address is Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland D04 E5W7.

Duration; Dissolution; Rights Upon Liquidation

The Company's duration is unlimited. The Company may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding up, a special resolution of shareholders is required. The Company may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where it has failed to file certain returns.

The Company's Constitution provides that the ordinary shareholders are entitled to participate pro rata in a winding up, but their right to do so may be subject to the rights of any preferred shareholders to participate under the terms of any series or class of preferred shares.

Certificated Shares

Pursuant to the Companies Act, a shareholder is entitled to be issued a share certificate on request and subject to payment of a nominal fee.

No Sinking Fund

Ordinary shares have no sinking fund provisions.

Stock Exchange Listing

Ordinary shares are listed on The NASDAQ Global Select Market under the trading symbol "JAZZ." Ordinary shares are not currently intended to be listed on the Irish Stock Exchange.

Transfer and Registration of Shares

The transfer agent and registrar for ordinary shares is Computershare Trust Company, N.A. Its address is 250 Royall Street, Canton, MA 02021. An affiliate of the transfer agent maintains the share register, registration in which is determinative of ownership of ordinary shares. A shareholder who holds shares beneficially is not the holder of record of such shares. Instead, the depository (for example, Cede & Co., as nominee for DTC) or other nominee is the holder of record of those shares. Accordingly, a transfer of shares from a person who holds such shares beneficially to a person who also holds such shares beneficially through a depository or other nominee will not be registered in the Company's official share register, as the depository or other nominee will remain the record holder of any such shares.

A written instrument of transfer is required under Irish law in order to register on the Company's official share register any transfer of shares (i) from a person who holds such shares directly to any other person, (ii) from a person who holds such shares beneficially but not directly to a person who holds such shares directly, or (iii) from a person who holds such shares beneficially to another person who holds such shares beneficially where the transfer involves a change in the depository or other nominee that is the record owner of the transferred shares. An instrument of transfer is also required for a shareholder who directly holds shares to transfer those shares into his or her own broker account (or vice versa). Such instruments of transfer may give rise to Irish stamp duty, which must be paid prior to registration of the transfer on the Company's official Irish share register. However, a shareholder who directly holds shares may transfer those shares into his or her own broker account (or vice versa) without giving rise to Irish stamp duty provided there is no change in the ultimate beneficial ownership of the shares as a result of the transfer and the transfer is not made in contemplation of a sale of the shares.

Any transfer of ordinary shares that is subject to Irish stamp duty will not be registered in the name of the buyer unless an instrument of transfer is duly stamped and provided to the transfer agent. The Company, in its absolute discretion and insofar as the Companies Act or any other applicable law permit, may, or may provide that any of its subsidiaries will, pay Irish stamp duty arising on a transfer of ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of ordinary shares which would otherwise be payable by the transferee is paid by the Company or any of its subsidiaries on behalf of the transferee, then in those circumstances, the Company will, on its behalf or on behalf of its 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) to claim a first and permanent lien on ordinary shares on which stamp duty has been paid by the Company or its subsidiary for the amount of stamp duty paid. The Company's lien shall extend to all dividends paid on those ordinary shares. Parties to a share transfer may assume that any stamp duty arising in respect of a transaction in ordinary shares has been paid unless one or both of such parties is otherwise notified.

The Company's Constitution delegates to the secretary or assistant secretary of the Company the authority, on behalf of the Company, to execute an instrument of transfer on behalf of a transferring party. Under the Company's Constitution, the directors can also authorize any person to execute an instrument of transfer on behalf of a transferring party in certain circumstances.

In order to help ensure that the official share register is regularly updated to reflect trading of ordinary shares occurring through normal electronic systems, the Company intends to regularly produce any required instruments of transfer in connection with any transactions for which stamp duty is paid (subject to the reimbursement and set-off rights described above). In the event that the Company notifies one or both of the parties to a share transfer that its believes stamp duty is required to be paid in connection with the transfer and that the Company will not pay the stamp duty, the parties may either themselves arrange for the execution of the required instrument of transfer (and may request a form of instrument of transfer from the Company for this purpose) or request that the Company execute an instrument of transfer on behalf of the transferring party. In either event, if the parties to the share transfer have the instrument of transfer duly stamped (to the extent required) and then provide it to the Company's transfer agent, the buyer will be registered as the legal owner of the relevant shares on the Company's official Irish share register (subject to the suspension right described below).

The directors may suspend registration of transfers from time to time, not exceeding 30 days in aggregate each year.

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. Except as indicated below, dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities.

The Financial Transfers Act, 1992, provides that the Irish Minister for Finance can make provision for the restriction of financial transfers between Ireland and other countries. For the purposes of this Act, "financial transfers" include all transfers which would be movements of capital or payments within the meaning of the treaties governing the European Communities if they had been made between Member States of the Communities. This Act has been used by the Minister for Finance to implement European Council Directives, which provide for the restriction of financial transfers to certain countries, organizations and people including the Al-Qaeda network and the Taliban, Afghanistan, Belarus, Burma (Myanmar), Democratic People's Republic of Korea, Democratic Republic of Congo, Egypt, Iran, Iraq, Ivory Coast, Lebanon, Liberia, Libya, Republic of Guinea, Somalia, Sudan, and Syria.

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.

CONTRACT MANUFACTURING AGREEMENT

API AND DRUG PRODUCT

This Agreement is made as of 20 January 2020 (the **Effective Date**) between

Siegfried AG

Untere Bruehlstrasse 4, 4800 Zofingen, Switzerland (**Siegfried**);

and

Jazz Pharmaceuticals Ireland Limited

5th Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland (**Jazz**).

Recitals

A. Siegfried is engaged in the business of, among other things, providing development and/or manufacturing services with regard to drug substances and drug products for the pharmaceutical industry;

B. Jazz is engaged in the business of, among other things, developing, producing, formulating, distributing and commercializing pharmaceutical products;

C. Jazz desires to have Siegfried Manufacture and supply to Jazz Product (as defined herein) in commercial quantities; and

D. Siegfried, subject to the terms and conditions of this Agreement, desires to Manufacture and supply Product to Jazz.

Now, therefore, the Parties agree as follows:

1. Definitions

Unless elsewhere defined in this Agreement, each of the capitalized terms used in this Agreement (other than the names of the Parties and the headings of the Sections) shall have the meanings indicated below. Such meanings shall apply equally to all forms of such terms, including singular and plural forms, unless otherwise clearly indicated.

1.1 **Active Pharmaceutical Ingredient/API** shall mean the active pharmaceutical ingredient(s) set forth in Annex 1.1.

1.2 **Affiliate** shall mean with respect to any Party any person or entity Controlling, Controlled by, or under common Control with a Party at any time during the Term of this Agreement. For purposes of this definition, the term **Control** shall mean the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting stock, by contract or otherwise. In the case of a corporation, the term Control shall mean the direct or indirect ownership of at least fifty per cent (50%) of the outstanding voting stock.

1.3 **Agreement** shall mean this Contract Manufacturing Agreement, including its Annexes (and appendices, if applicable), and including the Quality Agreement, in each case as may be amended from time to time according to the applicable terms and conditions of this Agreement or the Quality Agreement.

1.4 **Alternative Manufacturer** shall have the meaning as set out in Section 12.10.

1.5 **API Manufacturing Site** shall mean Siegfried's facilities located at Untere Bruehlstrasse 4, 4800 Zofingen, Switzerland.

1.6 **Applicable Laws** shall mean all laws, rules and regulations applicable to the Manufacturing of API at the API Manufacturing Site or to the Manufacturing of Drug Product at the Drug Product Manufacturing Site, respectively, including without limitation the (i) U.S. Federal Food, Drug and Cosmetic Act, and all rules and regulations thereunder, (ii) EU Commission Directives 2001/83/EC as amended, and 2003/94/EC, and Directive 91/412/EEC, (iii) cGMP Regulations, and (iv) the counterparts to the foregoing in other jurisdictions, to the extent that Siegfried performs any Manufacturing in such jurisdiction.

1.7 **Arising Intellectual Property Rights** means all Intellectual Property Rights which are made, developed or reduced to practice by a Party in the performance of, or in connection with or related to, this Agreement.

1.8 **Batch** shall mean a specific quantity of Product or other Material that is intended to have uniform character and quality, within specified limits, and is produced during the same cycle of manufacture.

1.9 **Business Day** shall mean a day (not being a Saturday or Sunday) on which banks are open for business in Zurich, Switzerland, Hal-Far, Malta or Dublin, Ireland, as the context requires.

1.10 **cGMP** shall mean good manufacturing practices as described in regulations and guidance documents pertaining to manufacturing and quality control practice applicable for respective Product as may be further defined in the Quality Agreement.

1.11 **Change** shall mean any change to the Specifications, Master Batch Record, Raw Materials, Consigned Materials, Designated Vendor, API Manufacturing Site or the Drug Product Manufacturing Site, such Change being either (i) a **Required Change** (as

defined in Section 6.5), (ii) a **Customer Change** (as defined in Section 6.6), or (iii) a **Siegfried Change** (as defined in Section 6.7).

1.12 **Chemistry, Manufacturing and Control/CMC** shall mean the part of pharmaceutical development that deals with the nature of the API or Drug Product, respectively, the manner in which both are made, and the manner by which the manufacturing process is shown to be in control.

1.13 **Confidential Information** shall have the meaning as set out in Section 10.1.

1.14 **Consigned Materials** shall mean the materials that are owned by Jazz or that are to be provided by or on behalf of Jazz to Siegfried for the Manufacture of the API or Drug Product, respectively; including without limitation the Key Material and API (in accordance with Section 5.2).

1.15 **Designated Vendor** shall have the meaning as set out in Section 6.4.

1.16 **Delivery Shortfall** shall have the meaning as set out in Section 14.2.

1.17 **Drug Product** shall mean the drug product containing the API (film-coated tablets in bulk form), as set forth in Annex 1.2.

1.18 **Drug Product Manufacturing Site** shall mean Siegfried's Affiliate (Siegfried Malta Limited) facilities located in HHF070 Hal Far Industrial Estate, Hal Far BBG 3000, Malta.

1.19 **DEA** shall mean the United States Drug Enforcement Administration or any successor entity thereto.

1.20 **Effective Date** shall have the meaning set forth on the front page of this Agreement.

1.21 **EMA** shall mean the European Medicines Agency or any successor entity thereto.

1.22 **Entitled Person** shall have the meaning as set out in Section 10.3.

1.23 **Equipment** means any equipment used in the Manufacture of a Product by Siegfried hereunder.

1.24 **FDA** shall mean the United States Food and Drug Administration or any successor entity thereto.

1.25 **Forecast** shall have the meaning as set out in Section 3.2.

1.26 **Force Majeure Event** shall have the meaning as set out in Section 16.3.

1.27 **Hidden Defects** shall mean a failure of Product to conform to the Specifications upon delivery, such failure not being discoverable by Jazz or its designee upon reasonable physical inspection upon receipt of the Product pursuant to Section 4.3.

1.28 **Improvement** shall mean any result, data, documentation, invention, improvement, innovation, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable.

1.29 **Initial Period** shall have the meaning as set forth in Section 12.1.

1.30 **Intellectual Property Rights** shall mean, without limitation, all Improvements, inventions, patent applications, rights in patents, registered or unregistered design rights, copyrights, database rights, trademarks, trade names, know-how, trade secrets and other industrial or intellectual property rights of whatever kind.

1.31 **Key Material** shall mean the key starting material as set forth in Annex 1.3.

1.32 **Losses** shall mean all liabilities, claims, demands, actions, suits, losses, damages, costs and expenses (including reasonable attorney's fees) incurred by a Party.

1.33 **Manufacture/Manufacturing/Manufactured** shall mean all activities with respect to the manufacturing of the API or Drug Product, respectively, including, without limitation, the purchase of Raw Materials and primary packaging materials, production, quality control, quality assurance, release testing and stability testing, packaging and release of Product for shipment (but excluding, without limitation, (i) release of Drug Product for the market and (ii) shipment).

1.34 **Manufacturing Site** shall mean the API Manufacturing Site, the Drug Product Manufacturing Site, or both of them, as the case may be.

1.35 **Marketing Authorization/MA** shall mean the formal authorization (and associated documentation) granted or issued by a Regulatory Authority necessary for the lawful marketing and sale of the Drug Product in the respective country/countries of the Territory over which such Regulatory Authority has jurisdiction.

1.36 **Master Batch Record** shall mean the production Batch record for the Manufacture of the API or Drug Product, developed by Siegfried in part from the Technology, specifying the process, manufacture, deviations and testing of the API or Drug Product, respectively.

1.37 **Materials** shall mean Raw Materials and/or Consigned Materials.

1.38 **Non-Conformance Claim** shall have the meaning as set out in Section 4.3.

1.39 **Order** shall mean a purchase order issued by Jazz for a certain quantity of Product.

1.40 **Order Confirmation** shall mean a confirmation issued by Siegfried that an Order posted by Jazz shall be executed.

1.41 **Party/Parties** shall mean either Jazz or Siegfried, or both, as the context may require.

1.42 **Pre-Existing Intellectual Property Rights** of a Party means all Intellectual Property Rights owned, conceived, developed, first reduced to practice or otherwise made or acquired by such Party prior to the Effective Date hereof, including all modifications, adjustments or improvements thereto (to the extent such modifications, adjustments or improvements do not constitute any of the other Party's Arising Intellectual Property Rights in accordance with Section 11.2 or Section 11.3, as the case may be).

1.43 **Product/Products** shall mean the API or the Drug Product or the two of them, as the context may require.

1.44 **Quality Agreement** shall mean the quality technical agreement between Jazz and Siegfried which defines the quality assurance responsibilities of each Party in respect of Product quality and compliance under cGMP Regulations, as may be amended from time to time.

1.45 **Raw Materials** shall mean all raw materials, excipients, and processing, filling and packaging components, which are not Product or Consigned Materials and which are necessary to manufacture the API or Drug Product, respectively, as set forth in the relevant Master Batch Record.

1.46 **Recall** shall have the meaning as set out in Section 7.6.

1.47 **Regulatory Authority** shall mean the governmental authority or authorities, which are responsible for approving the conduct of clinical trials, marketing and sale of pharmaceutical products and shall be EMA and FDA.

1.48 **Specifications** shall mean the description of technical requirements the API or Drug Product has to conform to, as set out in detail in the Quality Agreement.

1.49 **Technology** shall mean all information, Intellectual Property Rights and data in any form that Jazz has disclosed or will disclose, directly or indirectly, to Siegfried that may be necessary or useful for Manufacture of the API or Drug Product, respectively, as the same may be modified from time to time by Jazz in its sole discretion. All Technology shall constitute Confidential Information of Jazz, subject to Section 10.5.

1.50 **Term** shall have the meaning as set out in Section 12.2.

1.51 **Territory** shall mean the United States of America (with its territories, possessions, and protectorates, such as the Commonwealth of Puerto Rico), the member states of the European Union and/or European Economic Area (EU/EEA), Canada, United Kingdom (notwithstanding it being a member of the EU/EEA as of the Effective Date), Switzerland, Turkey, Australia, New Zealand, Brazil, Mexico, and any other country, which the Parties agree in writing to add to this definition of Territory in an amendment to this Agreement.

2. Scope of Work

2.1 Appointment. Jazz hereby appoints Siegfried, and Siegfried accepts such appointment, to (i) Manufacture and supply the Drug Product for or on behalf of Jazz at the Drug Product Manufacturing Site, (ii) Manufacture and supply the API for or on behalf of Jazz at the API Manufacturing Site, whereas the API may be supplied to Jazz or may be used by Siegfried in the Manufacture of the Drug Product and (iii) act as a broker for the transport of the API (owned by Jazz) from the API Manufacturing Site to the Drug Product Manufacturing Site, subject to the terms and conditions set forth in this Agreement.

2.2 Siegfried Malta Limited. Siegfried has entered into this Agreement on behalf of itself and its Affiliate, Siegfried Malta Limited, through which Siegfried shall be performing certain activities hereunder. Siegfried shall procure that Siegfried Malta Limited shall be bound by the applicable terms and conditions of this Agreement as if it were a direct Party hereto and shall procure the due performance thereof by Siegfried Malta Limited. Jazz shall only be entitled to engage and communicate directly with Siegfried Malta Limited upon prior consent of Siegfried.

2.3 Purchase Commitment. Subject to Section 2.3, during the Term, Jazz (and any of its Affiliates, or any transferee or successor in interest to Jazz's business or Product) shall order and purchase at least sixty percent (60%) of its requirements for the API and forty percent (40%) of its requirements for the Drug Product from Siegfried.

Subject to this minimum purchase commitment and Section 2.4 below, the Parties further agree on the following pricing mechanism:

a) For the API: [*]; or

b) For the Drug Product: [*]:

c) During the Term, but not more often than [*], upon reasonable prior written notice to Jazz and to such an extent as will not interfere with the normal operations of Jazz, an independent certified public accountant selected by Siegfried and reasonably acceptable to Jazz will have reasonable access during normal business hours to inspect, at Siegfried's expense, Jazz's books of accounts and other records pertaining to the purchase of API and Drug Product as may reasonably be necessary for the purpose of determining Jazz's compliance with the minimum purchase commitment provided for under this Agreement. Prior to commencing any such inspection and/or audit, the accountant shall enter into a reasonable and customary confidentiality agreement with Jazz which prohibits the disclosure of any information, except as provided in said confidentiality agreement or pursuant to court order, relating to Jazz and/or its Affiliates to any person or entity, including Siegfried, except that such accountant may issue a report to Siegfried, which report shall also be provided to Jazz, the sole purpose of which will be to report to Siegfried on Jazz's compliance or non-compliance with such minimum purchase commitment. Siegfried shall treat all information received from Jazz and/or its Affiliates and/or the accountant hereunder as Jazz's Confidential Information. In the event of any dispute between Jazz and Siegfried regarding the findings of any such inspection or audit, the Parties shall initially attempt in good faith to resolve the dispute amicably between themselves. The costs for such an audit shall be borne by Jazz in case of the discovery of any inaccuracies resulting in non-compliance with Jazz's minimum purchase commitment.

d) In the event (i) Siegfried does not deliver conforming Product as per Sections 3.7 and 14.1 or (ii) Jazz notifies Siegfried in writing that Jazz has reasonable and material quality concerns regarding Siegfried's Manufacture of the Product (including without limitation due to the occurrence of any major or critical deviations that have not been properly investigated by Siegfried (in Jazz's reasonable discretion) or any material breach by Siegfried of its obligations under the Quality Agreement that remain uncured after [*] as per Section 12.4), the Parties agree that Jazz may, upon written notice to Siegfried, temporally purchase (i) more than forty-percent (40%) of its requirements of API and/or (ii) more than sixty-percent (60%) of its requirements of Drug Product from other suppliers without constituting a breach of its obligations under Section 2.3 and without any penalty, surcharge or Volume Shortfall payment being due or owing (pursuant to Section 2.3a) or 2.3b)). This Section 2.3 c) will apply only to the extent and for so long as Siegfried does not deliver conforming Product as per Sections 3.7 and 14.1 (excluding any Force

Majeure Event or any reason caused due to an act or omission of Jazz); provided, however, that, if Siegfried resumes the capability to deliver (conforming) Product comprising at least eighty percent (80%) of Jazz's outstanding Product requirements, the requirements of this Section 2.3 shall be deemed to be reinstated (provided, however, that Jazz shall not be liable for any penalty, surcharge or Volume Shortfall payment in respect of any Product orders it committed to with another supplier during the period in which Siegfried did not or could not deliver conforming Product).

2.4 Exclusivity.

Without limiting Siegfried's other obligations hereunder (including without limitation its obligations under Sections 10 and 11), during the Term of this Agreement, neither Siegfried nor any of Siegfried's Affiliates engaged by Jazz (or any of Jazz's Affiliates) within the previous [*] shall develop, make, have made, use, sell, have sold, solicit, import or commercialize, or assist any third party in any of the foregoing (other than Jazz or its designee pursuant to this Agreement) with respect to

(i) Product and/or

(ii) any drug product containing the API

that directly or indirectly uses, relies on, references, incorporates, derives from or relates to in any way, in whole or in part, any of the Technology (except technology that is general knowledge and publicly known or in the public domain), Jazz's Confidential Information or Jazz's Intellectual Property Rights (including without limitation Jazz's Pre-Existing Intellectual Property Rights and Jazz's Arising Intellectual Property Rights). For the avoidance of doubt, Jazz acknowledges that nothing in this Agreement shall be construed as a representation or inference that Siegfried will not enter into business relationships with other third parties regarding products that are similar to or that may compete with any Product, Technology or process covered by this Agreement subject always to Siegfried's compliance with its obligations hereunder (including without limitation its obligations under Sections 10 and 11) and provided always that none of Jazz's Technology, Jazz's Confidential Information and/or Jazz's Intellectual Property Rights (including Jazz's Pre-Existing Intellectual Property Rights and Jazz's Arising Intellectual Property Rights) shall be used or disclosed in breach of this Agreement.

2.5 Controlled Substance. The Parties acknowledge that the API (and thus the Drug Product) may become scheduled under the Federal Controlled Substances Act and/or respective laws in other countries of the Territory (collectively, the **FCSA**). Jazz shall promptly inform Siegfried if the API will be subject to the FCSA, and the Parties will confer and discuss in good faith the necessary activities to be taken as needed to comply with the FCSA, and the allocation of costs therefore, including without limitation, amending this Agreement and obtaining the necessary licenses, authorizations and regulatory requirements.

