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

FORM 10-Q

(Mark One)

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 2017

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
011-353-1-634-7800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

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

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

Large accelerated filer	☒		Accelerated filer	☐
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	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 Exchange Act). Yes ☐ No ☒

As of October 31, 2017, 59,950,496 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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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, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Erwinase®, Defitelio® (defibrotide sodium), Defitelio® (defibrotide), Prialt® (ziconotide) intrathecal infusion, CombiPlex® and Vyxeos™ (daunorubicin and cytarabine) liposome for injection. This report also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 252,615	$ 365,963
Investments	200,000	60,000
Accounts receivable, net of allowances	258,616	234,244
Inventories	41,344	34,051
Prepaid expenses	29,249	24,501
Other current assets	49,120	29,310
Total current assets	830,944	748,069
Property and equipment, net	159,386	107,490
Intangible assets, net	3,019,035	3,012,001
Goodwill	941,428	893,810
Deferred tax assets, net, non-current	23,662	15,060
Deferred financing costs	8,149	9,737
Other non-current assets	16,420	14,060
Total assets	$ 4,999,024	$ 4,800,227
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 29,972	$ 22,415
Accrued liabilities	179,890	193,268
Current portion of long-term debt	36,094	36,094
Income taxes payable	13,603	4,506
Deferred revenue	8,618	1,123
Total current liabilities	268,177	257,406
Deferred revenue, non-current	18,270	2,601
Long-term debt, less current portion	1,543,819	1,993,531
Deferred tax liability, net, non-current	540,964	556,733
Other non-current liabilities	158,497	112,617
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	472	472
Additional paid-in capital	1,899,628	1,665,232
Accumulated other comprehensive loss	(158,987)	(317,333)
Retained earnings	728,123	528,907
Total shareholders' equity	2,469,297	1,877,339
Total liabilities and shareholders' equity	$ 4,999,024	$ 4,800,227

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product sales, net	$ 407,971	$ 371,621	$ 1,171,304	$ 1,084,647
Royalties and contract revenues	3,884	2,560	10,990	6,705
Total revenues	411,855	374,181	1,182,294	1,091,352
Operating expenses:				
Cost of product sales (excluding amortization of intangible assets)	31,203	24,311	84,940	71,730
Selling, general and administrative	124,523	124,368	401,106	375,751
Research and development	47,362	47,796	132,447	118,139
Acquired in-process research and development	75,000	15,000	77,000	23,750
Intangible asset amortization	47,313	26,453	99,164	75,832
Total operating expenses	325,401	237,928	794,657	665,202
Income from operations	86,454	136,253	387,637	426,150
Interest expense, net	(19,192)	(18,498)	(56,330)	(42,811)
Foreign exchange loss	(2,224)	(749)	(9,115)	(1,568)
Loss on extinguishment and modification of debt	—	(638)	—	(638)
Income before income tax provision and equity in loss of investees	65,038	116,368	322,192	381,133
Income tax provision	1,239	26,437	65,914	100,888
Equity in loss of investees	273	103	637	103
Net income	$ 63,526	$ 89,828	$ 255,641	$ 280,142
Net income per ordinary share:				
Basic	$ 1.06	$ 1.49	$ 4.26	$ 4.62
Diluted	$ 1.03	$ 1.45	$ 4.17	$ 4.51
Weighted-average ordinary shares used in per share calculations - basic	60,108	60,437	60,030	60,692
Weighted-average ordinary shares used in per share calculations - diluted	61,436	61,795	61,360	62,150

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income	$ 63,526	$ 89,828	$ 255,641	$ 280,142
Other comprehensive income (loss):				
Foreign currency translation adjustments	50,870	14,612	159,302	32,096
Unrealized loss on hedging activities, net of tax benefit (expense) of $(56), $0, $137 and $0, respectively	392	—	(956)	—
Other comprehensive income	51,262	14,612	158,346	32,096
Total comprehensive income	$ 114,788	$ 104,440	$ 413,987	$ 312,238

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

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

	Nine Months Ended September 30,	
	2017	**2016**
Operating activities		
Net income	$ 255,641	$ 280,142
Adjustments to reconcile net income to net cash provided by operating activities:		
Intangible asset amortization	99,164	75,832
Share-based compensation	79,579	74,490
Depreciation	9,288	8,165
Acquired in-process research and development	77,000	23,750
Loss on disposal of property and equipment	360	3
Deferred income taxes	(53,359)	(29,273)
Provision for losses on accounts receivable and inventory	1,825	1,764
Loss on extinguishment and modification of debt	—	638
Amortization of debt discount and deferred financing costs	19,234	16,418
Other non-cash transactions	14,480	1,460
Changes in assets and liabilities:		
Accounts receivable	(22,273)	(28,274)
Inventories	(7,132)	(14,117)
Prepaid expenses and other current assets	(10,590)	(8,512)
Other long-term assets	(1,825)	297
Accounts payable	6,130	(4,288)
Accrued liabilities	(23,583)	(7,792)
Income taxes payable	8,495	3,323
Deferred revenue	23,163	(682)
Other non-current liabilities	12,931	18,352
Net cash provided by operating activities	488,528	411,696
Investing activities		
Purchases of property and equipment	(20,072)	(8,410)
Acquisitions, net of cash acquired	—	(1,502,443)
Acquired in-process research and development	(77,000)	(23,750)
Acquisition of investments	(290,000)	(75,904)
Proceeds from maturity of investments	150,000	11,211
Acquisition of intangible assets	—	(150,000)
Net cash used in investing activities	(237,072)	(1,749,296)
Financing activities		
Net proceeds from issuance of debt	559,484	994,777
Proceeds from employee equity incentive and purchase plans	22,793	17,951
Repayments of long-term debt	(27,070)	(19,282)
Payment of employee withholding taxes related to share-based awards	(17,909)	(20,595)
Share repurchases	(56,425)	(259,819)
Repayments under revolving credit facility	(850,000)	—
Net cash provided by (used in) financing activities	(369,127)	713,032
Effect of exchange rates on cash and cash equivalents	4,323	2,350
Net decrease in cash and cash equivalents	(113,348)	(622,218)
Cash and cash equivalents, at beginning of period	365,963	988,785
Cash and cash equivalents, at end of period	$ 252,615	$ 366,567

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

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

1. The Company and Summary of Significant Accounting Policies

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

We have a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the 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 patients with narcolepsy;
- **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;
- **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; and
- **Vyxeos™ (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or AML, or AML with myelodysplasia-related changes.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying and investing in growth opportunities such as new treatment indications and new geographic markets;
- Acquiring or licensing rights to clinically meaningful and differentiated products that are on the market or product candidates that are in late-stage development; and
- Pursuing targeted development of post-discovery differentiated product candidates.

We apply a disciplined approach to allocating our resources between investments in our current commercial and development portfolio and acquisitions or in-licensing of new assets.

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.

Basis of Presentation

These unaudited condensed consolidated financial statements have been prepared following the requirements of the U.S. Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or U.S. GAAP, can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our annual consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2016.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. The results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017, for any other interim period or for any future period.

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

Significant Risks and Uncertainties

Our financial results remain significantly influenced by sales of Xyrem. In the three and nine months ended September 30, 2017, net product sales of Xyrem were $303.9 million and $874.2 million, respectively, which represented 74% and 75% of total net product sales, respectively. Our ability to maintain or increase product sales of Xyrem is subject to risks and uncertainties, including the potential U.S. introduction of a generic version of Xyrem before the entry dates specified in our settlements with certain companies that had filed abbreviated new drug applications, or ANDAs, with the FDA seeking approval to market a generic version of Xyrem or on terms that are different from those contemplated by the settlements; the potential U.S. introduction of an alternative product to Xyrem for treating cataplexy and/or EDS in narcolepsy; changes to, increases in or uncertainties around regulatory restrictions, including, among other things, changes to our Xyrem risk evaluation and mitigation strategy, or REMS, particularly in light of the FDA's waiver of the single shared REMS requirement for sodium oxybate and approval of a separate generic sodium oxybate REMS; any increase in pricing pressure from, or restrictions on reimbursement imposed by, third party payors; changes in healthcare laws and policy, including changes in requirements for patient assistance programs, rebates, reimbursement and coverage by federal healthcare programs, and changes resulting from increased scrutiny on pharmaceutical pricing and REMS programs by government entities; operational disruptions at the Xyrem central pharmacy or any failure to comply with our REMS obligations to the satisfaction of the FDA; any supply or manufacturing problems, including any problems with our sole source provider of the active pharmaceutical ingredient for Xyrem; continued acceptance of Xyrem by physicians and patients, even in the face of negative publicity that surfaces from time to time; changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem; and our U.S.-based sodium oxybate and Xyrem suppliers' ability to obtain sufficient quotas from the U.S. Drug Enforcement Administration, or DEA, to satisfy our needs for Xyrem.

Although Xyrem is protected by patents covering its manufacture, formulation, distribution system and method of use, eight companies have filed ANDAs with the FDA seeking approval to market a generic version of Xyrem. We filed patent lawsuits against each of the ANDA filers in the U.S. District Court for the District of New Jersey, or the District Court, and an additional lawsuit against the most recent ANDA filer, Ascent Pharmaceuticals, Inc., or Ascent, in the U.S. District Court for the Eastern District of New York, or EDNY, where Ascent is incorporated. On April 5, 2017, we settled all lawsuits against the first ANDA filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC), which acquired Roxane Laboratories, Inc., or West-Ward, granting West-Ward the right to sell an authorized generic version of Xyrem, or the West-Ward AG Product, commencing on January 1, 2023, or earlier under certain circumstances, and granting West-Ward a license to launch its generic sodium oxybate product as early as six months thereafter. In the second quarter of 2016, we had settled lawsuits with two of the other ANDA filers, granting those filers a license to manufacture, market and sell their generic versions of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events. In addition, on August 22, 2017, we settled all lawsuits with Ascent, granting Ascent a license to manufacture, market and sell its generic version of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events. For a description of our settlements with West-Ward and three of the other ANDA filers, see "Overview —Challenges, Risks and Trends Related to Our Lead Marketed Products" in Part I, Item 2 of this Quarterly Report on Form 10-Q. Lawsuits with the remaining non-settling ANDA filers have been consolidated as one case and remain pending in the District Court. Although no trial date has been set, discovery is scheduled to conclude in the second quarter of 2018, and the trial in this consolidated case could occur as early as mid-2018. For a description of these legal proceedings, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict the timing or outcome of the ANDA litigation proceedings against the remaining non-settling ANDA filers.

In July 2016, the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office issued final decisions that the claims of six patents listed in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, as covering the Xyrem REMS are unpatentable. We filed a notice of appeal of these decisions on February 22, 2017. If the United States Court of Appeals for the Federal Circuit upholds those decisions on appeal, these claims will be canceled, and we will not be able to enforce these patents. In March 2016, the PTAB partially instituted an inter partes review, or IPR, on three claims of a seventh REMS patent, declining to review 25 of 28 claims. The PTAB issued a final decision in March 2017 that the three claims they reviewed are unpatentable. We filed a notice of appeal of that decision on May 18, 2017, and the Court of Appeals for the Federal Circuit has consolidated the appeal of the March 2017 decision with the pending appeals of the July 2016 decisions. For a description of these legal proceedings, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any proceeding, including any appeal, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

On January 17, 2017, the FDA announced approval of the West-Ward ANDA, and on January 19, 2017, the FDA tentatively approved two additional ANDAs for generic versions of Xyrem, one for Amneal Pharmaceuticals, LLC, or Amneal, and one for Ohm Laboratories Inc., formerly known as Ranbaxy, Inc., or Ohm. West-Ward's ANDA approval includes a waiver that permits West-Ward to use a separate REMS program from the Xyrem REMS, or the generic sodium oxybate REMS, on the condition that the generic sodium oxybate REMS be open to all future sponsors of ANDAs or new drug applications, or NDAs,

for sodium oxybate products. We were not involved in the development of the generic sodium oxybate REMS. We continue to evaluate potential challenges based on the FDA's waiver of the requirement for a single, shared system REMS in connection with the approvals of the ANDAs, including whether the FDA's waiver decision meets the conditions for such a waiver under applicable law. We cannot predict whether or when we may pursue any such challenges or whether any such challenges would be successful.

The actual timing of any commercial launch of an authorized generic or generic version of Xyrem is uncertain. We do not believe a launch by an ANDA filer is likely to occur prior to either a date agreed in a settlement agreement between us and such ANDA filer or a decision by the District Court, or an appellate court, if applicable, in our ongoing patent litigation. However, notwithstanding our patents, and settlement agreements licensing those patents as of future dates, it is possible that West-Ward, Amneal, Ohm or any other company that receives FDA approval of an ANDA for a generic version of Xyrem or an NDA for another sodium oxybate product could introduce a generic version of Xyrem or other sodium oxybate product before the entry dates specified in our settlement agreements or before our patents expire, including if it is determined that the introduction of the competing product does not infringe our patents, if it is determined that our patents are invalid or unenforceable, or if a non-settling ANDA filer that has received approval for its product decides, before applicable ongoing patent litigation is concluded, to launch a sodium oxybate product at risk of being held liable for damages for patent infringement. In addition, even if we prevail in our ongoing litigation at trial or on appeal, we cannot guarantee that the court will grant an injunction that prevents the ANDA filers from marketing their generic versions of Xyrem. Instead the court may order an ANDA filer that is found to infringe to pay damages in the form of lost profits or a reasonable royalty, which could be significant. We expect that the launch of any generic version of Xyrem, including the West-Ward AG Product or other authorized generic version of Xyrem, or the approval and launch of other products that compete with Xyrem, could have a material adverse effect on our sales of Xyrem and on our business, financial condition, results of operations and growth prospects. For further discussion regarding the risks associated with the West-Ward settlement agreement, the tentative approval of the Amneal and Ohm ANDAs, potential approval or tentative approval of additional ANDAs, the potential launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate or other products that compete with Xyrem, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales," "*We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have*," and "Risks Related to Our Intellectual Property" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

In August 2015, we implemented the current Xyrem REMS, and we have submitted and expect to continue to submit ongoing assessments as set forth in the FDA's Xyrem REMS approval letter. However, we cannot guarantee that our implementation and ongoing assessments will be satisfactory to the FDA or that the Xyrem REMS will satisfy the FDA's expectations in its evaluation of the Xyrem REMS on an ongoing basis. Any failure to comply with the REMS obligations 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 take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects. Further, we cannot predict whether the FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the Xyrem REMS in connection with the anticipated distribution of the West-Ward AG Product, the approval of the generic sodium oxybate REMS or otherwise, or the potential timing, terms or propriety thereof. Any such modifications or additional requirements could make it more difficult or expensive for us to distribute Xyrem, make distribution easier for sodium oxybate competitors, impair the safety profile of Xyrem and/or negatively affect sales of Xyrem.

We may face pressure to modify the Xyrem REMS, or 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. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the approval of the generic sodium oxybate REMS, or licensing or sharing intellectual property pertinent to the Xyrem REMS or elements of the Xyrem REMS. For more information, see the risk factors under the headings "*The launch of a generic version of Xyrem or other sodium oxybate products that compete with Xyrem would adversely affect sales of Xyrem*" and "*We have incurred and expect to continue to 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*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

In September 2016, Jazz Pharmaceuticals, Inc., our wholly owned subsidiary, submitted a Citizen Petition to the FDA requesting that, for safety reasons, the FDA refuse to approve any sodium oxybate ANDA with a proposed package insert or REMS that omits the portions of the Xyrem package insert and the Xyrem REMS that instruct prescribers on adjusting the dose of the product when it is co-administered with divalproex sodium (also known as valproate or valproic acid). On January 17, 2017, the FDA granted the Citizen Petition with respect to the Xyrem package insert. The FDA concluded that it will not approve any sodium oxybate ANDA referencing Xyrem that does not include in its package insert the portions of the currently approved Xyrem package insert related to the drug-drug interaction, or DDI, with divalproex sodium. The FDA stated that it did not need to reach the question of whether the DDI information could have been excluded from the generic

sodium oxybate REMS materials because it was approving a REMS in connection with a sodium oxybate ANDA including that information. Our Xyrem patents include three method of administration patents relating to a DDI, or DDI patents, covering these instructions on the Xyrem package insert and Xyrem REMS. We cannot predict whether or when one or more of the ANDA filers may pursue a challenge to the FDA's response to the Citizen Petition or whether any such challenges would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of, or will otherwise obtain a judicial determination that the generic sodium oxybate package insert or the generic sodium oxybate REMS will infringe, any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents any non-settling ANDA filer or other company introducing a different sodium oxybate product from marketing its product. For a further discussion of risks and uncertainties related to our REMS, our REMS patents and our DDI patents, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales" and "Risks Related to Our Intellectual Property" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

We may also face competition from companies with other sodium oxybate products. For example, we are aware of a third party that has stated that it intends to file an NDA to market a once nightly formulation of sodium oxybate for treatment of cataplexy and/or EDS in narcolepsy under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which allows companies to seek approval of a product that is similar, but not identical, to a previously-approved brand-name product. We are also aware of a product to treat adult patients with narcolepsy with or without cataplexy that received marketing approval in Europe in 2016. While this product is currently not approved by the FDA for marketing in the U.S., the company that has exclusive U.S. commercialization rights to this product recently announced that it expects to establish an expanded access program for the product in early 2018 and submit an NDA to the FDA for the treatment of narcolepsy in adult patients during the first half of 2018. See the risk factor under the heading "*We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Obtaining and maintaining appropriate reimbursement for Xyrem in the U.S. is increasingly challenging due to, among other things, the attention being paid to healthcare cost containment and prescription drug pricing, pricing pressure from third party payors and increasingly restrictive reimbursement conditions being imposed by third party payors. In this regard, we have experienced and expect to continue to experience increasing pressure from third party payors to agree to discounts, rebates or other pricing terms for Xyrem. Any such restrictive pricing terms or additional reimbursement conditions could have a material adverse effect on our Xyrem revenues. In addition, drug pricing by pharmaceutical companies has recently come under close scrutiny, particularly with respect to companies that have increased the price of products after acquiring those products from other companies. We expect that healthcare policies and reforms intended to curb healthcare costs will continue to be proposed, which could limit the prices that we charge for our products, including Xyrem, limit our commercial opportunity and/or negatively impact revenues from sales of our products. Also, price increases on Xyrem and our other products, and negative publicity regarding pricing and price increases generally, whether with respect to our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of Xyrem and our other products.

In the three and nine months ended September 30, 2017, net product sales of our second largest product, Erwinaze/Erwinase (which we refer to in this report as Erwinaze unless otherwise indicated or the context otherwise requires), were $49.2 million and $149.6 million, respectively, which represented 12% and 13% of total net product sales, respectively. We seek to increase sales of Erwinaze, as well as to make Erwinaze more widely available, through ongoing sales and marketing activities.

Erwinaze is licensed from and manufactured by a single source, Porton Biopharma Limited, or PBL, which is wholly owned by the U.K. Secretary of State for Health. Our agreement with PBL, including our license, expires in December 2020, subject to five-year extensions unless terminated by either party in writing by December 2018. We cannot predict whether the term of the agreement will be extended or, if extended, the terms of any such extension.

Erwinaze was approved by the FDA under a biologics license application, or BLA, and was launched in the U.S. in November 2011. The FDA's approval of the BLA for Erwinaze includes a number of post-marketing commitments related to the manufacture of Erwinaze by PBL. We cannot predict if or when PBL will comply with its manufacturing-related post-marketing commitments that are part of the BLA approval. In January 2017, the FDA issued a warning letter to PBL indicating that it was not satisfied with PBL's response to the FDA Form 483 issued to PBL in March 2016, citing significant violations of current Good Manufacturing Practices, or cGMP, for finished pharmaceuticals and significant deviations from cGMP for active pharmaceutical ingredients, or APIs. In March 2017, PBL filed a response to the warning letter with the FDA. We attended a meeting with PBL and the FDA in the third quarter of 2017 to discuss the warning letter, and PBL continues to address the issues identified by the FDA in the warning letter. We cannot predict if or when PBL will correct the violations and deviations to the satisfaction of the FDA or whether the FDA will be satisfied with PBL's response to the warning letter. Any failure to do so could result in the FDA refusing admission of Erwinaze into the U.S., as well as additional enforcement actions by the FDA and other regulatory entities.

In addition, a significant challenge to our ability to maintain current sales levels and to increase sales is our need to avoid supply disruptions of Erwinaze due to capacity constraints, production delays, quality or regulatory challenges or other manufacturing difficulties. The current manufacturing capacity for Erwinaze is completely absorbed by demand for the product. We are working with PBL to evaluate potential expansion of its production capacity to increase the supply of Erwinaze over the longer term and to address the production delays and quality challenges, and related regulatory scrutiny. As a consequence of constrained manufacturing capacity, we have had an extremely limited or no ability to build product inventory levels that can be used to absorb disruptions to supply resulting from quality, regulatory or other issues. We have experienced product quality, manufacturing and inventory challenges that have resulted, and may continue to result from time to time through the remainder of 2017 and into 2018, in disruptions in our ability to supply certain markets and have caused, and may in the future cause, us to implement batch-specific, modified product use instructions. Most recently, we experienced supply disruptions in the third quarter of 2017 in the U.S. and certain other countries. As capacity constraints and supply disruptions continue, whether as a result of continued quality or other manufacturing issues, regulatory issues or otherwise, we will be unable to build a desired excess level of product inventory, our ability to supply the market may continue to be compromised and physicians' decisions to use Erwinaze have been, and in the future may continue to be, negatively impacted. Additional Erwinaze supply disruptions and/or our inability to expand production capacity could materially adversely affect our sales of and revenues from Erwinaze and our potential future maintenance and growth of the market for this product.

Our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of other risks and uncertainties, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that population, our need to apply for and receive marketing authorizations, through the European Union's, or EU's, mutual recognition procedure or otherwise, in certain additional countries if we decide to launch promotional efforts in those countries, as well as those other risks and uncertainties discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

In the three and nine months ended September 30, 2017, net product sales of Defitelio/defibrotide represented 8% of total net product sales for both periods. We acquired this product in January 2014 in connection with our acquisition of Gentium S.r.l., or Gentium, which we refer to as the Gentium Acquisition, and secured worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. We began to commercialize Defitelio in certain European countries in 2014. The process of maintaining pricing and reimbursement approvals is complex and varies from country to country. Many European countries periodically review their reimbursement classes, which could have an adverse impact on the reimbursement status of Defitelio. We cannot predict the outcome of periodic pricing and reimbursement reviews across Europe. If we are unable to maintain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our anticipated revenue from and growth prospects for Defitelio in the EU could be negatively affected.

In March 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, and our U.S. commercial launch is still at an early stage. Our ability to realize the anticipated benefits from our investment in Defitelio is subject to risks and uncertainties, including the continued acceptance of Defitelio in the U.S. by hospital pharmacy and therapeutics committees and the continued availability of adequate coverage and reimbursement by government programs and third party payors; the limited experience of U.S. physicians in diagnosing and treating VOD, particularly in adults, and the possibility that physicians may not initiate or may delay initiation of treatment while waiting for VOD symptoms to improve, or terminate treatment before the end of the recommended dosing schedule; our ability to successfully maintain or grow sales of Defitelio in Europe and other non-U.S. countries; delays or problems in the supply or manufacture of the product; the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in HSCT treatment protocols reduce the incidence of VOD diagnosis); our ability to meet the post-marketing commitments and requirements imposed by the FDA in connection with its approval of our NDA for Defitelio; and our ability to obtain marketing approval in other countries and to develop the product for additional indications, as well as those other risks and uncertainties discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. If sales of Defitelio 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.

In addition, we made a significant investment in Vyxeos through the acquisition of Celator Pharmaceuticals Inc., or Celator, in July 2016, or the Celator Acquisition. On August 3, 2017, the FDA approved our NDA for Vyxeos for the treatment of adults with newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes. We launched and began shipping Vyxeos in the U.S. in August 2017, and the launch is at an early stage. We submitted a marketing authorization application for Vyxeos to the European Medicines Agency in the fourth quarter of 2017. Our ability to realize the anticipated benefits from our investment in Vyxeos is subject to additional 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; delays or problems in the supply or manufacture of the product, including the ability of the third parties upon which we rely to manufacture Vyxeos and its APIs to manufacture sufficient quantities in accordance with

applicable specifications; the need to establish pricing and reimbursement support for Vyxeos in the U.S. and in other countries; the acceptance of Vyxeos in the U.S. and other countries by hospital pharmacy and therapeutics committees and the availability of adequate coverage and reimbursement by government programs and third party payors; the approval and use of new and novel compounds in AML that are only approved for use in combination with other agents and that have not been tested in combination with Vyxeos; and the limited size of the population of high-risk AML patients who may potentially be indicated for treatment with Vyxeos, particularly given the ongoing clinical trials by other companies with the same patient population, as well as those other risks and uncertainties discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. If sales of Vyxeos do not reach the levels we expect, or we are unable to obtain regulatory approval for Vyxeos in Europe in a timely manner, or at all, our anticipated revenue from Vyxeos would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In May and October 2016 and in February 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients and documents concerning the provision of financial assistance to Medicare patients taking drugs sold by us. We are cooperating with the investigation, and the outcome of this investigation could include an enforcement action or a settlement with the federal government. The Office of the Inspector General has established guidelines that permit pharmaceutical manufacturers to 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. 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 by the federal government. If the federal government were to file an enforcement action against us as a result of the investigation and could establish the elements of a violation of relevant laws, we could be subject to damages, fines and penalties, which could be substantial, along with other criminal, civil or administrative sanctions. Any settlement with the federal government could result in substantial payments and entry into a corporate integrity agreement, which would impose costs and burdens on the operation of our business. For more information, see the risk factors under the headings "*Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and these changes could have a material adverse effect on our business and financial condition*" and "*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*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Other key challenges and risks that we face include risks and uncertainties related to:

- the challenges of protecting and enhancing our intellectual property rights;
- the challenges of achieving and maintaining commercial success of our products;
- delays or problems in the supply or manufacture of our products and product candidates, particularly with respect to certain products as to which we maintain limited inventories, our dependence on single source suppliers for most of our products, product candidates and APIs, and the requirement that we and our product suppliers be qualified by the FDA to manufacture product and comply with applicable manufacturing regulations;
- the need to obtain and maintain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and pharmaceutical pricing in the U.S. and worldwide, including the need to obtain and maintain reimbursement for Xyrem in the U.S. in an environment in which we are subject to increasingly restrictive conditions for reimbursement required by government programs and third party payors;
- our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business;
- the challenges of compliance with the requirements of the FDA, the DEA, and comparable non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, patient assistance programs, adverse event reporting and product recalls or withdrawals;
- the difficulty and uncertainty of pharmaceutical product development, including the timing thereof, and the uncertainty of clinical success, such as the risk that results from preclinical studies and/or early clinical trials may not be predictive of results obtained in later and larger clinical trials planned or anticipated to be conducted for our product candidates;

- the inherent uncertainty associated with the regulatory approval process, especially as we continue to increase investment in our product pipeline development projects and undertake multiple planned regulatory submissions for our product candidates;
- the risks associated with business combination or product or product candidate acquisition transactions, such as the challenges inherent in the integration of acquired businesses with our historical business, the increase in geographic dispersion among our centers of operation and the risks that we may acquire unanticipated liabilities along with acquired businesses or otherwise fail to realize the anticipated benefits (commercial or otherwise) from such transactions; and
- possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

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 II, Item 1A of this Quarterly Report on Form 10-Q.

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. We assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion of derivative instruments, if any, to current earnings. 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.

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 September 30, 2017, we had foreign exchange forward contracts with notional amounts totaling $330.6 million. As of September 30, 2017, the asset fair value of outstanding foreign exchange forward contracts was $11.8 million. As of September 30, 2017, 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 $1.1 million as of September 30, 2017. The counterparties to these contracts are large multinational commercial banks, and we believe the risk of nonperformance is not material.

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 we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on our financial position, liquidity or results of operations. As of September 30, 2017, five customers accounted for 91% of gross accounts receivable, including Express Scripts Specialty Distribution Services, Inc. and its affiliates, or Express Scripts, which accounted for 72% of gross accounts receivable, and McKesson Corporation and affiliates, or McKesson, which accounted for 17% of gross accounts receivable. As of

December 31, 2016, five customers accounted for 90% of gross accounts receivable, including Express Scripts, which accounted for 73% of gross accounts receivable, and McKesson, which accounted for 13% of gross accounts receivable.

We depend on single source suppliers for most of our products, product candidates and their APIs. We commenced manufacturing of Xyrem in our facility in Athlone, Ireland in the third quarter of 2016.

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

Net Income per Ordinary Share

Basic net income per ordinary share is based on the weighted-average number of ordinary shares outstanding. Diluted net income per ordinary share is based on the weighted-average number of ordinary shares outstanding and potentially dilutive ordinary shares outstanding.

Basic and diluted net income per ordinary share were computed as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Numerator:				
Net income	$ 63,526	$ 89,828	$ 255,641	$ 280,142
Denominator:				
Weighted-average ordinary shares used in per share calculation - basic	60,108	60,437	60,030	60,692
Dilutive effect of employee equity incentive and purchase plans	1,328	1,358	1,330	1,458
Weighted-average ordinary shares used in per share calculation - diluted	61,436	61,795	61,360	62,150
Net income per ordinary share:				
Basic	$ 1.06	$ 1.49	$ 4.26	$ 4.62
Diluted	$ 1.03	$ 1.45	$ 4.17	$ 4.51

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans, 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, 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 2021 Notes and the 2024 Notes, which we refer to together as 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 for the three and nine months ended September 30, 2017 and 2016 did not exceed the effective exchange prices per ordinary share of the Exchangeable Senior Notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Exchangeable Senior Notes	3,958	2,878	3,238	2,878
Options to purchase ordinary shares and RSUs	2,998	2,851	3,175	2,688
Ordinary shares under ESPP	16	45	9	72

Recent Accounting Pronouncements

In August 2017, the Financial Accounting Standards Board, or FASB, issued ASU No. 2017-12, "Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities". ASU No. 2017-12 amends and simplifies existing guidance in order to allow companies to more accurately present the economic effects of risk management activities in their financial statements. ASU No. 2017-12 is effective for reporting periods beginning after December 15, 2018, with early adoption permitted. We are currently assessing the impact of adoption of ASU No. 2017-12 on our consolidated financial statements and our approach to adoption.

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.