2.6 Relationship Management. Upon execution of this Agreement, each Party shall forthwith appoint one of its employees to be a relationship manager responsible for liaison

between the Parties. Those representatives shall meet periodically as agreed to review the current status of the business relationship, including, but not limited to, Equipment and facilities updates, current and anticipated need of each Product (current and anticipated inventory (as per Section 5.4), current and anticipated manufacturing capacity, planned work or changes to the Manufacturing Site, supply chain concerns, in particular without limitations, Materials in short supply or vendor performance, and manage any issues that have arisen. [*], the Parties shall organize business review meetings to discuss operational and strategic aspects relating to the execution of this Agreement as well as any issues communicated by either Party to the other Party. With the prior agreement of the Parties, the frequency of the meetings may be increased. The meetings may also be organized through media (teleconferences or videoconferences) and each Party shall bear its own costs in relation with all meetings organized under this Section 2.6.

2.7 Information. Jazz shall provide to Siegfried the Technology and such other information in Jazz's possession relating to the Products, which are useful and necessary for Siegfried in performing its obligations hereunder, in particular any information concerning any potential hazards involved in Manufacturing Product and other Safety, Health and Environment (SHE) requirements related to the handling of the Product or any waste. The Technology provided by Jazz to Siegfried hereunder shall be subject to the terms and conditions set forth in Sections 10 and 11.

3. Ordering, Purchase and Supply of Product

3.1 Jazz shall submit to Siegfried, upon [*] and then [*], an estimated (good faith) demand forecast of Jazz's requirements of each Product for the next [*].

3.2 Jazz shall submit to Siegfried, on a [*] basis, [*] prior to the beginning of each month, an estimated (good faith) demand forecast of Jazz's requirements of each Product for the next [*], as follows (each, a "**Forecast"**):

3.2.1 Drug Product Forecast: Jazz's [*] forecast for Drug Product shall set forth:

(i) the placed Orders for the next [*], which shall be binding on the Parties with respect to quantities and delivery dates;

(ii) the estimated forecast for the next [*], which shall not be binding.

3.2.2 The total lead-time for Manufacture of Drug Product shall be [*], provided sufficient quantity of API is available to Drug Product Manufacturing Site at least [*] prior to the confirmed delivery date.

3.2.3 API Forecast: Jazz's [*] forecast for API shall set forth:

(i) the placed Orders for the next [*], which shall be binding on the Parties with respect to quantities and delivery dates;

(ii) the estimated forecast for the [*], which shall not be binding.

3.2.4 The total lead-time for Manufacture of API shall be [*], provided sufficient quantity of Key Material is available to Siegfried at least [*] prior to the confirmed delivery date. In case (i) the Key Material is not available to Siegfried in sufficient quantity at least [*] prior to the confirmed delivery date or (ii) the API ordered by Jazz was not reflected in the [*] forecast, the Parties shall jointly agree on the lead time.

3.3 Siegfried shall use commercially reasonable efforts to supply Jazz, no later than [*], with a written summary report of the agreed Consigned Materials, API and Drug Product inventory for such prior month in the form used by Siegfried for its customers, in order that Jazz may properly account for the inventory held by Siegfried (and its Affiliates) pursuant to this Agreement. The Parties may agree that additional specialized reports shall be prepared by Siegfried in accordance with Jazz's reasonable instructions. The costs for such additional reports will be borne by Jazz.

3.4 Jazz acknowledges that Siegfried will rely on the accuracy of Jazz's Forecasts in planning its Manufacture, storage and transport of Product as well as its acquisitions of Raw Materials, as set forth in Section 5. If at any time Jazz finds that a Forecast is inaccurate in a material respect, Jazz shall inform Siegfried without delay and the Parties shall confer and discuss without delay how to proceed.

3.5 Jazz shall make all purchases of Product hereunder by submitting Orders to Siegfried in accordance with the respective Product Forecast. Each such Order shall be in writing and shall specify (i) the Product ordered, (ii) the quantity ordered), (iii) the price pursuant to Annex 1.4, and (iv) the requested delivery date, giving Siegfried no less than the number of days in advance of requested delivery to Jazz pursuant to Section 3.2 (the **Lead Time**). Lead Times for Product deliveries for validation campaigns and/or initial requirements of Product for launch in a country of the Territory shall be agreed upon between the Parties in good faith.

3.6 In accordance with Section 3.2.3 or 3.2.4, Siegfried shall use commercially reasonable efforts to execute Orders which exceed by [*] of the forecasted quantities. Orders exceeding [*] of the forecasted quantities shall be discussed between the Parties, but are only binding upon confirmation by Siegfried. Subject to this Section 3, Siegfried shall confirm to Jazz by way of an Order Confirmation that it will meet Jazz's quantity requirements in accordance with the delivery date(s) within [*] from the date of

the receipt of an Order from Jazz, whereupon the Order shall be confirmed, final, and binding on Siegfried.

3.7 Siegfried shall promptly and without undue delay notify Jazz in writing of any anticipated delay or of any circumstance rendering it unable to Manufacture and/or supply Product in accordance with the delivery date(s) and the estimated duration of such delay/circumstance(s). Upon such written notice, the Parties will work together to agree upon a revised delivery schedule and the Parties shall proceed in accordance with Section 14.1.

3.8 The Product shall be delivered from Siegfried to Jazz [*] (Incoterms 2010) API Manufacturing Site or Drug Product Manufacturing Site, and at the price as set out in Annex 1.4. To clarify, Jazz assumes all responsibilities and liability arising out of the shipment, transport, storage, handling and use of the Product after delivery by Siegfried to Jazz in accordance with the agreed [*] Incoterms.

4. Product Delivery and Conformance

4.1 Jazz shall procure the pick-up and shipment of the Product at the agreed delivery date. A storage fee shall apply for Product which is not picked-up and shipped at that agreed delivery date through no fault of Siegfried or upon mutual agreement and thus stored by or on behalf of Siegfried for more than [*] from the agreed delivery date, such storage fee shall be [*]. Upon prior written notice to Jazz, Siegfried shall have the right to ship Product that have been stored more than [*] from the agreed delivery date to Jazz or its designee.

4.2 Siegfried will provide to Jazz the documentation set forth in the Quality Agreement with each shipment of Product. Siegfried acknowledges that Jazz will rely on the accuracy and completeness of such documentation in its determination of conformance of Product with Specifications, cGMP, the Quality Agreement and Applicable Law.

4.3 Upon delivery of Product to Jazz (or its designee), Jazz shall carry out a reasonable physical inspection, or shall procure a designee to carry out a reasonable physical inspection, of the Product within [*] in order to determine compliance with the Specifications, the Quality Agreement, Applicable Law and cGMP at the time of delivery and all stages of Manufacture prior thereto. If, in either Party's opinion or determination, any Product Manufactured does not comply with the Specifications, the Quality Agreement, Applicable Law or cGMP upon delivery or at any stage of Manufacture prior thereto, then such Party shall promptly notify the other Party in writing thereof (which may include email notification) (**Non-Conformance Claim**). If Jazz does not notify Siegfried within [*] after delivery of the Product, then the Product is deemed accepted, provided that Jazz retains the right to reject the Product at a later time in the case of Hidden Defects as set out in Section 4.4.

4.4 Jazz retains the right to reject Product for a period of [*] after delivery to Jazz (or its designee) in case of Hidden Defects (which may include, without limitation, a Hidden Defect caused by or arising due to a material error in the documentation supplied by Siegfried under Section 4.2), provided that Jazz notifies Siegfried in writing within [*] of discovering the Hidden Defect.

4.5 Any Non-Conformance Claim made by Jazz shall specify in reasonable detail the nature and basis for the claim and cite Siegfried's relevant Batch numbers or other information to enable specific identification of the Product involved. Siegfried shall review any Non-Conformance Claim made by Jazz and provide Jazz with the results of such (interim) review without undue delay and, in any event, within [*] of receipt of Jazz's Non-Conformance Claim, as set forth in the Quality Agreement. If such review by Siegfried confirms that the identified Product did not comply with the Specifications, Applicable Law, the Quality Agreement or cGMP upon delivery or at any stage of Manufacture, then Jazz shall have the right to reject such Product and the Parties shall proceed according to Section 14.1. The nonconforming Product shall be disposed or delivered, at Siegfried's expense, to such destination as agreed by the Parties, in compliance with applicable environmental laws and regulations. Neither Party shall use or dispose of Product that does not, or of which either Party claims that it does not, conform to the Specifications, the Quality Agreement, Applicable Law and cGMP upon delivery or at any stage of Manufacture thereof, without the other Party's prior written consent.

4.6 Any Non-Conformance Claim made by Siegfried shall specify in reasonable detail the nature and basis for the claim and cite Siegfried's relevant Batch numbers or other information to enable specific identification of the Product involved. Jazz shall review any Non-Conformance Claim made by Siegfried and provide Siegfried with the results of such review within [*] of receipt of Siegfried's Non-Conformance Claim. If such review by Jazz confirms that the identified Product did not comply with the Specifications, Applicable Law, the Quality Agreement or cGMP upon delivery or at any stage of Manufacture, then Siegfried shall have the right to reject such Product and the Parties shall proceed according to Section 14.1. The nonconforming Product shall be disposed or delivered, at Siegfried's expense, to such destination as agreed by the Parties, in compliance with applicable environmental laws and regulations. Neither Party shall use or dispose of Product that does not, or of which either Party claims that it does not, conform to the Specifications, the Quality Agreement, Applicable Law and cGMP upon delivery or at any stage of Manufacture thereof, without the other Party's prior written consent.

4.7 If the Parties fail to agree as to whether a quantity of Product conforms to the Specifications, Applicable Law, the Quality Agreement or cGMP upon delivery or at any stage of Manufacture, the Parties shall have the Batch in dispute and/or relevant data or information investigated, tested and/or further analyzed by an independent testing laboratory or consultant (if the Parties mutually agree to refer to a consultant) selected by agreement between the Parties. The decision of the independent testing laboratory or

consultant shall be deemed final as to any dispute over Product conformance with Specifications, Applicable Law, the material provisions of the Quality Agreement or cGMP upon delivery or at any stage of Manufacture. Should the laboratory or consultant determine that the delivered Product does not conform to the Specifications, the Quality Agreement, Applicable Law or cGMP upon delivery or at any stage of Manufacture, then Siegfried shall bear all costs for the independent laboratory or consultant, and all shipment, disposal and other reasonable, direct costs and expenses for conducting the investigations and Jazz shall have the right to reject such Batch of Product and the Parties shall proceed according to Section 14.1. However, in case of wrongful rejection of Drug Product by Jazz, then Jazz shall bear the expenses of returning any rejected Drug Product to Siegfried and shall compensate Siegfried the reasonable, direct costs and expenses for conducting the investigations, including without limitation, related to the shipment of the Product (initial or replacement shipment, as the case may be) and any pending purchase price payment still due as set out in this Agreement.

5. Purchase, Storage and Transport of Materials

5.1 In accordance with Jazz's Forecast and Orders placed, Siegfried will obtain sufficient quantities of all Raw Materials at Siegfried's costs and expenses in sufficient quantities and of good quality as necessary to enable Siegfried to Manufacture and supply Product in accordance with Jazz's requirements. Jazz shall also bear the mutually agreed costs of all material to be used as reference standards or impurity standards in the Manufacture of Products, unless otherwise mutually agreed in writing.

5.2 Jazz shall obtain all right, title and interest in and to the API upon release by Siegfried, whereupon such (released) API becomes Consigned Materials. Jazz shall cause that the Key Material will be supplied in good quality as necessary to enable Siegfried to Manufacture Product in accordance with Jazz's Forecast and Orders (see i.a. Section 3.2.4 above), at Jazz's costs and expenses. Any import duties, taxes or other fees due to governmental authorities regarding Consigned Materials shall be paid by Jazz.

5.3 Jazz shall solely and exclusively retain all right, title and interest in and to all Consigned Material released by Siegfried and Jazz shall insure such Consigned Material against loss and damage. Siegfried shall be liable for any loss of or damage to such Consigned Material, including destruction and shipping costs, if such loss or damage was caused by Siegfried's gross negligence or willful misconduct.

5.4 Any inventory level of Key Material and Consigned Materials (particularly of consigned API) shall only be established upon mutual agreement and at Jazz's reasonable cost and expenses. Siegfried shall adopt appropriate warehousing controls to rotate Consigned Materials stock as mutually agreed (based on the First-In/First-Out (FiFo) principle unless otherwise agreed in writing), unless otherwise instructed by Jazz and agreed by Siegfried.

5.5 Siegfried agrees that, without prior written consent by Jazz, Consigned Materials shall: (i) be used solely for the purpose of the Manufacture and supply of Product; (ii) be used in compliance with all Applicable Laws; and (iii) not be transferred to any third party, except to any Affiliate or subcontractor of Siegfried as agreed in the Quality Agreement or otherwise in writing with Jazz (and Siegfried remains fully and directly responsible for the acts and omissions of such Affiliate or subcontractor, as if performed by Siegfried), unless otherwise agreed by the Parties in writing.

5.6 Until otherwise notified by Jazz to Siegfried with at least [*] prior notice or otherwise agreed by the Parties in writing, Siegfried shall act as a broker with regard to the transport of API owned by Jazz (Consigned Material) from the API Manufacturing Site to the Drug Product Manufacturing Site, at Jazz's reasonable and prior-agreed cost and expenses, and Siegfried shall appoint a qualified and approved subcontractor, as specified in the Quality Agreement and Jazz may monitor and approve Siegfried's shipping and freight practices as may be agreed in the Quality Agreement or otherwise in writing between the Parties. Siegfried shall only be responsible for the acts and omissions of all such logistics providers, if due Siegfried's gross negligence or willful misconduct.

5.7 Jazz agrees to reimburse Siegfried all reasonable cost and expenses incurred for the amount of inventory of Materials required to be written off as a result of Jazz requiring a change of Materials, in particular, without limitation, changes to specification or vendors, provided however, that Siegfried shall use commercially reasonable efforts to limit such loss of Materials.

5.8 Upon reasonable request of Jazz or expiration or termination of the Agreement, Siegfried will make such Consigned Materials available for collection by or on behalf of Jazz in good and usable condition and Jazz will pick-up such Consigned Materials within [*], at Jazz's cost and expenses.

6. Manufacture of Product

6.1 The terms of the Quality Agreement shall be deemed incorporated by reference into this Agreement.

6.2 Siegfried shall maintain the Manufacturing Sites and Equipment in a state of repair and operating efficiency consistent with the requirements of the Applicable Laws, cGMP, Specifications, the Quality Agreement, and Master Batch Record. Further details with regard to the Manufacturing Site shall be set forth in the Quality Agreement.

6.3 Siegfried shall obtain sufficient quantities of all Raw Materials to Manufacture and supply Product in accordance with Jazz's Forecast and shall ensure that such Raw Materials comply with the Specifications. Jazz shall reimburse Siegfried all costs and expenses reasonably incurred as a result of a change in the Specifications of such Raw Materials.

6.4 If Jazz, in its sole discretion, designates certain Raw Material or any other vendors, other than Siegfried or its Affiliates (each a **Designated Vendor**), then Siegfried shall obtain respective Raw Material(s) only from such Designated Vendors. Jazz shall reimburse Siegfried all costs and expenses reasonably incurred as a result from appointing or changing a Designated Vendor. Siegfried shall not be liable or responsible for any acts or omissions of such Designated Vendor, including without limitation, a delayed delivery, delivery of non-conforming Raw Material or other supply failure (unless and to the extent any such acts or omissions of such Designated Vendor arise as a result of Siegfried's negligence or wilful misconduct or any breach by Siegfried of its obligations hereunder).

6.5 In the event that either Party becomes aware and notifies the other Party that any Change is mandated by Applicable Laws (including, without limitation cGMP Regulations) or by a competent Regulatory Authority (**Required Change**), then Siegfried shall promptly (i) advise Jazz as to any quality assurance effect scheduling and, if applicable, Product price adjustments, which may reasonably and necessarily result therefrom, and (ii) make any necessary Required Change. Prior to implementation of such Required Change, the Parties shall negotiate in good faith on: (a) the allocation of the implementation costs with regard to the Product and any other products, (b) if applicable, the new Product price after the Required Change has been implemented; and (c) any other amendments to this Agreement which may be necessitated by such Required Change; provided always that all costs associated with Required Changes directly related to the Manufacturing Site that are not required solely to permit Siegfried to Manufacture the Product, or a group of products including the Product, shall be borne by Siegfried. Siegfried and Jazz shall cooperate in making any Required Changes and use commercially reasonable efforts to implement any Required Changes promptly in a manner that minimizes any effect on the supply hereunder to Jazz of the Product meeting Specifications.

6.6 In the event Jazz wishes to effect a Change which is not a Required Change (**Customer Change**), Jazz shall advise Siegfried in writing of such Customer Change as set forth in the Quality Agreement. If Siegfried (acting reasonably and promptly) deems, in its reasonable discretion, such Customer Change as implementable, then Siegfried shall provide (a) if applicable, an estimate of all reasonable, necessary and vouched implementation costs to be borne by Jazz, (b) if applicable, the new proposed Product price after the Customer Change has been implemented (if necessitated by such Customer Change), (c) the timing for implementation and (d) if applicable, an estimated amount of any Raw Materials rendered obsolete as a result of the Customer Change and respective costs to be borne by Jazz. Subject to Jazz's approval, Siegfried shall implement such Customer Change. Jazz shall bear the approved implementation costs (which include the costs for the Raw Materials rendered obsolete) and the new Product Price, if applicable, shall apply after the implementation.

6.7 In the event Siegfried wishes to effect a Change which is not a Required Change (**Siegfried Change**), Siegfried shall advise Jazz in writing of such Siegfried Change as

set forth in the Quality Agreement. Siegfried Changes will only be implemented following the approval of Jazz (acting reasonably and promptly), such approval not to be unreasonably conditioned, withheld or delayed. Unless otherwise agreed by the Parties, Siegfried's implementation costs of the Siegfried Changes will be borne by Siegfried. Both Parties shall negotiate in good faith (a) the timing for implementation and (b) an estimated amount of any Raw Material rendered obsolete as a result of the Siegfried Change. In allocating the costs, the Parties should consider whether such Siegfried Change is beneficial to either or both Parties.

7. Audits, Notification and Recall

7.1 Jazz has the right to carry out audits as set forth in the Quality Agreement. While on the Manufacturing Site, Jazz shall comply with all of Siegfried's applicable policies regarding, safety, health, data protection, confidentiality and the like which Siegfried, in its sole discretion, deems relevant.

7.2 Siegfried shall provide Jazz and its designees with reasonable access to its Manufacturing Site and the areas in which Materials or Product is Manufactured, stored, handled or shipped, and Jazz and its designees shall be permitted to review Siegfried's standard operating procedures related to Manufacture, storage, handling, general facilities, equipment and procedures required for compliance with cGMP.

7.3 Siegfried will use commercially reasonable efforts to obtain the right for Jazz to have similar audit rights for Siegfried's subcontractors, as set forth in the Quality Agreement.

7.4 Siegfried shall permit any Regulatory Authority to inspect relevant facilities, Equipment and records (including those of its Affiliates) at their request and shall resolve, and procure the resolution by its Affiliates, of all issues raised by a Regulatory Authority, if and to the extent such issues are relevant for the Manufacture of the Product or other cGMP-related obligations under this Agreement.

7.5 Each Party shall notify the other Party promptly of any serious or unexpected adverse reaction from the use of the Drug Product, which is reported to it or of which it becomes aware otherwise.

7.6 In the event either Party believes it may be necessary to conduct a recall or other similar action with respect to the Drug Product (each a **Recall**), the Parties shall consult with each other as to how best to proceed. If Siegfried reasonably requests a Recall and Jazz declines to act accordingly, Siegfried shall not be liable for any consequences or damages thereafter. Under no circumstances shall Siegfried be prohibited hereunder from taking any action that it is required to take by applicable law.

7.7 This Section applies to Affiliates of Siegfried and Siegfried shall procure the adherence of its Affiliates hereto and Jazz's right of audit thereof.

8. Compensation and Terms of Payment

8.1 In consideration for the services under the terms of this Agreement, Jazz shall pay Siegfried the prices as specified in, and in accordance with the payment terms set forth in, Annex 1.4.

8.2 All pricing, payments, credits, allowances or other monetary adjustments under this Agreement shall be in [*], as agreed between the Parties and set forth in the Annex 1.4.

8.3 The Parties may adjust prices upon mutual agreement based on (i) Raw Material price changes, (ii) indices, (iii) exchange rate variations as set forth in the Annex 1.4 or as otherwise agreed in writing.

8.4 Invoices shall be issued by Siegfried and sent to Jazz upon release of the Product.

8.5 Jazz shall pay such invoices to Siegfried within [*] after the date of receipt of such invoice. Each invoice shall, to the extent applicable, identify the Jazz Order number, Product quantities, unit price, freight charges and the total amount to be remitted by Jazz. Notwithstanding the foregoing, Jazz may withhold any amounts invoiced by Siegfried that it disputes in good faith and in writing prior to such [*] after the date of receipt of the respective invoice. If Jazz disputes any invoice, Jazz shall within [*] after such invoice is furnished to it notify Siegfried in writing that it disputes the accuracy or appropriateness of such invoice and specify the particular respects in which such invoice is inaccurate or inappropriate. The Parties will make good faith efforts to resolve any disputes within [*] thereafter. Any amounts that are disputed by Jazz and which the Parties determine are due following resolution of such dispute shall not be due until [*] following such resolution.

8.6 In the event any undisputed sum is not paid when due, then Jazz shall pay interest at a rate of [*] on the amount of such undisputed late sum (from the original due date until the date such undisputed late sum is paid).

9. Regulatory Affairs

9.1 Jazz shall be responsible for all regulatory filings in connection with the Product.

9.2 All information, documents and updates with regard to the Manufacture of Product which are in the possession of Siegfried and required by any Regulatory Authority shall, as reasonably requested by Jazz in connection with a submission for such regulatory filings, be as is provided by Siegfried to Jazz, free of charge.

9.3 Siegfried shall further provide Jazz, at Jazz's costs and expenses, with reasonable assistance in preparing or reviewing the regulatory filing or formulating responses to any questions and/or inquiries (i.e., deficiency letters) with respect to the above submissions.