In January 2017, the FASB issued ASU No. 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business" which provides clarification on the definition of a business and adds guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The standard is effective for us beginning January 1, 2018. Early adoption is permitted. The future impact of ASU No. 2017-01 will be dependent upon the nature of our future acquisition or disposition transactions, if any.

In October 2016, the FASB issued ASU No. 2016-16, "Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory" which requires an entity to recognize the income tax consequences of an intra-entity asset transfer, other than an intra-entity asset transfer of inventory, when the transfer occurs. The standard is effective for us beginning January 1, 2018. Early adoption is permitted. We plan to adopt ASU No. 2016-16 at its effective date and do not expect adoption to have a material impact on our results of operations and financial position.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments". ASU 2016-15 addresses how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for us beginning January 1, 2018. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)". Under the new guidance, lessees will be 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. ASU No. 2016-02 is effective beginning January 1, 2019 and early adoption is permitted. ASU No. 2016-02 must be adopted on a modified retrospective transition basis for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements. The adoption of ASU No. 2016-02 will result in a significant increase in our consolidated balance sheet for right-of-use assets and lease liabilities. While we are continuing to assess all potential impacts of the standard, we currently believe the most significant impact relates to our accounting for the lease agreements we entered into in January 2015 and September 2017 to lease office space located in Palo Alto, California in buildings constructed or to be constructed by the landlord, which are accounted for as build-to-suit arrangements under existing accounting standards, and the lease agreement we entered into in August 2016 for office space in Dublin, Ireland.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers". The standard states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this, an entity will need to identify the contract with a customer; identify the separate performance obligations in the contract; determine the transaction price; allocate the transaction price to the separate performance obligations in the contract; and recognize revenue when (or as) the entity satisfies each performance obligation. In August 2015, the FASB issued ASU No. 2015-14, "Revenue from Contracts with Customers: Deferral of the Effective Date", which deferred the effective date of ASU No. 2014-09. ASU No. 2014-09 will now be effective for us beginning January 1, 2018 and can be adopted on a full retrospective basis or on a modified retrospective basis. In March 2016, the FASB issued ASU No. 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations", which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing", which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, "Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients" related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. We plan to adopt ASU No. 2014-09 at its effective date

on a modified retrospective basis. We have substantially completed our review of existing revenue contracts and currently do not anticipate that the implementation of ASU No. 2014-09 will have a material impact on our results of operations and financial position. We are continuing to review the impact that the new standard will have on our financial statement disclosures and to identify any changes required to our accounting policies, business processes and internal controls to support the new accounting and disclosure requirements.

2. Collaboration and Option Agreement

In August 2017, we entered into a collaboration and option agreement with ImmunoGen, Inc., or ImmunoGen, granting us rights to opt into exclusive, worldwide licenses to develop and commercialize two early-stage, hematology-related antibody-drug conjugate, or ADC, programs, as well as an additional program to be designated during the term of the agreement. The programs covered under the agreement include IMGN779, a CD33-targeted ADC for the treatment of AML in Phase 1 testing, and IMGN632, a CD123-targeted ADC for hematological malignancies expected to enter clinical testing before the end of 2017.

Under the terms of the agreement, ImmunoGen will be responsible for the development of the three ADC programs 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 agreement, we paid ImmunoGen a non-refundable upfront payment of $75.0 million, which was charged to acquired in-process research and development, or IPR&D, expense upon closing of the transaction. Additionally, we will pay ImmunoGen up to $100 million in development funding over 7 years to support the three ADC programs. For each program, we may exercise our opt-in right at any time prior to a pivotal study or any time prior to a BLA upon payment of an option exercise fee. The option exercise fee depends on the timing of exercise and certain other conditions. For each program to which 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 of the applicable product in the U.S. and the EU. ImmunoGen has the right to co-commercialize one product (or two products, under certain limited circumstances) 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.

3. Cash and Available-for-Sale Securities

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

	September 30, 2017					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 122,154	$ —	$ —	$ 122,154	$ 122,154	$ —
Time deposits	220,000	—	—	220,000	20,000	200,000
Money market funds	110,461	—	—	110,461	110,461	—
Totals	$ 452,615	$ —	$ —	$ 452,615	$ 252,615	$ 200,000

	December 31, 2016					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 215,963	$ —	$ —	$ 215,963	$ 215,963	$ —
Time deposits	210,000	—	—	210,000	150,000	60,000
Totals	$ 425,963	$ —	$ —	$ 425,963	$ 365,963	$ 60,000

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 condensed consolidated statements of income. Our investments balance represents time deposits with original maturities of greater than three months.

4. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of September 30, 2017 and December 31, 2016 that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	September 30, 2017			December 31, 2016	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Assets:					
Available-for-sale securities:					
Time deposits	$ —	$ 220,000	$ 220,000	$ 210,000	$ 210,000
Money market funds	110,461	—	110,461	—	—
Interest rate contracts	—	201	201	—	—
Foreign exchange forward contracts	—	12,124	12,124	—	—
Totals	$ 110,461	$ 232,325	$ 342,786	$ 210,000	$ 210,000
Liabilities:					
Interest rate contracts	$ —	$ 1,322	$ 1,322	$ —	$ —
Foreign exchange forward contracts	—	291	291	—	—
Totals	$ —	$ 1,613	$ 1,613	$ —	$ —

As of September 30, 2017, 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 2017 or in 2016.

As of September 30, 2017, the estimated fair values of our 2021 Notes and 2024 Notes were approximately $607 million and $565 million, respectively. The fair values of our 2021 Notes and 2024 Notes were estimated using quoted market prices obtained from brokers (Level 2). The estimated fair value of our borrowing under our term loan was approximately equal to its book value based on the borrowing rates currently available for variable rate loans (Level 2).

5. Derivative 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 from March 3, 2017 until July 12, 2021. These agreements hedge contractual term loan interest rates. As of September 30, 2017, 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 12, 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 ineffective portion of the change in fair value is recognized directly in earnings.

The impact on accumulated other comprehensive loss and earnings from derivative instruments that qualified as cash flow hedges for the three and nine months ended September 30, 2017 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Interest Rate Contracts:	**2017**	**2016**	**2017**	**2016**
Loss recognized in accumulated other comprehensive loss, net of tax	$ (59)	$ —	$ (2,234)	$ —
Loss reclassified from accumulated other comprehensive loss to interest expense, net of tax	$ 451	$ —	$ 1,278	$ —

Assuming no change in LIBOR-based interest rates from market rates as of September 30, 2017, $1.2 million of losses recognized in accumulated other comprehensive loss will be reclassified to earnings over the next 12 months. The gains related to the ineffective portion of derivative instruments that qualified as cash flow hedges for the three and nine months ended September 30, 2017 were minimal.

We enter into foreign exchange forward contracts, with durations of up to 365 days, 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 September 30, 2017, the notional amount of foreign exchange contracts where hedge accounting is not applied was $330.6 million. The foreign exchange loss in our condensed consolidated statements of income included gains of $2.8 million and $11.8 million associated with foreign exchange contracts not designated as hedging instruments for the three and nine months ended September 30, 2017, respectively.

The cash flow effects of our derivative contracts for the nine months ended September 30, 2017 are included within net cash provided by operating activities in the condensed consolidated statements of cash flows.

The following table summarizes the fair value of outstanding derivatives as of September 30, 2017 (in thousands):

	September 30, 2017			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	**Fair Value**	**Balance Sheet Location**	**Fair Value**
Derivatives designated as hedging instruments:				
Interest rate contracts	Other non-current assets	$ 201	Accrued liabilities	$ 1,322
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	12,124	Accrued liabilities	291
Total fair value of derivative instruments		$ 12,325		$ 1,613

Although we do not offset derivative assets and liabilities within our condensed 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 condensed consolidated balance sheets of offsetting our interest rate contracts and foreign exchange forward contracts subject to such provisions (in thousands):

	September 30, 2017					
				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	$ 1,938	$ —	$ 1,938	$ (560)	$ —	$ 1,378
Derivative liabilities	$ (560)	$ —	$ (560)	$ 560	$ —	$ —

There were no outstanding derivatives as of December 31, 2016.

6. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Raw materials	$ 2,681	$ 1,547
Work in process	19,965	18,689
Finished goods	18,698	13,815
Total inventories	$ 41,344	$ 34,051

7. Goodwill and Intangible Assets

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

Balance at December 31, 2016	$ 893,810
Foreign exchange	47,618
Balance at September 30, 2017	$ 941,428

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

		September 30, 2017			December 31, 2016		
	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	15.1	$ 3,376,895	$ (505,369)	$ 2,871,526	$ 1,477,618	$ (410,523)	$ 1,067,095
Manufacturing contracts	0.6	12,647	(11,670)	977	11,278	(8,292)	2,986
Trademarks	—	2,905	(2,905)	—	2,872	(2,872)	—
Total finite-lived intangible assets		3,392,447	(519,944)	2,872,503	1,491,768	(421,687)	1,070,081
Acquired in-process research and development assets		146,532	—	146,532	1,941,920	—	1,941,920
Total intangible assets		$ 3,538,979	$ (519,944)	$ 3,019,035	$ 3,433,688	$ (421,687)	$ 3,012,001

The increase in the gross carrying amount of intangible assets as of September 30, 2017 compared to December 31, 2016 reflected the positive impact of foreign currency translation adjustments, which was due to the strengthening of the euro against the U.S. dollar. Additionally, after receiving FDA approval of our NDA for Vyxeos in August 2017, we reclassified $1.8 billion of acquired IPR&D from an indefinite-lived intangible asset to an acquired developed technology finite-lived intangible asset. This acquired developed technology asset is being amortized over its estimated useful life of 18 years.

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.

Based on finite-lived intangible assets recorded as of September 30, 2017, and assuming the underlying assets will not be impaired and that we will not change the expected lives of the assets, future amortization expenses were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2017 (remainder)	$ 52,966
2018	208,830
2019	208,595
2020	205,644
2021	204,609
Thereafter	1,991,859
Total	$ 2,872,503

8. Certain Balance Sheet Items

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

	September 30, 2017	December 31, 2016
Construction-in-progress	$ 82,802	$ 33,427
Land and buildings	46,616	46,033
Manufacturing equipment and machinery	22,903	19,596
Computer software	19,281	17,832
Leasehold improvements	12,953	9,328
Computer equipment	11,912	10,980
Furniture and fixtures	3,373	2,436
Subtotal	199,840	139,632
Less accumulated depreciation and amortization	(40,454)	(32,142)
Property and equipment, net	$ 159,386	$ 107,490

Accrued liabilities consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Rebates and other sales deductions	$ 76,930	$ 72,344
Employee compensation and benefits	46,672	43,363
Royalties	11,309	11,643
Accrued construction-in-progress	5,488	1,597
Inventory-related accruals	3,843	3,350
Sales returns reserve	3,470	4,366
Professional fees	3,244	4,596
Clinical trial accruals	2,657	10,139
Selling and marketing accruals	2,384	3,924
Accrued interest	2,347	5,179
Accrued contract termination fees	—	11,612
Other	21,546	21,155
Total accrued liabilities	$ 179,890	$ 193,268

9. Debt

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

	September 30, 2017	December 31, 2016
2021 Notes	$ 575,000	$ 575,000
Unamortized discount and debt issuance costs on 2021 Notes	(86,663)	(101,094)
2021 Notes, net	488,337	473,906
2024 Notes	575,000	—
Unamortized discount and debt issuance costs on 2024 Notes	(163,363)	—
2024 Notes, net	411,637	—
Term loan	679,939	705,719
Borrowings under revolving credit facility	—	850,000
Total debt	1,579,913	2,029,625
Less current portion	36,094	36,094
Total long-term debt	$ 1,543,819	$ 1,993,531

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.

We allocated the total issuance costs incurred of $15.5 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.

As of September 30, 2017, the carrying value of the equity component of the 2024 Notes, net of equity issuance costs, was $149.8 million.

The 2021 Notes and the 2024 Notes were issued by Jazz Investments I Limited, or the Issuer, a 100%-owned finance subsidiary of Jazz Pharmaceuticals plc. The 2021 Notes and the 2024 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 2021 or the 2024 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.

Maturities

Scheduled maturities with respect to our long-term debt principal balances outstanding as of September 30, 2017 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2017 (remainder)	$ 9,023
2018	40,606
2019	58,652
2020	76,699
2021	1,075,801
Thereafter	575,000
Total	$ 1,835,781

10. 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 and 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 September 30, 2017 and December 31, 2016. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

We have noncancelable operating leases for our office buildings and we are obligated to make payments under noncancelable operating leases for automobiles used by our sales force. Future minimum lease payments under our noncancelable operating and facility leases as of September 30, 2017 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2017 (remainder)	$ 6,615
2018	15,811
2019	16,885
2020	19,127
2021	19,166
Thereafter	165,797
Total	$ 243,401

In January 2015, we entered into an agreement to lease office space located in Palo Alto, California in a building subsequently constructed by the landlord. We began to occupy this office space in October 2017. In September 2017, we entered into an agreement to lease office space located in Palo Alto, California in a second building to be constructed by the same landlord. We expect to occupy this office space by the end of 2019. In connection with these leases, the landlord is providing a tenant improvement allowance for the costs associated with the design, development and construction of tenant improvements for the leased facilities. We are obligated to fund all costs incurred in excess of the tenant improvement allowance. The scope of the planned tenant improvements do not qualify as “normal tenant improvements” under the lease accounting guidance. Accordingly, for accounting purposes, we have concluded we are the deemed owner of the buildings during the construction period. As of September 30, 2017, we recorded project construction costs of $60.9 million incurred by the landlord as construction-in-progress in property and equipment, net and a corresponding financing obligation in other non-current liabilities in our condensed consolidated balance sheets. We will increase the asset and financing obligation as additional building costs are incurred by the landlord during the construction period. We recorded rent expense associated with the ground leases of $0.5 million and $1.4 million in the three and nine months ended September 30, 2017, respectively, in our condensed consolidated statements of income.

As of September 30, 2017, we had $43.2 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

We are involved in legal proceedings, including the following matters:

Xyrem ANDA Matters. On December 10, 2012, we received a notice of Paragraph IV Patent Certification, or Paragraph IV Certification, from Amneal that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On January 18, 2013, we filed a lawsuit against Amneal in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Amneal’s ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. On November 21, 2013, we received a notice of Paragraph IV Certification from Par Pharmaceutical, Inc., or Par, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 27, 2013, we filed a lawsuit against Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Par’s ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents.

In April 2014, Amneal asked the District Court to consolidate its case with the Par case, stating that both cases would proceed on the schedule for the Par case. The District Court granted this request in May 2014. The order consolidating the cases extended Amneal’s 30-month stay period to coincide with the date of Par’s 30-month stay period. The stay expired on May 20, 2016.

Additional patents covering Xyrem have been issued since April 2014 and have been listed in the Orange Book for Xyrem. Amneal and Par have given us additional notices of Paragraph IV Certifications regarding such patents, and we have filed additional lawsuits against Amneal and Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Amneal’s and Par’s ANDAs and seeking a permanent injunction to prevent Amneal and Par from introducing a generic version of Xyrem that would infringe our patents. In March 2016, Par moved to dismiss claims involving our patents covering a part of the Xyrem label that instructs prescribers on adjusting the dose of Xyrem when it is being co-administered with divalproex sodium (also known as valproate or valproic acid), or our DDI patents. In August 2016, we and Par stipulated to dismiss claims relating to our patents covering the formulation of Xyrem on the grounds that Par had notified

FDA that it had converted its Paragraph IV Certifications to Paragraph III Certifications. In September 2017, we and Amneal stipulated to dismiss claims relating to certain of our patents covering the formulation of Xyrem on the grounds that Amneal had notified FDA that it had converted its Paragraph IV Certifications as to these patents to Paragraph III Certifications.

On October 30, 2014, we received a notice of Paragraph IV Certification from Teva Pharmaceutical Industries Ltd., formerly known as Watson Laboratories, Inc., or Teva, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 11, 2014, we filed a lawsuit against Teva in the District Court alleging that our patents covering Xyrem are or will be infringed by Teva's ANDA and seeking a permanent injunction to prevent Teva from introducing a generic version of Xyrem that would infringe these patents. In March 2015, Teva moved to dismiss the portion of the case based on our Orange Book-listed REMS patents on the grounds that these patents do not cover patentable subject matter. In November 2015, the District Court administratively terminated this motion to dismiss (without prejudice) pending the outcome of IPR proceedings before the PTAB relating to the patents that were the subject of Teva's motion. Since March 2015, we have received an additional notice of Paragraph IV Certification from Teva regarding newly issued patents for Xyrem listed in the Orange Book, and we have filed an additional lawsuit against Teva in the District Court alleging that our patents covering Xyrem are or will be infringed by Teva's ANDA and seeking a permanent injunction to prevent Teva from introducing a generic version of Xyrem that would infringe these patents.

In April 2015, the District Court issued an order that consolidated all then-pending lawsuits against Amneal, Par and Teva into one case.

On July 23, 2015, we received a notice of Paragraph IV Certification from Lupin Inc., or Lupin, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On September 2, 2015, we filed a lawsuit in the District Court alleging that our patents covering Xyrem are or will be infringed by Lupin's ANDA and seeking a permanent injunction to prevent Lupin from introducing a generic version of Xyrem that would infringe our patents.

In January, April and June 2016, the District Court issued orders consolidating all of the cases then pending against Amneal, Par, Teva and Lupin into a single case for all purposes. Although no trial date has been set, discovery is scheduled to conclude in the second quarter of 2018, and the trial in this consolidated case could occur as early as mid-2018.

Additional patents covering Xyrem have been issued since June 2016 and have been listed in the Orange Book for Xyrem. We have received additional Paragraph IV Certification notices from Amneal regarding such patents and have filed new lawsuits in the District Court, alleging that our additional patents covering Xyrem are or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents.

On June 14, 2017, we received a notice of Paragraph IV Certification from Ascent that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On July 27, 2017, we filed lawsuits against Ascent in the District Court as well as in the EDNY, where Ascent is incorporated, alleging that our patents covering Xyrem are infringed or will be infringed by Ascent's ANDA and seeking a permanent injunction to prevent Ascent from introducing a generic version of Xyrem that would infringe our patents. On August 22, 2017, we settled all lawsuits with Ascent, granting Ascent a license to manufacture, market and sell its generic version of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events.

We had previously settled lawsuits with three other ANDA filers, and the specific terms of the settlement agreements are confidential. The settlements do not resolve the consolidated case against Amneal, Par, Teva and Lupin, which remains pending. We cannot predict the specific timing or outcome of events with respect to the remaining defendants or the impact of developments involving any specific parties or patents on other ongoing proceedings with any ANDA filer.

Xyrem Post-Grant Patent Review Matters. In January 2015, certain of the ANDA filers filed petitions for IPR with respect to the validity of the six REMS patents. In July 2016, the PTAB issued final decisions that the claims of these six patents are unpatentable; as a result, if the United States Court of Appeals for the Federal Circuit upholds those decisions on appeal, these claims will be canceled. We have filed notices of appeal with respect to these IPR decisions to the United States Court of Appeals for the Federal Circuit. In September 2015, certain of the ANDA filers filed a petition for IPR with respect to the validity of an additional REMS patent. In March 2016, the PTAB partially instituted an IPR on three claims of a seventh REMS patent, declining to review 25 of 28 claims. In March 2017, the PTAB issued a final decision that the three claims that were reviewed by the PTAB are unpatentable. We have filed a notice of appeal of that decision on May 18, 2017, and the Court of Appeals for the Federal Circuit has consolidated the appeal of the March 2017 decision with the pending appeals of the July 2016 decisions.

We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any pending IPR or other proceeding, the outcome of any appeal of the July 2016 and March 2017 IPR decisions with respect to the REMS patents or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

Shareholder Litigation Matters Relating to Celator Acquisition. On June 21, 2016, a putative class-action lawsuit challenging our Celator Acquisition, captioned *Dunbar v. Celator Pharmaceuticals, Inc.*, or the Dunbar action, was filed in the Superior Court of New Jersey. We refer to our acquisition of Celator in this report as the Celator Acquisition. The complaint was filed against Celator, each member of the Celator board of directors, Jazz Pharmaceuticals plc and our wholly owned subsidiary Plex Merger Sub, Inc., or Plex. The complaint generally alleges that the Celator directors breached their fiduciary duties in connection with the Celator Acquisition, and that Jazz Pharmaceuticals plc and Plex aided and abetted these alleged breaches of fiduciary duty. The complaint also generally asserts that the Celator directors breached their fiduciary duties to Celator's public stockholders by, among other things, (i) agreeing to sell Celator to us at an inadequate price, (ii) implementing an unfair process, (iii) agreeing to certain provisions of the merger agreement for the Celator Acquisition that allegedly favored us and deterred alternative bids, and (iv) failing to disclose purportedly material information in Celator's Schedule 14D-9 filing with the U.S. Securities and Exchange Commission, or SEC. The plaintiff sought, among other things, an injunction against the consummation of the Celator Acquisition and an award of costs and expenses, including a reasonable allowance for attorneys' and experts' fees.

Between June 27, 2016 and June 29, 2016, two putative class-action lawsuits challenging the Celator Acquisition, captioned *Palmisciano v. Celator Pharmaceuticals, Inc.*, or the Palmisciano action, and *Barreto v. Celator Pharmaceuticals, Inc.*, or the Barreto action, were filed in the District Court. The complaints were filed against Celator and each member of the Celator board of directors. The complaints assert causes of action under sections 14 and 20 of the Securities Exchange Act of 1934, as amended, predicated on Celator's and the Celator directors' alleged failure to disclose purportedly material information in Celator's Schedule 14D-9 filing with the SEC. The plaintiffs sought, among other things, an injunction against the consummation of the Celator Acquisition and an award of costs and expenses, including a reasonable allowance for attorneys' and experts' fees. Neither Jazz Pharmaceuticals plc nor Plex were named defendants in these actions.

On July 6, 2016, the defendants to the Dunbar action, the Palmisciano action and the Barreto action entered into a memorandum of understanding, or MOU, regarding settlement of these actions with the plaintiffs. The MOU outlines the terms of the parties' agreement in principle to settle and release all claims which were or could have been asserted in these actions. In consideration for such settlement and release, the parties to these actions agreed, among other things, that Celator would amend its Schedule 14D-9 to include certain supplemental disclosures. The Schedule 14D-9 was amended by Celator on July 6, 2016, and the Celator Acquisition was completed on July 12, 2016. In June 2017, the parties to the MOU agreed to terminate the MOU, and the plaintiffs agreed to voluntarily dismiss the remaining actions. Thereafter, the parties negotiated and ultimately agreed, in October 2017, on a mootness fee paid to plaintiffs' counsel. The Dunbar, Palmisciano and Barreto actions have each been dismissed with prejudice.

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

Other Contingencies

In May 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, and, for Xyrem, documents concerning the provision of financial assistance to Medicare patients. In October 2016, we received a second subpoena updating and further specifying document requests regarding support to 501(c)(3) organizations that provide financial assistance to Medicare patients and the provision of financial assistance for Medicare patients taking drugs sold by us. In February 2017, we received a third subpoena requesting documents regarding our support to a specific 501(c)(3) organization that established a fund for narcolepsy patients in January 2017. Other companies have disclosed similar subpoenas and continuing inquiries. We are cooperating with this investigation. We are unable to predict how long this investigation will continue, whether we will receive additional subpoenas in connection with this investigation, or its outcome, but we expect that we will continue to incur significant costs in connection with the investigation, regardless of the outcome. If the federal government were to file an enforcement action against us as a result of the investigation and could establish the elements of a violation of relevant laws, we could be subject to damages, fines and penalties, which could be substantial, along with other criminal, civil or administrative sanctions. Any settlement with the federal government could result in substantial payments and entry into a corporate integrity agreement, which would impose costs and burdens on the operation of our business. For more information, see the risk factor under the heading "*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*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

11. Shareholders' Equity

The following tables present a reconciliation of our beginning and ending balances in shareholders' equity for the nine months ended September 30, 2017 and 2016 (in thousands):

	Total Shareholders' Equity
Shareholders' equity at January 1, 2017	$ 1,877,339
Issuance of 2024 Notes	149,767
Issuance of ordinary shares in conjunction with employee equity incentive and purchase plans	22,793
Employee withholding taxes related to share-based awards	(17,909)
Share-based compensation	79,745
Shares repurchased	(56,425)
Other comprehensive income	158,346
Net income	255,641
Shareholders' equity at September 30, 2017	$ 2,469,297

	Total Shareholders' Equity
Shareholders' equity at January 1, 2016	$ 1,706,333
Issuance of ordinary shares in conjunction with employee equity incentive and purchase plans	17,951
Employee withholding taxes related to share-based awards	(20,595)
Share-based compensation	75,176
Shares repurchased	(259,819)
Other comprehensive income	32,096
Net income	280,142
Shareholders' equity at September 30, 2016	$ 1,831,284

Share Repurchase Program

In November 2016, our board of directors authorized a new share repurchase program pursuant to which we are 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 the nine months ended September 30, 2017, we spent a total of $56.4 million to purchase 0.4 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $141.73 per share. As of September 30, 2017, the remaining amount authorized under the share repurchase program was $225.1 million.

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of September 30, 2017 and December 31, 2016 were as follows (in thousands):

	Net Unrealized Losses From Hedging Activities	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2016	$ —	$ (317,333)	$ (317,333)
Other comprehensive income (loss) before reclassifications	(2,234)	159,302	157,068
Amounts reclassified from accumulated other comprehensive loss	1,278	—	1,278
Net other comprehensive income (loss)	(956)	159,302	158,346
Balance at September 30, 2017	$ (956)	$ (158,031)	$ (158,987)

During the nine months ended September 30, 2017, other comprehensive income (loss) reflects foreign currency translation adjustments, primarily due to the strengthening of the euro against the U.S. dollar, and the net unrealized losses on derivatives that qualify as cash flow hedges.

12. 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 a summary of total revenues (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Xyrem	$ 303,870	$ 285,907	$ 874,222	$ 816,412
Erwinaze/Erwinase	49,173	42,986	149,585	143,907
Defitelio/defibrotide	31,213	28,137	97,351	79,280
Vyxeos	9,719	—	9,719	—
Prialt® (ziconotide) intrathecal infusion	7,930	8,783	21,303	23,065
Other	6,066	5,808	19,124	21,983
Product sales, net	407,971	371,621	1,171,304	1,084,647
Royalties and contract revenues	3,884	2,560	10,990	6,705
Total revenues	$ 411,855	$ 374,181	$ 1,182,294	$ 1,091,352

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
United States	$ 372,846	$ 339,825	$ 1,068,716	$ 991,557
Europe	24,937	25,788	83,667	79,557
All other	14,072	8,568	29,911	20,238
Total revenues	$ 411,855	$ 374,181	$ 1,182,294	$ 1,091,352

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Express Scripts	74%	76%	74%	75%
McKesson	14%	13%	14%	14%

The following table presents total long-lived assets, consisting of property and equipment, by location (in thousands):

	September 30, 2017	December 31, 2016
United States	$ 84,764	$ 35,791
Ireland	64,947	62,453
Italy	7,917	7,000
Other	1,758	2,246
Total long-lived assets	$ 159,386	$ 107,490

13. Share-Based Compensation

Share-based compensation expense related to share options, RSUs and grants under our ESPP was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Selling, general and administrative	$ 20,903	$ 19,511	$ 61,582	$ 60,664
Research and development	4,650	4,056	13,651	10,867
Cost of product sales	1,573	1,307	4,346	2,959
Total share-based compensation expense, pre-tax	27,126	24,874	79,579	74,490
Income tax benefit from share-based compensation expense	(6,354)	(8,486)	(23,816)	(24,341)
Total share-based compensation expense, net of tax	$ 20,772	$ 16,388	$ 55,763	$ 50,149

Share Options

The table below shows the number of shares underlying options granted to purchase our ordinary shares, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Shares underlying options granted (in thousands)	87	147	1,343	1,247
Grant date fair value	$ 45.87	$ 42.89	$ 42.69	$ 40.85
Black-Scholes option pricing model assumption information:				
Volatility	35%	37%	35%	39%
Expected term (years)	4.3	4.2	4.3	4.2
Range of risk-free rates	1.6-1.8%	0.8-1.0%	1.6-1.8%	0.8-1.5%
Expected dividend yield	—%	—%	—%	—%

Restricted Stock Units

The table below shows the number of RSUs granted covering an equal number of our ordinary shares and the weighted-average grant date fair value of RSUs granted:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
RSUs granted (in thousands)	35	59	537	495
Grant date fair value	$ 148.60	$ 138.55	$ 137.23	$ 126.80

The fair value of RSUs is determined on the date of grant based on the market price of our ordinary shares on that date. The fair value of RSUs is expensed ratably over the vesting period, generally over four years.

As of September 30, 2017, compensation cost not yet recognized related to unvested share options and RSUs was $83.2 million and $100.5 million, respectively, which is expected to be recognized over a weighted-average period of 2.7 years and 2.6 years, respectively.

14. Income Taxes

Our income tax provision was $1.2 million and $65.9 million in the three and nine months ended September 30, 2017, respectively, compared to $26.4 million and $100.9 million for the same periods in 2016. The effective tax rates were 1.9% and 20.5% in the three and nine months ended September 30, 2017, respectively, compared to 22.7% and 26.5% for the same periods in 2016. The decrease in the effective tax rates for the three and nine months ended September 30, 2017 compared to the same periods in 2016 was primarily due to the release of a valuation allowance held against certain foreign net operating losses and the release of reserves related to unrecognized tax benefits upon the expiration of a statute of limitation. The effective tax rate for the three months ended September 30, 2017 was lower than the Irish statutory rate of 12.5% primarily due to the release of a valuation allowance held against certain foreign net operating losses and the release of reserves related to unrecognized tax benefits upon the expiration of a statute of limitation. The effective tax rate for the nine months ended September 30, 2017 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, unrecognized tax benefits, and various expenses not deductible for tax purposes, partially offset by originating tax credits and deductions available in relation to subsidiary equity. 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.

Our net deferred tax liability primarily arose due to the Celator Acquisition. The balance is net of deferred tax assets which are comprised primarily of U.S. federal and state net operating loss carryforwards, foreign net operating loss carryforwards and other temporary differences. We maintain a valuation allowance against certain foreign and U.S. federal and state deferred tax assets. Each reporting period, we evaluate the need for a valuation allowance on our deferred tax assets by jurisdiction and adjust our estimates as more information becomes available.