9.4 Jazz shall provide, and Siegfried shall review, the CMC and other portions of Jazz's proposed regulatory filings relating to Siegfried's Manufacturing procedures or otherwise related to Siegfried's key obligations hereunder before the regulatory filings are submitted with relevant Regulatory Authorities and Jazz shall consider Siegfried's comments thereto in good faith.

9.5 The Parties acknowledge that the ultimate decision of whether any Drug Product will be approved for marketing and sale rests with the Regulatory Authorities of the respective market in the Territory and that Siegfried shall not be liable for the failure of the Regulatory Authorities to issue such Marketing Authorization approval other than due to Siegfried's gross negligence or willful misconduct or material breach of any of its obligations, warranties or undertakings hereunder.

9.6 The Parties acknowledge that the Manufacturing Site and/or the Drug Product Manufacturing Site has the required certifications from the Regulatory Authorities (the FDA, the EMA), which currently allows the Product distribution also in Canada and Australia by GMP certificates mutual recognition. In case a Product launch in other specific countries of Territory would require additional certifications, Parties will discuss in good faith and agree in prior on the plausibility, and costs and timelines associated.

10. Confidential Information

10.1 **Confidential Information** shall mean any information of whatever kind (including without limitation, data, compilations, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies and techniques), and all tangible and intangible embodiments and oral disclosures thereof of any kind whatsoever, (including without limitation, samples, apparatus, compositions, documents, drawings, machinery, patent applications, records and reports), which has been or will be disclosed by or on behalf of one Party (**Disclosing Party**) to the other Party (**Receiving Party**) in connection with this Agreement, and which is confidential or proprietary to the Disclosing Party or an Affiliate thereof, including, without limitation, any and all information pertaining to the Products and information which relates to the business of either Party, including business plans, strategies, operations, policies, procedures, pricing, techniques, accounts, marketing plans, financial plans and status, and personnel of either Party; provided that such information was designated in writing as *"Confidential"* or *"Proprietary"* information at the time of the initial disclosure or by confirmation in writing to the Receiving Party within [*] of the initial disclosure and further provided always that, notwithstanding the foregoing, information shall be subject to the obligations set forth herein and constitute Confidential Information, even if not identified or marked as confidential or proprietary, if the Receiving Party knows, or in the exercise of reasonable business

judgment should know, such information to be confidential or proprietary to the Disclosing Party.

10.2 Each Receiving Party agrees to retain in strict confidence any Confidential Information of the Disclosing Party (or its Affiliates or contractors), whether disclosed prior to, or after the Effective Date and not to use any such Confidential Information for any purpose except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and not to disclose, divulge or otherwise communicate any such Confidential Information to any third party.

10.3 The Receiving Party may disclose Confidential Information of the Disclosing Party to its Affiliates or its (or its Affiliate's) officers, directors, employees, agents, consultants, licensees, subcontractors or representatives (each an **Entitled Person**), who, in each case, (i) need to know such information for purposes of the implementation and performance by the Receiving Party of this Agreement, and (ii) are subject to confidentiality and non-use restrictions covering the Confidential Information that are at least as stringent at those contained herein, provided that the Receiving Party shall, nevertheless, remain fully liable for any breach by any of its Entitled Persons of their confidentiality obligations in respect of the Confidential Information.

10.4 Each Party agrees to use with respect to Confidential Information of the other Party at least the same standard of care as it uses to protect proprietary or confidential information of its own of comparable sensitivity and to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Entitled Persons.

10.5 The provisions of Section 10.1 shall not apply to any Confidential Information disclosed hereunder which (a) was independently developed or independently known by the Receiving Party prior to its disclosure to the Receiving Party by the Disclosing Party, as evidenced by written or electronic records; or (b) was before or after the date of such disclosure in the public domain or lawfully disclosed to the Receiving Party by an independent, unaffiliated third party rightfully in possession of the Confidential Information and not under any confidentiality obligation with regard to such Confidential Information; or (c) is required to be disclosed by the Receiving Party to the officials of a Regulatory Authority or to comply with applicable laws, to defend or prosecute litigation or to comply with Applicable Law, judicial orders or valid subpoenas, provided that the Receiving Party provides prior written notice of such intended disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure. The burden of proof of the foregoing exceptions shall lie with the Receiving Party. Specific information disclosed as part of the Confidential Information shall not be deemed to be in the public domain or in prior possession of the Receiving Party merely because it is included in more general information in the public domain or in the prior possession of the Receiving Party.

10.6 Except as otherwise expressly stated under this Agreement, nothing herein shall be construed as giving either Party any right, title or interest in or ownership of the Confidential Information of the other Party.

10.7 Except as may be required by law or regulation (including securities law and related filings), or in response to a valid subpoena or other judicial order, neither Party shall disclose the terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that the Parties may disclose the terms of this Agreement to the Parties' or third parties' accountants and attorneys, provided any such attorney or accountant receiving information concerning the terms of this Agreement is either bound by professional secrecy or agrees to be bound by confidentiality obligations equal to this Section 10 with respect to such information.

10.8 The Parties acknowledge that any breach of this Section 10 may constitute irreparable harm, and that the non-breaching Party shall be entitled to seek specific performance or injunctive relief to enforce this Section 10 in addition to whatever remedies such Party may otherwise be entitled to at law.

10.9 Upon termination or expiration of this Agreement (in whole or in part), each Party shall immediately deliver to the other (and cause any of its Entitled Persons to so deliver), at such Party's expense, all Confidential Information of the other Party (in the case of partial termination, that relates to the Terminated Product), including without limitation any and all copies, duplications, summaries and/or notes thereof or derived thereof, regardless of the format, and all remaining samples of Product (or, in the case of partial termination, Terminated Product), provided however, that both Parties may keep (i) such original documents, copies and samples as required by law or (ii) one set of such information in its legal files or archives for the sole purpose of monitoring its compliance with its obligations hereunder and neither Party shall be required to delete copies made in routine back up of its information technology systems (if access to such material is limited to members of such Party's information technology department only). Any information retained by a Party pursuant to this Section 10.9 shall be subject to the confidentiality obligations set forth herein.

11. Intellectual Property

11.1 Siegfried acknowledges that Jazz Confidential Information and Jazz's Pre-Existing Intellectual Property Rights provided to, utilized or observed by Siegfried pursuant to this Agreement shall be and remain the sole and exclusive property of Jazz. Likewise, Jazz acknowledges that Siegfried Confidential Information and Siegfried's Pre-Existing Intellectual Property Rights utilized by Siegfried pursuant to this Agreement shall be and remain the sole and exclusive property of Siegfried.

11.2 All rights, title, and interest in and to any Arising Intellectual Property Rights shall be the sole and exclusive property of Jazz to the extent any such Arising Intellectual Property Rights (i) incorporate, (ii) are derived from or (iii) relate to any of Jazz's Pre-Existing

Intellectual Property Rights, Jazz Product(s) (including without limitation Product development and use, whether patentable or not, Product Manufacture, manufacturing processes and procedures, Product analytical processes, procedures, methods or results and any route(s) of synthesis) and/or Jazz Confidential Information (**Jazz Arising Intellectual Property Rights**), and Siegfried hereby assigns, and transfers to Jazz its entire right, title and interest in and to any and all Jazz Arising Intellectual Property Rights. Jazz shall have the sole right to file and seek protection for any Jazz Arising Intellectual Property Rights. During the Term of this Agreement and for a period of [*] thereafter, upon request by Jazz and at Jazz's reasonable expense, Siegfried shall, and shall cause its employees and Affiliates and employees of its Affiliates, to promptly take all reasonable acts and things and execute all documents as Jazz may reasonably request, to transfer, assign and vest in Jazz the ownership and registration of Jazz Arising Intellectual Property Rights, and thereafter Jazz shall be responsible for and shall control, at its sole expense, the preparation, prosecution, maintenance and enforcement of all patent applications, resulting patents, and any other forms of Jazz Arising Intellectual Property Rights. In the event Jazz decides to file and prosecute patent applications on any Jazz Arising Intellectual Property Rights, Siegfried shall provide Jazz with reasonable assistance to obtain and defend such Jazz Arising Intellectual Property Rights at Jazz's reasonable cost and expense.

11.3 Jazz agrees that, as between Siegfried and Jazz, Siegfried shall own all Arising Intellectual Property Rights of a general nature generated or derived by Siegfried in the course of performing its obligations hereunder which (i) do not incorporate, (ii) are not derived from, (iii) are not specific to or dependent upon and (iv) do not relate in any way, either directly or indirectly, in whole or in part, to (a) Jazz's Pre-Existing Intellectual Property Rights, (b) Jazz Arising Intellectual Property Rights, (c) Jazz Confidential Information and/or (d) Jazz Product(s) (**Siegfried Arising Intellectual Property Rights**) and Jazz hereby assigns, and transfers to Siegfried its entire right, title and interest in and to any and all Siegfried Arising Intellectual Property Rights. Siegfried hereby grants Jazz a non-exclusive, worldwide, irrevocable, transferable, royalty-free license to use such Siegfried Arising Intellectual Property Rights to the extent that, and limited to, the development, manufacturing, sale, commercialization or any other use of the Product is dependent upon such license.

11.4 In the event of patent infringement or regulatory litigation or other legal proceedings, involving the Product, Siegfried shall have the right to suspend further supply of the Product to the extent this is required by a court order or arbitral award or order (whether interim or final). Such suspension shall be deemed a temporary suspension of Siegfried's supply obligations under this Agreement; provided, that if such suspension continues for more than [*], the Parties shall jointly attempt in good faith to modify this Agreement to resolve the situation but if they are unable to do so within the following [*] either Party may terminate this Agreement by notice to the other Party.

12. Term and Termination

12.1 This Agreement shall become effective on the Effective Date and, unless earlier terminated in accordance with this Section 12 or other applicable term of this Agreement, shall continue in full force and effect until December 31, 2024 (**Initial Period**).

12.2 Unless earlier terminated in accordance with any applicable term of this Agreement, this Agreement shall automatically renew for consecutive periods of one (1) year each unless one of the Parties notifies the other of its election not to renew the Agreement, either in whole or in part, at least eighteen (18) months prior to the end of the Initial Period or the renewal term then in effect, in which case this Agreement shall terminate, either in whole or in part (as the case may be), upon the expiration of such term (**Term**).

12.3 Either Party may terminate the Agreement immediately, by providing written notice to the other Party following the occurrence of any of the following events:

(a) the liquidation or dissolution of the other Party, or the commencement of insolvency procedures or any proceeding under any bankruptcy, insolvency or moratorium law, or any other law or laws for the relief of debtors which proceeding is not dismissed within [*], or the appointment of any receiver, trustee or assignee to take possession of the properties of the other Party;

(b) the sale, lease or other disposition of at least seventy-five percent (75%) of the other Party's business or assets, to a person other than an Affiliate of such Party; or

(c) the cessation of all or substantially all of the other Party's business operations.

12.4 If a Party breaches a material term or condition of this Agreement, the non-breaching Party shall have the right to terminate this Agreement, either in whole or in part, after [*] prior written notice to the other Party unless any such breach is cured within said [*]. Termination shall be in addition to all other rights and remedies available to the non-breaching Party at law or in equity.

12.5 This Agreement may be terminated, in whole or in part, by [*] written notice given by Jazz to Siegfried, as follows:

(a) If any required license, permit or certificate of Siegfried is not approved or not issued, or is withdrawn or suspended, by any Regulatory Authority; or

(b) If Drug Product is withdrawn or deleted by any Regulatory Authority so that there are no remaining markets available;

(c) If Jazz decides to permanently cease the commercialisation of Product.

12.6 This Agreement may be terminated, in whole or in part, by [*] written notice given by Siegfried to Jazz, as follows:

(a) If Jazz does not commercially launch any Drug Product within [*] after receipt of approval from any Regulatory Authority;

(b) If Jazz ceases commercial sale of Drug Product after commercial launch; or

(c) If Jazz does not purchase at least the total volume of Drug Product that requires Siegfried to Manufacture [*] of API during any [*] period after commercial launch of the Drug Product.

12.7 Any and all references to termination of this Agreement "in part" or "partial termination" throughout this Agreement shall mean that the applicable Party may, subject to and in accordance with the provisions of this Agreement, terminate this Agreement solely in respect of the Manufacture and supply of either (i) the API or (ii) the Drug Product (hereinafter referred to as the "Terminated Product"), in which case:

(a) the Agreement shall be terminated solely in respect of the Terminated Product;

(b) the Agreement shall continue in full force and effect in respect of the other non-terminated Product(s) (the "Non-Terminated Product");

(c) the provisions of the Agreement (including, without limitation, all applicable references to "Product") shall be construed accordingly; and

(d) for the avoidance of doubt, the terms of Section 2.3 shall apply accordingly solely in respect of the Non-Terminated Product and Jazz shall have no further obligations pursuant thereto in respect of the Terminated Product.

12.8 Upon expiration or termination of this Agreement, in whole or in part, Siegfried shall have the right to deliver to Jazz (and Jazz shall have the obligation to take delivery of) all Product (or, in the case of partial termination, all Terminated Product) already Manufactured by Siegfried pursuant to any Order and the remaining Materials that relate to the Terminated Product maintained by Siegfried pursuant to Section 5 and Jazz shall pay the price for such Products or Terminated Product (as the case may be) or Materials, provided however, that Siegfried uses commercially reasonable efforts to limit such loss of Materials.

12.9 Neither the expiration nor the termination of this Agreement, in whole or in part, shall relieve the Parties of their obligations (in the case of partial termination, as they relate to the Terminated Product) incurred prior to such expiration or termination. All provisions that, by their express or implied terms, are meant to survive termination of the Agreement, in particular all rights and obligations set forth in Sections 8 (Compensation and Terms of Payment), 10 (Confidential Information), 11 (Intellectual Property), 14.1 (Liability and Indemnity), 16 (Miscellaneous) and 17 (Applicable Law and Dispute Resolution) shall continue irrespective of such termination.

12.10 At all times during the Term, Jazz shall have the right to make Product and to have Product made by an Affiliate or third party manufacturer (**Alternative Manufacturer**) on its behalf, subject to the terms and conditions of this Agreement, including, without limitation Sections 2.3 (Purchase Commitment), 10 (Confidentiality), and 11 (Intellectual Property). Prior to appointing such an Alternative Manufacturer, Jazz and Siegfried shall, without delay, confer and discuss in good faith if and how any Affiliate of Siegfried may be appointed as alternative manufacturing site.

12.11 In the event Jazz intends to engage an Alternative Manufacturer at any time (including during the Term or upon termination of this Agreement in whole or in part), Siegfried shall, at the request of Jazz and subject to Jazz's reasonable cooperation, provide documents already prepared by Siegfried as may be necessary or helpful for the technology transfer of the manufacturing process for Product and the regulatory qualification to Jazz or the Alternative Manufacturer (including all know-how necessary or reasonably useful to enable Jazz or the Alternative Manufacturer to manufacture Product), provided that Siegfried will not be required to (i) prepare, translate or otherwise generate documents, unless otherwise agreed by Siegfried (acting reasonably) and at Jazz' reasonable costs and expenses, (ii) provide Siegfried Confidential Information, or (ii) grant licenses to Siegfried Pre-Existing Intellectual Property Rights or Siegfried Arising Intellectual Property Rights to a third party Alternative Manufacturer.

12.12 In the event of transfer to Jazz or its Affiliate, at the request of Jazz and subject to Jazz's reasonable cooperation, the Parties shall confer and discuss a technology transfer plan prepared by Jazz and agreed by Siegfried (such agreement not to be unreasonably withheld, conditioned or delayed), including applicable fees (**Jazz Technology Transfer Plan**). Such Jazz Technology Transfer Plan may, as applicable, provide for reasonable technical assistance regarding the manufacture, testing and supply of Product, including access to technical personnel, as may be helpful for Jazz or its Affiliate to implement such process to manufacture Product. Subject to Siegfried's approval and consent of the scope of the Jazz Technology Transfer Plan and cost and expenses therefore (such approval and consent not to be unreasonably withheld, conditioned or delayed), Siegfried shall implement the Jazz Technology Transfer Plan and Jazz shall reimburse Siegfried for all reasonable costs and expenses incurred by Siegfried to conduct such technology transfer and technical assistance, unless otherwise mutually agreed in writing.

13. Representations and Warranties

13.1 Each Party represents and warrants to the other Party (i) that it has the legal power, authority and right to enter into this Agreement and to perform its respective obligations set forth herein, (ii) that this Agreement has been duly executed and delivered by each Party and constitutes the valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, and (iii) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms hereof does not and will not conflict with or result in a breach of any term of, or constitute a

default under (i) any agreement or instrument binding or affecting it or its property; (ii) its charter documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound.

13.2 Siegfried represents, warrants and covenants to Jazz that all Product Manufactured pursuant to this Agreement shall conform with Specifications, Applicable Law and the Master Batch Record upon delivery and all Product has been Manufactured in accordance with cGMP and the material provisions of the Quality Agreement.

13.3 Jazz represents, warrants and covenants that the Technology and the Consigned Materials provided to Siegfried by or on behalf of Jazz hereunder, and used by Siegfried for the performance of its obligations in accordance with the terms of this Agreement and Jazz's instructions, does not infringe or misappropriate and, to the best of Jazz' knowledge, will not infringe or misappropriate the Intellectual Property Rights of any third party.

13.4 EXCEPT AS EXPRESSLY WARRANTED IN THIS AGREEMENT, NEITHER PARTY EXTENDS ANY OTHER WARRANTIES OR REPRESENTATIONS COVERING THE PRODUCT OR THE TECHNOLOGY, EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. EACH PARTY'S LIABILITY UNDER THESE WARRANTY PROVISIONS SHALL BE STRICTLY LIMITED TO THE REMEDIES PROVIDED FOR UNDER THIS AGREEMENT.

14. Liability and Indemnity

14.1 If Siegfried is unable to meet the delivery dates or other agreed time lines regarding the delivery of Product, or in case Product does not comply with Specifications, Applicable Law, cGMP or the Quality Agreement upon delivery and is rejected by Jazz (acting reasonably) in accordance with Section 4, Siegfried shall promptly, at Jazz's election: (i) for delayed delivery, use all commercially reasonable efforts to deliver the delayed Product as soon as possible after the original delivery date (or such later date as may be agreed by Jazz, acting reasonably), at no additional cost to Jazz and Siegfried shall bear the reasonable and documented transport costs for expedited delivery; (ii) for non-conforming Product, (a) replace any rightfully rejected Product with conforming Product as soon as possible (or such later date as may be as agreed by Jazz, acting reasonably) at no additional cost to Jazz or, if delivery of conforming Product is not possible within reasonable additional time, Siegfried shall refund to or credit Jazz all amounts paid by Jazz to Siegfried for such rightfully rejected Product, and (b) Siegfried shall bear the reasonable and documented transport, packaging, and destruction costs for such non-conforming Product. As agreed by the parties pursuant to Section 2.3, and upon Jazz' written notification as per Section 2.3, Jazz may temporally purchase (i) more than forty-percent (40%) of its requirements of API and/or (ii) more than sixty-percent (60%) of its requirements of Drug Product from other suppliers without constituting a breach of its

obligations under Section 2.3 and without any penalty, surcharge or Volume Shortfall payment being due or owing (pursuant to Section 2.3a) or 2.3b)). Except in the case of Siegfried's gross negligence or willful misconduct, and with the exception of the remedy set forth under Section 14.2 below, such delivery, replacement, credit or refund shall be the only remedy available to Jazz in case of late deliveries or non-conforming Product.

14.2 If Siegfried fails to deliver conforming Drug Product within a grace period of [*] after the original delivery date on [*] consecutive occasions within [*] (excluding, without limitation, due to any Force Majeure Event or any reason caused due to an act or omission of Jazz) (**Delivery Shortfall**), Jazz shall be entitled to terminate this Agreement, either in whole or in part, upon [*] written notice to Siegfried.

14.3 Siegfried shall indemnify, defend and hold Jazz, its directors, officers, employees and Affiliates, harmless against all Losses arising out of or in connection with third party claims, suits, actions, demands or judgments to the extent arising out of (i) the breach of any of Siegfried's obligations, warranties or representations under this Agreement, except to the extent such Losses are caused by Jazz's negligence or willful misconduct.

14.4 Jazz shall indemnify, defend and hold Siegfried, its directors, officers, employees and Affiliates harmless against all Losses, arising out of or in connection with third party claims, suits, actions, demands or judgments to the extent arising out of (i) the breach of any of Jazz's obligations, warranties or representations under this Agreement, of (ii) the death of or injury to any person or any damage to property caused by Jazz' commercialization or use of Product except to the extent such Losses are caused by Siegfried's negligence or willful misconduct.

14.5 With respect to any indemnification obligation under this Agreement, the following conditions shall be applicable:

(a) The Party seeking to be indemnified shall notify the indemnifying Party promptly in writing of any claim which may give rise to an obligation on the part of the indemnifying Party hereunder; and

(b) the indemnifying Party shall be allowed to timely take the sole control of the defense of any such action and claim, including all negotiations for the settlement, or compromise of such claim or action at its sole expense; and

(c) the Party to be indemnified shall, at the expense of the indemnifying Party, render reasonable assistance, information, co-operation and authority to permit the indemnifying Party to defend such action; and

(d) no settlement or compromise shall be binding on a Party hereto without its prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

14.6 During the Term of this Agreement, Siegfried and Jazz shall each obtain and carry in full force and effect adequate commercial, general liability insurance as common in the industry, including product liability insurance, which shall protect the Parties with respect to liability claims covered by Sections 14.3 and 14.4. Such insurance shall be written by a reputable insurance company and shall be endorsed to include product liability coverage. A Party shall provide another Party on request with a copy of certificates of insurance evidencing the same.