We are required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As a result, we have established a liability for certain tax benefits which we judge may not be sustained upon examination. Our most significant tax jurisdictions are Ireland, the U.S. (both at the federal level and in various state jurisdictions), Italy and France. Because of our net operating loss carryforwards and tax credit carryforwards, substantially all of our tax years remain open to federal, state, and foreign tax examination. Certain of our subsidiaries are currently under examination by the French tax authorities for the years ended December 31, 2012 and 2013. These examinations may lead to ordinary course adjustments or proposed adjustments to our taxes. In December 2015, we received proposed tax assessment notices from the French tax authorities for 2012 and 2013 relating to certain transfer pricing adjustments. The notices propose additional French tax of approximately $45.2 million, including interest and penalties through the date of the assessment, translated at the foreign exchange rate at September 30, 2017. We disagree with the proposed assessment and intend to contest it vigorously.

Item 2. 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 condensed consolidated financial statements and the notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. 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 could impact our business. In particular, we encourage you to review the risks and uncertainties described in "Risk Factors" in Part II, Item 1A in this Quarterly Report on Form 10-Q. 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. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business, financial condition or results of operations. See the "Cautionary Note Regarding Forward-Looking Statements" that appears at the end of this discussion. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Overview

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

We have a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the 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 patients with narcolepsy;
- **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;
- **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; and
- **Vyxeos™ (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or AML, or AML with myelodysplasia-related changes.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying and investing in growth opportunities such as new treatment indications and new geographic markets;
- Acquiring or licensing rights to clinically meaningful and differentiated products that are on the market or product candidates that are in late-stage development; and
- Pursuing targeted development of post-discovery differentiated product candidates.

We apply a disciplined approach to allocating our resources between investments in our current commercial and development portfolio and acquisitions or in-licensing of new assets.

In the three and nine months ended September 30, 2017, our total net product sales increased by 10% and 8%, respectively, compared to the same periods in 2016, primarily due to an increase in Xyrem product sales. We expect total net product sales to increase in 2017 over 2016, primarily due to expected growth in sales of Xyrem and Defitelio, as well as sales of Vyxeos. Our ability to increase net product sales is subject to a number of risks and uncertainties as set forth below and under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. For additional information regarding our net product sales, see "—Results of Operations."

Significant Developments Affecting Our Business

On August 3, 2017, the FDA approved our new drug application, or NDA, for Vyxeos for the treatment of adults with newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes. We launched and began shipping Vyxeos in the U.S. in August 2017.

In July 2017, we announced that we entered into a license agreement with XL-protein GmbH, or XLp, for the rights to develop, manufacture and commercialize products using XLp's PASylation® Technology to extend the plasma half-life of selected asparaginase product candidates.

In August 2017, we announced that we entered into a collaboration and option agreement with ImmunoGen, Inc., or ImmunoGen, granting us rights to opt into exclusive, worldwide licenses to develop and commercialize two early-stage, hematology-related antibody-drug conjugate, or ADC, programs, as well as an additional program to be designated during the term of the agreement.

In addition, in August 2017, Jazz Investments I Limited, our wholly owned subsidiary, completed a private placement of $500.0 million principal amount of 1.50% exchangeable senior notes due 2024, or the 2024 Notes, and in September 2017, sold an additional $75.0 million principal amount of 2024 Notes. We used the net proceeds from the issuance of the 2024 Notes to repay $500.0 million in outstanding borrowings under our revolving credit facility and to pay related fees and expenses. We used the remainder of the net proceeds for general corporate purposes.

On November 2, 2017, we submitted a marketing authorization application, or MAA, for Vyxeos to the European Medicines Agency, or EMA.

Continued Emphasis on Research and Development

During the nine months ended September 30, 2017, we continued our focus on research and development activities, which currently include clinical development of new product candidates, activities related to line extensions and new indications for existing products and the generation of additional clinical data for existing products, all in our sleep and hematology/oncology therapeutic areas.

A summary of our ongoing development activities is provided below:

Project	Disease Area	Status
Sleep		
JZP-110	Excessive sleepiness, or ES, in obstructive sleep apnea, or OSA	Top-line data from two Phase 3 trials received in first quarter of 2017; full data presented in second quarter of 2017; plan to submit an NDA to the FDA in fourth quarter of 2017
JZP-110	ES in narcolepsy	Top-line data from Phase 3 trial received in second quarter of 2017; full data presented in second quarter of 2017; plan to submit an NDA to the FDA in fourth quarter of 2017
JZP-110	ES in Parkinson's disease	First patient enrolled in Phase 2 trial in first quarter of 2017
Xyrem	EDS and cataplexy in pediatric narcolepsy patients with cataplexy	Top-line data from Phase 3 trial received in second quarter of 2017; full data presented in second quarter of 2017; expect to submit a supplemental NDA, or sNDA, and pediatric written request report to the FDA in mid-2018
JZP-507	EDS and cataplexy in narcolepsy	Preparing to submit an NDA to the FDA by mid-2018
JZP-258	EDS and cataplexy in narcolepsy	First patient enrolled in Phase 3 trial being conducted in the European Union, or EU, and U.S. in first quarter of 2017; subject to results of trial, expect to submit an NDA to the FDA in 2019
Oxybate once-nightly dosing	Narcolepsy	Program progressing; evaluation of deuterated oxybate and other formulation options continues as part of once-nightly development process
Hematology/Oncology		
Vyxeos	High-risk AML	NDA approved by FDA on August 3, 2017 for the treatment of adults with newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes; submitted an MAA to the EMA in fourth quarter of 2017
Defibrotide	Prevention of VOD in high-risk patients following HSCT	First patient enrolled in Phase 3 trial in first quarter of 2017
Defibrotide	Prevention of acute Graft versus Host Disease, or aGvHD, following HSCT	Expect to initiate Phase 2 trial in fourth quarter of 2017
Asparaginase	ALL and other hematologic disorders	Evaluation of early-stage product candidates

In the sleep therapeutic area, we have the following ongoing and planned development activities:

- *JZP-110.*

  Phase 3 Clinical Trials. JZP-110 is a late-stage investigational compound being developed for potential treatment of ES in patients with narcolepsy and ES in patients with OSA. We acquired worldwide development, manufacturing and commercial rights to JZP-110 from Aerial BioPharma LLC, or Aerial, in January 2014, other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights. We conducted two Phase 3 clinical trials in patients with ES associated with OSA and one Phase 3 clinical trial in patients with ES associated with narcolepsy. In the second quarter of 2017, we presented positive efficacy results along with safety results from our two Phase 3 clinical trials in patients with ES associated with OSA and one Phase 3 clinical trial in patients with ES associated with narcolepsy. In addition, we enrolled approximately 635 patients from our Phase 2 and Phase 3 clinical trials in an ongoing open label extension trial evaluating the long-term safety and maintenance of efficacy of JZP-110, and we recently completed the interim data analysis in this trial. We believe that we have all of the clinical data necessary to support our planned submission of an NDA to the FDA in the fourth quarter of 2017 to seek approval for JZP-110 in the treatment of ES associated with OSA and ES associated with narcolepsy.

  Phase 2 Clinical Trial. We commenced patient enrollment in a Phase 2 clinical trial of JZP-110 in patients with ES associated with Parkinson's disease in the first quarter of 2017. We expect to enroll approximately 50 adult patients in this trial. There are no FDA-approved therapies for ES in Parkinson's disease in the U.S.

  Other Activities. We are also evaluating future pipeline expansion opportunities for JZP-110 in other disorders and conditions, as well as opportunities for geographic expansion.

- *Xyrem.*

  Phase 3 Clinical Trial of Xyrem in Children and Adolescents. While in many patients narcolepsy can begin during childhood and adolescence, there has been limited information on the treatment of pediatric narcolepsy patients with Xyrem. We worked with the FDA and several leading specialists to design a clinical trial to generate additional data on the treatment of pediatric narcolepsy patients with Xyrem. 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. In the second quarter of 2017, we presented positive efficacy results along with the safety results from this trial. We anticipate submitting an sNDA and pediatric written request report to the FDA in mid-2018.

- *JZP-507.*

  JZP-507 is an investigational new drug candidate with a 50% reduction in sodium content compared to Xyrem that in a pilot study has demonstrated bioequivalence to Xyrem. We are investigating JZP-507 for the potential treatment of both narcolepsy with cataplexy and EDS in narcolepsy. We are preparing to submit an NDA to the FDA by mid-2018. We believe that JZP-507 would offer a clinically meaningful benefit to patients compared to Xyrem.

- *JZP-258.*

  JZP-258 is an investigational new drug candidate that contains 90% less sodium than Xyrem and is being developed for the potential treatment of both narcolepsy with cataplexy and EDS in narcolepsy. We believe that JZP-258 would offer a clinically meaningful benefit to patients compared to Xyrem. We enrolled the first patient in a Phase 3 clinical trial of JZP-258 in the EU and U.S. in the first quarter of 2017, and, subject to the results of this trial, we anticipate submitting an NDA to the FDA in 2019.

  We are also pursuing activities related to the potential development of once-nightly dosing options for narcolepsy patients that we believe would provide clinically meaningful improvements to patients compared to Xyrem. We are exploring formulation options, including an evaluation of deuterated oxybate.

In the hematology and oncology therapeutic area, we have the following ongoing and planned development activities:

- *Vyxeos*. Vyxeos has received Orphan Drug Designation by both the FDA and the European Commission, or EC, for the treatment of AML. We submitted an MAA for Vyxeos to the EMA in the fourth quarter of 2017. The EMA has granted accelerated assessment of the MAA for Vyxeos; accelerated assessment is granted for products expected to be of major interest for public health and can potentially shorten the duration of the EMA's review by up to six months.

  We are also assessing the potential for approval of Vyxeos in other countries and for development of Vyxeos in indications in addition to the treatment of adults with newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes.

- *Defibrotide.*

  Phase 3 Clinical Trial. In the first quarter of 2017, we enrolled the first patient in a Phase 3 clinical trial of defibrotide to evaluate the safety and efficacy of defibrotide for the prevention of VOD in high-risk and very high-risk patients following HSCT. We expect to enroll approximately 400 patients in this global trial and, depending on the results from the interim analysis, the enrollment could increase to up to approximately 600 patients.

  Planned Phase 2 Clinical Trial. We expect to initiate a Phase 2 trial to evaluate defibrotide for the prevention of aGvHD following HSCT in the fourth quarter of 2017.

  Other Activities. In July 2017, we obtained regulatory approval of defibrotide in Canada and launched the product in Canada in the third quarter of 2017. We are also evaluating the potential of defibrotide in additional post-HSCT complications, as well as investigating defibrotide's potential utility in other serious, life-threatening conditions.

For 2017 and beyond, we expect that our research and development expenses will continue to increase from historical levels, particularly as we prepare for a number of anticipated regulatory submissions, initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates. Our ability to continue to undertake our planned development activities, as well as the success of these activities, are subject to a number of risks and uncertainties, including the risk factors under the headings "Risks Related to Our Business" and "Risks Related to Our Industry" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Challenges, Risks and Trends Related to Our Lead Marketed Products

Xyrem. Xyrem is our largest selling product, and our financial results are significantly influenced by sales of Xyrem, which accounted for 74% and 75% of our net product sales for the three and nine months ended September 30, 2017, respectively, and 75% of our net product sales for the year ended December 31, 2016. As a result, we continue to place a high priority on seeking to maintain and increase sales of Xyrem in its approved indications, while remaining focused on ensuring the safe and effective use of the product. We are also focusing on product development efforts relating to Xyrem, including seeking to enhance and enforce our intellectual property rights and to develop product, service and safety improvements for patients.

Our future plans assume that sales of Xyrem will increase, although our plans assume a slower rate of increase than in recent years. While Xyrem product sales grew from 2015 to 2016 and from 2014 to 2015, we cannot assure you that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in July 2017, and we cannot assure you that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes.

Our ability to maintain or increase Xyrem product sales is subject to risks and uncertainties, including those discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, including those related to:

- the potential U.S. introduction of a generic version of Xyrem before the entry dates specified in our settlements with certain companies that had filed abbreviated new drug applications, or ANDAs, with the FDA seeking approval to market a generic version of Xyrem or on terms that are different from those contemplated by the settlements, as further described below;
- the potential U.S. introduction of an alternative product to Xyrem for treating cataplexy and/or EDS in narcolepsy;
- changes to, increases in or uncertainties around regulatory restrictions, including, among other things, changes to our Xyrem risk evaluation and mitigation strategy, or REMS, particularly in light of the FDA's waiver of the single shared systems REMS requirement for sodium oxybate and approval of a separate generic sodium oxybate REMS, as further described below;
- any increase in pricing pressure from, or restrictions on reimbursement imposed by, third party payors;
- changes in healthcare laws and policy, including changes in requirements for patient assistance programs, rebates, reimbursement and coverage by federal healthcare programs, and changes resulting from increased scrutiny on pharmaceutical pricing and REMS programs by government entities;
- operational disruptions at the Xyrem central pharmacy or any failure to comply with our REMS obligations to the satisfaction of the FDA;
- any supply or manufacturing problems, including any problems with our sole source provider of the active pharmaceutical ingredient, or API, for Xyrem;
- continued acceptance of Xyrem by physicians and patients, even in the face of negative publicity that surfaces from time to time;

- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem; and
- our U.S.-based sodium oxybate and Xyrem suppliers' ability to obtain sufficient quotas from the U.S. Drug Enforcement Administration, or DEA, to satisfy our needs for Xyrem.

Although Xyrem is protected by patents covering its manufacture, formulation, distribution system and method of use, eight companies have filed ANDAs with the FDA seeking approval to market a generic version of Xyrem. We filed patent lawsuits against each of the ANDA filers in the U.S. District Court for the District of New Jersey, or the District Court, and an additional lawsuit against the most recent ANDA filer, Ascent Pharmaceuticals, Inc., or Ascent, in the U.S. District Court for the Eastern District of New York, where Ascent is incorporated. On April 5, 2017, we settled all lawsuits against the first ANDA filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC), which acquired Roxane Laboratories, Inc., or West-Ward, granting West-Ward the right to sell an authorized generic version of Xyrem, or the West-Ward AG Product, commencing on January 1, 2023, or earlier under certain circumstances, and granting West-Ward a license to launch its generic sodium oxybate product as early as six months thereafter. In the second quarter of 2016, we had settled lawsuits with two of the other ANDA filers, granting those filers a license to manufacture, market and sell their generic versions of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events. In addition, on August 22, 2017, we settled all lawsuits with Ascent, granting Ascent a license to manufacture, market and sell its generic version of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events. Lawsuits with the remaining non-settling ANDA filers have been consolidated as one case and remain pending in the District Court. Although no trial date has been set, discovery is scheduled to conclude in the second quarter of 2018, and the trial in this consolidated case could occur as early as mid-2018. For a description of these legal proceedings, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict the timing or outcome of the ANDA litigation proceedings against the remaining non-settling ANDA filers.

In July 2016, the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office issued final decisions that the claims of six patents listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, as covering the Xyrem REMS are unpatentable. We filed a notice of appeal of these decisions on February 22, 2017. If the United States Court of Appeals for the Federal Circuit upholds those decisions on appeal, these claims will be canceled, and we will not be able to enforce these patents. In March 2016, the PTAB partially instituted an inter partes review, or IPR, on three claims of a seventh REMS patent, declining to review 25 of 28 claims. The PTAB issued a final decision in March 2017 that the three claims they reviewed are unpatentable. We filed a notice of appeal of that decision on May 18, 2017, and the Court of Appeals for the Federal Circuit has consolidated the appeal of the March 2017 decision with the pending appeals of the July 2016 decisions. For a description of these legal proceedings, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any proceeding, including any appeal, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

In September 2016, Jazz Pharmaceuticals, Inc., our wholly owned subsidiary, submitted a Citizen Petition to the FDA requesting that, for safety reasons, the FDA refuse to approve any sodium oxybate ANDA with a proposed package insert or REMS that omits the portions of the Xyrem package insert and the Xyrem REMS that instruct prescribers on adjusting the dose of the product when it is co-administered with divalproex sodium (also known as valproate or valproic acid). On January 17, 2017, the FDA granted the Citizen Petition with respect to the Xyrem package insert. The FDA concluded that it will not approve any sodium oxybate ANDA referencing Xyrem that does not include in its package insert the portions of the currently approved Xyrem package insert related to the drug-drug interaction, or DDI, with divalproex sodium. The FDA stated that it did not need to reach the question of whether the DDI information could have been excluded from the generic sodium oxybate REMS materials because it was approving a REMS in connection with a sodium oxybate ANDA including that information. Our Xyrem patents include three method of administration patents relating to a DDI, or DDI patents, covering these instructions on the Xyrem package insert and Xyrem REMS. We cannot predict whether or when one or more of the ANDA filers may pursue a challenge to the FDA's response to the Citizen Petition or whether any such challenges would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of, or will otherwise obtain a judicial determination that the generic sodium oxybate package insert or the generic sodium oxybate REMS will infringe, any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents any non-settling ANDA filer or other company introducing a different sodium oxybate product from marketing its product. For further discussion of risks and uncertainties related to our REMS, our REMS patents and our DDI patents, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales" and "Risks Related to Our Intellectual Property" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

On January 17, 2017, the FDA announced approval of the West-Ward ANDA, and on January 19, 2017, the FDA tentatively approved two additional ANDAs for generic versions of Xyrem, one for Amneal Pharmaceuticals, LLC, or Amneal, and one for Ohm Laboratories Inc., formerly known as Ranbaxy, Inc., or Ohm. West-Ward's ANDA approval includes a waiver

that permits West-Ward to use a separate REMS program from the Xyrem REMS, or the generic sodium oxybate REMS, on the condition that the generic sodium oxybate REMS be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. We were not involved in the development of the generic sodium oxybate REMS. We continue to evaluate potential challenges based on the FDA's waiver of the requirement for a single, shared system REMS in connection with the approvals of the ANDAs, including whether the FDA's waiver decision meets the conditions for such a waiver under applicable law. We cannot predict whether or when we may pursue any such challenges or whether any such challenges would be successful.

In connection with FDA approval of the current Xyrem REMS in February 2015, the FDA indicated that it intends to 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 in connection with the anticipated distribution of the West-Ward AG Product, the approval of the generic sodium oxybate REMS or otherwise, or the potential timing, terms or propriety thereof. Any such modifications or additional requirements could make it more difficult or expensive for us to distribute Xyrem, make distribution easier for sodium oxybate competitors, impair the safety profile of Xyrem and/or negatively affect sales of Xyrem. We also may face pressure 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. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the approval of the generic sodium oxybate REMS, or licensing or sharing intellectual property pertinent to the Xyrem REMS or elements of the Xyrem REMS.

The actual timing of any commercial launch of an authorized generic or generic version of Xyrem is uncertain. We do not believe a launch by an ANDA filer is likely to occur prior to either a date agreed in a settlement agreement between us and such ANDA filer or a decision by the District Court, or an appellate court, if applicable, in our ongoing patent litigation. However, notwithstanding our patents, and settlement agreements licensing those patents as of future dates, it is possible that West-Ward, Amneal, Ohm or any other company that receives FDA approval of an ANDA for a generic version of Xyrem or an NDA for another sodium oxybate product could introduce a generic version of Xyrem or other sodium oxybate product before the entry dates specified in our settlement agreements or before our patents expire, including if it is determined that the introduction of the competing product does not infringe our patents, if it is determined that our patents are invalid or unenforceable, or if a non-settling ANDA filer that has received approval for its product decides, before applicable ongoing patent litigation is concluded, to launch a sodium oxybate product at risk of being held liable for damages for patent infringement. In addition, even if we prevail in our ongoing litigation at trial or on appeal, we cannot guarantee that the court will grant an injunction that prevents the ANDA filers from marketing their generic versions of Xyrem. Instead the court may order an ANDA filer that is found to infringe to pay damages in the form of lost profits or a reasonable royalty, which could be significant.

We expect that the launch of any generic version of Xyrem, including the West-Ward AG Product or other authorized generic version of Xyrem, or the approval and launch of other products that compete with Xyrem, could have a material adverse effect on our sales of Xyrem and on our business, financial condition, results of operations and growth prospects. For example, we are aware of a third party that has stated that it intends to file an NDA to market a once nightly formulation of sodium oxybate for treatment of cataplexy and/or EDS in narcolepsy under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which allows companies to seek approval of a product that is similar, but not identical, to a previously-approved brand-name product. We are also aware of a product to treat adult patients with narcolepsy with or without cataplexy that received marketing approval in Europe in 2016. While this product is currently not approved by the FDA for marketing in the U.S., the company that has exclusive U.S. commercialization rights to this product recently announced that it expects to establish an expanded access program for the product in early 2018 and submit an NDA to the FDA for the treatment of narcolepsy in adult patients during the first half of 2018. For further discussion regarding the risks associated with the West-Ward settlement agreement, the tentative approval of the Amneal and Ohm ANDAs, potential approval or tentative approval of additional ANDAs, the potential launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate or other products that compete with Xyrem, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales," "*We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have*," and "Risks Related to Our Intellectual Property" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Erwinaze/Erwinase. Sales of our second largest product, Erwinaze/Erwinase (which we refer to in this report as Erwinaze unless otherwise indicated or the context otherwise requires), accounted for 12% and 13% of our net product sales for the three and nine months ended September 30, 2017, respectively, and 14% for the year ended December 31, 2016. We seek to increase sales of Erwinaze, as well as to make Erwinaze more widely available, through ongoing sales and marketing activities.

However, a significant challenge to our ability to increase sales is our extremely limited inventory of Erwinaze, past and continuing supply disruptions and our need to minimize or avoid additional supply disruptions due to capacity constraints,

production delays, quality or regulatory challenges and other manufacturing difficulties. Erwinaze is licensed from and manufactured by a single source, Porton Biopharma Limited, or PBL.

In January 2017, the FDA issued a warning letter to PBL indicating that it was not satisfied with PBL's responses to the FDA Form 483 issued to PBL in March 2016, citing significant violations of the FDA's current Good Manufacturing Practices, or cGMP, for finished pharmaceuticals and significant deviations from cGMP for APIs. In March 2017, PBL filed a response to the warning letter with the FDA. We attended a meeting with PBL and the FDA in the third quarter of 2017 to discuss the warning letter, and PBL continues to address the issues identified by the FDA in the warning letter. We cannot predict whether the FDA's required remediation activities will further strain manufacturing capacity and adversely affect Erwinaze supply, particularly in light of our extremely limited product inventory. We also cannot predict if or when PBL will correct the violations and deviations to the satisfaction of the FDA or whether the FDA will be satisfied with PBL's response to the warning letter. Any failure to do so could result in the FDA refusing admission of Erwinaze in the U.S., as well as additional enforcement actions by the FDA and other regulatory entities. Any of these actions could have a material adverse effect on our sales of, and revenues from, Erwinaze and limit our potential future maintenance and growth of the market for this product.

Moreover, the current manufacturing capacity for Erwinaze is completely absorbed by demand for the product. We are working with PBL to evaluate potential expansion of its production capacity to increase the supply of Erwinaze over the longer term and to address the production delays and quality challenges, and related regulatory scrutiny. As a consequence of constrained manufacturing capacity, we have had an extremely limited or no ability to build product inventory levels that can be used to absorb disruptions to supply resulting from quality, regulatory or other issues. We have experienced product quality, manufacturing and inventory challenges that have resulted, and may continue to result from time to time through the remainder of 2017 and into 2018, in disruptions in our ability to supply certain markets and have caused, and may in the future cause, us to implement batch-specific, modified product use instructions. Most recently, we experienced supply disruptions in the third quarter of 2017 in the U.S. and certain other countries. As capacity constraints and supply disruptions continue, whether as a result of continued quality or other manufacturing issues, regulatory issues or otherwise, we will be unable to build a desired excess level of product inventory, our ability to supply the market may continue to be compromised and physicians' decisions to use Erwinaze have been, and in the future may continue to be, negatively impacted. Additional Erwinaze supply disruptions and/or our inability to expand production capacity could materially adversely affect our sales of and revenues from Erwinaze and our potential future maintenance and growth of the market for this product, as further discussed in "Risk Factors" in Part I, Item 1A of this Quarterly Report on Form 10-Q.

Defitelio/defibrotide. Sales of Defitelio/defibrotide were 8% of our net product sales for the three and nine months ended September 30, 2017 and 7% of our net product sales for the year ended December 31, 2016. We began to commercialize Defitelio in certain European countries in 2014. On March 30, 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, and our U.S. commercial launch is still at an early stage.

Our ability to realize the anticipated benefits from our investment in Defitelio is subject to risks and uncertainties, including the risk factors set forth under the heading "Risks Related to Our Business" in Item II, Part 1A of this Quarterly Report on Form 10-Q. If sales of Defitelio 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.

Vyxeos. On August 3, 2017, the FDA approved our NDA for Vyxeos for the treatment of adults with newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes. We launched and began shipping Vyxeos in the U.S. in August 2017, and the commercial launch is at an early stage.

Our ability to realize the anticipated benefits from our investment in Vyxeos is subject to risks and uncertainties, including the risk factors set forth under the heading "Risks Related to Our Business" in Item II, Part 1A of this Quarterly Report on Form 10-Q. If sales of Vyxeos do not reach the levels we expect, or we are unable to obtain regulatory approval for Vyxeos in Europe in a timely manner, or at all, or we experience delays or problems in the supply or manufacture of Vyxeos, 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.

Other Challenges and Risks

We anticipate that we will continue to face a number of other challenges and risks to our business and our ability to execute our strategy in 2017 and beyond. Some of these challenges and risks are specific to our business, and others are common to companies in the pharmaceutical industry with development and commercial operations.

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.

Several states have recently passed laws aimed at increasing transparency relating to drug pricing, and other states may do so in the future. Both the U.S. House of Representatives and the U.S. Senate have conducted several hearings with respect to pharmaceutical drug pricing practices, including in connection with the investigation of specific price increases by several pharmaceutical companies. Moreover, the Federal Trade Commission, or FTC, has been paying increasing attention to the use of REMS by companies selling branded products, in particular as to whether a REMS may be deliberately being used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. The FDA has recently stated that it will seek to coordinate with the FTC in identifying and publicizing practices the FTC finds to be anticompetitive and has further stated that the FDA has concerns related to the role of REMS programs in delaying approval of generic products. If we become the subject of any government investigation with respect to our drug pricing or other business practices, including as they relate to the Xyrem REMS, we could incur significant expense and could be distracted from operation of our business and execution of our strategy.

In May and October 2016 and in February 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients and documents concerning the provision of financial assistance to Medicare patients taking drugs sold by us. We are cooperating with the investigation, and the outcome of this investigation could include an enforcement action or a settlement with the federal government. The Office of the Inspector General has established guidelines that permit pharmaceutical manufacturers to 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. 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 by the federal government. If the federal government were to file an enforcement action against us as a result of the investigation and could establish the elements of a violation of relevant laws, we could be subject to damages, fines and penalties, which could be substantial, along with other criminal, civil or administrative sanctions. Any settlement with the federal government could result in substantial payments and entry into a corporate integrity agreement, which would impose costs and burdens on the operation of our business. For more information, see the risk factors under the headings "*Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and these changes could have a material adverse effect on our business and financial condition*" and "*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*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Other key challenges and risks that we face include risks and uncertainties related to:

- the challenges of protecting and enhancing our intellectual property rights;
- the challenges of achieving and maintaining commercial success of our products;
- delays or problems in the supply or manufacture of our products and product candidates, particularly with respect to certain products as to which we maintain limited inventories, our dependence on single source suppliers for most of our products, product candidates and APIs, and the requirement that we and our product suppliers be qualified by the FDA to manufacture product and comply with applicable manufacturing regulations;
- the need to obtain and maintain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and pharmaceutical pricing in the U.S. and worldwide, including the need to obtain and maintain reimbursement for Xyrem in the U.S. in an environment in which we are subject to increasingly restrictive conditions for reimbursement required by government programs and third party payors;
- our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business;
- the challenges of compliance with the requirements of the FDA, the DEA and comparable non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, patient assistance programs, adverse event reporting and product recalls or withdrawals;
- the difficulty and uncertainty of pharmaceutical product development, including the timing thereof, and the uncertainty of clinical success, such as the risk that results from preclinical studies and/or early clinical trials may not be predictive of results obtained in later and larger clinical trials planned or anticipated to be conducted for our product candidates;

- the inherent uncertainty associated with the regulatory approval process, especially as we continue to increase investment in our product pipeline development projects and undertake multiple planned regulatory submissions for our product candidates;
- the risks associated with business combination or product or product candidate acquisition transactions, such as the challenges inherent in the integration of acquired businesses with our historical business, the increase in geographic dispersion among our centers of operation and the risks that we may acquire unanticipated liabilities along with acquired businesses or otherwise fail to realize the anticipated benefits (commercial or otherwise) from such transactions; and
- possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

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 II, Item 1A of this Quarterly Report on Form 10-Q.

Results of Operations

The following table presents our revenues and expenses (in thousands, except percentages):

	Three Months Ended September 30,		Increase/	Nine Months Ended September 30,		Increase/
	2017	2016	(Decrease)	2017	2016	(Decrease)
Product sales, net	$ 407,971	$ 371,621	10%	$ 1,171,304	$ 1,084,647	8%
Royalties and contract revenues	3,884	2,560	52%	10,990	6,705	64%
Cost of product sales (excluding amortization of intangible assets)	31,203	24,311	28%	84,940	71,730	18%
Selling, general and administrative	124,523	124,368	—%	401,106	375,751	7%
Research and development	47,362	47,796	(1)%	132,447	118,139	12%
Acquired in-process research and development	75,000	15,000	400%	77,000	23,750	224%
Intangible asset amortization	47,313	26,453	79%	99,164	75,832	31%
Interest expense, net	19,192	18,498	4%	56,330	42,811	32%
Foreign exchange loss	2,224	749	197%	9,115	1,568	481%
Loss on extinguishment and modification of debt	—	638	N/A(1)	—	638	N/A(1)
Income tax provision	1,239	26,437	(95)%	65,914	100,888	(35)%
Equity in loss of investees	273	103	165%	637	103	518%

(1) Comparison to prior period not meaningful.