14.7 NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR SPECIAL, PUNITIVE, INCIDENTAL, INDIRECT (EXCEPT WITH RESPECT TO THE INDEMNIFICATION AGAINST CLAIMS OF THIRD PARTIES UNDER SECTION 14), OR CONSEQUENTIAL DAMAGES OF THE OTHER PARTY OR ANY THIRD PARTY, INCLUDING BUT NOT LIMITED TO CLAIMS BASED ON LOST PROFITS, LOSS OF TIME, LOSS OF OPPORTUNITY OR ANY OTHER ECONOMIC LOSS SUFFERED OR INCURRED AS A RESULT OF THIS AGREEMENT.

14.8 WITH THE EXCEPTION OF ANY LIABILITY ARISING DUE TO GROSS NEGLIGENCE, FRAUD, WILFUL MISCONDUCT OR BREACH OF SECTION 10 (CONFIDENTIAL INFORMATION) OR SECTION 11 (INTELLECTUAL PROPERTY) HEREOF, AND IF AND TO THE EXTENT PERMITTED BY APPLICABLE LAW, EACH PARTY'S MAXIMUM LIABILITY UNDER THIS AGREEMENT SHALL BE LIMITED TO [*].

15. Anti-Bribery and Anti-Corruption

15.1 Each Party shall comply fully at all times with all applicable laws and regulations, including without limitation any applicable anti-corruption laws, regulations and standards, of the territories in which Jazz or Siegfried, respectively, conduct business or activities hereunder or which are relevant to the operation of this Agreement (including but not limited to the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act 2010) (collectively, the **Anti-Corruption Laws**). Each Party will ensure that its personnel have read, understood and shall comply with the Anti-Corruption Laws.

15.2 Each Party shall at all times comply with their respective code of conducts. Any non-compliance of the Anti-Corruption Laws or otherwise relevant in connection with this Agreement shall be reported to the other Party without any delay. Siegfried acknowledges that Jazz's Code of Conduct is available online at **www.jazzpharmaceuticals.com** or will be handed out as a hard copy upon request. Jazz acknowledges that Siegfried's Code of Business Conduct is available online at **www.siegfried.ch** or will be handed out as a hard copy upon request.

15.3 Without limiting its obligations under Sections 15.1 and 15.2, each Party agrees that it has not, and covenants that it will not, in connection with the performance of this Agreement, promise, authorize, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value, directly or indirectly: (i) to any individual

including Government Officials; or (ii) to an intermediary for payment to any individual including Government Officials; or (iii) to any political party. For the purpose of this Section, "**Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government: (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office.

15.4 Without limiting its obligations under Sections 15.1 and 15.2, each Party agrees and covenants that no payments or transfers of value shall be made, promised, authorized, ratified or offered with the purpose or effect of public or commercial bribery, acceptance of or acquiescence in extortion, kickbacks or other unlawful or improper means of securing an improper advantage or obtaining or retaining business.

15.5 Each Party agrees and covenants that it has not permitted and will not permit anyone acting on its behalf to violate the Anti-Corruption Laws.

16. Miscellaneous

16.1 *No set-off.* Neither Party shall be entitled to set off any of its rights or obligations under this Agreement against the rights or obligations of another Party without having first obtained the prior written consent of that other Party.

16.2 *Sub-contracting*. Other than laboratory services as is necessary, Siegfried shall not be permitted to subcontract Manufacturing under this Agreement to any third party (other than certain activities hereunder to Siegfried Malta), without Jazz's prior written consent. If a subcontractor is appointed by Siegfried, Siegfried shall be responsible for all work performed by, and all acts, omissions and breaches of, such subcontractor as if performed or made by itself.

16.3 *Force Majeure.* A Party shall be excused from performing its obligations under this Agreement (other than obligations of payment) to the extent that its performance is delayed or prevented by any cause beyond such Party's reasonable control, including, but not limited to, act of God (such as extreme weather), fire, (naturally caused) flood, explosion, disease, war, insurrection, civil strike, riots, government action power failure or energy shortages (**Force Majeure Event**). Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in this Agreement that falls due during or subsequent to the occurrence of any of the disabilities referred to herein shall be automatically extended for a period of time equal to the period of such disability. The prevented Party shall immediately notify the other Party if, by reason of any Force Majeure Event, the prevented Party is unable to meet any deadline or time for performance specified in this Agreement. In the event that such Force Majeure Event cannot be removed or

overcome within [*] (or such other period as the Parties jointly shall determine) from the date the Party affected first became affected, then the non-prevented Party may at any time after the expiration of such period, by written notice to the other Party, either (i) suspend this Agreement, in whole or in part, for as long as such Force Majeure Event continues to exist, or (ii) terminate this Agreement, in whole or in part, with immediate effect.

16.4 *Precedence of Agreement*. Unless expressly agreed otherwise in writing, the terms outlined in this Agreement shall prevail over any terms and conditions outlined in any Order or Order Confirmation for Product and any general terms and conditions of a Party, and such terms and conditions are hereby expressly excluded. In case of discrepancies between this Agreement and an Annex hereto, the provisions of this Agreement shall prevail.

16.5 *No assignment.* This Agreement is binding upon and shall inure to the benefit of the Parties hereto and their successors and permitted assigns. This Agreement and any rights or obligations hereunder may be assigned or delegated only (i) with the consent of the other Party, not to be unreasonably withheld, conditioned or delayed, or (ii) by Jazz to its Affiliates or to the successor to all or substantially all of the business of Jazz (whether by merger, consolidation, asset transfer or similar transaction) to which this Agreement relates. Any other assignment or delegation by either Party without the prior written consent of the other Party is void.

16.6 *No waiver.* The failure by either Party at any time to enforce any of the terms, provisions or conditions of this Agreement or to exercise any right hereunder shall not constitute or be construed to constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same.

16.7 *Independent Parties.* Nothing in this Agreement shall be deemed or construed to constitute or create between the Parties hereto a partnership, joint venture, agency, or other relationship other than as expressly set forth herein. Neither Party shall have authority to speak for, represent or obligate the other Party in any way without prior written consent of the other Party.

16.8 *Entire Agreement.* This Agreement (together with the Quality Agreement) contains the full understanding of the Parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto (other than, for the avoidance of doubt, the Master Development Services Agreement and any Confidential Disclosure Agreement executed by the Parties and/or their Affiliates, each of which shall remain in full force and effect in accordance with its respective terms). No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the Parties.

16.9 *Severability.* If any portion of this Agreement is held invalid by a court of competent jurisdiction, such portion shall be deemed to be of no force and effect and this Agreement shall be construed as if such portion had not been included herein, provided

however, if the deletion of such provision materially impairs the commercial value of this Agreement to either Party, the Parties shall attempt to renegotiate such provision in good faith. The fact that any provision of this Agreement shall be prohibited or unenforceable in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the Parties to this Agreement waive any provision of law that renders any provision of this Agreement prohibited or unenforceable in any respect.

16.10 *Notices.* Any notice required under this Agreement shall be effective only if it is in writing and (i) delivered in person or (ii) deposited with a nationally recognized overnight courier service, or (iii) sent by registered mail or (iv) dispatched by e-mail (pdf), in which case such notice is to be confirmed by registered mail within [*]; in either case any notice is to be addressed to the applicable address set forth below or any other address as designated by either Party.

if to Siegfried	**Siegfried AG** Untere Brühlstrasse 4, 4800 Zofingen, Switzerland Attention: [*] Email: [*]
with a copy to:	**Siegfried AG** Untere Brühlstrasse 4, 4800 Zofingen, Switzerland Legal Department Email: [*]
if to Jazz:	**Jazz Pharmaceuticals Ireland Limited** Waterloo Exchange, Waterloo Road, Dublin 4, Ireland Attention: Legal Department Fax/e-mail: [*]

Either Party may change the above addresses, but no such change shall have any effect until the other Party has been properly notified with written notice of the change of the address.

16.11 *Compliance with Laws.* Each Party shall comply with all Applicable Law governing its performance of the terms of this Agreement, including, but not limited to, those relating to health, safety and the environment, fair labor practices, unlawful discrimination, debarment, supply chain transparency and modern slavery, anti-corruption and anti-bribery laws.

16.12 *Hardship.* If during the Term of this Agreement, the performance of the Agreement should lead to unreasonable hardship for the one or the other Party, both Parties shall undertake reasonable endeavors to discuss in good faith a possible amicable resolution or possible amendment to this Agreement in light of the change in circumstances; provided always, however, that (i) neither Party shall have any obligation to amend this Agreement or to waive or modify any of its rights under this Agreement and (ii)

notwithstanding any claim of unreasonable hardship by a Party pursuant to this Section 16.12, each Party shall remain fully liable for the performance of its obligations and duties under this Agreement unless and until, and only to the extent that, the Parties mutually agree in writing to alter or modify such obligations or duties by amending the provisions hereof (which alteration or modification shall only be binding if made in writing and signed by both Parties in accordance with the terms of this Agreement).

17. Applicable Law and Dispute Resolution

17.1 This Agreement shall be governed by German laws without regard to its conflict of laws provisions and the provisions of the UN Convention regarding Contracts on the International Sale of Goods (Vienna Convention).

17.2 All disputes arising out of or in connection with this Agreement, including disputes on its conclusion, binding effect, amendment or termination, shall be resolved exclusively by arbitration in accordance with the Arbitration Rules of the German Arbitration Institute (DIS) in force on the date on which the Notice of Arbitration is submitted in accordance with these Rules, agree as follows:

a) The number of arbitrators shall be three (3).

b) The seat of the arbitration shall be Hannover, Germany.

c) The arbitral proceedings shall be conducted in English.

17.3 Notwithstanding any other provision of this Agreement, each Party shall still be entitled to access the courts in Hannover, Germany, to obtain appropriate injunctive relief.

[remainder of page intentionally left blank]

List of Annexes

Annex	Description	Content
1.1	API	Description of API
1.2	Drug Product	Description of Drug Product
1.3	Key Material	Description of Key Material
1.4	Commercial Terms	Price, MOQ and other commercial terms

Intending to be bound by the provisions hereof, each of the parties hereto have caused this Agreement to be executed personally or by its duly authorized representative, to be effective as of the Effective Date.

Siegfried AG

/s/ Luca Parlanti
Name / function

Dr. Luca Parlanti
Head of Exclusive Sales
Drug Substance
Siegfried AG

/s/ Marco Henneböhle
Name / function

Dr. Marco Henneböhle
Director Business Development
Exclusive Synthesis Europe
Siegfried AG

Jazz Pharmaceuticals Ireland Limited

/s/ Kathleen Gibbons
Name / function

Kathleen Gibbons
VP, Finance

ANNEX 1.1 - API

[*]

/s/ Henn
Siegfried

/s/ KG
Jazz

ANNEX 1.2 – Drug Product

[*]

/s/ Henn
Siegfried

/s/ KG
Jazz

ANNEX 1.3 - Key Material

[*]

/s/ Henn
Siegfried

/s/ KG
Jazz

ANNEX 1.4 – Commercial Terms

[*]

/s/ Henn Siegfried

/s/ KG Jazz

[*]

/s/ Henn
Siegfried

/s/ KG
Jazz

Exhibit 10.22

WITHOUT PREJUDICE / SUBJECT TO CONTRACT

Compromise Agreement

THIS AGREEMENT is made on 05 Oct 2019

BETWEEN

(1) **JAZZ PHARMACEUTICALS IRELAND LIMITED** a company incorporated under the laws of Ireland having its registered office at Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4 (the "**Company**");

AND

(2) **PAUL TREACY** of Ireland (the "**Employee**").

(Each a "**Party**" and collectively the "**Parties**")

WHEREAS:

A. The Employee is presently employed by the Company on the terms and the conditions set out in a contract of employment dated 10 June 2014, executed by the Employee on 23 June 2014, and amended by letter dated 8 December 2014 (the "**Employment Contract**").

B. It is agreed that the three-month notice of termination of the Employee's employment pursuant to clause 15 of the Employment Contract shall officially begin as of 1 October 2019 (the "**Notice Effective Date**").

C. The Company is entering into this Agreement for itself and on behalf of each of its Associated Undertakings.

IT IS HEREBY AGREED as follows:

1. **Termination of employment; Transition Assistance**.

1.1 The Employee's employment with the Company shall terminate on 31 December 2019 (the "**Termination Date**"). Prior to the Notice Effective Date, the Employee will reasonably cooperate with the Company and provide full transition assistance with respect to his role, duties and projects, including, but not limited to, working closely with Daniel Swisher on preparing and implementing a mutually acceptable communication plan regarding his departure (including internal and external communications), and the transition plan for his responsibilities and relationships.

1.2 Save as set out in this Agreement, the Employee's entitlement to salary and all other benefits associated with his employment by the Company shall continue until the Termination Date when they shall cease.

1.3 By reason of the termination of his employment, the Employee is entitled to receive the following payments:

1.3.1 salary and contractual benefits up to and including the Termination Date; and

1.3.2 payment in lieu of outstanding annual leave accrued by the Employee, but not taken at the Termination Date.

1.4 The payments specified in clause 1.3 shall be paid in the ordinary course via Company payroll and shall be subject to such income tax, PRSI and USC and other deductions as the Company is required (or permitted) to deduct from the gross amount and remit to the Irish Revenue Commissioners and/ or any other tax or, governmental or, fiscal authority ("**Revenue**") under the relevant tax and social welfare (or equivalent) legislation.

2. **Garden Leave**

2.1 Between the Notice Effective Date and the Termination Date, the Employee shall be on paid garden leave. During the garden leave period, the Company shall not be obliged to provide the Employee with any work or assign to him any powers, duties or functions (and shall be entitled to appoint the Employee's successor). Save as agreed or requested by the Company, during the garden leave period the Employee: shall be removed from his position and not undertake any job duties; shall not enter any premises of the Company or any Associated Undertaking; and shall not engage in any contact (whether or not initiated by him), other than social contact, with any customer, client, supplier, consultant or agent of the Company or any Associated Undertaking.

2.2 For the avoidance of doubt, during the garden leave period the Employee shall continue to be bound by the duties of fidelity and good faith and shall comply with any and all relevant obligations under the Employment Contract or implied by common law (including but not limited to the duties of confidentiality and trust and confidence).

2.3 During the garden leave period, the Company may require the Employee to undertake at his home or at the premises of the Company or any Associated Undertaking or at such place reasonably nominated by the Company such reasonable duties as the Company may at its discretion assign to him and to provide any reasonable assistance requested by the Company or any Associated Undertaking. In particular, the Employee shall be required to provide full transition assistance to the Company including (but not limited to) assistance with regard to a mutually acceptable communication plan regarding his departure, and the transition of his responsibilities and relationships. The Employee shall hold himself available and remain contactable during normal business hours (other than agreed holidays or authorised sickness) to perform any such duties or provide any such assistance and shall ensure that the Company has up to date contact details for him.

3. **Consideration, settlement, release and discharge**

3.1 As compensation for the Employee's loss of employment, and subject to compliance by the Employee with his obligations under this Agreement, including providing the transition assistance discussed in clause 1.1 and signing and returning the Supplemental Waiver of Claims referred to in clause 9 (below), the Company shall make an ex gratia payment (the "**Termination Payment**") to the Employee by no later than the Payment Date (defined below) consisting of the following amounts: (a) 2019 bonus in the amount of €180,000; (b) 2020 bonus in the amount of €180,000; (c) twenty-four (24) months of basic salary in the amount of €800,000; and (d) an amount equivalent to twenty-four (24) months of the Employee's regular monthly employee benefits in effect as of the Termination Date.

3.2 The Termination Payment shall be in full and final settlement, release and discharge of any and all actions or causes of actions, claims, complaints, contracts, liabilities and agreements (if any) as the Employee has or may have against the Company and/or any Associated Undertaking, and its or their employees, officers, shareholders and agents, whether arising under Statute, common law, contract, tort (including claims for personal injuries), equity or otherwise arising out of his employment and/or the termination of such employment.

3.3 For the purposes of this Agreement, the expression '**Statute**' shall include, but not be limited to the following:

- the Redundancy Payments Acts 1967- 2014;

- the Terms of Employment (Information) Acts 1994 - 2014;
- the Minimum Notice and Terms of Employment Acts 1973 - 2005;
- the Protection of Employment Act 1977 - 2014;
- the Protection of Employment (Exceptional Collective Redundancies and Related Matters) Act 2007;
- the Organisation of Working Time Act 1997;
- the Payment of Wages Act 1991;
- the Unfair Dismissals Acts 1977 - 2015;
- the Protected Disclosures Act 2014;
- the Employment Equality Acts 1998 - 2015;
- the European Communities (Protection of Employees on Transfer of Undertakings) Regulations 2003;
- the Maternity Protection Acts 1994 and 2004;
- the Adoptive Leave Acts 1995 and 2005;
- the Parental Leave Acts 1998 and 2006;
- the Paternity Leave and Benefit Act 2016;
- the National Minimum Wage Acts 2000 and 2015;
- the Carer's Leave Act 2001 (as amended);
- the Protection of Employees (Part-Time Work) Act 2001;
- the Protection of Employees (Fixed-Term Work) Act 2003;
- the Industrial Relations Acts, 1946 - 2015;
- the Data Protection Acts 1988 - 2018;
- the Workplace Relations Act 2015;
- the Employment (Miscellaneous Provisions) Act 2018; and
- the Safety Health and Welfare at Work Act 2005 - 2014.

3.4 For the purposes of clause 3.1, the "**Payment Date**" shall mean the date which is 30 days after the date on which the Company receives from the Employee a duly executed copy of the Supplemental Waiver of Claims (provided that the Employee signs and returns this Agreement by no later than 4 October 2019).

3.5 The Employee acknowledges that the payment to him of the Termination Payment is made without any admission of any liability or breach of statute or law by the Company or of any duty or obligation owed to him by the Company.

3.6 Subject to the Employee's signature of the Form of letter attached at Appendix 1 in a form satisfactory to the Company, the Termination Payment will be made in the most tax efficient manner permitted by law provided that this does not result in any additional cost or liability whatsoever to the Company and, subject thereto, the Termination Payment shall be subject to such income tax, PRSI, USC and other deductions as the Company is required to deduct from the gross amount and remit to Revenue under the relevant tax and social welfare legislation.

3.7 The Employee hereby agrees to indemnify and hold harmless the Company and any Associated Undertaking in full (on a continuing basis) against any tax liabilities, charges, levies, duties, social security liabilities, withholdings, other fiscal impositions and other similar deductions of any kind whatsoever, including any interest, charges, surcharges, fines and penalties thereon or claims made by Revenue arising from or in connection with the payment of the Termination Payment and any other payments contemplated under this Agreement, which may arise subsequent to the date hereof.

4. **Continuing obligations**

4.1 The Employee shall continue to be bound by any of the provisions of the Employment Contract which are expressed to take effect on or to continue after the termination of his employment including, but not limited to, clauses 23, 24 and 25 thereof.

4.2 The Employee hereby covenants and agrees that he will not, from the Termination Date, hold himself out or expressly or impliedly represent to any third party that he has the authority to speak for, represent or in any way bind the Company, or any of its Associated Undertakings.

4.3 Without prejudice to any obligations owed by him under the Employment Contract, the Employee acknowledges that during the term of his employment, he had access to information which is confidential and/or proprietary to the Company, including but not limited to trade secrets, know-how, information that results from research and development, technical data, information concerning past, existing or prospective customers and/or suppliers and other information of a commercial, financial or technical nature relating in any way whatsoever to the business and affairs of the Company, and its Associated Undertakings ("**Confidential Information**"). The Employee undertakes and agrees that all Confidential Information shall be and remain at all times the exclusive property of the Company. The Employee further undertakes and agrees that he will not at any time prior to or following the termination of his employment with the Company reveal, publish or disclose Confidential Information to any person, association, future employer or company nor shall he use it for his own benefit or for the benefit of others without prior written consent of a duly authorised officer of the Company.

5. **Return of property**

5.1 The Employee shall, no later than the Notice Effective Date, deliver up to the Company, all property belonging to the Company in his possession or under his control including but not limited to any Company vehicle and all accessories, Company mobile phone, laptop and any other electronic communication devices, security card or key to the premises, Company credit cards, Company files, personnel records, books, returns, Company information, memoranda, data, correspondence and all documentation prepared or obtained by the Employee in the course of his employment with the Company relating to its business and affairs; and the Employee undertakes not to retain copies of any of the foregoing documents without the prior written consent of the Company. The Employee agrees to provide a warranty to the Company, upon request, as to his compliance with this provision.

5.2 The Employee shall, no later than the Notice Effective Date, provide to the Company full details of all then current passwords used by the Employee in respect of computer equipment belonging to the Company or any Associated Undertaking and, having forwarded a copy to the Company, irretrievably delete from any computer drives, disks, tapes or other re-usable material and/or from any website and/or email account in the Employee's possession or under his control (but which do not belong to the Company or any Associated Undertaking) any information belonging or relating to the business of the Company or any Associated Undertaking, their customers, clients or suppliers.

After deleting such material, the Employee shall at the Company's request warrant in writing that he has complied with this clause.

6. **No voluntary disclosure**

Except as disclosure may be required by law (including corporate filing requirements), the Parties agree that the terms of this Agreement are confidential as between the Parties and that they shall not voluntarily divulge or publish, directly or indirectly, any information whatsoever regarding the substance, terms or existence of this Agreement. Notwithstanding the foregoing, the Parties may disclose this Agreement to their legal and other professional advisors, and the Employee may disclose this Agreement in confidence to his immediate family members.

7. **No adverse remarks**

The Employee shall not at any time make any negative or adverse remarks whatsoever concerning the Company or any Associated Undertaking or any of its or their shareholders, directors, officers, employees or agents or concerning the business, operations, technologies, products, services, marketing strategies, pricing policies, management affairs, financial condition, systems and procedures, controls, books and records, or service provider of the Company or any Associated Undertaking. The following individuals shall be instructed not to make negative or adverse remarks whatsoever concerning the Employee's employment with the Company: Bruce Cozadd, Chief Executive Officer; Daniel Swisher, President and Chief Operating Officer; Heidi Manna, Chief Human Resources Officer; and the members of the Board of Directors of Jazz Pharmaceuticals plc.