Revenues

The following table presents our product sales, royalties and contract revenues, and total revenues (in thousands, except percentages):

	Three Months Ended September 30,		Increase/	Nine Months Ended September 30,		Increase/
	2017	2016	(Decrease)	2017	2016	(Decrease)
Xyrem	$ 303,870	$ 285,907	6%	$ 874,222	$ 816,412	7%
Erwinaze/Erwinase	49,173	42,986	14%	149,585	143,907	4%
Defitelio/defibrotide	31,213	28,137	11%	97,351	79,280	23%
Vyxeos	9,719	—	N/A(1)	9,719	—	N/A(1)
Prialt® (ziconotide) intrathecal infusion	7,930	8,783	(10)%	21,303	23,065	(8)%
Other	6,066	5,808	4%	19,124	21,983	(13)%
Product sales, net	407,971	371,621	10%	1,171,304	1,084,647	8%
Royalties and contract revenues	3,884	2,560	52%	10,990	6,705	64%
Total revenues	$ 411,855	$ 374,181	10%	$ 1,182,294	$ 1,091,352	8%

(1) Comparison to prior period not meaningful.

Product Sales, Net

Xyrem product sales increased in the three and nine months ended September 30, 2017 compared to the same periods in 2016. The product sales increase in the three months ended September 30, 2017 was primarily due to a higher average net selling price, partially offset by a slight decrease in sales volume. The product sales increase in the nine months ended September 30, 2017 was 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 2017 and in July 2017. Erwinaze product sales increased in the three and nine months ended September 30, 2017 compared to the same periods in 2016 primarily due to higher sales volume. The Erwinaze sales volume increase was primarily due to timing of sales following supply interruptions. The Erwinaze product sales increase in the three months ended September 30, 2017 was partially offset by a change in payer mix. Defitelio/defibrotide product sales increased in the three months ended September 30, 2017 compared to the same period in 2016, primarily due to higher sales volume and, to a lesser extent, the impact of foreign exchange rates. Defitelio/defibrotide product sales increased in the nine months ended September 30, 2017 compared to the same period in 2016, primarily due to the launch of Defitelio in the U.S. in April 2016 and, to a lesser extent, higher net sales outside the U.S. primarily due to higher sales volume. Vyxeos product sales in the three and nine months ended September 30, 2017 were $9.7 million following its launch in August 2017. Prialt product sales decreased in the three and nine months ended September 30, 2017 compared to the same periods in 2016 primarily due to a decrease in sales volume. Other product sales in the three months ended September 30, 2017 were consistent with other product sales in the same period in 2016. Other product sales decreased in the nine months ended September 30, 2017 compared to the same period in 2016 primarily due to a decrease in sales of our psychiatry products due to generic competition. We expect total product sales will increase in 2017 over 2016, primarily due to anticipated growth in sales of Xyrem and Defitelio, as well as sales of Vyxeos.

Royalties and Contract Revenues

Royalties and contract revenues increased in the three and nine months ended September 30, 2017 compared to the same periods in 2016 primarily due to higher contract revenues from out-licensing agreements. We expect royalties and contract revenues in 2017 to increase compared to 2016 primarily due to higher contract revenues from out-licensing agreements.

Cost of Product Sales

Cost of product sales increased in the three and nine months ended September 30, 2017 compared to the same periods in 2016, primarily due to an increase in net product sales. Gross margin as a percentage of net product sales was 92.4% and 92.7% in the three and nine months ended September 30, 2017, respectively, compared to 93.5% and 93.4% for the same periods in 2016. The decrease in the gross margin percentage in the three and nine months ended September 30, 2017 was primarily due to a change in product mix. We expect that our gross margin as a percentage of net product sales will not change materially in 2017 compared to 2016.

Selling, General and Administrative Expenses

Selling, general and administrative expenses in the three months ended September 30, 2017 were consistent with the same period in 2016, primarily due to an increase in compensation-related expenses of $10.6 million driven by higher headcount and other expenses related to the expansion of our business and expenses related to the U.S. launch of Vyxeos, partially offset by a decrease in transaction and integration expenses of $10.3 million. Selling, general and administrative expenses increased in the nine months ended September 30, 2017 compared to the same period in 2016, primarily due to an increase in compensation-related expenses of $25.2 million driven by higher headcount and other expenses related to the expansion of our business, costs relating to our narcolepsy disease awareness campaign, expenses related to the U.S. launch of Vyxeos and an increase in legal fees and expenses, partially offset by a decrease in transaction and integration expenses of $12.5 million. We expect selling, general and administrative expenses in 2017 to increase compared to 2016, 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 and increases in expenses related to the U.S. launch of Vyxeos and our narcolepsy disease awareness campaign.

Research and Development Expenses

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Clinical studies and outside services	$ 26,197	$ 31,040	$ 67,885	$ 74,898
Personnel expenses	15,777	12,957	48,331	34,184
Other	5,388	3,799	16,231	9,057
Total	$ 47,362	$ 47,796	$ 132,447	$ 118,139

Research and development expenses decreased by $0.4 million in the three months ended September 30, 2017 and increased by $14.3 million in the nine months ended September 30, 2017 compared to the same periods in 2016. Clinical studies and outside services costs decreased in the three and nine months ended September 30, 2017 compared to the same periods in 2016 primarily due to lower clinical trial costs for JZP-110 studies for ES associated with OSA and with narcolepsy, partially offset by an increase in expenses related to the company's ongoing clinical development programs and regulatory activities. Personnel expenses increased by $2.8 million and $14.1 million in the three and nine months ended September 30, 2017, respectively, compared to the same periods in 2016, primarily driven by increased headcount in support of our development programs.

For 2017 and beyond, we expect that our research and development expenses will continue to increase from historical levels, particularly as we prepare for a number of anticipated regulatory submissions, 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 our product candidates, and the consequences to our business, financial position and growth prospects can be found in “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Acquired In-Process Research and Development

Acquired in-process research and development, or IPR&D, expense in the three and nine months ended September 30, 2017 primarily related to an upfront payment of $75.0 million in connection with a collaboration and option agreement with

ImmunoGen to acquire rights to opt into exclusive, worldwide licenses to develop and commercialize two early-stage, hematology-related ADC programs, as well as an additional program to be designated during the term of the agreement. Acquired IPR&D expense in the three months ended September 30, 2016 related to upfront and option payments of $15.0 million made to Pfenex Inc., or Pfenex, for 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. Acquired IPR&D expense in the nine months ended September 30, 2016 consisted of the upfront and option payments of $15.0 million made to Pfenex and a payment of $8.8 million in connection with the acquisition of intellectual property and know-how related to recombinant crisantaspase.

Intangible Asset Amortization

Intangible asset amortization increased by $20.9 million and $23.3 million in the three and nine months ended September 30, 2017, respectively, compared to the same periods in 2016. Intangible asset amortization increased primarily due to the commencement of amortization of the Vyxeos intangible asset upon FDA approval in August 2017. We expect intangible asset amortization to increase in 2017 compared to 2016 as a result of the FDA's approval of Vyxeos and commencement of amortization of the related intangible asset.

Interest Expense, Net

In July 2016, we entered into an amendment to our secured credit agreement, or the amended credit agreement, which provides for a revolving credit facility of $1.25 billion, of which $1.0 billion was drawn to partially fund our acquisition of Celator Pharmaceuticals Inc. in July 2016, or the Celator Acquisition, and a $750.0 million term loan facility. As of September 30, 2017, $685.8 million principal amount of the term loan remained outstanding. In the third quarter of 2017, we issued $575.0 million principal amount of 2024 Notes, which remained outstanding at September 30, 2017. We used the net proceeds from the issuance of the 2024 Notes to repay outstanding borrowings under the revolving credit facility. Interest expense, net increased by $0.7 million in the three months ended September 30, 2017 compared to the same period in 2016 primarily due to interest expense on the 2024 Notes and higher interest rates on our term loan borrowings, partially offset by a reduction in interest expense following repayment of the revolving credit facility in full during the quarter.

Interest expense, net increased by $13.5 million in the nine months ended September 30, 2017 compared to the same period in 2016, primarily due to the increase in our average debt balance and higher interest rates in the 2017 period. We expect interest expense will be higher in 2017 compared to 2016 primarily due to the increase in our average debt balance.

Foreign Exchange Loss

The foreign currency exchange loss in the three and nine months ended September 30, 2017 primarily related to the translation of euro-denominated net monetary liabilities, primarily intercompany balances, held by subsidiaries with a U.S. dollar functional currency.

Loss on Extinguishment and Modification of Debt

In the three and nine months ended September 30, 2016, we recorded a loss of $0.6 million in connection with our entry into the amended credit agreement in July 2016, which was primarily comprised of new third party fees associated with the modified debt.

Income Tax Provision

Our income tax provision was $1.2 million and $65.9 million in the three and nine months ended September 30, 2017, respectively, compared to $26.4 million and $100.9 million for the same periods in 2016. The effective tax rates were 1.9% and 20.5% in the three and nine months ended September 30, 2017, respectively, compared to 22.7% and 26.5% for the same periods in 2016. The decrease in the effective tax rates for the three and nine months ended September 30, 2017 compared to the same periods in 2016 was primarily due to the release of a valuation allowance held against certain foreign net operating losses and the release of reserves related to unrecognized tax benefits upon the expiration of a statute of limitation. The effective tax rate for the three months ended September 30, 2017 was lower than the Irish statutory rate of 12.5% primarily due to the release of a valuation allowance held against certain foreign net operating losses and the release of reserves related to unrecognized tax benefits upon the expiration of a statute of limitation. The effective tax rate for the nine months ended September 30, 2017 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, unrecognized tax benefits, and various expenses not deductible for tax purposes, partially offset by originating tax credits and deductions available in relation to subsidiary equity.

Equity in Loss of Investees

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

Liquidity and Capital Resources

In the third quarter of 2017, we completed a private placement of the 2024 Notes resulting in net proceeds to us, after debt issuance costs, of $559.5 million. We used the net proceeds from the issuance of the 2024 Notes to repay $500.0 million in outstanding borrowings under our revolving credit facility and to pay related fees and expenses and the remainder of the net proceeds for general corporate purposes.

As of September 30, 2017, we had cash, cash equivalents and investments of $452.6 million, borrowing availability under our revolving credit facility of $1.25 billion and long-term debt principal balance of $1.8 billion. Our long-term debt included $685.8 million aggregate principal amount term loan, $575.0 million principal amount of our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, and $575.0 million principal amount of the 2024 Notes. We generated cash flows from operations of $488.5 million during the nine months ended September 30, 2017, and we expect to continue to generate positive cash flows from operations during 2017.

We believe that our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future. 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 risk factors under the headings *"Xyrem is our largest selling product, and our inability to maintain or increase sales of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects," "The launch of a generic version of Xyrem or other sodium oxybate products that compete with Xyrem would adversely affect sales of Xyrem," "The distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk evaluation and mitigation strategy, and these restrictions and requirements, as well as the potential impact of changes to these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem,"* and *"To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business"* set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q. 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, 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 new share repurchase program pursuant to which we are authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300 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. In the nine months ended September 30, 2017, we spent a total of $56.4 million to purchase 0.4 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $141.73 per share.

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

	Nine Months Ended September 30,	
	2017	2016
Net cash provided by operating activities	$ 488,528	$ 411,696
Net cash used in investing activities	(237,072)	(1,749,296)
Net cash provided by (used in) financing activities	(369,127)	713,032
Effect of exchange rates on cash and cash equivalents	4,323	2,350
Net decrease in cash and cash equivalents	$ (113,348)	$ (622,218)

Net cash provided by operating activities of $488.5 million for the nine months ended September 30, 2017 related to net income of $255.6 million, adjusted for acquired IPR&D expense of $77.0 million and non-cash items of $170.6 million primarily related to intangible asset amortization and share-based compensation expense. This was partially offset by a net cash outflow of $14.7 million related to changes in operating assets and liabilities. Net cash provided by operating activities of $411.7 million for the nine months ended September 30, 2016 related to net income of $280.1 million, adjusted for acquired IPR&D expense of $23.8 million and non-cash items of $149.5 million primarily related to intangible asset amortization and share-based compensation expense. This was partially offset by a net cash outflow of $41.7 million related to changes in operating assets and liabilities.

Net cash used in investing activities for the nine months ended September 30, 2017 primarily related to the net acquisition of investments of $140.0 million, upfront payments for acquired IPR&D of $77.0 million primarily related to a collaboration and option agreement with ImmunoGen and purchases of property and equipment of $20.1 million. Net cash used in investing activities for the nine months ended September 30, 2016 primarily related to the Celator Acquisition for $1.5 billion, a $150.0 million milestone payment to Sigma-Tau Pharmaceuticals, Inc. that was triggered by the FDA approval of Defitelio on March 30, 2016, net acquisition of investments of $64.7 million, upfront and option payments of $23.8 million to acquire IPR&D and purchases of property and equipment of $8.4 million.

Net cash used in financing activities for the nine months ended September 30, 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 $56.4 million, repayment of our term loan principal of $27.1 million and payment of employee withholding taxes of $17.9 million related to share-based awards, partially offset by net proceeds from issuance of debt of $559.5 million and proceeds from employee equity incentive and purchase plans of $22.8 million. Net cash provided by financing activities for the nine months ended September 30, 2016 primarily related to net proceeds from issuance of debt of $994.8 million and proceeds from employee equity incentive and purchase plans of $18.0 million, partially offset by repurchase of ordinary shares under our prior share repurchase program of $259.8 million, payment of employee withholding taxes of $20.6 million related to share-based awards and repayment of our term loan principal of $19.3 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 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, Jazz Pharmaceuticals plc, as guarantor, and certain of our wholly owned subsidiaries, as borrowers, entered into Amendment No. 1 to our 2015 credit agreement. The amended credit agreement provides for a revolving credit facility of $1.25 billion, which replaces the revolving credit facility of $750.0 million provided for under the 2015 credit agreement, and a $750.0 million term loan facility, of which $685.8 million principal amount was outstanding as of September 30, 2017. 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, and we expect to use the proceeds from future loans under the revolving credit facility, if any, for general corporate purposes, including corporate development activities. As of September 30, 2017, we did not have any outstanding borrowings under the revolving credit facility.

Under the amended credit agreement, the term loan matures on July 12, 2021 and the revolving credit facility terminates, and any loans outstanding thereunder become due and payable, on July 12, 2021.

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 1.50% to 2.25% per annum, based upon our secured leverage ratio, or (b) the prime

lending rate, plus an applicable margin ranging from 0.50% to 1.25% 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.

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 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 reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), and (3) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

Principal repayments of the term loan, which are due quarterly, began in December 2016 and are equal to 5.0% per annum of the principal amount outstanding on July 12, 2016 of $721.9 million during the first two years, 7.5% per annum during the third year, 10.0% per annum during the fourth year and 12.5% per annum during the fifth year, with any remaining balance payable on the maturity date.

The amended credit agreement contains financial covenants that require Jazz Pharmaceuticals plc and its restricted subsidiaries to not (a) exceed a maximum secured net leverage ratio or (b) fall below a cash interest coverage ratio. We were, as of September 30, 2017, and are currently, 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 s

emi-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 September 30, 2017 (in thousands):

	Payments Due By Period				
Contractual Obligations (1)	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 years**
Term loan - principal	$ 685,781	$ 36,094	$ 126,328	$ 523,359	$ —
Term loan - interest (2)	76,008	22,352	40,320	13,336	—
Exchangeable Senior Notes - principal	1,150,000	—	—	575,000	575,000
Exchangeable Senior Notes - interest (3)	103,333	19,239	38,813	28,031	17,250
Revolving credit facility - commitment fee (4)	14,375	3,802	7,615	2,958	—
Commitment to equity method investees	28,900	5,900	14,000	9,000	—
Purchase and other obligations (5)	133,547	43,216	31,261	37,977	21,093
Operating and facility lease obligations (6)	243,401	18,410	35,268	38,533	151,190
Total	$ 2,435,345	$ 149,013	$ 293,605	$ 1,228,194	$ 764,533

(1) This table does not include potential future milestone payment 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 2014, we signed a definitive agreement with Aerial under which we acquired worldwide development, manufacturing and commercial rights to JZP-110 (other than in certain jurisdictions in Asia where SK retains rights). Aerial and SK are currently eligible to receive milestone payments up to an aggregate of $270 million based on development, regulatory and sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales of JZP-110. In July 2016, we entered into an agreement with Pfenex that granted us worldwide rights to develop and commercialize multiple early-stage hematology product candidates. The agreement also includes an option for us to negotiate a license for a recombinant pegaspargase product candidate with Pfenex. Under the agreement, Pfenex received upfront, option and development milestone payments totaling $15.8 million and may be eligible to receive additional payments of up to $165 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 $273 million, of which up to $120 million will become due and payable to Perrigo Company plc (formerly Elan Pharmaceuticals, Inc.) in tiered

contingent payments, with the first such payment becoming due if net sales of Prialt of at least $75 million are achieved in a calendar year. The remainder would become due and payable to other third parties upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones, the timing and likelihood of which are not known. We are also obligated under these agreements to pay royalties on net sales of certain products at specified rates, which royalties are dependent on future product sales and are not provided for in the table above as they are not estimable.

(2) Estimated interest for variable rate debt was calculated based on the interest rates in effect as of September 30, 2017. The interest rate for our term loan borrowing was 2.99% as of September 30, 2017. Interest that is fixed, associated with our interest rate swaps, is calculated based on the fixed interest swap rate as of September 30, 2017.

(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 September 30, 2017 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 0.30% and assumed undrawn amounts of $1.25 billion as of September 30, 2017 to estimate commitment fees owed.

(5) Consists primarily of non-cancelable commitments to ImmunoGen, under our collaboration and option agreement, and to third party manufacturers.

(6) Consists primarily of the minimum lease payments for our office buildings and automobile lease payments for our sales force. This includes a lease agreement we entered into in January 2015 to lease office space located in Palo Alto, California, which we began to occupy in October 2017, and a lease agreement we entered into in September 2017 to lease additional office space located in Palo Alto, California in a second building to be constructed by the same landlord, which we expect to occupy by the end of 2019. We are obligated to make lease payments totaling approximately $197 million over the initial term of these leases. Not included in the table above are our estimated costs of approximately $19 million associated with the design, development and construction of tenant improvements under these lease agreements, which estimate does not include a tenant improvement allowance to be provided by the landlord. Operating expenses associated with our leased office buildings are also 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. 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. 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 Estimates

To understand our financial statements, it is important to understand our critical accounting estimates. The preparation of our financial statements in conformity with U.S. generally accepted accounting principles, or U.S. GAAP, requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in determining the amounts to be deducted from gross revenues, in particular estimates of government rebates, which include Medicaid and TRICARE rebates, and estimated product returns. Significant estimates and assumptions are also required to determine whether to capitalize intangible assets, the amortization periods for identifiable intangible assets, the potential impairment of goodwill and other intangible assets, income taxes and share-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable. Although we believe our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2016. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 current plans, objectives, estimates, expectations and intentions 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 risk factors in greater detail under Part II, Item 1A of this Quarterly Report on Form 10-Q. 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 plans, objectives, estimates, expectations and intentions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results and the timing of events 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 undertake no obligation to update or supplement any forward-looking statements publicly, or to update or supplement 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Except as set forth below, during the three and nine months ended September 30, 2017, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2016.

Swap Agreements and Interest Rate Risk. We are exposed to risks associated with changes in interest rates in connection with our term loan borrowings. On July 12, 2016, we entered into the amended credit agreement, which provides for a revolving credit facility of $1.25 billion replacing our prior revolving credit facility of $750.0 million, and a $750.0 million term loan facility, of which $685.8 million principal amount was outstanding as of September 30, 2017. There were no borrowings outstanding under the revolving credit facility as of September 30, 2017. 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 the remainder of 2017 would increase or decrease by $1.0 million, based on the unhedged portion of our outstanding variable rate borrowings.

In the third quarter of 2017, we completed a private placement of $575.0 million aggregate principal amount of the 2024 Notes. The 2024 Notes have a fixed annual interest rate of 1.50% and we, therefore, do not have economic interest rate exposure on the 2024 Notes. However, the fair value of the 2024 Notes is exposed to interest rate risk. Generally, the fair value of the 2024 Notes will increase as interest rates fall and decrease as interest rates rise. The fair value of the 2024 Notes is also affected by volatility in our ordinary share price. As of September 30, 2017, the fair value of the 2024 Notes was estimated to be $565 million.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2017.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer

and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting. During the quarter ended September 30, 2017, there have been 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.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

Xyrem ANDA Matters. On December 10, 2012, we received a notice of Paragraph IV Patent Certification, or Paragraph IV Certification, from Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an abbreviated new drug application, or ANDA, to the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. On January 18, 2013, we filed a lawsuit against Amneal in the U.S. District Court for the District of New Jersey, or the District Court, alleging that our patents covering Xyrem are infringed or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. On November 21, 2013, we received a notice of Paragraph IV Certification from Par Pharmaceutical, Inc., or Par, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 27, 2013, we filed a lawsuit against Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Par's ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents.

In April 2014, Amneal asked the District Court to consolidate its case with the Par case, stating that both cases would proceed on the schedule for the Par case. The District Court granted this request in May 2014. The order consolidating the cases extended Amneal's 30-month stay period to coincide with the date of Par's 30-month stay period. The stay expired on May 20, 2016.

Additional patents covering Xyrem have been issued since April 2014 and have been listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, for Xyrem. Amneal and Par have given us additional notices of Paragraph IV Certifications regarding such patents, and we have filed additional lawsuits against Amneal and Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Amneal's and Par's ANDAs and seeking a permanent injunction to prevent Amneal and Par from introducing a generic version of Xyrem that would infringe our patents. In March 2016, Par moved to dismiss claims involving our patents covering a part of the Xyrem label that instructs prescribers on adjusting the dose of Xyrem when it is being co-administered with divalproex sodium (also known as valproate or valproic acid), or our method of administration patents relating to a drug-drug interaction, or DDI patents. In August 2016, we and Par stipulated to dismiss claims relating to our patents covering the formulation of Xyrem on the grounds that Par had notified FDA that it had converted its Paragraph IV Certifications to Paragraph III Certifications. In September 2017, we and Amneal stipulated to dismiss claims relating to certain of our patents covering the formulation of Xyrem on the grounds that Amneal had notified FDA that it had converted its Paragraph IV Certifications as to these patents to Paragraph III Certifications.

On October 30, 2014, we received a notice of Paragraph IV Certification from Teva Pharmaceutical Industries Ltd., formerly known as Watson Laboratories, Inc., or Teva, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 11, 2014, we filed a lawsuit against Teva in the District Court alleging that our patents covering Xyrem are or will be infringed by Teva's ANDA and seeking a permanent injunction to prevent Teva from introducing a generic version of Xyrem that would infringe these patents. In March 2015, Teva moved to dismiss the portion of the case based on our Orange Book-listed REMS patents on the grounds that these patents do not cover patentable subject matter. In November 2015, the District Court administratively terminated this motion to dismiss (without prejudice) pending the outcome of inter partes review, or IPR, proceedings before the Patent Trial and Appeal Board, or PTAB, relating to the patents that were the subject of Teva's motion. Since March 2015, we have received an additional notice of Paragraph IV Certification from Teva regarding newly issued patents for Xyrem listed in the Orange Book, and we have filed an additional lawsuit against Teva in the District Court alleging that our patents covering Xyrem are or will be infringed by Teva's ANDA and seeking a permanent injunction to prevent Teva from introducing a generic version of Xyrem that would infringe these patents.

In April 2015, the District Court issued an order that consolidated all then-pending lawsuits against Amneal, Par and Teva into one case.

On July 23, 2015, we received a notice of Paragraph IV Certification from Lupin Inc., or Lupin, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On September 2, 2015, we filed a lawsuit in the District Court alleging that our patents covering Xyrem are or will be infringed by Lupin's ANDA and seeking a permanent injunction to prevent Lupin from introducing a generic version of Xyrem that would infringe our patents.

In January, April and June 2016, the District Court issued orders consolidating all of the cases then pending against Amneal, Par, Teva and Lupin into a single case for all purposes. Although no trial date has been set, discovery is scheduled to conclude in the second quarter of 2018, and the trial in this consolidated case could occur as early as mid-2018.

Additional patents covering Xyrem have been issued since June 2016 and have been listed in the Orange Book for Xyrem. We have received additional Paragraph IV Certification notices from Amneal regarding such patents and have filed new lawsuits in the District Court, alleging that our additional patents covering Xyrem are or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents.

On June 14, 2017, we received a notice of Paragraph IV Certification from Ascent Pharmaceuticals, Inc., or Ascent, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On July 27, 2017, we filed lawsuits against Ascent in the District Court as well as in the U.S. District Court for the Eastern District of New York, where Ascent is incorporated, alleging that our patents covering Xyrem are infringed or will be infringed by Ascent's ANDA and seeking a permanent injunction to prevent Ascent from introducing a generic version of Xyrem that would infringe our patents. On August 22, 2017, we settled all lawsuits with Ascent, granting Ascent a license to manufacture, market and sell its generic version of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events.

We had previously settled lawsuits with three other ANDA filers, and the specific terms of the settlement agreements are confidential. The settlements do not resolve the consolidated case against Amneal, Par, Teva and Lupin, which remains pending. We cannot predict the specific timing or outcome of events with respect to the remaining defendants or the impact of developments involving any specific parties or patents on other ongoing proceedings with any ANDA filer.

Xyrem Post-Grant Patent Review Matters. In January 2015, certain of the ANDA filers filed petitions for IPR with respect to the validity of the six REMS patents. In July 2016, the PTAB issued final decisions that the claims of these six patents are unpatentable; as a result, if the United States Court of Appeals for the Federal Circuit upholds those decisions on appeal, these claims will be canceled. We have filed notices of appeal with respect to these IPR decisions to the United States Court of Appeals for the Federal Circuit. In September 2015, certain of the ANDA filers filed a petition for IPR with respect to the validity of an additional REMS patent. In March 2016, the PTAB partially instituted an IPR on three claims of a seventh REMS patent, declining to review 25 of 28 claims. In March 2017, the PTAB issued a final decision that the three claims that were reviewed by the PTAB are unpatentable. We have filed a notice of appeal of that decision on May 18, 2017, and the Court of Appeals for the Federal Circuit has consolidated the appeal of the March 2017 decision with the pending appeals of the July 2016 decisions.

We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any pending IPR or other proceeding, the outcome of any appeal of the July 2016 and March 2017 IPR decisions with respect to the REMS patents or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

Shareholder Litigation Matters Relating to Celator Acquisition. On June 21, 2016, a putative class-action lawsuit challenging our acquisition of Celator Pharmaceuticals, Inc., or Celator, captioned *Dunbar v. Celator Pharmaceuticals, Inc.*, or the Dunbar action, was filed in the Superior Court of New Jersey. We refer to our acquisition of Celator in this report as the Celator Acquisition. The complaint was filed against Celator, each member of the Celator board of directors, Jazz Pharmaceuticals plc and our wholly owned subsidiary Plex Merger Sub, Inc., or Plex. The complaint generally alleges that the Celator directors breached their fiduciary duties in connection with the Celator Acquisition, and that Jazz Pharmaceuticals plc and Plex aided and abetted these alleged breaches of fiduciary duty. The complaint also generally asserts that the Celator directors breached their fiduciary duties to Celator's public stockholders by, among other things, (i) agreeing to sell Celator to us at an inadequate price, (ii) implementing an unfair process, (iii) agreeing to certain provisions of the merger agreement for the Celator Acquisition that allegedly favored us and deterred alternative bids, and (iv) failing to disclose purportedly material information in Celator's Schedule 14D-9 filing with the U.S. Securities and Exchange Commission, or SEC. The plaintiff sought, among other things, an injunction against the consummation of the Celator Acquisition and an award of costs and expenses, including a reasonable allowance for attorneys' and experts' fees.

Between June 27, 2016 and June 29, 2016, two putative class-action lawsuits challenging the Celator Acquisition, captioned *Palmisciano v. Celator Pharmaceuticals, Inc.*, or the Palmisciano action, and *Barreto v. Celator Pharmaceuticals, Inc.*, or the Barreto action, were filed in the District Court. The complaints were filed against Celator and each member of the Celator board of directors. The complaints assert causes of action under sections 14 and 20 of the Securities Exchange Act of 1934, as amended, predicated on Celator's and the Celator directors' alleged failure to disclose purportedly material information in Celator's Schedule 14D-9 filing with the SEC. The plaintiffs sought, among other things, an injunction against the consummation of the Celator Acquisition and an award of costs and expenses, including a reasonable allowance for attorneys' and experts' fees. Neither Jazz Pharmaceuticals plc nor Plex were named defendants in these actions.

On July 6, 2016, the defendants to the Dunbar action, the Palmisciano action and the Barreto action entered into a memorandum of understanding, or MOU, regarding settlement of these actions with the plaintiffs. The MOU outlines the terms of the parties' agreement in principle to settle and release all claims which were or could have been asserted in these actions. In consideration for such settlement and release, the parties to these actions agreed, among other things, that Celator would amend its Schedule 14D-9 to include certain supplemental disclosures. The Schedule 14D-9 was amended by Celator on

July 6, 2016, and the Celator Acquisition was completed on July 12, 2016. In June 2017, the parties to the MOU agreed to terminate the MOU, and the plaintiffs agreed to voluntarily dismiss the remaining actions. Thereafter, the parties negotiated and ultimately agreed, in October 2017, on a mootness fee paid to plaintiffs' counsel. The Dunbar, Palmisciano and Barreto actions have each been dismissed with prejudice.

Government Matter. In May and October 2016 and in February 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients and documents concerning the provision of financial assistance to Medicare patients taking drugs sold by us. We are cooperating with this investigation. We are unable to predict the outcome of this investigation. For more information, see Note 10, Commitments and Contingencies, to our condensed consolidated financial statements included in Part I of this Quarterly Report on Form 10-Q.

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

Item 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 Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and accompanying notes.

Risks Related to Xyrem and the Significant Impact of Xyrem Sales

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

Xyrem is our largest selling product, and our financial results are significantly influenced by sales of Xyrem, which accounted for 74% and 75% of our net product sales for the three and nine months ended September 30, 2017, respectively, and 75% of our net product sales for the year ended December 31, 2016. Our future plans assume that sales of Xyrem will increase, although our plans assume a slower rate of increase than in recent years. While Xyrem product sales grew from 2015 to 2016, we cannot assure you that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in July 2017, and we cannot assure you that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes.

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

- the potential U.S. introduction of a generic version of Xyrem before the entry dates specified in our settlements with certain companies that had filed abbreviated new drug application, or ANDAs, with the U.S. Food and Drug Administration, or FDA, seeking approval to market a generic version of Xyrem or on terms that are different from those contemplated by the settlements, as further described below;
- the potential U.S. introduction of an alternative product to Xyrem for treating cataplexy and/or excessive daytime sleepiness, or EDS, in narcolepsy;
- changes to, increases in or uncertainties around regulatory restrictions, including, among other things, changes to our Xyrem risk evaluation and mitigation strategy, or REMS, particularly in light of the FDA's waiver of the single shared system REMS requirement for sodium oxybate and approval of a separate generic sodium oxybate REMS, as further described below;
- any increase in pricing pressure from, or restrictions on reimbursement imposed by, third party payors;
- changes in healthcare laws and policy, including changes in requirements for patient assistance programs, rebates, reimbursement and coverage by federal healthcare programs, and changes resulting from increased scrutiny on pharmaceutical pricing and REMS programs by government entities;
- operational disruptions at the Xyrem central pharmacy or any failure to comply with our REMS obligations to the satisfaction of the FDA;
- any supply or manufacturing problems, including any problems with our sole source provider of the active pharmaceutical ingredient, or API, for Xyrem;
- continued acceptance of Xyrem by physicians and patients, even in the face of negative publicity that surfaces from time to time;

- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem; and
- our U.S.-based sodium oxybate and Xyrem suppliers' ability to obtain sufficient quotas from the U.S. Drug Enforcement Administration, or DEA, to satisfy our needs for Xyrem.

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

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

The launch of a generic version of Xyrem or other sodium oxybate products that compete with Xyrem would adversely affect sales of Xyrem.

Although Xyrem is protected by patents covering its manufacture, formulation, distribution system and method of use, eight companies have filed ANDAs with the FDA seeking approval to market a generic version of Xyrem. We filed patent lawsuits against each of the ANDA filers in the U.S. District Court for the District of New Jersey, or the District Court. On April 5, 2017, we settled all lawsuits against the first ANDA filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC), which acquired Roxane Laboratories, Inc., or West-Ward, granting West-Ward the right to sell an authorized generic version of Xyrem, or the West-Ward AG Product, commencing on January 1, 2023, or earlier under certain circumstances, and granting West-Ward a license to launch its own generic sodium oxybate product as early as six months thereafter. In accordance with legal requirements, we and West-Ward submitted our settlement agreement to the U.S. Federal Trade Commission, or FTC, and the U.S. Department of Justice, or DOJ, for review. We also settled lawsuits with three of the other ANDA filers, granting those filers a license to manufacture, market and sell their generic versions of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events. Lawsuits with the remaining non-settling ANDA filers have been consolidated as one case and remain pending in the District Court. Although no trial date has been set, discovery is scheduled to conclude in the second quarter of 2018, and the trial in this consolidated case could occur as early as mid-2018. We cannot predict the timing or outcome of the ANDA litigation proceedings against the remaining non-settling ANDA filers. For a description of these legal proceedings, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q.

Certain ANDA filers had also filed petitions for inter partes review, or IPR, by the Patent Trial and Appeal Board, or the PTAB, of the U.S. Patent and Trademark Office, or USPTO, with respect to the validity of certain distribution, method of use and formulation patents covering Xyrem. The PTAB instituted IPR trials with respect to patents and patent claims that are the subject of certain of these petitions. In July 2016, the PTAB issued final decisions that the claims of six patents listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, as covering the Xyrem REMS are unpatentable. We filed a notice of appeal of these decisions on February 22, 2017. If the United States Court of Appeals for the Federal Circuit upholds those decisions on appeal, those claims will be canceled, and we will not be able to enforce those patents. In March 2016, the PTAB partially instituted an IPR on three claims of a seventh REMS patent, declining to review 25 of 28 claims, and issued a final decision in March 2017 that the three claims they reviewed are also unpatentable. We filed a notice of appeal of that decision on May 18, 2017, and the Court of Appeals for the Federal Circuit has consolidated the appeal of the March 2017 decision with the pending appeals of the July 2016 decisions. For a description of these legal proceedings, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any proceeding, including any appeal, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

On January 17, 2017, the FDA announced approval of West-Ward's ANDA for a generic version of Xyrem. The FDA's letter approving West-Ward's ANDA notes that, as the first ANDA applicant, West-Ward is eligible for 180 days of generic drug exclusivity for its generic product. West-Ward's ANDA approval also includes a waiver that permits West-Ward to use a separate REMS program from the Xyrem REMS, or the generic sodium oxybate REMS, on the condition that the generic sodium oxybate REMS be open to all future sponsors of ANDAs or new drug applications, or NDAs, for sodium oxybate products. On January 19, 2017, the FDA tentatively approved two additional ANDAs for generic versions of Xyrem, one for Amneal Pharmaceuticals, or Amneal, and one for Ohm Laboratories Inc., formerly known as Ranbaxy, Inc., or Ohm, and we believe that it is likely that the FDA will approve or tentatively approve additional ANDAs.

The actual timing of any commercial launch of an authorized generic or generic version of Xyrem is uncertain. In particular, in our settlement with West-Ward, we have agreed that West-Ward's AG Product launch date (and thus, potentially, its generic product launch date) could accelerate to earlier than January 1, 2023 under certain circumstances, including events related to the market entry of other generic versions of Xyrem, a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, or a substantial reduction in Xyrem net sales over specified periods of time.

To the extent that one or more of the non-settling ANDA filers continues to litigate our Xyrem patents and obtains a final judicial decision prior to January 1, 2023 that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, West-Ward's entry date would be accelerated to approximately the date of that final decision. In addition, one or more of the non-settling ANDA filers could potentially enter the market at such time to the extent that such filer(s) obtains or maintains FDA approval for its generic product and is able to distribute its product through an approved sodium oxybate REMS.

It is also possible that one or more of the non-settling ANDA filers that obtains or maintains FDA approval for its generic product and is able to distribute its product through an approved sodium oxybate REMS could launch its generic product in the absence of a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable. Circumstances that could result in such a launch include a judicial determination that the introduction of a generic product does not infringe our patents; a judicial determination not to grant an injunction that prevents any non-settling ANDA filer from marketing its generic product; or a decision by a non-settling ANDA filer, before applicable ongoing patent litigation is concluded, to launch a generic product at risk of being held liable for damages for patent infringement. It is also possible that we could enter into settlement agreements with one or more additional ANDA filers that would permit such filer to enter the market on or prior to the entry date(s) agreed with West-Ward. In the event of any such market entry by another ANDA filer, West-Ward's entry date would be accelerated to a date on or prior to the date of such entry, except in limited circumstances related to an "at risk" launch by a non-settling ANDA filer.

A substantial reduction in Xyrem net sales at the level required to accelerate West-Ward's entry date under our settlement could occur under various circumstances, including if we introduce, or a third party introduces, a product to treat EDS or cataplexy in narcolepsy that substantially erodes Xyrem net sales prior to January 1, 2023. For example, in addition to any products we might develop, other companies could also develop products that are similar, but not identical, to Xyrem, such as an alternative formulation or an alternative formulation combined with a different delivery technology, and seek approval in the U.S. through an NDA approval pathway under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, by referencing Xyrem and relying, to some degree, on the FDA's approval of Xyrem and related determinations of safety and efficacy. In particular, Avadel Pharmaceuticals plc, or Avadel, a company that is using its proprietary technology for delivery of a sodium oxybate formulation to eliminate second nighttime dosing for narcolepsy patients, has stated that it is conducting a Phase 3 pivotal trial pursuant to an FDA-approved special protocol assessment, and has indicated that it intends to seek approval of its product candidate using a Section 505(b)(2) NDA approval pathway, which allows companies to seek approval of a product that is similar, but not identical, to a previously-approved brand-name product. If Avadel successfully develops, obtains FDA approval of and launches this product candidate, we expect that the launch of the approved product would compete with Xyrem and could result in a substantial reduction of Xyrem net sales, which could have the additional negative effect of potentially triggering acceleration of market entry of the West-Ward AG Product or West-Ward's own generic sodium oxybate product.

After any introduction of a generic product, a significant percentage of the prescriptions written for Xyrem may be filled with the generic product, resulting in a loss in sales of branded Xyrem, although we would continue to receive revenue based on sales of any authorized generic product. Generic competition often also results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. West-Ward will establish the price of the West-Ward AG Product or West-Ward's own generic sodium oxybate product, and the price set by West-Ward may place downward pricing pressure on the price of Xyrem. In addition, 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 where a generic version is available. In addition, the FDA's approval of the generic sodium oxybate REMS means that such generic products could be distributed through multiple pharmacies. Such changes in the distribution of sodium oxybate may lead to negative experiences for patients, prescribers and the public that could impact acceptance of Xyrem as a treatment for EDS and cataplexy in narcolepsy.

We expect that the launch of any generic version of Xyrem, including the West-Ward AG Product or other authorized generic version of Xyrem, or the approval and launch of other products that compete with Xyrem, could have a material adverse effect on our sales of Xyrem and on our business, financial condition, results of operations and growth prospects. For further discussion regarding the risks associated with the West-Ward settlement agreement, the tentative approval of the Amneal and Ohm ANDAs, potential approval or tentative approval of additional ANDAs, the potential launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate or other products that compete with Xyrem, as well as other risks and challenges we face with respect to Xyrem, see the other risk factors under the heading "Risks Related to Xyrem and the Significant Impact of Xyrem Sales" and the risk factors under the headings "*We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have*" and "Risks Related to Our Intellectual Property" in this Part II, Item 1A.

The distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk evaluation and mitigation strategy, and these restrictions and requirements, as well as the potential impact of changes to these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management and controlled distribution system, or Xyrem Risk Management Program, to help ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. The Xyrem Risk Management Program included elements such as patient and physician education, a database of information to track and report certain information, and the use of a single central pharmacy to distribute Xyrem. The Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS, was deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act, or FDAAA. The FDAAA, which amended the FDCA, required that deemed REMS and related documents be updated to comply with the current requirements for REMS documents. In February 2015, the FDA notified Jazz Pharmaceuticals, Inc., our wholly owned subsidiary, of the FDA's approval of the current Xyrem REMS, which includes provisions requiring distribution through a single pharmacy.

The 2015 Xyrem REMS approval letter included statements from the FDA that (i) the approval action should not be construed or understood as agreement with what the FDA stated was our position that dispensing through a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh its risks, and that the FDA has continuing concerns that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system, and (ii) as with all REMS, the FDA intends to 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 in connection with the approval of the generic sodium oxybate REMS, the anticipated distribution of the West-Ward AG Product, or otherwise, or the potential timing, terms or propriety thereof. Any such modifications or additional requirements could make it more difficult or expensive for us to distribute Xyrem, make distribution easier for sodium oxybate competitors, impair the safety profile of Xyrem and/or negatively affect sales of Xyrem. Moreover, a sodium oxybate distribution system that is less restrictive than the Xyrem REMS, such as the generic sodium oxybate REMS approved by the FDA in January 2017, may increase the risks associated with sodium oxybate distribution, as patients, consumers and others may not differentiate generic sodium oxybate from Xyrem, or differentiate between the different REMS programs. Any negative outcomes, including but not limited to risks to the public, caused by or otherwise related to a separate generic sodium oxybate REMS, could have a significant negative impact in terms of product liability, goodwill, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, any of which could have a material adverse effect on our Xyrem revenues.

In August 2015, we implemented the current Xyrem REMS, and we have submitted and expect to continue to submit ongoing assessments as set forth in the FDA's Xyrem REMS approval letter. However, we cannot guarantee that our implementation and ongoing assessments will be satisfactory to the FDA or that the Xyrem REMS will satisfy the FDA's expectations in its evaluation of the Xyrem REMS on an ongoing basis. Any failure to comply with the REMS obligations 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 take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

While we have an exclusive agreement with Express Scripts Specialty Distribution Services, Inc., or Express Scripts, the central pharmacy for Xyrem, through June 2019, if the central pharmacy does not fulfill its contractual obligations to us, fails to meet the requirements of the Xyrem REMS applicable to the central pharmacy, provides timely notice that it wants to terminate our agreement, refuses or fails to adequately serve patients, or fails to promptly and adequately address operational challenges, whether expected or unexpected, 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 and other insurers who pay for Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under 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.

Section 505-1(i)(1) of the FDCA generally provides that (i) an ANDA that references a drug subject to a REMS with elements to assure safe use, or ETASU, is required to have a REMS with the same elements as the reference listed drug, or RLD, and (ii) the ANDA drug and the RLD shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and approve an ANDA with a separate REMS with differing but comparable aspects of ETASU if the FDA either determines that the burden of creating a single shared system outweighs its benefit, or if the ANDA applicant certifies that it has been unable to obtain a license to any aspects of the REMS for the RLD that are covered by a patent or a trade secret. The FDCA provides that the FDA may seek to negotiate a license between the ANDA applicant

and the sponsor of the RLD before granting a waiver of the single shared system requirement. The FDCA further states that a REMS shall not be used by the NDA holder to block or delay generic drugs or drugs covered by an application under Section 505(b)(2) from entering the market.

In January 2017, the FDA announced approval of the West-Ward ANDA and waived the shared REMS requirement. The FDA's waiver of the shared REMS requirement permits West-Ward to use a separate REMS program from the Xyrem REMS, or the generic sodium oxybate REMS, on the condition that the generic sodium oxybate REMS be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. In connection with the waiver, FDA issued a statement that it considers the generic sodium oxybate REMS to have the same ETASU as the Xyrem REMS and operationalizes those elements in a comparable manner to achieve the same level of safety as the Xyrem REMS. We were not involved in development of the generic sodium oxybate REMS and were not consulted regarding any features of this REMS. Our settlement agreement with West-Ward does not directly impact the FDA's waiver of the single shared system REMS requirement or West-Ward's or any other ANDA filer's ability to develop and implement the generic sodium oxybate REMS for its generic sodium oxybate product. 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 Xyrem or the consequences of distribution of sodium oxybate through the generic sodium oxybate REMS approved by the FDA. We expect that the launch of any generic version of Xyrem, including the West-Ward AG Product or other authorized generic version of Xyrem, or the approval and launch of other products that compete with Xyrem, could have a material adverse effect on our sales of Xyrem and on our business, financial condition, results of operations and growth prospects.

We may face pressure to 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.

We cannot predict the outcome or impact on our business of any future action that we may take with respect to the approval of the generic sodium oxybate REMS, or licensing or sharing intellectual property pertinent to the Xyrem REMS or elements of the Xyrem REMS.

In September 2016, Jazz Pharmaceuticals, Inc., our wholly owned subsidiary, submitted a Citizen Petition to the FDA requesting that, for safety reasons, the FDA refuse to approve any sodium oxybate ANDA with a proposed package insert or REMS that omits the portions of the Xyrem package insert and the Xyrem REMS that instruct prescribers on adjusting the dose of the product when it is co-administered with divalproex sodium (also known as valproate or valproic acid). On January 17, 2017, the FDA granted the Citizen Petition with respect to the Xyrem package insert. The FDA concluded that it will not approve any sodium oxybate ANDA referencing Xyrem that does not include in its package insert the portions of the currently approved Xyrem package insert related to the drug-drug interaction with divalproex sodium. The FDA stated that it did not need to reach the question of whether the drug-drug interaction information could have been excluded from the generic sodium oxybate REMS materials because it was approving a REMS in connection with a sodium oxybate ANDA including that information. Our Xyrem patents include three method of administration patents relating to a drug-drug interaction, or DDI patents, covering these instructions on the Xyrem package insert and Xyrem REMS. We cannot predict whether or when one or more of the ANDA filers may pursue a challenge to the FDA's response to the Citizen Petition or whether any such challenges would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of any of our patents or will otherwise obtain a judicial determination that the generic sodium oxybate package insert or the generic sodium oxybate REMS will infringe any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents any non-settling 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.

For further discussion regarding these matters, see the risk factors under the headings "*The launch of a generic version of Xyrem or other sodium oxybate products that compete with Xyrem would adversely affect sales of Xyrem*" and "Risks Related to Our Intellectual Property" in this Part II, Item 1A.

The FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular to whether a REMS may be deliberately being used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. The FDA has recently stated that it will seek to coordinate with the FTC in identifying and publicizing practices the FTC finds to be anticompetitive and has further stated that the FDA has concerns related to the role of REMS programs in delaying approval of generic products. It is possible that the FTC, the FDA, other governmental authorities or other third parties could claim or determine that we are using the Xyrem REMS in an anticompetitive manner (including in light of the FDA's statement in the Xyrem REMS approval letter that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the FDCA) or have engaged in other anticompetitive practices. The FDCA 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. Several of the ANDA applicants have asserted that our REMS patents should not have been listed in the Orange Book and that the Xyrem REMS is blocking competition. We cannot predict the outcome of these claims in the ongoing litigation or the impact of any similar claims that may be made in the future.

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 or taking or requiring us to take other actions that could have an adverse effect on Xyrem's commercial success. Our Xyrem REMS includes unique features that provide more extensive information about adverse events, including deaths, than is generally available for other products that are not subject to similar REMS requirements.

The FDA has required that Xyrem's labeling include a boxed warning regarding the risk of central nervous system depression and misuse and abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product cannot be advertised through reminder ads, or ads that mention the pharmaceutical brand name but not the indication or medical condition it treats. We cannot predict whether the FDA will require additional warnings, including boxed warnings, to be included on Xyrem's labeling. Warnings in the Xyrem labeling and any limitations on our ability to advertise and promote Xyrem may have affected, and could in the future negatively affect, Xyrem sales and therefore our business, financial condition, results of operations and growth prospects.

Any failure to demonstrate our substantial compliance with applicable regulatory requirements to the satisfaction of the FDA or any other 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. For more information, see the risk factor under the heading "*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*" in this Part II, Item 1A.

Risks Related to Our Business

While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products and, in the case of our product candidates, our ability to obtain regulatory approval in the U.S. and Europe and, if approved, to successfully launch and commercialize those product candidates. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to Xyrem, we are commercializing a portfolio of products, including our other lead marketed products, Erwinaze, Defitelio and Vyxeos, and we are making significant investments in other product candidates that are currently not approved as marketed products in any jurisdiction.

Erwinaze

Erwinaze (called Erwinase in markets outside the U.S.), a biologic product, is used in conjunction with chemotherapy to treat patients with acute lymphoblastic leukemia, or ALL, with hypersensitivity to *E. coli*-derived asparaginase. Erwinaze was approved by the FDA under a biologics license application, or BLA, and was launched in the U.S. in November 2011. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere. Erwinaze is licensed from and manufactured by a single source, Porton Biopharma Limited, or PBL, which is wholly owned by the U.K. Secretary of State for Health. Our agreement with PBL, including our license, expires in December 2020, subject to five-year extensions unless terminated by either party in writing by December 2018. We cannot predict whether the term of the agreement will be extended or, if extended, the terms of any such extension.

Erwinaze represents an important part of our strategy to grow sales of our existing products. However, our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of challenges, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that population and our need to apply for and receive marketing authorizations, through the European Union's, or EU's, mutual recognition procedure or otherwise in certain additional countries if we decide to launch promotional efforts in those countries. Another significant challenge to our ability to maintain current sales levels and to increase sales is our extremely limited inventory of Erwinaze, past and continuing supply disruptions and our need to minimize or avoid additional supply disruptions due to capacity constraints, production delays, quality or regulatory challenges and other manufacturing difficulties. See the discussion regarding Erwinaze supply issues in the risk factor under the heading "*The loss of our single source suppliers, delays or problems in the supply of our products for commercial sale or our product candidates for use in our clinical trials, or our or our suppliers' failure to comply with manufacturing regulations, could materially and adversely affect our business, financial condition, results of operations and growth prospects*" in this Part II, Item 1A.

We also face numerous other risks that may impact Erwinaze sales, including regulatory risks, the development of new asparaginase treatments or treatment protocols that could reduce the rate of hypersensitivity in patients with ALL, the development of new treatment protocols for ALL that may not include asparaginase-containing regimens, difficulties with obtaining and maintaining favorable pricing and reimbursement arrangements, and potential competition from future biosimilar

products. In addition, if we fail to comply with our obligations under our agreement with the licensor and supplier of Erwinaze or lose rights to Erwinaze, including if our agreement terminates at the end of its current term in December 2020, or if we otherwise fail to maintain or grow sales of Erwinaze, our growth prospects could be negatively affected.

Defitelio

We made a significant investment in Defitelio in 2014, adding the product to our portfolio as a result of our acquisition of Gentium S.r.l, or Gentium, which we refer to as the Gentium Acquisition, and then securing worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. We began to commercialize Defitelio in certain European countries in 2014. On March 30, 2016, the FDA approved our NDA for Defitelio 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. We launched Defitelio in the U.S. shortly after FDA approval, and our U.S. commercial launch is still at an early stage.

Our ability to realize the anticipated benefits from this investment is subject to risks and uncertainties, including:

- the continued acceptance of Defitelio in the U.S. by hospital pharmacy and therapeutics committees and the continued availability of adequate coverage and reimbursement by government programs and third party payors;
- the limited experience of U.S. physicians in diagnosing and treating VOD, particularly in adults, and the possibility that physicians may not initiate or may delay initiation of treatment while waiting for VOD symptoms to improve, or terminate treatment before the end of the recommended dosing schedule;
- our ability to successfully maintain or grow sales of Defitelio in Europe and other non-U.S. countries;
- delays or problems in the supply or manufacture of the product;
- the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in HSCT treatment protocols reduce the incidence of VOD diagnosis);
- our ability to meet the post-marketing commitments and requirements imposed by the FDA in connection with its approval of our NDA for Defitelio; and
- our ability to obtain marketing approval in other countries and to develop the product for additional indications.

The process of maintaining pricing and reimbursement approvals is complex and varies from country to country. Many European countries periodically review their reimbursement classes, which could have an adverse impact on the reimbursement status of Defitelio. We cannot predict the outcome of any periodic reviews required to maintain pricing and reimbursement approvals across Europe. In addition, orphan products that have a significant impact on patient survival, such as Defitelio, may be budgeted on a local rather than national level. The balance of all of these factors will determine our ability to maintain favorable pricing and reimbursement approvals in Europe. Furthermore, after initial pricing 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 countries. If any of these events occurs, our anticipated revenue from Defitelio in the EU would be negatively affected. If we are unable to maintain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our anticipated revenue from and growth prospects for Defitelio in the EU could be negatively affected. In addition, our ability to commercialize Defitelio successfully in the U.S. will depend on, among other things, the continued availability of adequate coverage or reimbursement by U.S. government programs and third party payors.

The European Commission, or EC, granted marketing authorization to Defitelio 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. A marketing authorization granted under exceptional circumstances is subject to approval conditions and an annual reassessment of the risk-benefit balance by European Medicines Agency, or EMA. As a result, if we fail to meet the approval condition for Defitelio established by the EC, which requires that we set up a patient registry to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use, or if it is determined that the balance of risks and benefits of using Defitelio changes materially, the EMA could vary, suspend or withdraw the marketing authorization for Defitelio. In addition, the FDA imposed several post-marketing commitments and requirements in connection with its approval of our NDA for Defitelio in March 2016, 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. We may be unable to comply with these or other post-marketing obligations imposed as part of the marketing approvals for Defitelio. If we fail to meet any of these post-marketing obligations, our sales of and revenues from Defitelio could be materially adversely affected, and our potential future maintenance and growth of the market for this product may be limited.

The size of the population of VOD patients who are indicated for treatment with Defitelio is limited, and changes in HSCT treatment protocols could reduce the incidence of VOD diagnosis. Changes in treatment protocols that reduce the incidence of VOD diagnosis could adversely affect our anticipated revenues from Defitelio and our business, financial condition, results of operations and growth prospects.

We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in additional indications. We cannot know when, if ever, defibrotide will be approved in any other country or under what circumstances, and what, if any, additional clinical or other development activities will be required in order to potentially obtain such regulatory approval and the cost associated with such required activities, if any. If we fail to obtain approval for defibrotide in other countries or for new indications, or if any future approvals we receive are for narrower indications than we expect, our anticipated revenue from defibrotide and our growth prospects would be negatively affected.

Due to the limited amount of historical sales data from commercialization of Defitelio, our Defitelio sales will be difficult to predict from period to period. As a result, Defitelio sales results or trends in any period are not necessarily indicative of future performance. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from Defitelio would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we fail to maintain or increase prescriptions and revenue from sales of Xyrem, Erwinaze and Defitelio, our business, financial condition, results of operations and growth prospects could be materially adversely affected. We may choose to increase the price of our products, and price adjustments may negatively affect our sales volumes. Also, sales of each of our products may fluctuate significantly from quarter to quarter, depending on the number of patients receiving treatment, the availability of supply to meet the demand for the product, the dosing requirements of treated patients and other factors. The market price of our ordinary shares may decline if sales of our products do not continue or grow at the rates anticipated by financial analysts or investors.

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

Vyxeos

We made a significant investment in Vyxeos through the acquisition of Celator Pharmaceuticals, Inc., or Celator, which we refer to as the Celator Acquisition. Vyxeos is the first injectable fixed ratio, drug delivery combination oncology product based on the CombiPlex technology platform approved by the FDA and that we expect to be considered for approval by the EMA. On August 3, 2017, the FDA approved our NDA for Vyxeos for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or AML, or AML with myelodysplasia-related changes. We launched and began shipping Vyxeos in the U.S. in August 2017, and our U.S. commercial launch is still at an early stage.

We submitted a marketing authorization application, or MAA, for Vyxeos in Europe in the fourth quarter of 2017. We cannot predict whether we will be able to obtain approval in Europe in a timely manner, if at all.

Our ability to realize the anticipated benefits from our investment in Vyxeos is subject to a number of additional 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;
- delays or problems in the supply or manufacture of the product, including the ability of the third parties upon which we rely to manufacture Vyxeos and its APIs to manufacture sufficient quantities in accordance with applicable specifications;
- the need to establish pricing and reimbursement support for Vyxeos in the U.S. and in other countries;
- the acceptance of Vyxeos in the U.S. and other countries by hospital pharmacy and therapeutics committees and the availability of adequate coverage and reimbursement by government programs and third party payors;
- the approval and use of new and novel compounds in AML that are only approved for use in combination with other agents and that have not been tested in combination with Vyxeos; and
- the limited size of the population of high-risk AML patients who may potentially be indicated for treatment with Vyxeos, particularly given the ongoing clinical trials by other companies with the same patient population.

Due to the lack of historical sales data from commercialization of Vyxeos, our Vyxeos sales will be difficult to predict from period to period. As a result, Vyxeos sales results or trends in any period may not necessarily be indicative of future performance. If sales of Vyxeos do not reach the levels we expect, or we are unable to obtain regulatory approval for Vyxeos in Europe in a timely manner, or at all, 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.

In addition, the FDA imposed several post-marketing commitments and requirements in connection with its approval of our NDA for 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 the event that we are unable to comply with these or other post-marketing obligations imposed as part of the marketing approval for Vyxeos, our sales of and revenues from Vyxeos could be materially adversely affected, and our potential future maintenance and growth of the market for this product may be limited.

Product Candidates

In furtherance of our growth strategy, we have made significant investments in a number of product candidates. We recently announced positive efficacy results from our two Phase 3 clinical trials of JZP-110, a late-stage investigational compound being developed for potential treatment of excessive sleepiness, or ES, in patients with obstructive sleep apnea, or OSA, and from our Phase 3 clinical trial of JZP-110 in patients with narcolepsy. We are planning to submit an NDA to the FDA in the fourth quarter of 2017 to seek approval for JZP-110 in the treatment of ES associated with OSA and ES associated with narcolepsy. We cannot predict whether we will be able to submit our NDA in a timely manner. If we are able to submit our NDA, we cannot predict whether our NDA will be approved by the FDA in a timely manner, if at all. It is possible that the FDA may ask an advisory committee, which provides the FDA with independent expert advice and recommendations, to review our clinical trial data. The advisory committee may recommend against approval of our NDA, may recommend conditioning approval on our conducting one or more potentially time-consuming and costly clinical trials to provide supporting data either before approval or as a post-marketing commitment, or may recommend narrower or more restricted labeling than we may propose.

We also have ongoing development activities for two other products in our sleep therapeutic area. For JZP-507, an investigational new drug candidate with a 50% reduction in sodium content compared to Xyrem that in a pilot study has demonstrated bioequivalence to Xyrem, we are preparing to submit our NDA to the FDA by mid-2018 and, subject to the results of an ongoing Phase 3 trial, for JZP-258, an investigational new drug candidate that contains 90% less sodium than Xyrem, we expect to submit our NDA to the FDA in 2019. With respect to JZP-507, while we believe that we have a path to obtain the data necessary to complete our planned NDA submission for JZP-507 by mid-2018, we may not be able to generate sufficient data on our anticipated timing, or at all, or may be required to conduct more extensive studies than we currently anticipate, either of which could delay or prevent submission of an NDA.

Any failure or delay in completing necessary clinical trials and conducting other activities, including chemistry, manufacturing and controls, or CMC, activities, that are required to complete our planned NDA submissions and obtain regulatory approval could materially and adversely affect our business, financial condition, results of operations and growth prospects. See the discussion under the heading "*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*" in this Part II, Item 1A for a discussion of risks related to our clinical trials of JZP-110 and other product candidates. See also the discussions under the headings "*The loss of our single source suppliers, delays or problems in the supply of our products for commercial sale or our product candidates for use in our clinical trials, or our or our suppliers' failure to comply with manufacturing regulations, could materially and adversely affect our business, financial condition, results of operations and growth prospects*" and "*The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates*" in this Part II, Item 1A.

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.

The loss of our single source suppliers, delays or problems in the supply of our products for commercial sale or our product candidates for use in our clinical trials, or our or our suppliers' 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 manufacturers 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. These difficulties can be heightened when we or our suppliers are required to produce finished product at commercial scale or to produce increased quantities to meet growing demand. In addition, we and our suppliers are subject to the FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and other equivalent rules and regulations prescribed by non-U.S. regulatory authorities. If we or any of our suppliers encounter these or any other 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.

We received FDA approval of our manufacturing and development facility in Athlone, Ireland in June 2016, and we commenced commercial operations at this facility in the third quarter of 2016. We are using this facility for the manufacture of Xyrem and development-stage products, including JZP-507 and JZP-258. However, other than our Athlone facility and our

manufacturing plant in Italy where we produce the defibrotide drug substance, we currently do not have our own commercial manufacturing capability for our products, product candidates or their APIs, or packaging capability. 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. These single source arrangements put us at risk of interruption in supply in the event of manufacturing, quality or compliance difficulties at our suppliers.