8. **Independent legal advice**

8.1 The Employee confirms and agrees that he has been advised to and afforded the opportunity of obtaining independent legal advice regarding the contents and effect of this Agreement.

8.2 The Employee acknowledges that he understands the effect and implications of this Agreement. The Employee confirms that he has signed this Agreement with full understanding that he is releasing and compromising any and all claims that he has or might have against the Company arising from or connected with his employment with the Company and the termination of such employment.

9. **Supplemental waiver of claims**

The Employee acknowledges that the payment of the Termination Payment is conditional upon the Employee signing and returning the Supplemental Waiver of Claims (set out in Schedule A to this Agreement) to Heidi Manna, Chief Human Resources Officer, on or within 7 days from the Termination Date.

10. **General**

10.1 This Agreement shall be governed by and construed in accordance with the laws of Ireland and the courts of Ireland shall have exclusive jurisdiction to deal with all disputes arising from or touching upon this Agreement.

10.2 For the purposes of this Agreement, "**Associated Undertaking**" means any undertaking which from time to time is a subsidiary of the Company or is a holding company of the Company or a subsidiary of any such holding company ("**holding company**" and "**subsidiary**" having the meanings set out in section 7 and 8 of the Irish Companies Act 2014). By way of example, but not limitation, Jazz Pharmaceuticals plc is an Associated Undertaking;

10.3 This Agreement contains the whole agreement between the Parties relating to the matters provided for in this Agreement and supersedes all previous agreements (if any) between the Parties in respect

of such matters and each Party acknowledges that in agreeing to enter into this Agreement they have not relied on any representations or warranties except for those contained in this Agreement.

10.4 This Agreement, although marked “without prejudice” and “subject to contract” shall, upon signature by both parties, be treated as an open document evidencing an agreement that is and will be binding on the parties.

10.5 This Agreement may be executed by the parties to this Agreement on separate counterparts, each of which when executed shall constitute the original and all such counterparts together constitute but one and the same instrument.

[Signature page follows.]

Dated the 5 day of October 2019.

SIGNED: */s/ Paul Treacy*
Paul Treacy

DATE: 05 Oct 2019.

IN THE PRESENCE OF:
Witness */s/ Veronique O'Sullivan*

Witness name, occupation and address
VERONIQUE O'SULLIVAN
PUBLIC SERVANT
15 ARDFIELD MEADOWS
ARDFIELD, DOUGLAS, CORK.

SIGNED: */s/ Heidi Manna*
For and on behalf of the Company

DATE: 9/4/19

APPENDIX 1

Confirmation Letter

Mr Paul Treacy

Private & Confidential

Jazz Pharmaceuticals Ireland Limited
Fifth Floor,
Waterloo Exchange,
Waterloo Road,
Dublin 4

Dear Sirs

I refer to the ex gratia Termination Payment referenced in clause 3.1 of the Compromise Agreement between me and Jazz Pharmaceuticals Ireland Limited (the "**Company**"), to be paid to me by the Company in connection with the termination of my employment.

The term "**Termination Date**" has the same meaning as in the Compromise Agreement that I entered into with the Company.

I confirm that I have not made a claim under section 123, section 201 or Schedule 3 of the Taxes Consolidation Act 1997 (as amended) within the period of ten years prior to the Termination Date.

I further confirm that the aggregate amount of all tax free payments made to me in respect of any and all ex-gratia payments received by me during my lifetime, including the tax exempt amount in respect of the proposed ex-gratia payment in clause 3.1 of the Compromise Agreement, does not exceed the limit of €200,000 as set out in section 201(8) of the Taxes Consolidation Act 1997 (as amended).

I am entitled to receive a tax-free lump sum in the future under the Company's occupational pension plan. The net present value as at the Termination Date of the future tax-free lump sum is approximately €164,491.70

Yours sincerely	Witness Name:	/s/ VERONIQUE O'SULLIVAN
	Witness Address:	15 ARDFIELD MEADOWS, CORK
/s/ Paul Treacy	Witness Occupation:	PUBLIC SERVANT
Paul Treacy		
Date: 14 NOV 2019	Date: 05 . OCT 2019	

SCHEDULE A

Supplemental Waiver of Claims

In further consideration of the terms and conditions of the Compromise Agreement executed by me on 05 October 2019, I accept the terms and conditions of this supplemental waiver of claims ("**Waiver**") and waive as a full and final settlement, and satisfaction of any and all claims, actions or causes of action, suits, complaints, contracts or liabilities of whatsoever nature made and/or which may be made by me in Ireland and/or in any other jurisdiction anywhere in the world against the Company and any Associated Undertakings and/or each and all of their respective directors, officers, employees, shareholders and agents in connection with and/or arising out of and/or concerning my employment with the Company and/or the termination of such employment.

Without prejudice to the generality of the foregoing, I hereby acknowledge and agree that the provisions made in the Compromise Agreement constitute a full and final settlement of all claims, actions or causes of action and demands made and/or which may be made by me against the Company, any Associated Undertakings and the other persons referred to above, whether such claims arise at common law, in equity, pursuant to Statute (including but not limited to the Redundancy Payments Acts 1967 - 2014; the Terms of Employment (Information) Acts 1994 -2014; the Minimum Notice and Terms of Employment Acts 1973 - 2005; the Protection of Employment Act 1977-2014; the Protection of Employment (Exceptional Collective Redundancies and Related Matters) Act 2007; the Organisation of Working Time Act 1997; the Payment of Wages Act 1991; the Unfair Dismissals Acts 1977 - 2015; the Protected Disclosures Act 2014; the Employment Equality Acts 1998 - 2015; the European Communities (Protection of Employees on Transfer of Undertakings) Regulations 2003; the Maternity Protection Acts 1994 and 2004; the Adoptive Leave Acts 1995 and 2005; the Parental Leave Acts 1998 and 2006; the Paternity Leave and Benefit Act 2016; the National Minimum Wage Acts 2000 and 2015; the Carer's Leave Act 2001 (as amended); the Protection of Employees (Part-Time Work) Act 2001; the Protection of Employees (Fixed-Term Work) Act 2003; the Industrial Relations Acts, 1946 - 2015; the Data Protection Acts 1988 - 2018; the Workplace Relations Act 2015; the Employment (Miscellaneous Provisions) Act 2018, and the Safety Health and Welfare at Work Act 2005-2014) or pursuant to contract, in tort (including personal injury claims) or otherwise, howsoever arising.

I acknowledge that I have read, advised of and been given an opportunity to take legal advice on the Compromise Agreement and the provisions hereof and that I understand, accept and agree to the contents of the same and, furthermore, that I am signing this Waiver voluntarily without coercion of any description and with full understanding that I am releasing and compromising any and all claims and demands of every nature whatsoever that I have or might have against the Company and its Associated Undertakings and the other persons referred to above, save only in respect of the obligations of the Company as set out in the Compromise Agreement.

Dated this 6 day of JAN [month] 2020 [year]

Signed by: */s/ Paul Treacy* Witness: */s/ Veronique O'Sullivan*

PAUL TREACY

Exhibit 10.27

[Jazz Pharmaceuticals Letterhead]

PERSONAL, PRIVATE AND CONFIDENTIAL

Mr. Finbar Larkin
[Address]

Terms and Conditions of Employment

Dear Finbar,

On behalf of Jazz Pharmaceuticals Ireland Limited of 4th Floor, Connaught House, 1 Burlington Road, Dublin 4, registered at the Companies Registration Office with company number 429847 (the "**Company**"), I am very pleased to offer you employment with the Company.

Your employment will be subject to the following terms and conditions.

1. POSITION

Your position with the Company will be as Executive Director, Technical Operations or such other role as the Company considers appropriate.

2. COMMENCEMENT DATE

Your employment will be deemed to have commenced on 9th April 2013 or an earlier date as advised and the terms and conditions set out in this contract will take effect from such date. No employment with a previous employer counts towards your period of continuous service with the Company.

You shall not work for anyone else while you are employed by the Company.

3. PLACE OF WORK

You will be normally based at the Company's offices at 4th Floor, Connaught House, 1 Burlington Road, Dublin 4 but will be required to travel within Ireland and abroad in carrying out your responsibilities.

You will be required to travel to the United States of America and other locations from time to time. Where you are required to work outside Ireland for a period of at least one month, prior to departure, you will be provided with written terms and conditions which will apply for the period spent abroad.

4. HOURS OF WORK

You will determine your own hours of work and will be required to work the requisite hours and days in order to best perform your duties and to this end a degree of flexibility will be required on your part. You shall work a minimum of 37.5 hours per week from 9:00 am to 5:30 pm Monday to Friday, with a break of one hour for lunch each day. No

extra remuneration will be paid for additional hours worked or where work is required to be performed on a weekend.

5. REPORTING STRUCTURE

You will report directly to the Vice President, Product Development, Michael Desjardin. However the reporting structure may change from time to time, at the discretion of the Chief Financial Officer, the Chief Executive Officer or the Board of Directors (the "**Board**").

6. SALARY

6.1. Your initial salary will be €170,000 per annum and shall accrue from day to day. This will be paid to you monthly in arrears on the last day of each month by credit transfer directly to your bank account. Your salary will be subject to annual review each year on the anniversary of the date of this contract. There is no obligation to award an increase. There will be no review of the salary after notice has been given by either party to terminate your employment.

6.2. All payments to you will be subject to deductions of tax, PRSI, Universal Social Charge and any other deductions required by law or provided for in this contract. You will be notified each month by the Company of the amount of your gross and net remuneration and of the nature and amount of all deductions.

6.3. For the purposes of the National Minimum Wage Act, 2000, the pay reference period shall be a month. In accordance with section 23 of the Act, you may request from the Company a written statement of your average hourly rate of pay for any pay reference period (other than a current pay reference period) falling within the twelve month period immediately preceding the request.

6.4. The Company may deduct from your salary, or other sums owed to you, any money owed to the Company by you. Where the Company suffers loss as a result of your actions or omissions, deductions will be made only after you have received written notification providing at least one full week's notice that the deduction will be made. The deduction must take place within 6 months of the loss/cost originally being incurred.

7. BONUS

7.1. You may be entitled to be considered for a bonus based on your performance. Any bonus payment will be made entirely at the sole discretion of the Board, at such intervals and subject to such conditions as the Board may in its absolute discretion determine from time to time.

7.2. Any bonus payment to you shall be purely discretionary and shall not form part of your contractual remuneration under this contract. If the Company makes a payment to you, it shall not be obliged to make subsequent bonus payments.

7.3. You will not be entitled to a bonus if your employment has been terminated, or notice of such termination has been given by either you or the Company, prior to the date the bonus is paid.

8. EQUITY

Subject to approval by the Board of Director, your offer includes a grant of options to purchase 3,150 Jazz Pharmaceuticals ordinary shares and a grant of 1,575 restricted stock units (RSUs) giving you a right to receive Jazz Pharmaceuticals ordinary shares at a future date. Subject to the plan as in effect and your continued employment on each vesting date as per the Company equity plan.

9. EXPENSES

All properly vouched and authorised expenses incurred by you on Company business will be reimbursed by the Company.

10. HOLIDAYS

10.1. You will be entitled to 21 days' holidays (exclusive of all Irish bank and other public holidays in accordance with the Organisation of Working Time Act 1997) in each year. Your holidays are to be taken by arrangement with the Company, at such time or times that the Company considers to be most convenient having regard to the requirements of your position.

10.2. The Company's holiday year runs from 1 January to 31 December. Holidays from the previous year may not be carried over to the following year except with the Company's consent. Upon notice of termination of employment being served by either party, the Company may, subject to the provisions of the Organisation of Working Time Act 1997, require you to take any unused holidays accrued at that time during any notice period. Alternatively, the Company may, at its discretion, on termination of the employment, make a payment in lieu of accrued contractual holiday entitlement.

10.3. If you are ill during a period of annual leave and have a valid medical certificate for the days that you were ill, these sick days will not be counted as annual leave days.

10.4. If on termination of employment, you have taken in excess of your accrued holiday entitlement, the Company shall be entitled to recover from you by way of deduction from any payments due to you or otherwise, one day's pay for each excess day (calculated at l/260th of your salary for each excess day).

11. PENSION

At this time, the Company has no pension scheme. The Company does provide access to a personal retirement savings account (PRSA). If you wish to begin making contributions to a PRSA, please contact Bridget O'Brien. If and when the Company installs a pension scheme, you will be eligible to participate in accordance with the plan.

12. DUTIES

You will carry out duties as assigned to you from time to time by the Company. Your area of work and/or specific responsibilities may be altered from time to time by the Company as the circumstances of the business dictate.

13. PERIOD OF EMPLOYMENT

Subject to the provisions of Clauses 15, 16 and 22, your employment will continue until terminated by you or the Company giving the other at least 8 weeks' written notice of termination (or, if longer, the period required by law).

14. PAYMENT IN LIEU OF NOTICE / GARDEN LEAVE

Where notice of termination of your employment is given, whether by you or the Company, the Company will have the right to:

14.1. pay you in lieu of notice the amount of your entitlement to salary in respect of such notice period; or

14.2. require you to cease performing or exercising during some or all of the remainder of any notice period some or all of the powers, authorities and discretions delegated to you in your employment and/or to cease attending your place of work during such period.

15. TERMINATION WITHOUT NOTICE

Your employment may be terminated without prior notice if, at any time after the date of this contract, you:

15.1. are guilty of any material breach or non-observance of the provisions contained in this contract;

15.2. are guilty of any serious or gross misconduct and/or negligence in the discharge of the duties of your employment or in connection with or affecting the business of the Company;

15.3. commit any serious act of dishonesty or repeated acts of dishonesty;

15.4. cease to be eligible to work in the Republic of Ireland; or

15.5. are convicted of a criminal offence which the Company considers affects or could affect your position within the Company (other than minor traffic offences).

16. NORMAL RETIREMENT AGE

The Company's normal retirement age is 65. Your employment will end automatically on your 65th birthday if it has not terminated before then in accordance with the provisions of this contract.

17. ILLNESS

17.1. Absences from work for whatever reason must be notified to your Manager as soon as possible before your usual start time on the first day of absence. You should telephone your Manager and confirm the reason for your absence and the expected length of such

absence. Text messaging and emails are unacceptable means of communication for this purpose.

17.2. Payment of salary for any absences attributable to illness will be entirely at the sole discretion of the Company.

17.3. If you are at any time prevented by illness, injury, accident or any other circumstances from discharging all your duties for a period of three consecutive days, then a satisfactory certificate will be required from your doctor in respect of such absence.

17.4. The Company reserves the right, at any time, to require you to undergo a medical examination by a Doctor or Consultant nominated by the Company, in which event you agree to consent to this request and the Company will bear the cost of such examination.

17.5. If your absence is or appears to be occasioned by actionable negligence, nuisance or breach of any statutory duty on the part of a third party in respect of which damages are or may be recoverable, you shall immediately notify your Manager of that fact and of any claim, compromise, settlement or judgment made or awarded in connection with it and all relevant particulars that the Company may reasonably require. You shall, if you have been in receipt of salary for a period of absence and if required by the Company, refund to the Company that part of any damages or compensation recovered by you relating to the loss of earnings for the period of sickness as the Company may reasonably determine less any costs borne by you in connection with the recovery of such damages or compensation, provided that the amount to be refunded shall not exceed the total amount paid to you by the Company in respect of the period of sickness.

18. DISCIPLINARY RULES AND PROCEDURE

18.1. You will conduct yourself with propriety at all times and with due regard for the Company and each of its associated companies and the clients and employees of each such company.

18.2. In the event that your conduct or performance falls short of the standards required by the Company or the Board in any respect, (other than cases of misconduct) you will receive at first instance, a verbal warning, followed, if necessary in the event of a repetition, by a written warning which, in appropriate circumstances, may be deemed to be a final written warning. In the event of further breach of conduct or poor performance, and following due investigation during which you will be afforded an opportunity to make whatever representations you consider appropriate, your employment may be terminated by the Company, with or without notice as is deemed appropriate. Where appropriate, because of the gravity of your conduct or performance, the Company reserves the right to commence this procedure at any stage

18.3. In order to investigate a complaint against you, the Company may suspend you on full pay for as long as may be necessary to carry out an investigation and hold a disciplinary hearing.

19. MONITORING

19.1. You consent to the Company monitoring and recording any use that you make of the Company's electronic communications systems for the purpose of ensuring that the Company's rules are being complied with and for legitimate business purposes. You shall comply with any electronic communication systems policies that the Company may issue from time to time.

20. CONFIDENTIALITY

20.1. You will not, except as authorised or required by your duties, reveal to any person, persons or company any information of a confidential or proprietary nature, including any trade secrets, secret or confidential operations, processes or dealings or any information concerning the organisation, business, finances, transactions or affairs of the Company, its subsidiary or associated companies or their existing or potential customers including but not limited to: client lists, prices, financial information, information on the marketing and development of products, which may come to your knowledge during the period of your employment with the Company ("**Confidential Information**"). You will keep all Confidential Information entrusted to you completely secret and will not use or attempt to use any Confidential Information in any manner which may injure or cause loss either directly or indirectly to the Company or any of its subsidiary or associated companies or their existing or potential customers or its or their business or businesses. This restriction will continue to apply after the termination of your employment without limit in point of time but will cease to apply to information or knowledge which may reasonably be said to have come into the public domain other than by reason of breach of the provisions of this contract.

20.2. You will not during the term of your employment with the Company make, otherwise than for the benefit of the Company, any notes or memoranda relating to any matter within the scope of the business of the Company, its subsidiary or associated companies or their existing or potential customers or concerning any of the dealings or affairs of any such company nor will you either during the term of your employment with the Company or afterwards use or permit to be used any such notes or memoranda otherwise than for the benefit of the Company, it being the intention of the parties that all such notes or memoranda made by you will be the property of the Company and left at its offices upon the termination of your employment with the Company.

21. PROPRIETARY RIGHTS

21.1. In this Clause 21, "**IP**" means all intellectual property rights of whatever nature, including copyright (present and future), moral rights, patents, trademarks, trade names, domain names, rights in get-up, goodwill and the right to sue for passing off or unfair competition, rights in computer software, design rights, rights to inventions and database rights (whether or not any of these is registered and including any applications for registration of any such rights), rights to preserve the confidentiality of information (including trade secrets and know-how) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for and be granted, renewals or extensions of, and rights to claim priority from, such

rights and all similar or equivalent rights or forms of protection which may now or in the future subsist in any part of the world.

21.2. You will immediately disclose to the Company in writing full details of any discovery, invention, process or improvement in procedure made or discovered by you (whether or not in conjunction with any other person or persons) together with all works embodying IP rights while in the employment of the Company in connection with or in any way affecting or relating to the business of the Company, its subsidiary or associated companies or capable of being used or adapted for use therein or in connection therewith ("**Inventions**"). You acknowledge that all IP rights subsisting (or which may in the future subsist) in all such Inventions and works shall automatically, on creation, vest in the Company absolutely. To the extent that they do not vest automatically, you hold them on trust for the Company. You agree promptly to execute all documents and do all acts as may, in the opinion of the Company, be necessary to give effect to this clause.

21.3. If and whenever required so to do (whether during or after the termination of your employment), you will without charge and at the expense of the Company or its nominee apply or join in applying for letters, patents or other forms of protection for any IP referred to in this Clause 20 and execute all instruments and do all things considered necessary in the absolute discretion of the Company in relation to the said IP including vesting all rights and titles to such IP, when obtained, in the Company (or its nominee) as sole beneficial owner, or in such other person as the Company may require.

21.4. You irrevocably appoint the Company to be your attorney in your name and on your behalf to execute and do any such instruments or things and generally to use your name for the purpose of giving to the Company (or its nominee) the full benefit of the provisions of this Clause 21. A certificate in writing signed by any executive or the Secretary of the Company that any instrument or act falls within the authority conferred in this Clause 21.4 will be conclusive evidence that such is the case in favour of a third party.

22. RESTRICTIVE COVENANTS

22.1. You may not during the period of your employment with the Company, without prior written consent of the Company, engage, whether directly or indirectly, in any business or employment which is similar to or competitive with the business of the Company or its subsidiary or associated companies or which may in the Company's opinion impair your ability to act at all times in the best interest of the Company.

22.2. In order to protect the Confidential Information and business connections of the Company to which you have access as a result of your employment, you covenant with the Company that you shall not:

22.2.1. for 6 months after the date of the termination of your employment, in the Republic of Ireland be employed, engaged, concerned or interested, in any business directly competing with the products sold by the Company or its subsidiary or associated companies at that time.

22.2.2. for a period of 6 months after the termination of your employment, offer to employ or otherwise entice away from the Company or its subsidiary or associated companies, any

person who was at any time in the twelve months prior to the termination of your employment with the Company employed or engaged by the Company or its subsidiary or associated companies.

22.2.3. for a period of 6 months after the termination of your employment, solicit or endeavour to entice away from the Company or its subsidiary or associated companies the business or custom of any firm, company or person who, during the 12 months before your termination of employment was a customer or prospective customer of the Company or its subsidiary or associated companies about whom you became aware or informed in the course of your employment, with a view to providing goods or services to that firm, company or person in competition with the services provided by the Company.

22.2.4. for a period of 6 months after the termination of your employment, be involved with the provision of goods or services to (or otherwise have any business dealings with) any firm, company or person who, during the 12 months before the termination of your employment, was in the habit of dealing with the Company or its subsidiary or associated companies, in the course of any business concern which is in competition with the business of the Company.

22.2.5. at any time after the termination of your employment, represent yourself as connected with the Company as agent, consultant, director, employee, owner, partner, shareholder or in any other capacity.

22.3. You acknowledge and agree that all of the restrictions contained in this contract are reasonable and necessary to protect the interests of the Company and its subsidiary and associated companies and you agree that the Company may seek equitable remedies to enforce them in addition to any other legal remedies it has.

22.4. The restrictions above apply to you acting directly or indirectly and on your own behalf or on behalf of, or in conjunction with, any firm, company or person.

22.5. The time periods for which the restrictions apply shall be reduced by any period that you spend on garden leave.

22.6. If any provision in this Clause 22 is deemed to be, or becomes invalid, illegal, void or unenforceable under applicable laws, such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable (including, by way of example, by restricting the area, duration and/or scope of the covenants in to such area, duration and/or scope as would be held reasonable), or if it cannot be so amended without materially altering the intention of the parties, it will be deleted, but the validity, legality and enforceability of the remaining provisions of this contract shall not be impaired or affected in any way.

23. PROBATIONARY PERIOD

22.1 The first six months of your employment will be on a probationary basis. The Company may, at its discretion, extend the probationary period for a further period of up to four months where it deems appropriate. During the probationary period your performance and suitability will be monitored and your employment is subject to the satisfactory completion of the probationary period. Your employment may be terminated at any time

during the probationary period on the giving of two weeks' notice by you or by the Company. The Company reserves the right to make a payment in lieu of notice.

24. DATA PROTECTION ACTS 1988 AND 2003

24.1. You hereby acknowledge that during the course of your employment with the Company, the Company will keep personal data and sensitive personal data (e.g. doctor's certificates or medical reports) relating to you on computer and in manual files/paper files. You hereby acknowledge and agree that the Company is permitted to hold and process personal information about you as part of its personnel and other business records and may use such information in the course of the Company's business. You further agree that the Company may disclose such information to third parties in the event that such disclosure is in the Company's view required by the proper conduct of the Company's business. This clause applies to information held, used or disclosed in any medium.

25. HEALTH & SAFETY

25.1. The Company takes seriously its obligations regarding the safety, health and welfare of its employees and in that regard your attention is drawn to the Company safety statement (which is available for viewing on the intranet). By signing this contract, you agree to take reasonable care of your own safety and health and that of any other persons who may be affected by your acts or admissions while at work. You also agree to cooperate with the Company and any other person to enable compliance with any provision of the Safety, Health and Welfare at Work Acts 1989 and 2005 and any Regulation made thereunder.

26. COLLECTIVE AGREEMENT

26.1. There is no collective agreement which directly affects your employment.

27. MISCELLANEOUS PROVISIONS

27.1. Notices. Any notice under this contract will be given in writing and will be deemed to have been duly given if delivered personally to the addressee or the duly authorised agent of the addressee or sent by prepaid registered post to the last known address of the party to whom such notice is given. Any such notice will be deemed to have been duly given at the time of delivery if delivered personally, or two working days after posting if sent by prepaid registered post.

27.2. Entire Agreement. This contract is in substitution for all previous agreements and undertakings (if any) either written or verbal between the Company and you, and all such agreements and undertakings will be deemed to have been terminated by mutual consent as from the date of your execution of this contract.

27.3. Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of Ireland, and shall be subject to the exclusive jurisdiction of the Irish courts.

27.4. The information contained in this contract constitutes a written statement of particulars of your employment with the Company in accordance with the requirements of section 3 of the Terms of Employment Act 1994 and 2001.

***

If you choose to accept the terms and conditions of employment set out in this contract, please sign the enclosed copy of the contract and return it to me.

Yours sincerely

/s/ Fintan Keegan

Fintan Keegan
Duly authorised for and on behalf of
Jazz Pharmaceuticals Ireland Limited

I accept employment with the Company on the terms and conditions as set out in the Company's contract of which this is a copy.

Signed: /s/ Finbar Larkin

Dated: 22 Feb 2013

Exhibit 10.28A

Dated: 13 December 2019

EMPLOYMENT CONTRACT

between

JAZZ PHARMACEUTICALS UK LIMITED

and

Samantha Pearce

CONTENTS

THIS AGREEMENT ("Agreement") is dated 13 December 2019.

Parties:

(1) JAZZ PHARMACEUTICALS UK LIMITED whose registered office is at Spires House, Wing B, Building 5700, John Smith Drive, Oxford Business Park South, Oxford OX4 2RW (the "Company"); and

(2) Samantha Pearce of [Address] ("Employee").

Agreed terms

1. Interpretation

1.1 The definitions and rules of interpretation in this clause 1.1 apply in this Agreement.

"Appointment" means the employment of the Employee by the Company on the terms of this agreement.

"Associated Employer" has the meaning given to it in the Employment Rights Act 1996.

"Capacity" means as agent, consultant, director, employee, owner, partner, shareholder or in any other capacity.

"Commencement Date" is 2 March 2020.

"Confidential Information" means information (whether or not recorded in documentary form, or stored on any magnetic or optical disk or memory) relating to the business, products, affairs and finances of the Company or any Group Company for the time being confidential to the Company or any Group Company and trade secrets including, without limitation, technical data and know-how relating to the business of the Company or any Group Company or any of their business contacts.

"Employee's family" means the Employee's spouse or civil partner and children under the age of 18.

"Employee Handbook" means the Company's employee handbook as amended from time to time (and the other policies referenced therein), which generally is posted on the Jazz intranet (JazzNet).

"Employment Inventions" means any invention which is made wholly or partially by the Employee at any time during the course of her employment with the Company (whether or not during working hours or using Company premises or resources, and whether or not recorded in material form).

“Employment IPRs” means Intellectual Property Rights created by the Employee in the course of her employment with the Company (whether or not during working hours or using Company premises or resources).

“Garden Leave” means any period during which the Company has exercised its rights under clause 19.

“Group Company” means the Company, any company of which it is a Subsidiary (its holding company) and any Subsidiaries of the Company or of any such holding company.

“Incapacity” means any sickness or injury which prevents the Employee from carrying out her duties.

“Intellectual Property Rights” means patents, rights to inventions, copyright and related rights, trademarks, trade names and domain names, rights in get-up, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database rights, topography rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

“Invention” means any invention, idea, discovery, development, improvement or innovation, whether or not patentable or capable of registration, and whether or not recorded in any medium.

“Pre-Contractual Statement” means any undertaking, promise, assurance, statement, representation, warranty or understanding (whether in writing or not) of any person (whether party to this Agreement or not) relating to the Employee’s employment under this Agreement which is not expressly set out in this Agreement or any documents referred to in it.

“Restricted Business” means those parts of the business of the Company and any Group Company with which the Employee was involved to a material extent in the twelve months prior to Termination.

“Restricted Customer” means any firm, company or person who, during the twelve (12) months prior to Termination, was a customer of or in the habit of dealing with the Company or any Group Company and with whom the Employee had material contact or for whom she was responsible or in respect of whom the Employee was in possession of confidential information.

“Restricted Person” means anyone employed or engaged by the Company or any Group Company who could materially damage the interests of the Company or any Group Company if they were involved in any Capacity in any business concern which competes with any Restricted Business and with

whom the Employee materially dealt or managed in the twelve months prior to Termination within the course of her employment.

"Subsidiary" means in relation to a company (a holding company), a subsidiary (as defined in section 736 of the Companies Act 1985) and any other company which is a subsidiary (as so defined) of a company which is itself a subsidiary of such holding company.

"Termination" means the termination of the Employee's employment with the Company however caused including, without limitation, termination by the Company in repudiatory breach of contract.

1.2 The headings in this Agreement are inserted for convenience only and shall not affect its construction.

1.3 A reference to a particular law is a reference to it as it is in force for the time being, taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it.

2. Term of appointment

2.1 The Company shall employ the Employee and the Employee shall serve the Company on the terms of this Agreement.

2.2 The first six months of the Appointment shall be a probationary period and the Appointment may be terminated during this period at any time on one week's prior notice. The Company may, at its discretion, extend this period. During this probationary period the Employee's performance and suitability for continued employment will be monitored. At the end of the probationary period the Employee will be informed in writing if she has successfully completed her probationary period.

2.3 The Appointment shall commence on the Commencement Date and shall continue, subject to the remaining terms of this Agreement, until terminated by either party giving the other not less than six months prior notice in writing.

2.4 The Employee represents and warrants to the Company that, by entering into this Agreement or performing any of her obligations under it, she will not be in breach of any court order or any express or implied terms of any contract or other obligation binding on her and undertakes to indemnify the Company against any claims, costs, damages, liabilities or expenses which the Company may incur as a result if she is in breach of any such obligations.

2.5 The Employee warrants that she is entitled to work in the United Kingdom without any additional approvals and will notify the Company immediately if she ceases to be so entitled during the Appointment.

2.6 The Employee consents to the transfer of her employment under this agreement to an Associated Employer at any time during the Appointment.

3. Duties

3.1 The Employee shall serve the Company as Head of Europe and RoW or such other role as the Company considers appropriate.

3.2 This position is at the level of Senior Vice President.

3.3 The role is reporting to Dan Swisher, President and Chief Operating Officer. The reporting structure can be changed by the Company at its sole discretion at any time during the Employment.

3.4 During the Appointment the Employee shall:

(a) unless prevented by Incapacity, devote the whole of her time, attention and abilities to the business of the Company or any other Group Company;

(b) diligently exercise such powers and perform such duties as may from time to time be assigned to her by the Company;

(c) comply with all reasonable and lawful directions given to her by the Company;

(d) promptly make such reports to her manager in connection with the affairs of any Group Company on such matters and at such times as are reasonably required;

(e) report her own wrongdoing and any wrongdoing or proposed wrongdoing of any other employee or director of any Group Company under the reporting procedures set forth in the Employee Handbook and/or the global Jazz Pharmaceuticals Code of Conduct (to the extent applicable);

(f) use her best endeavours to promote, protect, develop and extend the business of any Group Company;

(g) consent to the Company monitoring and recording any use that she makes of the Company's electronic communications systems for the purpose of ensuring that the Company's rules are being complied with and for legitimate business purposes; and

(h) comply with any applicable electronic communication systems policy that the Company and/or any Group Company may issue from time to time.

3.5 The Employee's attention is drawn to the UK Employee Handbook (containing various rules and procedures), and the global Jazz Pharmaceuticals Code of Conduct, both of which are available on the Jazz Intranet (JazzNet). The UK Employee Handbook does not form part of the Employee's contract of employment with the Company. For the avoidance of doubt, to the extent that there is any conflict between the terms of this Agreement and the UK Staff Handbook, this Agreement shall prevail.

Code of Conduct

3.6 JAZZ PHARMACEUTICALS UK LIMITED and Jazz Pharmaceuticals are committed to integrity and the pursuit of excellence in all we do. We fulfill these commitments while upholding a high level of ethical conduct. The Code of Conduct is one element of Jazz Pharmaceuticals' efforts to ensure lawful and ethical conduct by the company and its subsidiaries and their employees, officers and directors. It is a condition of employment that you read, agree to and sign Jazz Pharmaceuticals' Code of Conduct in the first week of employment.

4. Place of work

4.1 The Employee's normal place of work is the Jazz Pharmaceuticals Oxford office or such other place within a reasonable distance which the Company may reasonably require for the proper performance and exercise of her duties.

4.2 The Employee agrees to travel on any Group Company's business (both within the United Kingdom or abroad) as may be required for the proper performance of her duties under the Appointment. There are no additional terms which apply where the Employee is required to work outside the UK for a period of more than one month. The Company reserves the right to issue terms relating to the Employee's work outside the UK and any such terms will be notified to her separately.

5. Hours of work

5.1 The Employee's normal working hours shall be 9.00am to 5.30pm on Mondays to Fridays and such additional hours as are necessary for the proper performance of her duties. The Employee acknowledges that she shall not receive further remuneration in respect of such additional hours.

5.2 Due to the autonomous nature of the Employees' role, the duration of the Employee's working time is not measured or monitored, or determined by the Company and the limitations on weekly working time set out in Regulation 4 of the Working Time Regulations 1998 (the "Regulations") (or such other regulations amending or substituting those from time to time) does not apply to the Employee's Appointment. In the event that any additional hours worked by the Employee outside normal working hours are not covered by regulation 20(2) of the Regulations, the Employee agrees that the 48 hour limit on the working week stipulated in the Regulations will not apply to her and she must give three months' written notice to the Company if she wishes to change this.

6. Salary

6.1 The Employee shall be paid an initial basic salary of £325,000 [*three hundred and twenty five thousand pounds*] per annum.

6.2 The Employee's basic salary shall accrue from day to day and be payable monthly in arrears on the Company's scheduled pay dates directly into the Employee's bank or building society.

6.3 Salaries are normally reviewed on or about 1 March of each year. Employees whose Appointment begins on or after 1 November are not eligible for salary review the following March. The Company is under no obligation to award an increase following a salary review. There will be no review of the basic salary after notice has been given by either party to terminate the Appointment.

6.4 The Company may deduct from the basic salary, or any other sums owed to the Employee, any money owed to any Group Company by the Employee, and the Employee hereby consents to such deductions.

7. Expenses

7.1 The Company shall reimburse (or procure the reimbursement of) all reasonable expenses wholly, properly and necessarily incurred by the Employee in the course of the Appointment, subject to production of receipts or other appropriate evidence of payment.

7.2 The Employee shall abide by the Company's policies on expenses as communicated to her from time to time.

7.3 Any credit card supplied to the Employee by the Company shall be used only for expenses incurred by her in the course of the Appointment.

8. Bonus

8.1 The Company may in its absolute discretion pay the Employee a bonus of such amount, at such intervals and subject to such conditions as the Company may in its absolute discretion determine. With respect to an annual bonus for the calendar year in which the Employee is hired, the Employee will be eligible for consideration of a prorated bonus for the year of hire only if the Employee is hired no later than 31 October of such year; and if the Employee is hired on 1 November or later, the Employee is not eligible for consideration of any annual bonus for the year of hire.

8.2 Any bonus payment to the Employee shall be purely discretionary and shall not form part of the Employee's contractual remuneration under this Agreement. If the Company makes a bonus payment to the Employee in respect of a particular financial year of the Company (being the period from 1 January to 31 December), it shall not be obliged to make subsequent bonus payments in respect of subsequent financial years of the Company.

8.3 The Company may alter the terms of any bonus targets or withdraw them altogether at any time without prior notice.

8.4 Notwithstanding clause 8.1, the Employee shall in any event have no right to a bonus or a time-apportioned bonus if her employment terminates for any reason or she is under notice of termination (whether given by the Employee or the Company) at or prior to the date when a bonus might otherwise have been payable.

8.5 Any bonus payable in accordance with clause 8 shall not be pensionable.

9. Permanent health insurance

9.1 The Employee shall be entitled to participate in the Company's permanent health insurance scheme at the Company's expense, subject to:

(a) the terms of the Company's scheme, as amended from time to time;

(b) the rules or insurance policy of the relevant insurance provider, as amended from time to time; and

(c) the Employee satisfying the normal underwriting requirements of the relevant insurance provider of the Company's scheme and the premium being at a rate which the Company considers reasonable.

Full details of the scheme are available from the Human Resources Department.

9.2 The Company shall only be obliged to make payments to the Employee under the scheme if it has received payment from the insurance provider for that purpose.

9.3 The Company in its sole and absolute discretion reserves the right to discontinue, vary or amend the scheme (including the level of the Employee's cover) at any time on reasonable notice to the Employee.

9.4 If the insurance provider refuses for any reason to provide permanent health insurance benefit to the Employee, the Company shall not be liable to provide to the Employee any replacement benefit of the same or similar kind or to pay any compensation in lieu of such benefit.

9.5 If the Employee is receiving benefits under the Company's permanent health insurance scheme the Company shall be entitled to appoint a successor to the Employee to perform all or any of the duties required of the Employee under the terms of the Appointment and the Employee's duties shall be amended accordingly.

9.6 The receipt by the Employee of any benefits under a permanent health insurance scheme operated by the Company shall not prejudice the Company's rights to terminate this Appointment in accordance with the terms of this Agreement. In the event that the Company terminates the Appointment in accordance with its rights, the Employee acknowledges that she will not be entitled to any compensation for breach of contract or unfair dismissal in respect of the loss of any rights to permanent health insurance benefits.

10. Life assurance

10.1 The Employee shall be entitled to participate in the Company's life assurance scheme which shall pay to the Employee's nominated beneficiary or beneficiaries a sum equal to four (4) times the Employee's basic salary if the Employee dies during the Appointment. Participation is subject to:

(a) the terms of the Company's life assurance scheme, as amended from time to time;

(b) the rules or insurance policy of the relevant insurance provider, as amended from time to time; and

(c) the Employee satisfying the normal underwriting requirements of the relevant insurance provider of the Company's life assurance scheme and the premium being at a rate which the Company considers reasonable.

Full details of the scheme are available from the Human Resources Department.

10.2 If the insurance provider refuses for any reason to provide life assurance benefit to the Employee the Company shall not be liable to provide to the Employee any replacement benefit of the same or similar kind or to pay any compensation in lieu of such benefit.

10.3 The Company in its sole and absolute discretion reserves the right to discontinue, vary or amend its life assurance scheme (including the level of the Employee's cover) at any time on reasonable notice to the Employee.

11. Private medical insurance

11.1 The Employee and qualifying members of the Employee's family shall be entitled to participate in the Company's private medical insurance scheme subject to:

(a) the terms of that scheme, as amended from time to time;

(b) the rules or insurance policy of the relevant insurance provider, as amended from time to time; and

(c) the Employee and qualifying members of the Employee's family satisfying the normal underwriting requirements of the relevant insurance provider of the Company's private medical insurance scheme and the premium being at a rate which the Company considers reasonable.

Full details of the Company's private medical insurance scheme are available from the Human Resources Department.

11.2 If the insurance provider refuses for any reason to provide private medical insurance benefit to the Employee the Company shall not be liable to provide to the Employee any replacement benefit of the same or similar kind or to pay any compensation in lieu of such benefit.

11.3 The Company in its sole and absolute discretion reserves the right to discontinue, vary or amend the scheme (including the level of the Employee's cover) at any time on reasonable notice to the Employee.

12. Car Allowance

12.1 Provided that the Employee holds a current valid driving licence, the Employee shall receive a car allowance for use of the Employee's own car of £12,000 per annum, which shall be payable together with and in the same manner as the salary in accordance with clause 6. The car allowance shall not be treated as part of the basic salary for any purpose and shall not be pensionable.

12.2 The Company shall reimburse the Employee in respect of fuel costs for business miles at the Company's business mileage rate.

12.3 The Employee shall immediately inform the Company if she is disqualified from driving and shall cease to be entitled to receive the allowance under clause 12.1 or reimbursement of fuel expenses under clause 12.2.

13. Holidays

13.1 The Employee shall be entitled to 25 days' paid holiday in each holiday year, and 3 of these days must be taken between Christmas and New Year. In addition, the Employee is eligible for the usual public holidays in England and Wales to a maximum of 8 per year. The Company's holiday year runs between 1 January and 31 December. If the Appointment commences part way through the holiday year, the Employee's holiday entitlement during the first year of the Appointment shall be calculated on a pro-rata basis, rounded to the nearest whole day.

13.2 Holiday shall be taken at such time or times as shall be approved in advance by the Employee's manager. The Employee shall not, without the consent of her manager, carry forward any accrued and unused holiday entitlement to a subsequent holiday year, nor receive any payment in lieu in respect of such entitlement, save as provided in clause 13.3.

13.3 On termination of the Appointment, the Employee shall be entitled to be paid in lieu of accrued but untaken holiday save that, where such termination is pursuant to clause 18.4 or follows the Employee's resignation in breach of clause 2.3, such accrued but untaken holiday shall be based on the Employee's minimum holiday entitlement under the Working Time Regulations 1998 only and not on her entitlement under clause 13.1. For these purposes any paid holiday that has been taken by the Employee (including any paid holiday on public holidays) shall be deemed first to be statutory paid holiday. The amount of the payment in lieu shall be calculated on the basis that each day of paid holiday is equal to 1/260 of the salary. The Company reserves the right to exercise its discretion as to whether the Employee will be paid in lieu of accrued but untaken holidays or if the Employee will be asked to work those accrued but untaken holidays, if they fall within the notice period.

13.4 If the Employee has taken more holiday than her accrued entitlement at the date of termination of the Appointment, the Company shall deduct the appropriate amount from any payments due to the Employee (on the basis that each day of paid holiday is equal to 1/260 of the salary).

13.5 If either party has served notice to terminate the Appointment, the Company may require the Employee to take any accrued but unused holiday entitlement during the notice period or, if applicable, any such holiday shall be deemed to be taken during any period of Garden Leave.

14. Incapacity

14.1 If the Employee is absent due to sickness or injury she must inform her manager no later than 10.00am on the first day absent or as soon as possible given the time difference between the USA and the UK.

14.2 The Employee will be required to produce a self-certification form in respect of absences up to and including 5 working days. The Company reserves the right to require the Employee to obtain a Statement of fitness for work (Fit Note) from a Doctor in respect of any such period of absence.

14.3 The Employee must, if absent for a period of 7 consecutive days, provide the Company with a Statement of fitness for work (Fit Note), stating the reason for the absence and thereafter provide a like certificate each week to cover any subsequent periods of absence. The Company reserves the right at any time during the Employees absence to ask the Employee to produce a medical certificate (or Fit Note).

14.4 The Company reserves the right to ask the Employee to undergo a medical examination with a medical practitioner of the Company's choosing at any time during a period of absence due to illness or Incapacity subject to the provisions of the Access to Medical Reports Act 1988.

15. Outside interests

15.1 Subject to clause 15.2, during the Appointment the Employee shall not, except as a representative of the Company or with the prior written approval of the Company, whether paid or unpaid, be directly or indirectly engaged, concerned or have any financial interest in any Capacity in any other business, trade, profession or occupation (or the setting up of any business, trade, profession or occupation).