Siegfried USA, LLC and its affiliates, or Siegfried, have been our sole supplier of sodium oxybate, the API for Xyrem, since 2012. Siegfried supplies sodium oxybate to our U.S.-based manufacturer of Xyrem and, through a Siegfried affiliate in Europe, to our Athlone facility. We expect that Siegfried will continue to be our sole supplier of sodium oxybate for the foreseeable future, and we cannot assure you that Siegfried can or will continue to supply on a timely basis, or at all, sufficient quantities of API to enable the manufacture of the quantities of Xyrem that we need. Patheon Pharmaceuticals Inc., which we refer to together with its affiliates as Patheon, is our sole U.S.-based manufacturer and supplier of Xyrem. Although we have commenced manufacturing of Xyrem in our Athlone facility, we expect to rely on Patheon as our U.S.-based supplier of Xyrem for the foreseeable future, and we cannot assure you that Patheon can or will continue to supply on a timely basis, or at all, the quantities of Xyrem that we need from Patheon.

Sodium oxybate is a Schedule I controlled substance in the U.S. The DEA limits the quantity of 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 to manufacture and procure sodium oxybate in the U.S. Accordingly, we require DEA quotas for Siegfried in the U.S. to manufacture sodium oxybate and for Patheon, our U.S.-based Xyrem supplier, to procure the sodium oxybate from Siegfried to manufacture and supply us with Xyrem. Because the DEA typically grants quotas on an annual basis, Siegfried and Patheon are required to request and justify allocation of sufficient annual DEA quotas, as well as any additional DEA quotas necessary if our commercial or clinical requirements exceed the allocated quotas throughout the year. For the last few years, our suppliers were allocated only a portion of the published annual aggregate quota for the API. If one or more ANDA filers were to begin manufacturing a generic sodium oxybate product, generic manufacturers would need to obtain a portion of the annual aggregate API quota, which could decrease the DEA quota allocation obtained on our behalf by Siegfried and Patheon. In the past, we have had to engage in lengthy efforts to obtain the needed quotas after the original annual quotas had first been allocated. The need for quotas has prevented us in the past, and may prevent us in the future, from building significant inventories. For 2017, both Siegfried and Patheon have been allocated most, but not all, of their respective requested quotas. If, in the future, we and our third party suppliers cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

Erwinaze is licensed from and manufactured for us by a single source, PBL, which is wholly owned by the U.K. Secretary of State for Health. The FDA's approval of the BLA for Erwinaze includes a number of post-marketing commitments related to the manufacture of Erwinaze by PBL. We cannot predict if or when PBL will comply with its manufacturing-related post-marketing commitments that are part of the BLA approval. In January 2017, the FDA issued a warning letter to PBL indicating that it was not satisfied with PBL's response to the FDA Form 483 issued to PBL in March 2016, citing significant violations of cGMP for finished pharmaceuticals and significant deviations from cGMP for APIs. In March 2017, PBL filed a response to the warning letter with the FDA. We attended a meeting with PBL and the FDA in the third quarter of 2017 to discuss the warning letter, and PBL continues to address the issues identified by the FDA in the warning letter. We cannot predict if or when PBL will correct the violations and deviations to the satisfaction of the FDA or whether the FDA will be satisfied with PBL's response to the warning letter. Any failure to do so to the satisfaction of the FDA could result in the FDA refusing admission of Erwinaze into the U.S., as well as additional enforcement actions by the FDA and other regulatory entities.

In the United Kingdom, or UK, where PBL's manufacturing facilities are located, PBL is subject to similar inspections conducted by the UK Medicines and Healthcare Products Regulatory Agency, or MHRA. Inability to comply with regulatory requirements of the FDA, the MHRA or other competent authorities in the EU member states in which Erwinaze is subject to marketing authorization could adversely affect Erwinaze supply, particularly in light of our extremely limited product inventory, and could result in: enforcement actions by the FDA, 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; 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 limit our potential future maintenance and growth of the market for this product. In addition, if the FDA or any non-U.S. regulatory authority mandates any changes to the specifications for Erwinaze, we may face challenges having product produced to meet such specifications, and our supplier may increase its price to supply Erwinaze meeting such specifications, which may result in additional costs to us or a delay in supply and may decrease any profit we would otherwise achieve with Erwinaze.

Moreover, the current manufacturing capacity for Erwinaze is completely absorbed by demand for the product. As a consequence of constrained manufacturing capacity, we have had an extremely limited or no ability to build product inventory levels that can be used to absorb supply disruptions resulting from quality, regulatory or other issues. We have experienced product quality, manufacturing and inventory challenges that have resulted, and may continue to result from time to time through the remainder of 2017 and into 2018, in disruptions in our ability to supply certain markets and have caused, and may in the future cause, us to implement batch-specific, modified product use instructions. Most recently, we experienced supply disruptions in the third quarter of 2017 in the U.S. and certain other countries. We cannot predict whether the required remediation activities in connection with the January 2017 warning letter will further strain manufacturing capacity and adversely affect Erwinaze supply, particularly in light of our extremely limited product inventory. As capacity constraints and supply disruptions continue, whether as a result of continued quality or other manufacturing issues, regulatory issues or otherwise, we will be unable to build a desired excess level of product inventory, our ability to supply the market may continue to be compromised and physicians' decisions to use Erwinaze have been, and may continue to be, negatively impacted.

If quality or other manufacturing issues or regulatory difficulties persist and result in a disruption to supply or capacity constraints, under our agreement with PBL, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach or the cessation of manufacturing by our supplier. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming, might not be successful and would increase the likelihood of a delay or disruption in manufacturing or a shortage of supply of Erwinaze. If we fail to obtain a sufficient supply of Erwinaze, our sales of and revenues from Erwinaze, our potential future maintenance and growth of the market for this product, and/or our business, financial condition, results of operations and growth prospects could be materially adversely affected.

We are our sole supplier of, and we believe that we are currently the sole worldwide producer of, the defibrotide drug compound. We manufacture the defibrotide compound in a single facility located in Villa Guardia, near Como, Italy. Patheon currently processes the defibrotide compound into its finished vial form, and Patheon is the sole provider of our commercial and clinical supply of Defitelio. In 2015, the FDA issued an FDA Form 483 to Patheon Italia that included observations related to the Ferentino, Italy facility that manufactures Defitelio. Although we are advised that Patheon Italia remediated the observations to the FDA's satisfaction, the FDA will continue to inspect and evaluate this facility for ongoing compliance with applicable requirements. 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.

In addition, the API in Defitelio is derived from porcine DNA. If our porcine DNA supplier experiences safety or other issues that impact its ability to supply porcine materials to us as needed, we may not be able to find alternative suppliers in a timely fashion, which could negatively impact our supply of Defitelio.

Vyxeos is manufactured using Celator's CombiPlex technology. 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. Vyxeos is manufactured by Baxter Oncology GmbH, or Baxter, which is a sole source supplier from a single site location. Baxter successfully manufactured batches that were used in Celator's completed Phase 3 clinical trial for Vyxeos, but Baxter has since experienced batch failures due to mechanical, component and other issues. While other contract manufacturers may be able to produce Vyxeos, 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 Baxter does not deliver sufficient quantities of Vyxeos in accordance with applicable specifications on a timely basis, whether due to batch failures or other delays, our ability to successfully commercialize Vyxeos and generate sales of this product at the level we expect could be materially and adversely affected. See also the discussion under the heading "*While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products and, in the case of our product candidates, our ability to obtain regulatory approval in the U.S. and Europe and, if approved, to successfully launch and commercialize those product candidates. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects*" in this Part II, Item 1A.

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 could be materially and adversely affected.

To conduct our ongoing and any future clinical trials of, complete marketing authorization submissions for, and potentially launch our other product candidates, we need to have sufficient quantities of product manufactured. For example,

Siegfried has supplied us with both the API and finished product for our development activities involving JZP-110, including our Phase 3 clinical trials. We plan to have Siegfried manufacture and supply JZP-110 drug product for commercial sale should JZP-110 receive regulatory approval. Also, JZP-507 and JZP-258 are currently manufactured at our Athlone facility, and we expect to manufacture these products commercially at our Athlone facility should these candidates receive regulatory approval. However, there can be no assurance that we or our suppliers will be able to produce sufficient supplies of our product candidates in a timely manner or in accordance with applicable specifications. In addition, to obtain FDA approval of any product candidate, we or our supplier or suppliers for that product must obtain approval by the FDA to manufacture and supply product, in some cases based on qualification data provided to the FDA as part of our NDA submission. Any delay in generating, or failure to generate, data required in connection with submission of the CMC portions of any NDA could negatively impact our ability to meet our anticipated submission dates, and therefore our anticipated timing for obtaining FDA approval, or our ability to obtain FDA approval at all. In addition, any failure of us or a supplier to obtain approval by the FDA 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.

Failure by us or our third party suppliers to comply with regulatory requirements could adversely affect our or their ability to supply products or ingredients. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with applicable cGMP requirements. DEA regulations also govern U.S. facilities where controlled substances such as sodium oxybate are manufactured. Our manufacturing facilities and manufacturing facilities of our suppliers have been and are subject to periodic unannounced inspection by the FDA, the EMA, the DEA, the Italian Health Authority and other regulatory authorities, including state authorities and similar authorities in other jurisdictions, to confirm compliance with cGMP and other requirements. We and our third party suppliers must continually expend time, money and effort in production, record keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal and regulatory requirements subjects us and our suppliers to possible legal or 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. Moreover, our or our third party suppliers' facilities could be damaged by fire, flood, earthquake, power loss, telecommunication and information system failure, terrorism or similar events. Any of these events could cause a delay or interruption in manufacturing and potentially a supply shortage of our products, which could negatively impact our anticipated revenues.

If, for any reason, our suppliers, including any new suppliers, do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, if one of our suppliers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier. The FDA and similar international regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. The loss of one of our suppliers could require us to obtain regulatory clearance in the form of a "prior approval supplement" and to incur validation and other costs associated with the transfer of the API or product manufacturing process. We believe that it could take up to two years, or longer in certain cases, to qualify a new supplier, and we may not be able to obtain APIs or finished products from new suppliers on acceptable terms and at reasonable prices, or at all. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to obtain a sufficient quota from the DEA, if required, or to otherwise meet FDA or similar international regulatory body's requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, particularly since we do not have secondary sources for supply and manufacture of the APIs for our products or backup suppliers for our finished products.

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

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

We are headquartered in Dublin, Ireland and have multiple offices in the U.S., the UK, Italy and other countries in Europe. Our headcount has grown to approximately 1,140 as of November 2017. This includes employees in 14 countries in North America and Europe, a European commercial presence, a complex distribution network for products in Europe and additional territories, and manufacturing facilities in Italy and Ireland. In addition, we may expand our international operations

into other countries in the future, either organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, 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, among other things:

- the increased complexity and costs inherent in managing international operations;
- diverse regulatory, financial and legal requirements, and any future changes to such requirements, in one or more countries where we are located or do business;
- country-specific tax, labor and employment laws and regulations;
- applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions and any changes to them;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations, as well as maintaining positive interactions with unionized employees in one of our international locations;
- liabilities for activities of, or related to, our international operations, products or product candidates;
- changes in currency rates; and
- regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

As a result of our rapid growth, our business and corporate structure has become substantially more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage the increased complexity of our company, and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In recent years, the global economy has been impacted by the effects of an ongoing global financial crisis, including the European sovereign debt crisis, which has caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. In addition, we expect to continue to grow our product sales in Europe. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in Europe and the ongoing budgetary difficulties faced by a number of EU member states, including Greece and Spain, has led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our revenues and profitability.

In addition, in June 2016, eligible members of the electorate in the UK decided by referendum to leave the EU. On March 29, 2017, the government of the UK initiated the formal procedure for withdrawal from the EU. We have a significant office in Oxford, England, which focuses on commercialization of our products outside of the U.S., among other activities. We do not know to what extent, or when, the UK's withdrawal from the EU or any other future changes to membership in the EU will impact our business, if at all. In particular, our ability to conduct international business out of the UK may be adversely affected. For a further discussion, see the risks under the heading "*The results of the UK's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business*" in this Part II, Item 1A.

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 any of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved 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;
- 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 inventory, 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;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- the conditions for reimbursement required by, and appropriate pricing and availability of reimbursement from, third party payors; 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 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 gamma-hydroxybutyrate, or 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. Patients, physicians and regulators may therefore view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of its connection to GHB. Xyrem's label includes information about adverse events from GHB. Moreover, a sodium oxybate distribution system that is less restrictive than the Xyrem REMS, such as the generic sodium oxybate REMS approved by the FDA in January 2017, may increase the risks associated with sodium oxybate distribution, as patients, consumers and others may not differentiate generic sodium oxybate from Xyrem, or differentiate between the different REMS programs. Any negative outcomes, including but not limited to risks to the public, caused by or otherwise related to the separate generic sodium oxybate REMS could have a significant negative impact in terms of product liability, goodwill, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, any of which could have a material adverse effect on our Xyrem revenues.

In addition, we have periodically increased the price of Xyrem and may do so again in the future. We also have made and may in the future make similar price increases on our other products. Price increases on our products and negative publicity regarding pricing and price increases generally, whether on our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of our products. For additional discussion about payor acceptance, see the risk factor under the heading "*Price approvals and reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably*" in this Part II, Item 1A.

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

We intend to grow our business over the long term by acquiring or in-licensing and developing additional products and product candidates that we believe have significant commercial potential. Future growth through acquisition or in-licensing will depend upon the availability of suitable products and product candidates for acquisition or in-licensing on acceptable prices, terms and conditions.

Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities. In order to compete successfully to acquire attractive products or product candidates in the current business climate, we may have to pay higher prices for assets than may have been paid historically, which may make it more difficult for us to realize an adequate return on any acquisition.

Even if we are able to successfully identify and acquire, in-license or develop additional products or product candidates, we cannot assure you that we will be able to successfully manage the risks associated with integrating any products or product candidates or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing. We may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including if:

- we are unable to obtain and maintain adequate funding to complete the development of, obtain regulatory approval for and commercialize an acquired product candidate;
- a product candidate proves not to be safe or effective in later clinical trials;
- a product fails to reach its forecasted commercial potential as a result of pricing pressures or for any other reason;
- we experience negative publicity regarding actual or potential future price increases for that product or otherwise; or
- the integration of a product or product candidate gives rise to unforeseen difficulties and expenditures.

Any failure to identify and manage these risks and uncertainties effectively would have a material adverse effect on our business.

For example, in July 2016 we made a substantial investment in Celator through the Celator Acquisition. The aggregate consideration for the Celator Acquisition was $1.5 billion. The Celator Acquisition broadened our hematology/oncology portfolio with the acquisition of worldwide development and commercialization rights to Vyxeos. The FDA approved our NDA for Vyxeos in the U.S. on August 3, 2017, and we launched in the U.S. shortly thereafter. Our U.S. commercial launch is still at an early stage. We submitted an MAA to the EMA in the fourth quarter of 2017. If we are unable to obtain regulatory approval for Vyxeos in Europe in a timely manner, or at all, or if sales of Vyxeos in the U.S., and in Europe following any regulatory approval, do not reach the levels we expect, our anticipated revenue from the product would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. See also the discussion under the heading "*While Xyrem remains our largest product, our success also depends on our ability to*

effectively commercialize our other products and, in the case of our product candidates, our ability to obtain regulatory approval in the U.S. and Europe and, if approved, to successfully launch and commercialize those product candidates. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects" in this Part II, Item 1A.

In addition, product and product candidate acquisitions create other uncertainties and risks, particularly when the acquisition takes the form of a merger or other business consolidation, such as the Celator Acquisition. Our business acquisitions have required, and any similar future transactions will also require, significant efforts and expenditures, including with respect to transition activities and integrating the acquired business with our historical business. We may encounter unexpected difficulties, or incur unexpected costs, in connection with potential acquisitions and similar transactions, which include:

- high acquisition costs;
- 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 assimilating employees and corporate cultures;
- the failure to retain key managers and other personnel;
- the challenges in controlling additional costs and expenses in connection with and as a result of any acquisition;
- 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.

If any of these or other factors impair our ability to integrate or otherwise manage an acquired business efficiently and successfully, we may be required to spend time or money on integration activities that otherwise would be spent on the development and expansion of our business. Resulting operating inefficiencies could increase costs and expenses more than we planned, could negatively impact the market price of our ordinary shares and could otherwise distract us from the execution of our strategy. Failure to maintain effective financial controls and reporting systems and procedures during and after integration of an acquired business could also impact our ability to produce timely and accurate financial statements.

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.

Since 2014, we have made significant investments into expanding our product development pipeline and expect to continue to increase our research and development organization. Significant clinical, development and financial resources will be required to progress product candidates through clinical trials and the regulatory approval process to develop them into commercially viable products. We have a number of product candidates under development. We also intend to pursue clinical development of other product candidates that we may acquire or in-license in the future. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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. Results of limited preclinical studies, including studies of our product candidates in animal models, may not predict the results of human clinical trials of those product candidates. Similarly, results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. In that case, the FDA or any equivalent non-U.S. regulatory agency may determine our data is not sufficiently compelling to warrant marketing approval and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in preclinical studies or earlier clinical trials. If a product candidate fails at any stage of development and does not receive regulatory approval, we will not be able to commercialize it and receive any return on our investment in that product candidate.

Although we received positive results from our two Phase 3 clinical trials of JZP-110 in patients with ES associated with OSA and our Phase 3 clinical trial of JZP-110 in patients with ES associated with narcolepsy, if we submit an NDA to the FDA for approval and the FDA determines that our safety or efficacy data do not warrant marketing approval, we may be required to

conduct additional clinical trials, which could be costly and time-consuming, or we may not be able to commercialize JZP-110, in which event we would not receive any return on our investment.

Our development pipeline projects may not be successful, and any adverse events or other information generated during the course of studies related to existing 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 information could otherwise have a material adverse effect on a related commercial product. Any failure or delay in completing clinical trials for line extensions or the generation of additional clinical data could materially and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

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:

- 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, also known as an ethics committee in Europe, to conduct a clinical trial at a prospective study site;
- delays or failures in recruiting patients to participate in a clinical trial;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA and other regulatory agencies' requirements, commonly referred to as good clinical practices;
- unforeseen safety issues, including negative results from ongoing preclinical studies and clinical trials and adverse events associated with product candidates;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- difficulty identifying or enrolling eligible patients, in some cases based on the number of clinical trials with enrollment criteria targeting the same patient population;
- failure of our third party clinical trial managers to satisfactorily perform their contractual duties, comply with regulations or meet expected deadlines; or
- insufficient funds to complete the trials.

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

We rely on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties, and, as a result, they may not treat our clinical studies as a high priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and non-U.S. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Our failure, or the failure of our product suppliers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

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

The commercial 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, have fewer side effects, are easier to administer or are less expensive than our products. The pharmaceutical industry is highly competitive and dominated by a number of large, established pharmaceutical companies, as well as specialty pharmaceutical companies that market products and develop product candidates in sleep, hematology/oncology, pain and other therapeutic areas. Many of our competitors, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. They can spend more on, and have more expertise in, research and development, regulatory, manufacturing, distribution and sales activities. As a result, our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may and may market their products more effectively than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through focused development programs and collaborative arrangements with large, established companies.

While Xyrem is the only product approved by the FDA and currently marketed in the U.S. for the treatment of both cataplexy and EDS in patients with narcolepsy, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors or selective norepinephrine reuptake inhibitors, even though these products are not approved by the FDA for the treatment of cataplexy. Other treatments for EDS in patients with narcolepsy include stimulants and wakefulness promoting agents, such as Provigil® (modafinil) and Nuvigil® (armodafinil), as well as generic versions of Provigil, the only other products both approved by the FDA and currently marketed for the treatment of EDS in patients with narcolepsy. Provigil, its generic equivalents and Nuvigil are also approved for improving wakefulness in patients with EDS associated with treated OSA or shift work disorder.

We are also aware of products being developed by others for use as treatment options in cataplexy and/or EDS in patients with narcolepsy, including a product to treat adult patients with narcolepsy with or without cataplexy that received marketing approval in Europe in 2016. While this product is currently not approved by the FDA for marketing in the U.S., the company that has exclusive U.S. commercialization rights to this product recently announced that it expects to establish an expanded access program for the product in early 2018 and submit an NDA to the FDA for the treatment of narcolepsy in adult patients during the first half of 2018. The receipt of marketing approval and commercialization of this product in the U.S. for the treatment of narcolepsy could, depending on the targeted patient population, negatively impact our ability to maintain and grow sales of Xyrem.

The FDA has approved or tentatively approved ANDAs seeking to market generic versions of Xyrem, and we believe that it is likely that the FDA will approve or tentatively approve additional ANDAs. In addition, in connection with our settlement agreement with West-Ward in April 2017, we granted West-Ward the right to sell the West-Ward AG Product commencing on January 1, 2023, or earlier under certain circumstances, and granted West-Ward a license to launch its generic sodium oxybate product as early as six months thereafter. Other companies could also develop products that are similar, but not identical, to Xyrem, such as an alternative formulation or an alternative formulation combined with a different delivery technology, and seek approval in the U.S. through a Section 505(b)(2) NDA approval pathway by referencing Xyrem and relying, to some degree, on the FDA's approval of Xyrem and related determinations of safety and efficacy. For example, Avadel has stated that it is conducting a Phase 3 pivotal trial pursuant to an FDA-approved special protocol assessment, and has indicated that it intends to seek approval of its product candidate using a Section 505(b)(2) NDA approval pathway, which allows companies to seek approval of a product that is similar, but not identical, to a previously-approved brand-name product. If Avadel successfully develops, obtains FDA approval of and launches this product candidate, we expect that the launch of the approved product would compete with Xyrem and could result in a substantial reduction of Xyrem net sales, which could have the additional negative effect of potentially triggering acceleration of market entry of the West-Ward AG Product or West-Ward's own generic sodium oxybate product.

We expect that the launch of any generic version of Xyrem, including the West-Ward AG Product or other authorized generic version of Xyrem, or the approval and launch of other products that compete with Xyrem, could have a material adverse effect on our sales of Xyrem and on our business, financial condition, results of operations and growth prospects. For further discussion regarding the risks associated with the West-Ward settlement agreement, the tentative approval of the Amneal and Ohm ANDAs, potential approval or tentative approval of additional ANDAs, the potential launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate or other products that compete with Xyrem, as well as other risks and challenges we face with respect to Xyrem, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales" and "Risks Related to Our Intellectual Property" in this Part II, Item 1A.

While there is currently no direct competition to Erwinaze to treat ALL patients with hypersensitivity to *E. coli*-derived asparaginase, other companies have developed or are developing new treatments for ALL, including new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL, and new treatment protocols are being developed for ALL that may not include asparaginase-containing regimens. For example, a number of companies are developing new

immunotherapy treatments for relapsed or refractory ALL patients, including one treatment that was recently approved. The development of these new treatments could negatively impact our ability to grow sales of Erwinaze in patient populations where the benefit of an asparaginase-containing regimen is not well established.

With respect to Vyxeos, AML, a cancer indication for which we have begun to commercialize Vyxeos, has established therapies. A key consideration in the treatment of AML patients is the patient's suitability for chemotherapy. The patient population studied in the Vyxeos Phase 3 clinical trial included AML patients deemed able to tolerate chemotherapy. There are existing options for the treatment of newly-diagnosed AML patients who can tolerate chemotherapy, such as cytarabine in combination with an anthracycline (i.e., daunorubicin), known as 7+3. In addition, we are aware of several other products that have been recently approved by the FDA or are in development for use as treatment options for AML patients, such as targeted agents (FLT-3, IDH-1, IDH-2, CD-33, CAR T-cell). Some of the patient populations being studied for, or treated by, these products overlap with the patient population studied in the Vyxeos Phase 3 clinical trial. The existence of established treatment options and the development of competing products for the treatment of newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes could negatively impact our ability to successfully commercialize Vyxeos and achieve the level of sales we expect, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

We also face competition, and may in the future face additional competition, from manufacturers of generic drugs, including in connection with the FDA's recent approval and tentative approvals of generic versions of Xyrem, and the potential launch of such generic versions of Xyrem and/or the West-Ward AG Product. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the U.S. allows for, and in some instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available. Other companies could also develop products that are similar, but not identical, to our marketed products, such as an alternative formulation of our product or an alternative formulation combined with a different delivery technology, and seek approval in the U.S. by referencing our products and relying, to some degree, on the FDA's finding that our products are safe and effective. For more information, see the risk factor under the heading *"The launch of a generic version of Xyrem or other sodium oxybate products that compete with Xyrem would adversely affect sales of Xyrem"* in this Part II, Item 1A.

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

Our ability to continue to grow further requires that we compete successfully with specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. These competitors include established companies that may have a competitive advantage over us due to their size and financial resources.

We cannot predict whether historical revenues from named patient programs for our hematology/oncology products will continue or whether we will be able to continue to distribute those products on a named patient basis.

In certain European countries, reimbursement for products that have not yet received marketing authorization may be provided through national named patient programs. Erwinase and Defitelio are available on a named patient basis in many countries where they are not commercially available. Such reimbursement may cease to be available if authorization for a named patient program expires or is terminated. While we generate revenue from the distribution of these products through named patient programs, we cannot predict whether historical revenues from these programs will continue, whether we will be able to continue to distribute our products on a named patient basis in these countries, whether we will be able to commercialize our products in countries where the products have historically been available on a named patient basis, or whether commercial revenues will exceed revenues historically generated from sales on a named patient basis. Any failure to

maintain revenues from sales of Erwinase and/or Defitelio 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.

If we fail to attract, retain and motivate key personnel or to retain the members of our executive management team, our operations and our future growth may be adversely affected.

Our success and our ability to grow depend in part on our continued ability to attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team and other critical personnel, all of whom work on many complex matters that are essential to our success. We do not carry “key person” insurance. The loss of services of one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities. Any employee may terminate his or her employment at any time without notice or with only short notice and without cause or good reason. The resulting loss of institutional knowledge may negatively impact our operations and future growth.

In addition, to grow our company we will need additional personnel. Competition for qualified personnel in the pharmaceutical industry is very intense. If we are unable to attract, retain and motivate quality individuals, including in our research and development operations, which are continuing to expand, our business, financial condition, results of operations and growth prospects could be adversely affected.

We also depend on the unique abilities, industry experience and institutional knowledge of the members of our board of directors to efficiently set company strategy and effectively guide our executive management team. We cannot be certain that future board turnover will not negatively affect our business.

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

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems 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. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. From time to time, our systems have been subject to cyber-attacks.

Significant disruptions of our 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 lead to increased harm of the type described above. 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.

The results of the UK’s referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

On March 29, 2017, the government of the UK initiated the formal procedure for withdrawal from the EU. The procedure involves a two-year negotiation period in which the UK and the EU must conclude an agreement setting out the terms of the UK's withdrawal and the arrangements for the UK's future relationship with the EU. This negotiation period could be extended by a unanimous decision of the European Council in agreement with the UK.

The referendum has created significant uncertainty concerning the future relationship between the UK and the EU. This includes the laws and regulations that will apply as the UK determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the UK's withdrawal could result in significant complexity and risks. The tax consequences of the UK's withdrawal from the EU are uncertain as well.

The UK referendum has also given rise to calls for the governments of other EU member states to consider withdrawal from the EU. These developments, or the perception that they could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets. They may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets.

We have a significant office in Oxford, England, which focuses on commercialization of our products outside of the U.S., among other activities. We do not know to what extent, or when, the UK's withdrawal from the EU or any other future changes to membership in the EU will impact our business, if at all. In particular, our ability to conduct international business out of the UK may be adversely affected. For a further discussion, see the risks under the headings "*We have substantially expanded our international footprint and operations, and we may expand further in the future, but we do not yet have substantial historical experience in international markets and may not achieve the results that we, our shareholders or analysts who cover our business expect*" and "*The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates*" in this Part II, Item 1A.

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 and maintaining patent protection of our products and product candidates and their use and the methods used to manufacture and distribute them, as well as successfully defending these patents against third party challenges, and successfully protecting our trade secrets. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importation by third parties depends on the extent to which we have rights under valid and enforceable patents or have trade secrets that cover these activities. We cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents, that the patents we own and license, or any additional patents we may own or license, will prevent other companies from developing similar or therapeutically equivalent products, or that others will not be issued patents that may prevent the sale of our products or require licensing and the payment of significant fees or royalties.

The patent position of pharmaceutical companies can be highly uncertain and involve complex and often changing legal, regulatory and factual questions. 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 that cover or relate to our products and product candidates, including Xyrem, Defitelio and Vyxeos. 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. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented, potentially including by FDA approval of an ANDA that avoids infringement of our intellectual property.

Although Xyrem is covered by patents covering its formulation, distribution system and method of use, third parties are seeking to introduce generic versions of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy. Notwithstanding our patents, and settlement agreements licensing those patents as of future dates, it is possible that West-Ward, Amneal, Ohm or any other company that receives FDA approval of an ANDA for a generic version of Xyrem or an NDA for another sodium oxybate product could introduce a generic version of Xyrem or other sodium oxybate product before the entry dates specified in our settlement agreements or before our patents expire, including if it is determined that any such generic version of Xyrem or sodium oxybate product does not infringe our patents, if it is determined that our patents are invalid or unenforceable, or if a non-settling ANDA filer that has received approval for its product decides, before applicable ongoing patent litigation is concluded, to launch a sodium oxybate product at risk of being held liable for damages for patent infringement. For a description of our ongoing patent proceedings in the District Court and related regulatory matters and further discussion regarding the risks associated with our settlement agreement with West-Ward, the potential launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate or other products that compete with Xyrem, as well as other risks and challenges we face with respect to Xyrem, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales" and "*We have incurred and expect to continue to 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"* in this Part II, Item 1A.

The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require

licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that have a different scope of patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may independently develop similar or alternative products without infringing our intellectual property rights, 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;
- 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 the pending patent applications or issued patents of our licensors or partners;
- our pending patent applications may not result in issued patents;
- our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- our issued patents and the issued patents of our licensors or partners may be vulnerable to legal challenges as a result of changes in applicable law;
- we may not develop additional proprietary products that are patentable; or
- the patents of others may have an adverse effect on our business.

We also 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. We seek to protect our trade secrets and other unpatented proprietary information in part through confidentiality 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. In addition, if our employees, consultants, advisors or partners develop inventions or processes independently, or jointly with us, that may be applicable to our products, disputes may arise about ownership or proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those third parties or their employers. Enforcing a claim that a third party illegally obtained or is using any of our inventions or trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside of the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain patent and/or trade secret protection, for any reason, could have a material adverse effect on our business.

Certain of the products we sell have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. We rely on trade secrets and other unpatented proprietary information to protect our commercial position with respect to such products, which we may be unable to do. In some instances, we also rely on regulatory exclusivity. For example, Erwinaze has no patent protection. In addition to protection using trade secrets, Erwinaze has orphan drug exclusivity in the U.S. for a seven-year period from its FDA approval, which precludes approval of another product with the same principal molecular structure for the same indication until November 2018. Erwinaze, as a biologic product approved under a BLA, is also subject to the U.S. Biologics Price Competition and Innovation Act, or BPCIA. We believe that Erwinaze is protected by exclusivity that prevents approval of a biosimilar in the U.S. through late 2023 under the BPCIA. However, the BPCIA may evolve over time based on FDA issuance of guidance documents, proposed regulations, and decisions in the course of considering specific applications. As a result, it is possible that a potential competing drug product might obtain FDA approval before the orphan drug and expected BCPIA exclusivity periods have expired, which would adversely affect sales of Erwinaze. In the EU, the regulatory data protection and thus regulatory exclusivity period for Erwinase has lapsed. This also means that 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 would have been written for Erwinaze may be filled with the biosimilar version, resulting in a loss in sales of Erwinaze, and there may be a decrease in the price at which Erwinaze can be sold. Competition from a biosimilar product to Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. While the ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to contractual limitations, these contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our innovations and other confidential information, then

our ability to obtain patent protection or protect our proprietary information may be jeopardized. Moreover, a dispute may arise with our business partners over the ownership of rights to jointly developed intellectual property. Such disputes, if not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

We have incurred and expect to continue to 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. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and non-U.S. counterparts, and may file additional U.S. and non-U.S. patent applications. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted. Moreover, for a variety of reasons, including the existence of relevant prior research performed and the existence of conflicting patent applications submitted in the same manner or similar fields, there can be no assurance that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

If we choose to go to court to stop 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 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. As a result, entities associated with hedge funds as well as ANDA litigants have challenged valuable pharmaceutical patents through the IPR process. There is a risk that a court will decide that our patents are not valid or infringed, or that the PTAB will decide that certain patents are not valid, and that we do not have the right to stop a third party from using the patented subject matter. 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. For a description of our ongoing patent proceedings in the District Court and related regulatory matters and further discussion regarding the risks associated with our settlement agreement with West-Ward, the potential launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate or other products that compete with Xyrem, as well as other risks and challenges we face with respect to Xyrem, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q and the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales" and "*It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection"* in this Part II, Item 1A. We cannot assure you that our pending lawsuits, other lawsuits or proceedings we may file in the future, or our defense against any lawsuits or other proceeding that have been or will be brought against us will be successful in stopping the infringement of our patents, that any such litigation or other proceedings will be cost-effective, or that any of them will have a satisfactory result for us.

Litigation involving patent matters is frequently settled between the parties, rather than continuing to a court ruling, and we have settled patent litigation with four of the 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) and to call on legislators to pass stronger laws prohibiting such settlements. 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 DOJ for review. Accordingly, we and West-Ward submitted our April 2017 settlement agreement to the FTC and the DOJ for review. We may receive formal or informal requests from the FTC regarding our Xyrem patent settlements, including our April 2017 settlement with West-Ward, 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 this settlement, 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.

In the pharmaceutical and life sciences industry, like other industries, it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, which we may not be able to do.

Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. and many non-U.S. jurisdictions are typically not published until 18 months after their priority date, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our or our licensors' issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Patent interferences are limited or unavailable for patent applications filed after March 16, 2013.

Some of our competitors may be able to sustain the costs of complex patent and other intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

In September 2016, Jazz Pharmaceuticals, Inc., our wholly owned subsidiary, submitted a Citizen Petition to the FDA requesting that, for safety reasons, the FDA refuse to approve any sodium oxybate ANDA with a proposed package insert or REMS that omits the portions of the Xyrem package insert and the Xyrem REMS that instruct prescribers on adjusting the dose of the product when it is co-administered with divalproex sodium (also known as valproate or valproic acid). Our Xyrem patents include three DDI patents covering these instructions on the Xyrem package insert and Xyrem REMS. Our lawsuits against each of the Xyrem ANDA filers allege infringement of multiple patents, including the DDI patents, and seek a permanent injunction to prevent these Xyrem ANDA filers from introducing a generic version of Xyrem that would infringe our patents. On January 17, 2017, the FDA granted the Citizen Petition with respect to the Xyrem package insert. The FDA concluded that it will not approve any sodium oxybate ANDA referencing Xyrem that does not include in its package insert the portions of the currently approved Xyrem package insert related to the drug-drug interaction with divalproex sodium. The FDA stated that it did not need to reach the question of whether the drug-drug interaction information could have been excluded from the generic sodium oxybate REMS materials because it was approving a REMS in connection with a sodium oxybate ANDA including that information. We cannot predict whether or when one or more of the ANDA filers may pursue a challenge to the FDA's response to the Citizen Petition or whether any such challenges would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of any of our patents or will otherwise obtain a judicial determination that the generic sodium oxybate package insert or the generic sodium oxybate REMS will infringe any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents any non-settling 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. For further discussion regarding these matters, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales" and "Risks Related to Our Intellectual Property" in this Part II, Item 1A.

We also own method of use patents and trade secrets that cover elements of the Xyrem REMS, including patents that cover the use of a single central pharmacy to distribute Xyrem. In July 2016, the PTAB issued final decisions that the claims of six of seven REMS patents are unpatentable; as a result, if the United States Court of Appeals for the Federal Circuit upholds those decisions on appeal, these claims will be canceled. We have filed notices of appeal with respect to these IPR decisions to the United States Court of Appeals for the Federal Circuit. In September 2015, certain of the ANDA filers filed a petition for IPR with respect to the validity of an additional REMS patent. In March 2016, the PTAB partially instituted an IPR on a seventh REMS patent, declining to review 25 of 28 claims. In March 2017, the PTAB issued a final decision that the remaining three claims of the additional REMS patent are unpatentable. We filed a notice of appeal of that decision on May 18, 2017, and the Court of Appeals for the Federal Circuit has consolidated the appeal of the March 2017 decision with the pending appeals of the July 2016 decisions. For a description of these matters, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q.

The Xyrem REMS approval letter includes statements from the FDA that (i) the approval action should not be construed or understood as agreement with us that dispensing through a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh its risks, and that the FDA has continuing concerns that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system and (ii) as with all REMS, the FDA intends to 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 in connection with the approval of the generic sodium oxybate REMS, the anticipated distribution of the West-Ward AG Product, or otherwise, or the potential timing, terms or propriety thereof.

Any such modifications or additional requirements could potentially make it easier for future sodium oxybate competitors, make it more difficult or expensive for us to distribute Xyrem and/or negatively affect sales of Xyrem. In particular, depending on the nature of any such modifications or additional requirements, the ability of our existing patents and other intellectual property to protect our Xyrem distribution system from sodium oxybate competitors may be reduced. In addition, the extent of protection provided by our patents and other intellectual property related to the distribution of Xyrem depends on the nature of the distribution system that may be used by any sodium oxybate competitor. If the generic sodium oxybate REMS that has been approved by the FDA in connection with its approval of West-Ward's ANDA does not fall within the scope of any of the claims of our patents, those patents will not be a barrier to any non-settling ANDA filer's or other unlicensed sodium oxybate product manufacturer's entry into the market. We cannot be certain whether our existing patents, patents that may be granted in the future or other intellectual property will be construed to cover the generic sodium oxybate REMS. The interpretation of intellectual property protections and the effect of these protections are extremely complex, and we cannot predict the impact of any of these matters on our business.

Risks Related to Our Industry

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

The manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, record keeping, importing and exporting of our products and our research and development activities are subject to extensive regulation by the FDA, the DEA, the EC, the competent authorities of the EU member states and other regulatory authorities. Regulations differ from country to country. As a result of these regulations, product development, approval and commercialization processes are expensive and time-consuming. For example, 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, the EC or the competent authorities of the EU member states, as applicable. An application for marketing approval must contain information demonstrating the quality, safety and efficacy of the pharmaceutical product, including data from preclinical and clinical trials, information pertaining to the preparation and manufacture of the API, analytical methods, product formulation, details on the manufacture and stability of the finished pharmaceutical product and proposed product packaging and labeling. Submission of an application for marketing authorization does not assure approval for marketing in any jurisdiction, and we may encounter significant difficulties or costs in our efforts to obtain approval to market products.

We submitted an MAA for Vyxeos to the EMA in the fourth quarter of 2017, and we cannot predict whether we will be able to obtain approval of our MAA for Vyxeos in Europe in a timely manner, or at all. The EMA has granted accelerated assessment of our MAA, but if we are unable to respond to any EMA questions or resolve any EMA issues relating to our regulatory application in a timely manner, we or the EMA could decide to convert our accelerated assessment review for Vyxeos to a standard review timetable, which could delay the approval of our MAA. In addition, if the EMA determines that our safety or efficacy data do not warrant marketing approval, we could be required to conduct additional clinical trials, which could be costly and time-consuming and could delay the approval of our MAA, or we may not be able to commercialize Vyxeos in Europe. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs. Any delay or failure in obtaining approval of a drug candidate, or receipt of approval for narrower indications than sought, can have a negative impact on our financial performance.

An approved drug product or drug candidate that has not yet been approved by the FDA or equivalent authorities in other countries may be subject to scheduling as a controlled substance under the U.S. Controlled Substances Act, or 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, or equivalent requirements in other countries, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. For a drug approved by the FDA and determined to require control under the CSA, the CSA requires the DEA to issue an interim final order scheduling the drug within 90 days after the FDA approves the drug and the DEA receives a scientific and medical evaluation and scheduling recommendation from the U.S. Department of Health and Human Services, or

HHS. We expect that JZP-110 will be subject to scheduling under the CSA before it can be commercially launched. Moreover, depending on its scheduling, the manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use of JZP-110 may be subject to a significant degree of regulation by the DEA.

If the FDA, the EC or the competent authorities of the EU member states determine that a REMS or the imposition of post-marketing obligations is necessary to ensure that the benefits of the drug outweigh the risks, we may be required to include a proposed REMS as part of an NDA or BLA or to propose post-marketing obligations to be included in the marketing authorization for our products in the EU. In non-EU countries, we may also be required to include a patient package insert or a medication guide to provide information to consumers about the product's risks and benefits, a plan for communication to healthcare providers, and restrictions on the product's distribution. For example, the FDA requires a REMS for Xyrem, discussed in detail in the risk factor under the heading "*The distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk evaluation and mitigation strategy, and these restrictions and requirements, as well as the potential impact of changes to these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem*" in this Part II, Item 1A, and other products that we sell are or may become subject to a REMS specific to our product or shared with other products in the same class of drug. We cannot predict the impact that any new REMS requirements applicable to any of our products would have on our business.

The FDA approved the BLA for Erwinaze in the U.S. in November 2011, subject to certain post-marketing requirements, which have been completed, and compliance with multiple post-marketing commitments, including certain commitments that must be met by the product's manufacturer with respect to product manufacturing, which are outside of our control. While activities are underway to complete the post-marketing commitments, any inability to comply with regulatory requirements, including compliance with manufacturing-related post-marketing commitments that are part of the BLA approval, as well as other requirements monitored by the FDA, could adversely affect Erwinaze supply, particularly in light of our extremely limited product inventory, and could result in FDA approval being revoked, product release being delayed resulting in product shortage or product recalls, any of which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. See also the discussion under the heading "*The loss of our single source suppliers, delays or problems in the supply of our products for commercial sale or our product candidates for use in our clinical trials, or our or our suppliers' failure to comply with manufacturing regulations, could materially and adversely affect our business, financial condition, results of operations and growth prospects.*" in this Part II, Item 1A.

As another example, the marketing authorization in the EU for Defitelio requires us to comply with a number of post-marketing obligations, including obligations relating to the establishment of a patient registry to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use. In January 2017, we enrolled the first patient in the Defitelio 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. The FDA imposed several post-marketing commitments and requirements in connection with its approval of our NDA for Defitelio in March 2016, including the requirement that we conduct a clinical trial, or the Defitelio post-marketing trial, to analyze the safety of defibrotide versus best supportive care in the prevention of VOD in adult and pediatric patients. If we fail to complete any of these post-marketing obligations, including our failure to satisfactorily complete the Defitelio post-authorization study, the ongoing validity of the marketing authorization may be called into question, our sales of and revenues from Defitelio could be materially adversely affected and our potential future maintenance and growth of the market for this product may be limited.

A significant proportion of the regulatory framework in the UK is derived from EU directives and regulations, and for that reason, the UK's 2016 referendum regarding withdrawal from the EU could materially change the regulatory regime applicable to our operations, including with respect to the approval of our product candidates, as there is significant uncertainty concerning the future relationship between the UK and the EU. This includes the laws and regulations that will apply as the UK determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the UK's withdrawal could result in significant complexity and risks. A basic requirement related to the grant of a marketing authorization for a medicinal product in the EU is the requirement that the applicant is established in the EU. Following withdrawal of the UK from the EU, marketing authorizations previously granted to applicants established in the UK through the mutual recognition or decentralized procedures in which an EU member state other than the UK was the reference member state may no longer be valid. Moreover, depending upon the exact terms of the UK's withdrawal, there is an arguable risk that the scope of a marketing authorization for a medicinal product granted by the EC pursuant to the centralized procedure would not, in the future, include the UK. In these circumstances, an authorization granted by the UK's competent authorities would be required to place medicinal products on the UK market.

In addition, the laws and regulations that will apply after the UK withdraws from the EU may have implications for manufacturing sites that hold certification issued by the UK competent authorities. Our capability to rely on these manufacturing sites for products intended for the EU market would also depend upon the exact terms of the UK's withdrawal.

Any such changes to the regulatory regime could have a material adverse effect on the pharmaceutical industry generally and on our ability to obtain approval for our product candidates or, if approved, to successfully commercialize our product candidates. For a further discussion, see the risks under the heading "*The results of the UK's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business*" in this Part II, Item 1A.

Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and these changes could have a material adverse effect on our business and financial condition.

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, together, the Healthcare Reform Act, is a sweeping measure 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 Public Health Service's 340B drug pricing program, or the 340B program, 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 and improvements to the physician quality reporting system and feedback program.

Details of the changes to the Medicaid Drug Rebate program and the 340B program are discussed in the risk factor under the heading "*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 this Part II, Item 1A. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has increased and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where Medicaid patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, there have been delays in the implementation of key provisions of the Healthcare Reform Act, including the excise tax on generous employer-based health insurance plans. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

Moreover, legislative changes to or regulatory changes under the Healthcare Reform Act remain possible and appear likely in the 115th U.S. Congress and under the Trump Administration. The nature and extent of any legislative or regulatory changes to the Healthcare Reform Act are uncertain at this time. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third party payors to keep healthcare costs down while expanding individual healthcare benefits.

Likewise, in the countries in the EU, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third party payors, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Further, an increasing number of EU member states 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, the ongoing budgetary difficulties faced by a number of EU member states, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement for our products in

some countries, including some EU member states, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our products will obtain favorable reimbursement status in any country.

To help patients afford our products, we have various programs to assist them, including patient assistance programs, a Xyrem free product voucher program and co-pay coupon programs for Xyrem and certain other products. Additionally, we make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. Co-pay coupon programs, including our program for Xyrem, have received some negative publicity related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. In recent years, pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their co-pay programs under a variety of federal and state laws. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar lawsuits or insurer actions. In addition, in November 2013, the Centers for Medicare and Medicaid Services, or CMS, issued guidance to the issuers of qualified health plans sold through the Healthcare Reform Act's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the Office of Inspector General, or OIG, of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty 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.

Patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that permit pharmaceutical manufacturers to 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. 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, we could be subject to damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. In May and October 2016 and February 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients and documents concerning the provision of financial assistance to Medicare patients taking drugs sold by us. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses and reduce the availability of foundation support for our patients who need assistance. For more information, see the risk factor under the heading "*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*" in this Part II, Item 1A.

We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.

Oversight by FDA and Equivalent Non-U.S. Regulatory Authorities

We are subject to significant ongoing regulatory obligations with respect to our marketed products, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, record keeping, importing and exporting of our products are, and any of our product candidates that may be approved by the FDA, the EC, the competent authorities of the EU member states and other non-U.S. regulatory authorities will be, subject to extensive and ongoing regulatory requirements. These requirements apply both to us and to third parties we contract with to perform services and supply us with products. Failure by us or any of our third party partners, including suppliers, distributors and our central pharmacy for Xyrem, to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to approve a product candidate, withdrawal, suspension or variation of product approval, 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 have a significant impact on our sales, business and financial condition.

We monitor adverse events resulting from the use of our commercial products, as do the regulatory authorities, and we file periodic reports with the authorities concerning adverse events. The authorities review these events and reports, and if they determine that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing and/or require or conduct other actions, potentially including withdrawal or suspension of the product from the market, 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 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. The EMA's Pharmacovigilance Risk Assessment Committee, or the PRAC, may propose to the Committee for Human Medicinal Products that the marketing authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended, or withdrawn. An FDA Form 483 notice, if issued at the conclusion of an FDA inspection, 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 further regulatory enforcement action. For example, in April 2014, we received an FDA Form 483 at the conclusion of a pharmacovigilance inspection conducted by the FDA. The FDA Form 483 included observations relating to certain aspects of our adverse drug experience, or ADE, reporting system for all of our products, including Xyrem. We responded to the FDA Form 483 with a description of the corrective actions and improvements we had implemented before or shortly following the inspection and additional improvements that we planned to implement, and have now implemented, to address the observations in the FDA Form 483. In August 2014, the FDA issued an Establishment Inspection Report to us, which indicates that the inspection is closed. Although we have implemented improvements to our ADE reporting system, there can be no assurance that the FDA or other regulatory agencies will not identify additional matters in future pharmacovigilance inspections or that we will be able to adequately address any matters identified by the FDA or other regulatory agencies in the future, and the failure to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we receive regulatory approvals to sell our products, the FDA, the EC, the competent authorities of the EU member states and other non-U.S. regulatory authorities where our products are approved may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval clinical studies or trials. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the commercial potential of the product. If we become aware of problems with any of our products in the U.S., the EU or elsewhere in the world or at our third party suppliers' facilities, a regulatory agency may impose restrictions on our products, our suppliers, our other partners or us. In such an instance, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits. For example, in April 2015, Medtronic Inc., or Medtronic, announced a consent decree with the FDA related to Medtronic's SynchroMed® II implantable infusion pump systems. Our product Prialt is approved for administration to patients via that pump. While the Medtronic consent decree does not impact existing patients with the pump, physicians who want to implant the pump in new patients are required to complete a certification process to document medical necessity. While the approved indication for Prialt is one of the conditions eligible to support a showing of medical necessity provided by the consent decree, we cannot predict the impact of this new certification requirement on sales of Prialt.

EU legislation related to pharmacovigilance, or the assessment and monitoring of the safety of medicinal products, provides that the EMA and the competent authorities of the EU member states have the authority to require companies to conduct additional post-authorization efficacy studies and post-authorization safety studies. The legislation also governs the obligations of marketing authorization holders with respect to additional monitoring, adverse event management and reporting. Under the legislation and its related regulations and guidelines, we may be required to conduct a labor intensive collection of data regarding the risks and benefits of marketed products and may be required to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time-consuming and expensive and could impact our profitability. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

The FDA approved the BLA for Erwinaze in the U.S. in November 2011, subject to certain post-marketing requirements, which have been completed, and compliance with multiple post-marketing commitments, including certain commitments that must be met by the product's manufacturer with respect to product manufacturing, which are outside of our control. While activities are underway to complete the post-marketing commitments, any inability to comply with regulatory requirements, including compliance with manufacturing-related post-marketing commitments that are part of the BLA approval, as well as other requirements monitored by the FDA, could adversely affect Erwinaze supply and could result in FDA approval being revoked or product recalls, all of which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product.

The marketing authorization in the EU for Defitelio requires us to comply with a number of post-marketing obligations, including obligations relating to the establishment of a patient registry to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use. In January 2017, we enrolled the first patient in the Defitelio 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. The FDA imposed several post-marketing requirements and commitments in connection with its March 2016 approval of our NDA for Defitelio, including the requirement that we conduct the Defitelio post-marketing trial to analyze the safety of defibrotide versus best supportive care in the prevention of VOD in adult and pediatric patients. Additionally, the FDA imposed several post-marketing commitments and requirements in connection with its approval of our NDA for Vyxeos in August 2017, 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. If we fail to complete any of these post-marketing obligations for Defitelio or Vyxeos, including our failure to satisfactorily complete post-marketing studies and trials, the ongoing validity of the marketing authorizations may be called into question, our sales of and revenues from Defitelio and Vyxeos could be materially adversely affected and our potential future maintenance and growth of the markets for these products may be limited.

Erwinase and defibrotide are available on a named patient basis in many countries where they are not commercially available. If any such country's regulatory authorities determine that we are promoting Erwinase or defibrotide 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.

The FDA, the competent authorities of the EU member states and other governmental authorities require advertising and promotional 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 routinely provides its interpretations of that authority in informal communications and also in more formal communications such as untitled letters or warning letters, and although such communications may not be considered final agency decisions, companies may decide not to contest the agency's interpretations so as to avoid disputes with the FDA, even if they believe the claims to be truthful, not misleading and otherwise lawful. In recent years, certain courts have determined that the First Amendment of the U.S. Constitution permits communications regarding off-label uses of drug products, as long as such communications are truthful and not misleading. At the beginning of 2017, the FDA released proposed rule changes and draft guidance on the FDA's interpretation on the limitations of such speech. These cases and regulatory actions create additional uncertainty regarding the limits of permissible communication regarding our products.

The FDA, the competent authorities of the EU member states and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. A company that is found to have promoted an approved product for off-label uses may be subject to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company's 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. For all of our products, it is important that we maintain a comprehensive compliance program. 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 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, or DOC, the OIG and other regulatory bodies, as well as governmental authorities in those non-U.S. countries in which we commercialize our products. In addition to the FDCA, other federal, state and non-U.S. statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government healthcare programs. Our partners, including our suppliers and distributors and the central pharmacy for Xyrem, a controlled substance under the CSA, are also 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 necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA, 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.

In addition, the DEA limits the quantity of certain Schedule I controlled substances that may be produced or procured in the U.S. in any given calendar year through a quota system. Accordingly, we require DEA quotas for Siegfried in the U.S. to manufacture sodium oxybate and for Patheon, our U.S.-based Xyrem supplier, to procure the sodium oxybate from Siegfried in order to manufacture and supply us with Xyrem. Because the DEA typically grants quotas on an annual basis, Siegfried and Patheon are required to request and justify allocation of sufficient annual DEA quotas as well as additional DEA quotas if our commercial or clinical requirements exceed the allocated quotas throughout the year. For the last few years, our suppliers were allocated only a portion of the published annual aggregate quota for the API. If one or more ANDA filers were to begin manufacturing a generic sodium oxybate product, generic manufacturers would need to obtain a portion of the annual aggregate API quota, which could decrease the DEA quota allocation obtained on our behalf by Siegfried and Patheon. In the past, we have also had to engage in lengthy efforts to obtain the needed quotas after the original annual quotas had first been allocated. For 2017, both Siegfried and Patheon have been allocated most, but not all, of their respective requested quotas. If, in the future, our suppliers cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

The U.S. federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and Medicare patients, prescribers, purchasers and formulary managers on the other. The Healthcare Reform Act amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. 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 practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability, and therefore would be subject to a facts and circumstances analysis.

The 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. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Many pharmaceutical and other healthcare companies have been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company’s products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, in recent years the government and private whistleblowers have pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

In addition, the Physician Payment Sunshine Act, or Sunshine provisions, requires extensive tracking of payments and transfers of value to physicians and teaching hospitals and public reporting of the data collected. By March 31 of each calendar year, manufacturers covered under the Sunshine provisions are required to submit a report disclosing payments and transfers of value made in the preceding calendar year, and CMS then will publish the reported data on or before June 30 of the reporting year. Public reporting under the Sunshine provisions has resulted in increased scrutiny of the financial relationships between industry, teaching hospitals and physicians, and such scrutiny may negatively impact our ability to engage with physicians on matters of importance to us. In addition, 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, we may be subject to significant civil, criminal and administrative penalties, damages or fines.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. A number of states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states restrict when pharmaceutical companies may provide meals or gifts to prescribers or engage in other marketing-related activities. Other

states and cities require identification or licensing of sales representatives. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Massachusetts and Nevada require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Outside the U.S., we are subject to similar regulations in those countries where we market and sell products.

In May 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, and, for Xyrem, documents concerning the provision of financial assistance to Medicare patients. In October 2016, we received a second subpoena updating and further specifying document requests regarding support to 501(c)(3) organizations that provide financial assistance to Medicare patients and the provision of financial assistance for Medicare patients taking drugs sold by us. In February 2017, we received a third subpoena requesting documents regarding our support to a specific 501(c)(3) organization that established a fund for narcolepsy patients in January 2017. Other companies have disclosed similar subpoenas and continuing inquiries. The Office of the Inspector General has established guidelines that permit pharmaceutical manufacturers to 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. 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 by the federal government. We are cooperating with this investigation, and the outcome of this investigation could include an enforcement action or a settlement with the federal government. If the federal government were to file an enforcement action against us as a result of the investigation and could establish the elements of a violation of relevant laws, we could be subject to damages, fines and penalties, which could be substantial, along with other criminal, civil or administrative sanctions. Any settlement with the federal government could result in substantial payments and entry into a corporate integrity agreement, which would impose costs and burdens on the operation of our business. We are unable to predict how long this investigation will continue, whether we will receive additional subpoenas in connection with this investigation, or its outcome, but we expect that we will continue to incur significant costs in connection with the investigation, regardless of the outcome. We may also become subject to similar investigations by other state or federal governmental agencies or offices. Any additional investigations of our patient assistance programs or other business practices may result in damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions against us or 501(c)(3) organizations that we support (including organizations that provide assistance to narcolepsy and chronic pain patients). Such investigations may also result in negative publicity or other negative actions as to us or 501(c)(3) organizations that we support that could harm our reputation, impact our business practices, reduce demand for, or patient access to, Xyrem and Prialt and/or reduce coverage of Xyrem and Prialt, including by federal health care programs 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. For more information, see the risk factor under the heading "*Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and these changes could have a material adverse effect on our business and financial condition*" in this Part II, Item 1A.

In the EU, the advertising and promotion of our products are subject to EU member states' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU member states may apply to the advertising and promotion of medicinal products. These 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. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the EU. The applicable laws at EU level and in the individual EU member states also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

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 in the individual EU member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU member states. One example is the U.K. Bribery Act. As further discussed below, the U.K. Bribery Act applies to any company incorporated in or "carrying on business" in the U.K., irrespective of where in the world the alleged bribery activity occurs, which could have implications for our interactions with

physicians both in and outside of the U.K. Violation of these laws could result in substantial fines and imprisonment. Certain EU member states, such as France and Belgium, 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.

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 U.K. Bribery Act. The FCPA and similar anti-corruption laws generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other 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 U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including both U.K. and non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies which carry on a business or part of a business in the U.K. may be held liable for bribes given, offered or promised to any person, including non-U.K. government officials and private persons, in another 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 having in place adequate procedures designed to prevent bribery is an available defense. Furthermore, under the U.K. Bribery Act there is no exception for facilitation payments. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the 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. 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 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, which could have a material adverse impact on our business and financial condition.

We are also subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws include security breach notification requirements and protection of consumer health information. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Although there are legal mechanisms to facilitate the transfer of personal data from the European Economic Area, or EEA, and Switzerland to the U.S., the decision of the European Court of Justice that invalidated the safe harbor framework on which we previously relied has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the U.S. In February 2016, the EC announced an agreement with the DOC to replace the invalidated safe harbor framework with a new EU-U.S. "Privacy Shield." On July 12, 2016, the EC adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its recent ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and FTC and making commitments on the part of public authorities regarding access to information.

U.S.-based companies may certify compliance with the privacy principles of the Privacy Shield. Certification to the Privacy Shield, however, is not mandatory. If a U.S.-based company does not certify compliance with the Privacy Shield, it may rely on other authorized mechanisms to transfer personal data. In September 2016, we filed for certification for our U.S.-based subsidiaries under the Privacy Shield. This certification was approved in January 2017.

The privacy and data security landscape is still in flux. In September 2016, the Irish privacy advocacy group, Digital Rights Ireland, brought an action for annulment of the EC decision on the adequacy of Privacy Shield, Case T-670/16, which is pending before the European Court of Justice. In October 2016, a further action for annulment was brought by three French digital rights advocacy groups, La Quadrature du Net, French Data Network and the Fédération FDN. This case, Case T-738/16, is also currently pending before the European Court of Justice. Should the European Court of Justice invalidate the Privacy Shield, it will no longer be possible to transfer data from the EU to entities in the U.S. under a Privacy Shield certification, in which case other legal mechanisms would need to be put in place.

Healthcare providers who prescribe our products and research institutions that we collaborate with are 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. Although we are not directly subject to 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.

Failure to comply with current and future federal and state laws and regulations could result in government enforcement actions (including the imposition of significant penalties), criminal and civil liability for us and our officers and directors, private litigation and/or adverse publicity that negatively affects our business.

If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EEA or Switzerland to the U.S. (or other countries not considered by the EC to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the EC. The EU General Data Protection Regulation, which was officially adopted in April 2016 and will be applicable in May 2018, will introduce new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The EU General Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. In addition, data protection authorities of the different EU member states may interpret the EU Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU.

The number and complexity of both U.S. federal and state laws continue to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In addition, we expect private plaintiffs to continue to file lawsuits against pharmaceutical manufacturers under the whistleblower provisions of the False Claims Act and state equivalents and to seek out new theories of liability under those statutes. We also expect government enforcement agencies to continue to “intervene” in private whistleblower lawsuits, effectively converting the private lawsuit into a lawsuit by the government, which typically increases the likelihood that the lawsuit will result in increased expense for the company and/or a burdensome settlement. For example, federal enforcement agencies recently have shown interest in pharmaceutical companies’ product and patient assistance programs, including manufacturer reimbursement support services and relationships with specialty pharmacies. Some of these investigations have resulted in government enforcement authorities intervening in related whistleblower lawsuits and obtaining significant civil and criminal settlements. Other private whistleblowers have proceeded without government invention, causing considerable expense to targeted companies.