15.2 Notwithstanding clause 15.1, the Employee may hold an investment by way of shares or other securities of not more than 5% of the total issued share capital of any company (whether or not it is listed or dealt in on a recognised stock exchange) where such company does not carry on a business similar to or competitive with any business for the time being carried on by the Company or any Group Company.

15.3 The Employee agrees to disclose to the Company any matters relating to her spouse or civil partner (or anyone living as such), children or parents which may, in the reasonable opinion of the Company, be considered to interfere, conflict or compete with the proper performance of the Employee's obligations under this Agreement.

16. Confidential information

16.1 The Employee acknowledges that in the course of the Appointment she will have access to Confidential Information. The Employee has therefore agreed to accept the restrictions in this clause 16.

16.2 The Employee shall not (except in the proper course of her duties), either during the Appointment or at any time after its termination (howsoever arising), use, copy, transfer or disclose to any person, company or other organisation whatsoever (and shall use her best endeavours to prevent the use, copying, transfer, publication or disclosure of) any Confidential Information. This restriction does not apply to:

(a) any use or disclosure authorised by the Directors of the Company or required by law; or

(b) any information which is already in, or comes into, the public domain other than through the Employee's unauthorised disclosure; or

(c) prevent the Employee from making a protected disclosure within the meaning of section 43A of the Employment Rights Act 1996.

17. Intellectual property

17.1 The Employee acknowledges that all Employment IPRs, Employment Inventions and all materials embodying them shall automatically belong to the Company to the fullest extent permitted by law. To the extent that they do not vest in the Company automatically, the Employee holds them on trust for the Company.

17.2 The Employee acknowledges that, because of the nature of her duties and the particular responsibilities arising from the nature of her duties, she has, and shall have at all times while she is employed by the Company, a special obligation to further the interests of the Company.

17.3 To the extent that legal title in any Employment IPRs or Employment Inventions does not vest in the Company by virtue of clause 17.1, the Employee agrees, immediately upon creation of such rights and inventions, to offer to the Company in writing a right of first refusal to acquire them on arm´s length terms to be agreed between the parties. If the parties cannot agree on

such terms within 30 days of the Company receiving the offer, the Company shall refer the dispute to an independent arbitrator. The arbitrator's decisions shall be final and binding on the parties, and the costs of arbitration shall be borne equally by the parties. The Employee agrees that the provisions of this clause 17 shall apply to all Employment IPRs and Employment Inventions offered to the Company under this clause 17 until such time as the Company has agreed in writing that the Employee may offer them for sale to a third party.

17.4 The Employee agrees:

(a) to give the Company full written details of all Employment Inventions promptly on their creation;

(b) at the Company's request and in any event on the termination of her employment to give to the Company all originals and copies of correspondence, documents, papers and records on all media which record or relate to any of the Employment IPRs;

(c) not to attempt to register any Employment IPR nor patent any Employment Invention unless requested to do so by the Company; and

(d) to keep confidential each Employment Invention unless the Company has consented in writing to its disclosure by the Employee.

17.5 The Employee waives all her present and future moral rights which arise under the Copyright Designs and Patents Act 1988, and all similar rights in other jurisdictions relating to any copyright which forms part of the Employment IPRs, and agrees not to support, maintain nor permit any claim for infringement of moral rights in such copyright works.

17.6 The Employee acknowledges that, except as provided by law, no further remuneration or compensation other than that provided for in this Agreement is or may become due to the Employee in respect of her compliance with this clause. This clause is without prejudice to the Employee's rights under the Patents Act 1977.

17.7 The Employee undertakes to use her best endeavours to execute all documents and do all acts both during and after her employment by the Company as may, in the opinion of the Company, be necessary or desirable to vest the Employment IPRs in the Company, to register them in the name of the Company and to protect and maintain the Employment IPRs and the Employment Inventions. Such documents may, at the Company's request, include waivers of all and any statutory moral rights relating to any copyright works which form part of the Employment IPRs. The Company agrees to

reimburse the Employee's reasonable expenses of complying with this clause 17.7.

17.8 The Employee agrees to give all necessary assistance to the Company to enable it to enforce its Intellectual Property Rights against third parties, to defend claims for infringement of third party Intellectual Property Rights and to apply for registration of Intellectual Property Rights, where appropriate throughout the world, and for the full term of those rights.

17.9 The Employee hereby irrevocably appoints the Company to be her attorney to execute and do any such instrument or thing and generally to use her name for the purpose of giving the Company or its nominee the benefit of this clause 17. The Employee acknowledges in favour of a third party that a certificate in writing signed by any Director of the Company that any instrument or act falls within the authority conferred by this clause 17 shall be conclusive evidence that such is the case.

18. Termination

18.1 Notwithstanding clause 2.3, the Company may, in its sole and absolute discretion, terminate the Appointment at any time and with immediate effect by paying a sum in lieu of notice (Payment in Lieu) equal to the basic salary (as at the date of termination) which the Employee would have been entitled to receive under this Agreement during the notice period referred to in clause 2.3 (or, if notice has already been given, during the remainder of the notice period) less income tax and National Insurance contributions. For the avoidance of doubt, the Payment in Lieu shall not include any element in relation to:

(a) any bonus or incentive compensation payments that might otherwise have been due during the period for which the Payment in Lieu is made;

(b) any payment in respect of benefits which the Employee would have been entitled to receive during the period for which the Payment in Lieu is made, including but not limited to car allowance; and

(c) any payment in respect of any holiday entitlement that would have accrued during the period for which the Payment in Lieu is made.

18.2 The Company may pay any sums due under clause 18.1 in equal monthly instalments until the date on which the notice period referred to in clause 2.3 would have expired if notice had been given.

18.3 The Employee shall have no right to receive a Payment in Lieu unless the Company has exercised its discretion in clause 18.1. Nothing in this clause 18.3 shall prevent the Company from terminating the Appointment in breach.

18.4 The Company may also terminate the Appointment with immediate effect without notice, with no liability to make any further payment to the Employee (other than in respect of amounts accrued due at the date of termination) and without compensation, damages or otherwise if the Employee (without limitation):

(a) fails or ceases to meet the requirements of any regulatory body whose consent is required to enable her to undertake all or any of her duties under the Appointment or is guilty of a serious breach of the rules and regulations of such regulatory body or of any compliance manual of any Group Company; or

(b) is guilty of any gross misconduct; or

(c) commits any serious or repeated breach or non-observance of any of the provisions of this Agreement or refuses or neglects to comply with any reasonable and lawful directions of the Company; or

(d) is, in the reasonable opinion of the SVP Human Resources, President International, General Counsel or Directors of the Company, negligent and incompetent in the performance of her duties; or

(e) is declared bankrupt or makes any arrangement with or for the benefit of her creditors or has a county court administration order made against her under the County Court Act 1984; or

(f) is convicted of any criminal offence (other than an offence under any road traffic legislation in the United Kingdom or elsewhere for which a fine or non-custodial penalty is imposed) or any offence under any regulation or legislation relating to insider dealing; or

(g) becomes medically certified as non-compos mentis (of unsound mind) and/or deemed legally incompetent; or

(h) ceases to be eligible to work in the United Kingdom in accordance with section 8 of the Asylum and Immigration Act 1996; or

(i) is guilty of any fraud or dishonesty or acts in any manner which in the opinion of the Company brings or is likely to bring the Employee or any Group Company into disrepute or is materially adverse to the interests of any Group Company; or

(j) is guilty of a serious breach of any applicable rules issued by the Company or any Group Company from time to time regarding electronic communications systems.

18.5 The rights of the Company under clause 18.4 are without prejudice to any other rights that it might have at law to terminate the Appointment or to accept any breach of this Agreement by the Employee as having brought the Agreement to an end. Any delay by the Company in exercising its rights to terminate shall not constitute a waiver thereof.

18.6 Should the employee become incapacitated during the notice period, as a result of voluntary resignation, the company sick pay will be discretionary. However the employee will be entitled to statutory sick pay under government legislation.

19. Garden leave

19.1 Following service of notice to terminate the Appointment by either party, or if the Employee purports to terminate the Appointment in breach of contract, and, if the Company so decides, at any time during the Appointment or in order to investigate a reasonable belief that the Employee is guilty of gross misconduct, the Company may by written notice require the Employee not to perform any services (or to perform only specified services) for the Company or any Group Company until the termination of the Appointment (such period to be referred to as "Garden Leave").

19.2 During any period of Garden Leave the Company shall be under no obligation to provide any work to, or vest any powers in, the Employee, who shall have no right to perform any services for the Company or any Group Company.

19.3 During any period of Garden Leave the Employee shall:

(a) continue to receive her salary and all contractual benefits in the usual way and subject to the terms of any benefit arrangement;

(b) remain an employee of the Company and bound by the terms of this Agreement and her implied duties;

(c) not, without the prior written consent of the Employee's manager, attend her place of work or any other premises of the Company or any Group Company;

(d) not, without the prior written consent of her manager, contact or deal with (or attempt to contact or deal with) any officer, employee, consultant, client, customer, supplier, agent, distributor, shareholder, adviser or other business contact of the Company or any Group Company; and

(e) (except during any periods taken as holiday in the usual way) ensure that her manager knows where she will be and how she can be contacted during each working day and shall comply with any written requests to contact a specified employee of the Company at specified intervals.

20. Obligations upon termination

20.1 On termination of the Appointment (howsoever arising) or, if earlier, at the start of a period of Garden Leave, or at any other time at the request of the Company, the Employee shall:

(a) subject to clause 20.1(b) if applicable, immediately deliver to the Company all documents, books, materials, records, correspondence, papers and information (on whatever media and wherever located) relating to the business or affairs of the Company or any Group Company or their business contacts, any keys, credit card and any other property of the Company or any Group Company (including but not limited to laptop, computer equipment, and mobile phone), which is in her possession or under her control;

(b) where the Employee is on Garden Leave she shall not be required to return to the Company any property provided to her as a contractual benefit;

(c) irretrievably delete any information relating to the business of the Company or any Group Company stored on any magnetic or optical disk or memory and all matter derived from such sources which is in her possession or under her control outside the Company's premises, including but not limited to any personally-owned computer, laptop, mobile phone, or other electronic system or device;

(d) irretrievably delete all of the Employee's electronic personal information and personal files (which contain no information of the Company or any Group Company) from the Company's electronic devices (such as Company-provided laptop); and

(e) provide a signed statement that she has complied fully with her obligations under this clause 20.1.

20.2 On termination of the Appointment howsoever arising the Employee agrees that she shall not be entitled to any compensation of any kind for the loss of any rights or benefits under any share option, bonus, long-term incentive plan or other profit sharing scheme operated by the Company or any Group Company in which she may participate or have received awards in connection with the Appointment.

21. Post-termination restrictions

21.1 In order to protect the Confidential Information, trade secrets, goodwill and business connections of the Company and each Group Company to which she has access as a result of the Appointment and the stable workforce of the Company and each Group Company, the Employee covenants with the

Company (for itself and as trustee and agent for each Group Company) that she shall not:

(a) for six months after Termination solicit or endeavour to entice away from the Company or any Group Company the business or custom of a Restricted Customer with a view to providing goods or services to that Restricted Customer in competition with any Restricted Business; or

(b) for six months after Termination in the course of any business concern which is in competition with any Restricted Business, offer to employ or engage or otherwise endeavour to entice away from the Company or any Group Company any Restricted Person; or

(c) for three months after Termination, be involved in any Capacity with any business concern which is (or intends to be) in competition with any Restricted Business; or

(d) for three months after Termination be involved with the provision of goods or services to (or otherwise have any business dealings with) any Restricted Customer in the course of any business concern which is in competition with any Restricted Business; or

(e) at any time after Termination, represent herself as connected with the Company or any Group Company in any Capacity (with the exception of the Employee's connection as a shareholder of Jazz Pharmaceuticals plc, to the extent applicable).

21.2 None of the restrictions in clause 21.1 shall prevent the Employee from:

(a) holding an investment by way of shares or other securities of not more than 5% of the total issued share capital of any company, whether or not it is listed or dealt in on a recognised stock exchange; or

(b) being engaged or concerned in any business concern insofar as the Employee's duties or work shall relate solely to geographical areas where the business concern is not in competition with any Restricted Business; or

(c) being engaged or concerned in any business concern, provided that the Employee's duties or work shall relate solely to services or activities of a kind with which the Employee was not concerned to a material extent in the six months prior to Termination.

21.3 The restrictions imposed on the Employee by this clause 21 apply to her acting:

(a) directly or indirectly; and

(b) on her own behalf or on behalf of, or in conjunction with, any firm, company or person.

21.4 The periods for which the restrictions in clause 21.1 apply shall be reduced by any period that the Employee spends on Garden Leave immediately prior to Termination.

21.5 If the Employee receives an offer to be involved in a business concern in any Capacity during the Appointment, or prior to the expiry of the last of the covenants in this clause 21, the Employee shall give the person making the offer a copy of this clause 21 and shall tell the Company the identity of that person as soon as possible after accepting the offer.

21.6 The Company and the Employee entered into the restrictions in this clause 21 having been separately legally advised and the Employee agrees they are fair, reasonable and necessary to protect the goodwill and interests of the Company and the Group Companies.

21.7 Each of the restrictions in this clause 21 is intended to be separate and severable. If any of the restrictions shall be held to be void but would be valid if part of their wording were deleted, such restriction shall apply with such deletion as may be necessary to make it valid or effective.

21.8 The Employee will, at the request and expense of the Company, enter into a separate agreement with any Group Company in which she agrees to be bound by restrictions corresponding to those restrictions in this clause 21 (or such of those restrictions as may be appropriate) in relation to that Group Company.

22. Disciplinary and grievance procedures

22.1 The Employee is subject to the Company's disciplinary and grievance procedures as amended from time to time, copies of which are available from the Human Resources Department. These procedures do not form part of the Employee's contract of employment.

22.2 If the Employee wishes to appeal against a disciplinary decision she may do so in accordance with the Company's disciplinary procedure.

22.3 The Company may at any time suspend the Employee for a period of up to 20 working days during any period in which the Company is carrying out a disciplinary investigation into any alleged acts or defaults of the Employee. During any period of suspension the Employee shall continue to receive her salary and contractual benefits.

22.4 If the Employee wishes to raise a grievance, she may apply in writing in accordance with the Company's grievance procedure.

23. Pensions

23.1 During each year of the Appointment, the Company shall contribute an amount equal to 8% of the Employee's salary in equal monthly instalments in arrears to its group personal pension scheme (or such other HM Revenue and Customs (HMRC) registered group personal pension scheme as may be set up by the Company to replace its group personal pension scheme). The Company's contributions to such scheme shall be subject to the rules of the scheme and the tax relief and exemptions available from HMRC, as amended from time to time.

23.2 The Employee may contribute an agreed percentage, but at least 1%, of the Employee's salary, in equal monthly instalments in arrears, to the scheme. Such contributions by the Employee shall be made by way of deduction from the Employee's salary.

24. Reconstruction and amalgamation

If the Appointment is terminated at any time by reason of any reconstruction or amalgamation of the Company or any Group Company, whether by winding up or otherwise, and the Employee is offered employment with any concern or undertaking involved in or resulting from such reconstruction or amalgamation on terms which (considered in their entirety) are no less favourable to any material extent than the terms of this Agreement, the Employee shall have no claim against the Company or any such undertaking arising out of or connected with such termination.

25. Notices

25.1 Any notice given under this Agreement shall be in writing and signed by or on behalf of the party giving it and shall be served by delivering it personally, or sending it by pre-paid recorded delivery or registered post to the relevant party at (in the case of the Company) its registered office for the time being and (in the case of the Employee) her last known address. Any such notice shall be deemed to have been received:

(a) if delivered personally, at the time of delivery; and

(b) in the case of pre-paid recorded delivery or registered post, 48 hours from the date of posting.

25.2 In proving such service it shall be sufficient to prove that the envelope containing such notice was addressed to the address of the relevant party

and delivered either to that address or into the custody of the postal authorities as a pre-paid recorded delivery or registered post.

26. Entire agreement

Each party on behalf of itself (and in the case of the Company, as agent for any Group Companies) acknowledges and agrees with the other party (the Company acting on behalf of itself and as agent for each Group Company) that:

(a) this Agreement together with any documents referred to in it constitute the entire agreement and understanding between the Employee and the Company and any Group Company and supersedes any previous agreement between them relating to the Appointment (which shall be deemed to have been terminated by mutual consent);

(b) in entering into this Agreement neither party nor any Group Company has relied on any Pre-Contractual Statement; and

(c) the only remedy available to each party for breach of this Agreement shall be for breach of contract under the terms of this Agreement and no party shall have any right of action against any other party in respect of any Pre-Contractual Statement.

Nothing in this Agreement shall, however, operate to limit or exclude any liability for fraud.

27. Variation

No variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of each of the parties.

28. Counterparts

This Agreement may be executed in any number of counterparts, each of which, when executed and delivered, shall be an original, and all the counterparts together shall constitute one and the same instrument.

29. Third party rights

The Contracts (Rights of Third Parties) Act 1999 shall not apply to this Agreement and no person other than the Employee and the Company shall have any rights under it. The terms of this Agreement or any of them may be varied, amended or modified, or this Agreement may be suspended, cancelled or terminated, by agreement in writing between the parties, or this

Agreement may be rescinded (in each case), without the consent of any third party.

30. Governing law and jurisdiction

30.1 This Agreement shall be governed by and construed in accordance with the law of England and Wales.

30.2 Each party irrevocably agrees to submit to the exclusive jurisdiction of the courts of England and Wales over any claim or matter arising under or in connection with this Agreement.

Signed by Dan Swisher on behalf of JAZZ PHARMACEUTICALS UK LIMITED	))))	*/s/ Dan Swisher*
Signed by Samantha Pearce	))	*/s/ Samantha Pearce* 14-Dec-2019

Exhibit 10.28B

[Jazz Pharmaceuticals Letterhead]

CONFIDENTIAL

Samantha Pearce
[Address]

9 December 2019

Re: New Hire Equity Award

Dear Samantha,

Welcome to Jazz Pharmaceuticals. In connection with your employment by Jazz Pharmaceuticals UK Limited, you will also receive an equity award from Jazz Pharmaceuticals plc in the amounts shown below, subject to approval in accordance with the policies and guidelines of Jazz Pharmaceuticals plc.

Award of Stock Options: 25,500
Award of Restricted Stock Units (RSUs): 10,200

Your stock options will have an exercise price equal to the closing price of Jazz Pharmaceuticals plc ordinary shares on NASDAQ on the grant date, and will be made pursuant to the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan and subject to the other terms contained in your award agreement.

Your RSUs will represent your right to receive Jazz Pharmaceuticals plc ordinary shares upon vesting and settlement, according to the vesting schedule in your grant notice, and will be made pursuant to the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan and subject to the other terms contained in your award agreement. RSUs have no exercise price.

If you have questions, please feel free to discuss them with Stock Administration.

/s/ SP

Please initial to acknowledge receipt of this letter

Exhibit 10.34C

JAZZ PHARMACEUTICALS PLC

CASH BONUS PLAN

(U.S. AFFILIATES)

1. Purpose of the Plan.

The Jazz Pharmaceuticals plc Cash Bonus Plan (U.S. Affiliates) (the "***Plan***") is designed to provide meaningful incentive, on an annual basis, for employees of U.S. Affiliates of Jazz Pharmaceuticals plc (the "***Company***").

2. Eligibility.

In order to be eligible to participate in the Plan for a Plan Year, an employee (a) must be an active regular employee of a U.S. Affiliate of the Company whose Employment Start Date is October 31 of the Plan Year or earlier and (b) must not be eligible to participate in a commercial (including sales) or other similar incentive compensation plan. Employees who are not expressly classified by the U.S. Affiliate as "regular" employees, such as temporary or contract employees and interns, are not eligible to be Participants.

In order to be eligible to receive a Bonus for a Plan Year, a Participant must (i) continue to be an active regular employee of a U.S. Affiliate of the Company in good standing from the date his/her participation in the Plan commences for the Plan Year until the date Bonuses are paid for the Plan Year, except as provided in Section 6, and (ii) act in accordance with the Company's Code of Conduct, compliance policies and procedures, and those of the Participant's employer, and applicable laws and regulations during the Plan Year.

3. Target Bonus.

A Participant's Target Bonus generally will be based on the Participant's position and/or responsibility level. The Target Bonus for Participants and the amount of Bonus actually paid to a Participant in a Plan Year under the Plan may vary from year to year and between positions, and among positions at the same level. However, as a general guideline, the Target Bonuses which will typically be assigned to various categories of employees (and varying depending on responsibility levels within each category) are as follows:

Position	Target Bonus (Percent of Base Salary)
Senior Vice President who is an Executive Committee Member	45%
Senior Vice President who is not an Executive Committee Member	40%
Vice President	35%
Executive Director	30%
Senior Director	25%
Director	22%
Associate Director	20%
Senior Manager	18%
Manager	15%
Analyst/Senior Analyst	12%
Support/Senior Support	8%

If a Participant moves to a position and/or responsibility level with a higher Target Bonus during a Plan Year, the Participant's Target Bonus will be reset at such higher level for the entire Plan Year. If a Participant moves to a position and/or responsibility level with a lower Target Bonus during a Plan Year, the Participant's Target Bonus will be reset at the lower level for the entire Plan Year.

For any Participant who is a Section 16 Officer of Jazz Pharmaceuticals plc, the Board or the Compensation Committee will determine such Participant's Target Bonus for each Plan Year.

4. Bonus Pool and Bonuses.

Following the end of a Plan Year, the Board or the Compensation Committee will determine, in its sole discretion, the Bonus Pool for the Plan Year to be allocated for the payment of Bonuses to Participants. The Bonus Pool will be calculated by multiplying

(a) the sum of the following amounts for each Participant:
   (i) the Base Salary for such Participant, multiplied by
   (ii) such Participant's applicable Target Bonus;

with

(b) the percentage set by the Board or the Compensation Committee based upon its determination of the Company's success in achieving the objectives established by the Board or the Compensation Committee for funding the Bonus Pool for the Plan Year (the "***Bonus Pool Objectives***").