Recent changes in the law have reinforced and facilitated these trends. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government’s ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, and amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations, such as defining a “false” claim to include any claim based on a violation of the anti-kickback statute. While we cannot say with certainty what effect these changes have had or will have on our business, we anticipate that increased enforcement and litigation, including through government intervention in whistleblower lawsuits and private whistleblowers proceeding on their own, will continue for the foreseeable future. Responding to a whistleblower lawsuit, government investigation or enforcement action, defending any claims raised, and paying any resulting fines, damages, penalties or settlement amounts would be expensive and time-consuming, and could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects.

Several aspects of our business may subject us to antitrust scrutiny by the FTC or to civil litigation alleging violation of the antitrust laws. For example, the FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular to whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. The FDA has recently stated that it will seek to coordinate with the FTC in identifying and publicizing practices the FTC finds to be anticompetitive and has further stated that the FDA has concerns related to the role of REMS programs in delaying approval of generic products. It is possible that the FTC, the FDA, other governmental authorities or other third parties could claim or determine that we are using the Xyrem REMS in an anticompetitive manner (including in light of the FDA’s statement in the Xyrem REMS approval letter that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the FDCA) or have engaged in other anticompetitive practices. The FDCA further states that a REMS 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. Several of the ANDA applicants have asserted that our REMS patents should not have been listed in the Orange Book, and that the Xyrem REMS is blocking competition. Another area of potential antitrust scrutiny relates to the settlement of patent litigation with potential generic competitors. Parties to such settlement agreements in the U.S. are required by law to file the agreements with the FTC and the DOJ for review. Accordingly, we and West-Ward submitted our settlement agreement to the FTC and the DOJ for review. The FTC has publicly stated that, in its view, certain brand-generic settlement agreements violate the antitrust laws and has brought actions against certain branded and generic 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) and to call on legislators to pass stronger laws prohibiting such settlements. 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. We may receive formal or informal requests from the FTC regarding our Xyrem patent settlements, including our April 2017 settlement with West-Ward, 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 this settlement, 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.

Compliance with U.S. federal and state, EU and EU member state national laws that apply to pharmaceutical manufacturers is difficult and time-consuming, and companies that violate these laws may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and, in some cases, the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. If we or the other parties with whom we work fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

We manufacture certain APIs, including the defibrotide drug substance, at our manufacturing facilities in Italy. In addition, we have engaged a third party supplier to process defibrotide into the finished product in Italy. Our manufacturing facilities and those of our third party manufacturer are subject to continuing regulation by the Italian Health Authority and other Italian regulatory authorities with respect to the manufacturing of APIs and drug products, including the defibrotide drug substance and its finished form. These facilities are also subject to inspection by the competent authorities of the EU member states and regulation by the EMA. Following initial approval in a jurisdiction, the competent authorities will continue to inspect our manufacturing facilities and those of our third party supplier, in some cases, unannounced, to confirm ongoing compliance with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures, and we and our third party suppliers will need to ensure that all of our processes, methods and equipment are compliant with cGMP. If these authorities determine that either our facilities or our third party supplier's facility in Italy do not meet the standards of compliance required under applicable regulations, they may deny approval to manufacture our products, require us to stop manufacturing our products, deny approval to the sale of our products or suspend the sale of our products.

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 and have certain price reporting obligations to the Medicaid Drug Rebate program, several state Medicaid supplemental rebate programs and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug 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 sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program, such as expanding rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well and changing the definition of average manufacturer price. The Healthcare Reform Act also increased the minimum Medicaid rebate; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount at 100% of the average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. CMS recently 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.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The Healthcare Reform Act expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula 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. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Healthcare Reform Act obligates the Secretary of the HHS to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration, or HRSA, recently updated the agreement with participating manufacturers. The Healthcare Reform Act also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2018. Implementation of this final rule and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. 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.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. 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.

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. 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 information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS 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. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

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 participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of 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 that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health Service, and U.S. Coast Guard). 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. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $178,156 for each item of false information. These obligations also contain extensive disclosure and certification requirements.

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. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the 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.

Price approvals and reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably.

In both U.S. and non-U.S. markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the U.S., governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. In many countries, price approvals must be obtained before products can be placed on the market or submitted for reimbursement. Third party payors, including government payors, decide which drugs can 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 and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement and co-pay policies. We may need to conduct expensive pharmacoeconomic and/or clinical studies in order to demonstrate the cost-effectiveness of our products. Even with such studies, our products may be considered less safe, less effective or less cost-effective than other products, and third party payors may not provide and maintain price approvals, coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies and reforms intended to curb healthcare costs, particularly given the current atmosphere of mounting criticism of prescription drug costs in the U.S. These cost containment measures may include federal and state controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; pharmaceutical cost transparency bills that aim to require drug companies to justify their prices through required disclosures; controls on healthcare providers; challenges to the pricing of drugs, or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost effectiveness research, which may be used by government and private third party payors to make coverage and payment decisions.

Additionally, 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. Several states have recently passed laws aimed at increasing transparency relating to drug pricing, and other states may do so in the future. Both the U.S. House of Representatives and the U.S. Senate have conducted several hearings with respect to pharmaceutical drug pricing practices, including in connection with the investigation of specific price increases by several pharmaceutical companies. If we become the subject of any government investigation with respect to our drug pricing or other business practices, including as they relate to the Xyrem REMS, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. Any such investigation 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. In May and October 2016 and February 2017, we received subpoenas from the U.S. Attorney’s Office for the District of

Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients and documents concerning the provision of financial assistance to Medicare patients taking drugs sold by us. For more information, see the risk factors under the headings "*Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and these changes could have a material adverse effect on our business and financial condition*" and "*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*" in this Part II, Item 1A. 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 limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

In addition, much attention has been paid to legislation proposing federal rebates on Medicare Part D and Medicare Advantage utilization for drugs issued to certain groups of lower income beneficiaries and the desire to change the provisions that treat these dual-eligible patients differently from traditional Medicare patients. Any such changes could have a negative impact on revenues from sales of our products.

Further, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

Third party payors' practices may affect the conditions required for reimbursement and the availability of reimbursement for our products, including Xyrem, Defitelio and Vyxeos. Our business could be materially harmed if the Medicaid program, Medicare program or other third party payors in the U.S. or elsewhere were to deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms. This risk is particularly significant with respect to Xyrem, Defitelio and Vyxeos, in part due to payor sensitivity to the price of these products. Third party payors often require prior authorization for, require reauthorization for continuation of, or refuse to provide reimbursement for our products, and others may do so in the future. As a result of such practices, patients may not be able to obtain prescribed medications due to an inability to afford the medication. For example, we are experiencing increasingly restrictive conditions for reimbursement required by some third party payors for Xyrem, which may have a material effect on the overall level of reimbursement coverage for Xyrem. In addition, increases in reimbursement-related activities have extended the time required to fill prescriptions and could continue to do so in the future. Further, increasing consolidation among third party payors has led to fewer and larger third party payors with increased negotiating power. In particular, a small number of third party payors cover a significant portion of Xyrem patients. We have experienced and expect to continue to experience increasing pressure from third party payors to agree to discounts, rebates or other restrictive pricing terms for Xyrem. If we are unsuccessful in maintaining reimbursement for our products in a timely manner and at acceptable levels, if reimbursement for our products by third party payors is subject to restrictive pricing terms or overly restrictive reimbursement conditions, or if third party payors limit the indications for which our products will be reimbursed or refuse to provide reimbursement, the level of reimbursement for our products would be negatively impacted, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In many countries, procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing approval. We began to commercialize Defitelio in certain European countries in 2014. The process of maintaining pricing and reimbursement approvals is complex and varies from country to country. Many European countries periodically review their reimbursement classes, which could have an adverse impact on the reimbursement status of Defitelio. We cannot predict the outcome of any periodic reviews required to maintain pricing and reimbursement approvals across Europe. If we are unable to maintain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our anticipated revenue from and growth prospects for Defitelio in the EU could be negatively affected. In addition, on March 30, 2016, the FDA approved our NDA for defibrotide for the treatment of adult and pediatric patients with VOD, also known as SOS, with renal or pulmonary dysfunction following HSCT. We launched Defitelio in the U.S. shortly after FDA approval, and our U.S. commercial launch is still at an early stage. On August 3, 2017, the FDA approved our NDA for Vyxeos for the treatment of adults with newly-diagnosed therapy-related AML or AML with myelodysplasia-related changes. We launched Vyxeos in the U.S. shortly after FDA approval, and the launch is at an early stage. Our ability to commercialize Defitelio and Vyxeos successfully in the U.S. will depend on, among other things, the continued availability of adequate coverage or reimbursement by U.S. government programs and third party payors. For more information, see the risk factor under the heading "*While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products and, in the case of our product candidates, our ability to obtain regulatory approval in the U.S. and Europe and, if approved, to successfully launch and*

commercialize those product candidates. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects" in this Part II, Item 1A.

We cannot predict actions third party payors may take, or whether they will limit the price approvals, coverage and level of reimbursement for our products or refuse to provide and maintain any approvals or coverage at all. For example, because some of our products compete in a market with both branded and generic products, obtaining and maintaining price approvals and reimbursement coverage by government and private payors may be more challenging than for new chemical entities for which no therapeutic alternatives exist. Additionally, in many countries, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness to prescribe our products. For example, the U.S. federal government follows a Medicare severity diagnosis-related group, or MS-DRG, payment system for certain inpatient hospital services provided under Medicare, which some states also use for Medicaid. The MS-DRG system entitles a hospital to a fixed reimbursement based on discharge diagnoses rather than actual costs incurred in providing inpatient treatment, thereby increasing the incentive for the facility to limit or control expenditures for many healthcare products. For our products used in the inpatient hospital setting, there may not be sufficient reimbursement under the MS-DRG to fully cover the cost of our products. We cannot be sure that reimbursement amounts, or the lack of reimbursement, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to effectively commercialize our products.

Third party payors frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices or include other restrictive pricing terms. We have experienced increasing pressure from third party payors to agree to discounts, rebates or other restrictive pricing terms for products such as Xyrem. In addition, if our competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce our sales and harm our results of operations. 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 limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Any such requirements could have a negative impact on revenues from sales of our products.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. Certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. Any failure to cover our products appropriately, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the federal marketplace. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs, including as a result of legislative changes to these programs, would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressure in the U.S. in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations, additional legislative proposals to curb healthcare costs and negative publicity regarding pricing and price increases generally, 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. 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. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. We have periodically increased the price of Xyrem, most recently in July 2017, and we have made and may in the future make similar price increases on our other products. We cannot assure you that such price adjustments (particularly in the event a generic version with a lower price than Xyrem is introduced) will not negatively affect our reputation and our ability to secure and maintain reimbursement coverage for our products, which could negatively impact our sales volumes and revenue.

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. These EU member states include the UK, France, Germany, Ireland, Italy, Spain, and Sweden. 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 focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products, as well as their potential implications for the healthcare system. Those elements of medicinal products are 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. Pursuant to Directive 2011/24/EU, a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization between EU member states of the criteria taken into account in the conduct of HTA and their impact on pricing and reimbursement decisions.

The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product, however, still vary between EU member states and cannot be determined or anticipated in relation to our products at the present time. If we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected.

In the EU, our products are marketed through various channels and within different legal frameworks. In certain EU member states, reimbursement for unauthorized products may be provided through national named patient programs. Such reimbursement may no longer be available if authorization for named patient programs expire or are terminated or when marketing authorization is granted. In other EU member states, authorization and reimbursement policies may also delay commercialization of our products, or may adversely affect our ability to sell our products on a profitable basis. 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 member states.

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

There also continue to be legislative proposals to amend U.S. laws to allow the importation into the U.S. of prescription drugs, which can be sold at prices that are regulated by the governments of various non-U.S. countries. The potential importation of prescription drugs could pose significant safety concerns for patients, increase the risk of counterfeit products becoming available in the market, and could also have a negative impact on prescription drug prices in the U.S. For example, the potential importation of Xyrem without the safeguard of our Xyrem REMS could harm patients and could also negatively impact Xyrem revenues.

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 impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Some of our products, including Xyrem and Prialt, have boxed warnings in their labels. In addition, in the EU, Defitelio's label includes an inverted black triangle that indicates the product is subject to additional monitoring to permit quick identification of new safety information, as a condition of authorization of Defitelio under "exceptional circumstances." 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 liability claims may be brought by individuals seeking relief for themselves or by groups seeking to represent a class of injured patients. Further, third party payors, either individually or as a putative class, may bring actions seeking to recover monies spent on one of our products. The risk of product liability claims may also increase if a company receives a warning letter from a regulatory agency. Product liability claims are an inherent risk in our business, but we cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, 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. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims by individuals and third party payors. In addition, product liability claims could result in an 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 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.

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. Environmental and health and safety authorities in the relevant jurisdictions administer laws, which implement EU directives and regulations 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 or any migration of such 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. Our manufacturing activities in Italy and Ireland involve the controlled storage, use and disposal of chemicals and solvents. Even if our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by these EU laws and regulations, we cannot completely eliminate the risk of contamination or injury from hazardous materials. If an accident 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 on acceptable terms, or at all. We may incur significant costs to comply with current or future EU environmental laws and regulations.

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.

As of September 30, 2017, we had total indebtedness of approximately $1.8 billion, which included $685.8 million in outstanding term loan indebtedness under a secured credit agreement that we entered into in June 2015 and subsequently amended in July 2016, which we refer to as the amended credit agreement, $575.0 million of outstanding indebtedness under our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, which were issued in August 2014, and $575.0 million of outstanding indebtedness under our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, which were issued in August 2017 and which we refer to, together with the 2021 Notes, as the Exchangeable Senior Notes.

Our debt may:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for working capital, capital expenditures, acquisitions or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- result in dilution to our existing shareholders in the event exchanges of the 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.

Our ability to meet our debt service obligations will depend on our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control. If we do not have sufficient funds to meet our debt service obligations, we may be required to refinance or restructure all or part of our existing debt, sell assets, borrow more money or sell securities, none of which we can assure you that we would be able to do in a timely manner, or at all.

Covenants in our 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 provides for a $750.0 million principal amount term loan due in July 2021 and a $1.25 billion revolving credit facility, with any loans under such revolving credit facility due in July 2021, subject to early mandatory repayments under certain circumstances. 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;
- issue redeemable preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;
- make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

The amended credit agreement also includes financial covenants that require us to maintain a maximum secured leverage ratio and a minimum interest coverage ratio. Our ability to comply with these financial covenants may be affected by events beyond our control. In addition, the covenants under the amended credit agreement could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. 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. A default under the amended credit agreement could also lead to a default under other debt agreements or obligations, including the indentures governing the Exchangeable Senior Notes.

In addition, the holders of the Exchangeable Senior Notes have the ability to require us to repurchase their notes for cash if 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. Moreover, upon exchange of the Exchangeable Senior Notes, unless we elect to cause to be delivered solely ordinary shares to settle such exchange, we will be required to make cash payments in respect of the Exchangeable Senior Notes being exchanged. In this regard, it is our intent and policy to settle the principal amount of the Exchangeable Senior Notes in cash upon exchange. However, we may not have enough available cash or be able to obtain financing at the time we are required to make any required repurchases of surrendered Exchangeable Senior Notes or to pay cash upon exchanges of the Exchangeable Senior Notes. Our failure to repurchase the Exchangeable Senior Notes at a time when the repurchase is required by the indentures governing the Exchangeable Senior Notes or to pay any cash payable on future exchanges of the Exchangeable Senior Notes as required by the indentures governing the Exchangeable Senior Notes would constitute a default under that indenture. A default under those indentures could also lead to a default under other debt agreements or obligations, including the amended credit agreement. If the repayment of the related indebtedness were to be accelerated, we may not have sufficient funds to repay the related indebtedness, which could have a material adverse effect on our financial condition and our business. In this regard, if we are unable to repay amounts under 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.

We may not be able to generate sufficient cash to service our debt obligations.

Our ability to make payments on and to refinance our debt will depend on our future financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We may be unable to maintain a level of positive cash flows from operating activities sufficient to permit us to pay the principal and interest on our debt.

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 scheduled 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. The amended credit agreement restricts our ability to dispose of assets, use the proceeds from any disposition of assets and refinance our indebtedness. We may not be able to consummate or obtain proceeds from such dispositions, and any such proceeds may not be adequate to meet any debt service obligations then due.

In addition, our borrowings under the amended credit agreement are, and are expected to continue to be, at variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even if the amount borrowed remained the same, and our net income would decrease.

To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business.

The scope of our business and operations has grown substantially since 2012 through a series of transactions, including the business combination between Jazz Pharmaceuticals, Inc. and Azur Pharma, which we refer to as the Azur Merger, our acquisition of EUSA Pharma Inc., the Gentium Acquisition and the Celator Acquisition. To continue to grow our business over the longer term, we will need to commit substantial additional resources to in-licensing and/or acquiring new products and product candidates, and to costly and time-consuming product development and clinical trials of our product candidates. We also intend to continue to invest in our commercial operations in an effort to grow sales of our current and potential future products. Our ongoing capital requirements will depend on many factors, including many of those discussed above, such as:

- the revenues from our commercial products, which may be affected by many factors, including the extent of generic or other competition for Xyrem or our other products;
- the costs of our commercial operations;
- the costs of integration activities related to any future strategic transactions we may engage in;
- the cost of acquiring and/or in-licensing any new products and product candidates;
- the scope, rate of progress, results and costs of our development and clinical activities;
- the cost and timing of obtaining regulatory approvals and of compliance with laws and regulations;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the cost of investigations, litigation and/or settlements related to regulatory oversight and third party claims; and
- changes in laws and regulations, including, for example, healthcare reform legislation.

Our strategy includes the expansion of our business through the acquisition or in-licensing and development of additional marketed products or product candidates that are in late-stage development. We cannot assure you that we will continue to identify attractive opportunities. Even if appropriate opportunities are available, in order to compete successfully to acquire attractive products or product candidates in the current business climate, we may have to pay higher prices for assets than may have been paid historically, and we may not have the financial resources necessary to pursue them. As a result, we may be unable to expand our business if we do not have sufficient capital or cannot borrow or raise additional capital on attractive terms. In particular, our substantial indebtedness may limit our ability to borrow additional funds for acquisitions or to use our cash flow or obtain additional financing for future acquisitions. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

During the past several years, domestic and international financial markets have experienced extreme disruption from time to time, including, among other things, high volatility and significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. We expect to opportunistically seek access to the capital and credit markets to supplement our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility to satisfy our needs for working capital, capital expenditures and debt service requirements or to continue to grow our business over the longer term through product acquisition and in-licensing, product development and clinical trials of product candidates, and expansion of our commercial operations. In the event of adverse capital and credit market conditions, including as a result of the potential for the UK's withdrawal from the EU to contribute to sustained instability in the global financial markets, we may not be able to obtain capital market financing or credit on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects. Changes in our credit ratings issued by nationally recognized credit rating agencies could adversely affect our cost of financing and have an adverse effect on the market price of our securities.

We may not be able to successfully maintain our tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.

We are incorporated in Ireland and maintain subsidiaries in North America and a number of other foreign jurisdictions. We are able to achieve a low average tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, together with intra-group service and transfer pricing agreements, each on an arm's length basis. However, changes in tax laws in any of these jurisdictions could adversely affect our ability to do so in the future. Taxing authorities, such as the U.S. Internal Revenue Service, or the IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. We are subject to reviews and audits by the IRS and other taxing authorities from time to time, and the IRS or other taxing authority may challenge our structure and transfer pricing arrangements through an audit or lawsuit. For example, in December 2015, we received proposed tax assessment notices from the French tax authorities for 2012 and 2013 relating to certain transfer pricing adjustments. The notices propose additional taxes of approximately $45.2 million, including interest and penalties, through the date of the assessment translated at the foreign exchange rate at September 30, 2017. Responding to or defending against this and other challenges from taxing authorities could be expensive and consume time and other resources, and divert management's time and focus from operating

our business. We generally cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging our structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds. 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 Internal Revenue Code of 1986, as amended, or the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because 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. For us to be treated as a foreign corporation for U.S. federal tax purposes under Section 7874 of the Code, either (1) the former stockholders of Jazz Pharmaceuticals, Inc. must have owned (within the meaning of Section 7874 of the Code) less than 80% (by both vote and value) of our ordinary shares by reason of holding shares in Jazz Pharmaceuticals, Inc. after the Azur Merger (the "ownership test"), or (2) we must have substantial business activities in Ireland after the Azur Merger (taking into account the activities of our expanded affiliated group). The Jazz Pharmaceuticals, Inc. stockholders owned less than 80% of our share capital immediately after the Azur Merger by reason of their ownership of shares of Jazz Pharmaceuticals, Inc. common stock. As a result, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes under current law. It is possible that the IRS could disagree with the position that the ownership test is satisfied and assert that Section 7874 of the Code applies to treat us as a U.S. corporation following the Azur Merger. There is limited guidance regarding the Code Section 7874 provisions, including the application of the ownership test described above. The IRS continues to scrutinize transactions that are potentially subject to Section 7874, and has issued several sets of final and temporary regulations under Section 7874 since 2012. In April 2016, the IRS issued temporary regulations under Section 7874 reflecting guidance that the IRS previously announced in notices dated September 2014 and November 2015, as well as additional rules. In January 2017, the IRS issued final and temporary regulations under Section 7874 making further revisions to the prior guidance. 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 retroactive application to us, Jazz Pharmaceuticals, Inc., our respective shareholders and/or the Azur Merger. For more information, see the risk factor under the heading "*Future changes to the tax laws under which we expect to be treated as a foreign corporation for U.S. federal tax purposes or to other tax laws relating to multinational corporations could adversely affect us*," in this Part II, Item 1A.

Section 7874 of the Code limits our U.S. affiliates' ability to utilize their U.S. tax attributes to offset certain U.S. taxable income, if any, generated by certain taxable transactions.

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. Based on the limited guidance available, this limitation applies to us. As a result, 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. Notwithstanding this limitation, we plan to fully utilize our U.S. affiliates' U.S. NOLs prior to their expiration. As a result of this limitation, however, it may take our U.S. affiliates longer to use their NOLs. Moreover, contrary to these plans, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent our U.S. affiliates from fully utilizing their U.S. tax attributes prior to their expiration if our U.S. affiliates do not generate sufficient taxable income.

Our U.S. affiliates' ability to use their net operating losses to offset potential taxable income and related income taxes that would otherwise be due could be subject to further limitations if we do not generate taxable income in a timely manner or if the "ownership change" provisions of Sections 382 and 383 of the Code result in further annual limitations.

Our U.S. affiliates have a significant amount of NOLs. Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, our U.S. affiliates will generate sufficient taxable income to use all of the NOLs. In addition, realization of NOLs to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the "ownership change" provisions of

Sections 382 and 383 of the Code and similar state provisions, which may result in the expiration of additional NOLs before future utilization. In general, an "ownership change" occurs if, during a three-year rolling period, there is a change of 50% or more in the percentage ownership of a company by 5% shareholders (and certain persons treated as 5% shareholders), as defined in the Code and the U.S. Treasury Department regulations, or Treasury Regulations, promulgated thereunder. In this regard, we currently estimate that, as a result of these ownership change provisions, we have an annual limitation on the utilization of certain NOLs and credits of $274.0 million, before tax effect, for 2017, $142.0 million, before tax effect, for 2018 and a combined total of $341.7 million, before tax effect, for 2019 to 2032.

However, Sections 382 and 383 of the Code are extremely complex provisions with respect to which there are many uncertainties, and we have not requested a ruling from the IRS to confirm our analysis of the ownership change limitations related to the NOLs generated by our U.S. affiliates. Therefore, we have not established whether the IRS would agree with our analysis regarding the application of Sections 382 and 383 of the Code. If the IRS were to disagree with our analysis, or if our U.S. affiliates were to experience additional ownership changes in the future, we could be subject to further annual limitations on the use of the NOLs to offset potential taxable income and related income taxes that would otherwise be due.

Future changes to the tax laws under which we expect to be treated as a foreign corporation for U.S. federal tax purposes or to other tax laws relating to multinational corporations could adversely affect us.

As described above, under current law, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes. However, changes to the Code or the Treasury Regulations or other IRS guidance promulgated thereunder, including under Section 7874 of the Code, could adversely affect our status as a foreign corporation for U.S. federal tax purposes or could otherwise affect our effective tax rate, and any such changes could have prospective or retroactive application. Recent legislative proposals have aimed to expand the scope of U.S. corporate tax residence. This legislation, if passed, could adversely affect us. In addition, the Trump Administration and many members of the U.S. Congress have called for comprehensive tax reform and have stated that U.S. tax reform should be a priority. However, the nature and extent of any legislative changes to the U.S. federal income tax regime, as well as their impact on us, are uncertain at this time. In this regard, on November 2, 2017, the U.S. House of Representatives Committee on Ways and Means released draft legislation known as the Tax Cuts and Jobs Act designed to reform the U.S. federal income tax regime. Although it is not possible to determine the impact of any tax reform on us, tax reform, if enacted, could adversely affect our effective tax rate and our results of operations and financial condition.

The U.S. Congress, the EU, the Organization for Economic Co-operation and Development and other government agencies in jurisdictions where we and our affiliates do business have also had an extended focus on issues related to the taxation of multinational corporations. One example is 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. As a result, 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.

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. As of September 30, 2017, we had recorded $4.0 billion of intangible assets and goodwill related to our past acquisitions. Intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. 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.

We have significant operations in Europe as well as in the U.S., but we report revenues, costs and earnings in U.S. dollars. Our primary currency translation exposure relates to our subsidiaries that have functional currencies denominated in the euro. Exchange rates between the U.S. dollar and the euro have fluctuated and are likely to continue to fluctuate from period to period. Because our financial results are reported in U.S. dollars, we are exposed to foreign currency exchange risk as the 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 and Erwinase 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. In this regard, when the U.S. dollar strengthens against a foreign currency, the relative value of sales made in the foreign currency decreases. Conversely, when the U.S. dollar weakens against a foreign currency, the relative value of such sales increases. Accordingly, increases in the value of the U.S. dollar relative to foreign currencies, primarily the euro, could adversely affect our foreign revenues, perhaps significantly. In addition, as we continue to expand our

international operations, we will conduct more transactions in currencies other than the U.S. dollar, which could increase our foreign currency exchange risk. Given the volatility of exchange rates, as well as our expanding operations, we cannot assure you that we will be able to effectively manage currency transaction and/or translation risks. We use foreign exchange forward contracts to manage currency risk primarily related to certain intercompany balances denominated in non-functional currencies. 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. Fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations and financial condition.

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, for example, varying between a closing price high of $162.01 on April 27, 2017 and low of $96.74 on November 3, 2016 during the period from December 31, 2015 through September 30, 2017. The market price of our ordinary shares 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 volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. In particular, negative publicity regarding pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the market for life sciences 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 Xyrem and Defitelio and to successfully commercialize Vyxeos in the U.S. In addition, we will need to minimize future supply disruptions of Erwinaze in order to meet revenue expectations for Erwinaze. The risks and uncertainties associated with our ability to maintain or increase sales of Xyrem, Erwinaze and Defitelio and to successfully commercialize Vyxeos include those discussed elsewhere in these risk factors. In the past, following periods of volatility in the market or significant price decline, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In addition, the market price of our ordinary shares may decline if the effects of our transactions, including the Celator Acquisition and/or potential future acquisitions, on the financial results of our company 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 the Exchangeable Senior Notes who may view the 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 the Exchangeable Senior Notes.

Future sales of our ordinary shares in the public market could cause our share price to fall.

Sales of a substantial number of our ordinary shares in the public market, including sales by members of our management or board of directors, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity or equity-related securities. As of October 31, 2017, we had 59,950,496 ordinary shares outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, future issuances by us of our ordinary shares upon the exercise or settlement of equity-based awards and exchanges of the Exchangeable Senior Notes would dilute existing shareholders' ownership interests in our company, and any sales in the public market of these ordinary shares, or the perception that these sales might occur, could also adversely affect the market price of our ordinary shares.

Moreover, we have in the past and may in the future grant rights to some of our shareholders that require us to register the resale of our ordinary shares on behalf of these shareholders and/or facilitate offerings of ordinary shares held by these shareholders, including in connection with potential future acquisitions of additional products, product candidates or companies. We have also filed registration statements to register the sale of our ordinary shares reserved for issuance under our equity incentive and employee stock purchase plans, and we intend to file additional registration statements to register any shares automatically added each year to the share reserves under these plans.

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 and shareholder lawsuits. Likewise, 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 jurisdiction of the U.S.

Our articles of association, shareholder rights agreement, Irish law and the indentures governing the 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. For example, our articles of association:

- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes;
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association; and
- permit our board of directors to issue one or more series of preferred shares with rights and preferences, as our shareholders may determine by ordinary resolution.

In April 2017, we adopted a shareholder rights agreement, or rights agreement, with a 12-month term under which shareholders have certain ordinary share purchase rights if a person or group acquires 10% (or 20% in the case of a “13G Investor” as defined in the rights agreement) or more of our outstanding ordinary shares without the prior approval of our board of directors. The rights agreement could make it more difficult for a person or group to acquire a majority of our outstanding ordinary shares, and could otherwise prevent or delay an acquisition of us. The rights agreement could also reduce the price that investors might be willing to pay for our ordinary shares and result in the market price of our ordinary shares being lower than it would be without the rights agreement. In addition, the existence of the rights agreement itself may deter a potential acquiror from pursuing any acquisition of us at all. As a result, either by operation of the rights agreement or by its potential deterrent effect, acquisitions of us that our shareholders may consider in their best interests may not occur.

In addition to our articles of association and the rights agreement, several mandatory provisions of Irish law could prevent or delay an acquisition of us. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent, and the shareholder approval requirements for certain types of transactions differ from those in the U.S., and in some cases are greater, under Irish law. 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 the Exchangeable Senior Notes require us to repurchase the Exchangeable Senior Notes for cash if we undergo certain fundamental changes and, in certain circumstances, to increase the exchange rate for a holder of 2021 Notes or 2024 Notes. A takeover of us may trigger the requirement that we purchase the 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 you and other shareholders to elect directors other than the candidates nominated by our board.

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

Other than funds we have allocated for the purposes of supporting our share repurchase program authorized in November 2016, we anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs, acquire or in-license additional products and product candidates, and pursue other opportunities. If we propose to pay dividends in the future, we must do so in accordance with Irish law, which provides that distributions including dividend payments, share repurchases and redemptions be funded from "distributable reserves." In addition, our ability to pay cash dividends on or repurchase our ordinary shares is restricted under the terms of the amended credit agreement. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of 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.

A transfer of our ordinary shares may be subject to Irish stamp duty.

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer. This duty is currently charged at the