The Bonus Pool Objectives are related to the achievement of the overall corporate objectives established for the applicable Plan Year by the Board or the Compensation Committee (the "***Corporate Objectives***").

5. Bonus.

Except as provided in Section 6, a Participant's Bonus for a Plan Year will be based upon the following criteria: (a) the Company's success in achieving the Corporate Objectives established for the Plan Year, (b) the Participant's success in achieving his/her individual objectives established for the Plan Year (if applicable) and the Participant's contribution to the Company's success in achieving the Corporate Objectives, in each case while demonstrating Company values, and (c) the Participant's compliance with Company policies and those of Participant's employer. Except as provided in Section 6, the amount of Bonus actually paid to each Participant will be an amount equal to such Participant's Base Salary multiplied by the applicable Target Bonus (as may be adjusted up or down for each Participant by the Board, the Compensation Committee or the Company's management, as appropriate, based on the criteria set forth above). Each Participant's Bonus for a Plan Year will be approved by the Chief Executive Officer or his or her delegate, except that in the case of any Participant who is a Section 16 Officer of Jazz Pharmaceuticals plc, such Participant's Bonus will be approved by the Board or the Compensation Committee.

The total of all Bonuses paid under this Plan in any Plan Year may not exceed the Bonus Pool for such Plan Year unless such excess amount is specifically approved by the Board or the Compensation Committee. Except as provided in Section 6, no amounts will be payable to any Participant hereunder until the Bonus Pool and such Participant's Bonus have been determined as described above. Except as provided in Section 6, no Participant is entitled to any particular bonus, or any bonus, unless approved as described above.

6. Termination of Employment; Death; Retirement; Permanent Disability.

No Bonus will be paid to any Participant whose employment with a U.S. Affiliate of the Company terminates prior to the date Bonuses for a Plan Year are scheduled to be paid pursuant to Section 7, unless (a) such termination is due to the Participant's death, retirement or Permanent Disability, (b) the Board, the Compensation Committee, or the Company's management in appropriate circumstances in management's discretion determines that the Participant will be eligible to receive a Bonus, or (c) such condition is prohibited by regulations, laws, employment agreements or employment contracts applicable to a particular Participant.

In the case of a Participant whose employment with a U.S. Affiliate of the Company terminates (including due to death, retirement or Permanent Disability) prior to the date Bonuses for a Plan Year are scheduled to be paid and who becomes entitled to receive a Bonus pursuant to the foregoing paragraph, the amount of such Participant's Bonus for the Plan Year will be determined by the Board, the Compensation Committee, or the Company's management and may be prorated or otherwise determined based on the number of months employed during the Plan Year, performance or any other factors as decided by the Board, the Compensation Committee or the Company's management, as appropriate.

Any Participant whose employment with a U.S. Affiliate of the Company terminates (including due to death, retirement or Permanent Disability) prior to the date Bonuses for a Plan Year are scheduled to be paid and who becomes entitled to receive a Bonus pursuant to this Section 6 will be paid such Bonus at the time determined by the Company's management, which will in no event be later than the time at which other Participants' Bonuses for the Plan Year are scheduled to be paid pursuant to Section 7.

7. Payment of Bonuses.

Bonuses for a Plan Year will be paid in cash to a Participant (or his/her beneficiary, in the event of death) by March 15th of the following year, except (i) as is otherwise determined in the sole discretion of the Board, the Compensation Committee or the Company's management, as appropriate, or (ii) as may be necessary or advisable to comply with regulations, laws, employment agreements or employment contracts applicable to a particular Participant; *provided, however*, that in all cases, the payment date of any Bonus for any Participant who is subject to Section 409A of the Internal Revenue Code of 1986, as amended, or any state law of similar effect ("***Section 409A***") will be designed to either comply with Section 409A or satisfy an exemption from application of Section 409A, and the Plan will be administered and interpreted to the greatest extent possible in compliance with Section 409A or in accordance with such exemption, as applicable. Benefits under this Plan are not transferable, and the Plan is unfunded.

8. Withholding of Taxes.

Bonuses will be subject to income and employment tax withholding as required by applicable law.

9. Plan Amendments.

This Plan may be revised, modified, or terminated at any time in the sole discretion of the Board or the Compensation Committee. Without limiting the foregoing, the Plan may be revised, modified, or terminated with respect to a Participant or specific group of Participants as may be necessary or advisable to comply with the laws and regulations of the jurisdiction where such Participant or specific group of Participants are employed or where such Participant or specific group of Participants are tax residents.

10. No Employment Rights.

Nothing contained in this Plan is intended to confer any right upon any employee to continued employment with the Company or any U.S. Affiliate or other affiliate thereof.

11. Plan Administration.

This Plan will be administered by the Board or the Compensation Committee. The Board and the Compensation Committee shall have the sole discretion and authority to administer and interpret the Plan, and the decisions of the Board and the Compensation Committee shall in every case be final and binding on all persons having an interest in the Plan. Notwithstanding the foregoing, certain aspects of the Plan may be administered by the Chief Executive Officer or the Company's management, as specifically provided in the Plan, and in such event, the Chief Executive Officer or the Company's management shall have the sole discretion and authority to administer and interpret such aspects of the Plan, and the decisions of the Chief Executive Officer or the Company's management shall in such cases be final and binding.

12. Definitions.

"***Base Salary***" for a Participant means the total amount of base salary or base pay actually paid to the Participant during the period of his/her participation in the Plan for the Plan Year, rather than the Participant's base salary level or base pay level at any particular point during the Plan Year (*e.g.*, the Base Salary for a Participant whose base salary or base pay is adjusted during the Plan Year, for a Participant who is hired during the Plan Year, or for a Participant whose employment terminates during the Plan Year will be the total amount of base salary or base pay actually paid to the Participant during the period of his/her participation in the Plan for the Plan Year). Base Salary does not include any expense reimbursements, relocation payments, incentive compensation or bonuses, amounts received as a result of equity awards, overtime or shift differential payments or similar one-time or unusual payments. Any salary or pay earned for periods during which a Participant is on disciplinary action are excluded from Base Salary.

"***Board***" means the Board of Directors of Jazz Pharmaceuticals plc.

"***Bonus***" means a Participant's actual bonus for a Plan Year as determined in accordance with Section 5 or Section 6, if applicable.

"***Bonus Pool***" for a Plan Year means the aggregate dollar amount set by the Board or the Compensation Committee for the payment of Bonuses for such Plan Year to Participants as set forth in Section 4.

"***Chief Executive Officer***" means the Chief Executive Officer of Jazz Pharmaceuticals plc.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Employment Start Date***" means the first business day on which a Participant is an active regular employee of a U.S. Affiliate of the Company, on the U.S. Affiliate's payroll, as applicable.

"***Executive Committee Member***" means an employee of the Company who serves as a member of the Company's executive committee, as determined by the Chief Executive Officer from time to time.

"***Participant***" means an active regular employee of a U.S. Affiliate of the Company who meets all of the eligibility requirements set forth in Section 2.

"***Permanent Disability***" means that a Participant has become permanently disabled under any policy or program of disability income insurance then in force covering such Participant.

"***Plan***" means this Jazz Pharmaceuticals plc Cash Bonus Plan (U.S. Affiliates).

"***Plan Year***" means the calendar year.

"***Section 16 Officer***" means an individual who has been designated by the Board as an "officer" of Jazz Pharmaceuticals plc for the purposes of Section 16 of the Securities Exchange Act of 1934, as amended, and Rule 16a-1(f) thereunder.

"***Target Bonus***" means, for a Participant for a Plan Year, the percentage of Base Salary, based on such Participant's position and/or responsibility level in a Plan Year, that represents the amount of Bonus that such Participant may receive for such Plan Year, as may be adjusted with respect to such Participant for such Plan Year in the discretion of the Board, the Compensation Committee or the Chief Executive Officer or his or her delegate, as applicable.

"***U.S. Affiliate***" means any "parent" or "subsidiary" of the Company, as such terms are defined in Rule 405 of the Securities Act of 1933, as amended, that is organized under the laws of the United States.

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As approved by the Compensation Committee of the Board of Directors of Jazz Pharmaceuticals plc on 13 February 2013, as amended on 4 November 2015, as amended and restated on 2 November 2016, as amended and restated on 31 October 2018, and as amended and restated on 30 October 2019.

Exhibit 10.34D

JAZZ PHARMACEUTICALS

CASH BONUS PLAN
(IRELAND AND OTHER SPECIFIED AFFILIATES)

(Calendar Year 2020)

1. Purpose of the Plan.

The Jazz Pharmaceuticals Cash Bonus Plan (Ireland and Other Specified Affiliates) (Calendar Year 2020) (the "***Plan***") is designed to provide meaningful incentive, on an annual basis, for employees of Jazz Pharmaceuticals plc (the "***Company***") and employees of the Company's Ireland and Other Specified Affiliates for the Plan Year beginning 1 January 2020 and ending 31 December 2020.

2. Eligibility.

In order to be eligible to participate in the Plan for a Plan Year, an employee (a) must be an employee of the Company or an Ireland and Other Specified Affiliate (each, including Ireland, a "***Specified Affiliate***") whose Employment Start Date is 31 October of the Plan Year or earlier, and (b) must not be eligible to participate in a commercial (including sales) or other similar incentive compensation plan. Additionally, with respect to Gentium S.r.l., Jazz Pharmaceuticals Italy S.r.l. and any other Specified Affiliate in Italy (other than Jazz Healthcare Italy S.r.l.), only employees who are classified as "dirigenti" under Italian employment laws and are individually notified in a separate writing of their eligibility are eligible to participate in the Plan. Employees who are interns are not eligible to be Participants, to the extent permissible under applicable local law.

In order to be eligible to receive a Bonus for a Plan Year, a Participant must (i) continue to be an employee of the Company or a Specified Affiliate in good standing, as determined at the discretion of the employer, from the date his/her participation in the Plan commences for the Plan Year until the Bonus Payment Date (as defined in Section 7) for the Plan Year, except as provided in Section 6, (ii) act in accordance with the Company's Code of Conduct, compliance policies and procedures, and those of the Participant's employer, and applicable laws and regulations during the Plan Year, and (iii) not be serving a notice period as of the Bonus Payment Date for the Plan Year.

The Plan will automatically expire at the end of the indicated Plan Year, and no new plan will be implemented unless the Company announces otherwise.

3. Target Bonus.

The Target Bonus for Participants and the amount of Bonus actually paid to a Participant in a Plan Year under the Plan may vary from year to year and between positions, and among positions at the same level. No Participant has any contractual or otherwise acquired rights to a Target Bonus pursuant to any previous target bonus (whether set forth in a written plan or otherwise). The Board or the Compensation Committee retains the sole discretion to determine the Target Bonuses that apply to Participants, and such determination may include (but is not required) consideration of a Participant's position and/or responsibility level. Participants in Italy who are classified as "dirigenti" under Italian employment laws will be provided written notice specifying such Participant's Target Bonus and the below table does not apply to such Participants. For other Participants, the following table provides a general guideline as to the Target Bonuses which may typically be assigned to various categories of employees:

Position	Target Bonus (Percent of Base Salary)
Senior Vice President who is an Executive Committee Member	45%
Senior Vice President who is not an Executive Committee Member	40%
Vice President	35%
Executive Director	30%
Senior Director	25%
Director	22%
Associate Director	20%
Senior Manager	18%
Manager	15%
Analyst/Senior Analyst	12%
Support/Senior Support	8%

As additional general guidelines, if a Participant moves to a position and/or responsibility level with a higher Target Bonus during a Plan Year, the Participant's Target Bonus will be reset at such higher level for the entire Plan Year; and if a Participant moves to a position and/or responsibility level with a lower Target Bonus during a Plan Year, the Participant's Target Bonus will be reset at the lower level for the entire Plan Year, to the extent permissible under applicable local law.

For any Participant who is a Section 16 Officer of Jazz Pharmaceuticals plc, the Board or the Compensation Committee will determine such Participant's Target Bonus for the Plan Year.

4. Bonus Pool and Bonuses.

Following the end of a Plan Year, the Board or the Compensation Committee will determine, in its sole discretion, the Bonus Pool for the Plan Year to be allocated for the payment of Bonuses to Participants. The Bonus Pool will be calculated by multiplying

(a) the sum of the following amounts for each Participant:

(i) the Base Salary for such Participant, multiplied by
(ii) such Participant's applicable Target Bonus;

with

(b) the percentage set by the Board or the Compensation Committee based upon its determination of the Company's success in achieving the objectives established by the Board or the Compensation Committee for funding the Bonus Pool for the Plan Year (the "***Bonus Pool Objectives***").

The Bonus Pool Objectives are related to the achievement of the overall corporate objectives established for the applicable Plan Year by the Board or the Compensation Committee (the "***Corporate Objectives***").

At the discretion of the Board or the Compensation Committee, the Bonus Pool will be reduced by the amount of bonuses that are required to be paid to any Participants under applicable collective bargaining agreements, labor union arrangements, or the like, if any.

5. Bonus.

Except as provided in Section 6, a Participant's Bonus (on a gross basis) for a Plan Year will be based upon the following criteria: (a) the Company's success in achieving the Corporate Objectives established for the Plan Year, (b) the Participant's success in achieving his/her individual objectives established for the Plan Year (if applicable) and the Participant's contribution to the Company's success in achieving the Corporate Objectives, in each case while demonstrating Company values, and (c) the Participant's compliance with Company policies and those of Participant's employer as evaluated at the discretion of the employer. Applying these criteria, a participant may (or may not) be entitled to any Bonus. In the event that a Participant is to receive a Bonus, except as provided in Section 6, the amount of Bonus actually paid to each Participant will be an amount equal to such Participant's Base Salary multiplied by the applicable Target Bonus (as may be adjusted up or down for each Participant by the Board, the Compensation Committee or the Company's management, as appropriate, based on the criteria set forth above, and will be reduced by the amount of any bonuses that are required to be paid to the Participant under applicable collective bargaining agreements, labor union arrangements, or the like). Each Participant's Bonus for a Plan Year will be approved by the Chief Executive Officer or his or her delegate, except that in the case of any Participant who is a Section 16 Officer of Jazz Pharmaceuticals plc, such Participant's Bonus will be approved by the Board or the Compensation Committee.

The total of all Bonuses paid under this Plan in any Plan Year may not exceed the Bonus Pool for such Plan Year unless such excess amount is specifically approved by the Board or the Compensation Committee. Except as provided in Section 6, no amounts will be payable to any Participant hereunder until the Bonus Pool and such Participant's Bonus have been determined as described above. Except as provided in Section 6, no Participant is entitled to any particular bonus, or any bonus, unless approved as described above.

6. Termination of Employment; Death; Retirement; Permanent Disability.

No Bonus, prorated or otherwise, will be paid to any Participant whose employment with the Company or a Specified Affiliate terminates prior to the date Bonuses for a Plan Year are scheduled to be paid pursuant to Section 7, unless (a) such termination is due to the Participant's death, retirement or Permanent Disability, (b) the Board, the Compensation Committee, or the Company's management in appropriate circumstances in management's discretion determines that the Participant will be eligible to receive a Bonus, or (c) such condition is prohibited by regulations, laws, employment agreements or employment contracts applicable to a particular Participant.

In the case of a Participant whose employment with the Company or a Specified Affiliate terminates (including due to death, retirement or Permanent Disability) prior to the Bonus Payment Date and who becomes entitled to receive a Bonus pursuant to the foregoing paragraph, the amount of such Participant's Bonus for the Plan Year will be determined by the Board, the Compensation Committee, or the Company's management, and may be prorated or otherwise determined based on the number of months employed during the Plan Year, performance or any other factors as decided by the Board, the Compensation Committee or the Company's management, as appropriate, to the extent permissible under applicable local law.

Any Participant whose employment with the Company or a Specified Affiliate terminates (including due to death, retirement or Permanent Disability) prior to the Bonus Payment Date and who becomes entitled to receive a Bonus pursuant to this Section 6 will be paid such Bonus at the time determined by the Company's management, which will in no event be later than the Bonus Payment Date.

Unless otherwise required under applicable local law, payments under this Plan shall not be included in calculation of any payment in lieu of notice, severance pay, termination, indemnity or similar pay.

7. Payment of Bonuses.

Bonuses for a Plan Year will be paid in cash to a Participant (or his/her beneficiary, in the event of death) by 15 March of the following year (the "***Bonus Payment Date***"), except (i) as is otherwise determined in the sole discretion of the Board, the Compensation Committee or the Company's management, as appropriate, or (ii) as may be necessary or advisable to comply with regulations, laws, employment agreements or employment contracts applicable to a particular Participant. Benefits under this Plan are not transferable, to the extent permissible under applicable local law.

8. Withholding of Taxes and Mandatory Contributions.

Bonuses will be subject to applicable tax and social security withholding as required by applicable local laws.

9. Plan Amendments.

This Plan may be revised, modified, or terminated at any time in the sole discretion of the Board or the Compensation Committee. Without limiting the foregoing, the Plan may be revised, modified, or terminated with respect to a Participant or specific group of Participants as may be necessary or advisable to comply with the laws and regulations of the jurisdiction where such Participant or specific group of Participants are employed or where such Participant or specific group of Participants are tax residents.

10. No Employment Rights; No Acquired Rights.

Nothing contained in this Plan is intended to confer any right upon any employee to continued employment with the Company or any Specified Affiliate or other affiliate thereof.

Any payment of Bonuses would be on a voluntary and discretionary basis, without creating any contractual or other acquired right to participate with respect to a similar (or any other) bonus plan or to receive any similar awards (or benefits in lieu) in the future.

11. Plan Administration.

This Plan will be administered by the Board or the Compensation Committee. The Board and the Compensation Committee shall have the sole discretion and authority to administer and interpret the Plan, and the decisions of the Board and the Compensation Committee shall in every case be final and binding on all persons having an interest in the Plan. Notwithstanding the foregoing, certain aspects of the Plan may be administered by the Chief Executive Officer or the Company's management, as specifically provided in the Plan, and in such event, the Chief Executive Officer or the Company's management shall have the sole discretion and authority to administer and interpret such aspects of the Plan, and the decisions of the Chief Executive Officer or the Company's management shall in such cases be final and binding.

12. Definitions.

"***Base Salary***" for a Participant means the total amount of base salary or base pay actually paid to the Participant during the period of his/her participation in the Plan for the Plan Year, rather than the Participant's base salary level or base pay level at any particular point during the Plan Year (*e.g.,* the Base Salary for a Participant whose base salary or base pay is adjusted during the Plan Year, for a Participant who is hired during the Plan Year, or for a Participant whose employment terminates during the Plan Year will be the total amount of base salary or base pay actually paid to the Participant during the period of his/her participation in the Plan for the Plan Year). Base Salary does not include any benefits, expense reimbursements, relocation payments, incentive compensation or bonuses, amounts received as a result of equity awards, overtime or shift differential payments or similar one-time or unusual payments. Any salary or pay earned for periods

during which a Participant is on disciplinary action or serving a notice period are excluded from Base Salary to the extent permissible under applicable local law.

"***Board***" means the Board of Directors of Jazz Pharmaceuticals plc.

"***Bonus***" means a Participant's actual bonus for a Plan Year as determined in accordance with Section 5 or Section 6, if applicable.

"***Bonus Pool***" for a Plan Year means the aggregate dollar amount set by the Board or the Compensation Committee for the payment of Bonuses for such Plan Year to Participants as set forth in Section 4.

"***Chief Executive Officer***" means the Chief Executive Officer of Jazz Pharmaceuticals plc.

"***Compensation Committee***" means the Compensation Committee of the Board.

"***Employment Start Date***" means the first business day on which a Participant is an employee of the Company or a Specified Affiliate, on the Company's or such Affiliate's payroll, as applicable.

"***Executive Committee Member***" means an employee of the Company who serves as a member of the Company's executive committee, as determined by the Chief Executive Officer from time to time.

"***Ireland and Other Specified Affiliate***" means any "parent" or "subsidiary" of the Company that is organized under the laws of Ireland, under the laws of any other country within Europe, or under the laws of Canada. In addition, the Board or the Compensation Committee can designate any other "parent" or "subsidiary" of the Company to be included within this definition.

"***Participant***" means an employee of the Company or an Ireland and Other Specified Affiliate who meets all of the eligibility requirements set forth in Section 2.

"***Permanent Disability***" means that a Participant has become permanently disabled under any policy or program of disability income insurance then in force covering such Participant.

"***Plan***" means this Jazz Pharmaceuticals Cash Bonus Plan (Ireland and Other Specified Affiliates) (Calendar Year 2020).

"***Plan Year***" means the calendar year beginning 1 January 2020 and ending 31 December 2020, after which the Plan should expire.

"***Section 16 Officer***" means an individual who has been designated by the Board as an "officer" of Jazz Pharmaceuticals plc for the purposes of Section 16 of the Securities Exchange Act of 1934, as amended, and Rule 16a-1(f) thereunder.

"***Target Bonus***" means, for a Participant for a Plan Year, the percentage of Base Salary that represents the amount of Bonus that such Participant may receive for such Plan Year, as may be adjusted with respect to such Participant for such Plan Year in the discretion of the Board, the Compensation Committee or the Chief Executive Officer or his or her delegate, as applicable.

*****

As approved by the Compensation Committee of the Board of Directors of Jazz Pharmaceuticals plc on 30 October 2019.

AGREEMENT AND ACCEPTANCE

I acknowledge that this Cash Bonus Plan for the Plan Year beginning 1 January 2020 and ending 31 December 2020 supersedes and replaces all prior agreements, representations or understandings, whether written, oral or implied, between the Company, my employer and me, with respect to this subject matter. Further, I acknowledge that I have read, understand, and agree to comply with all of the terms and conditions of this Cash Bonus Plan.

Employee Signature:

Date: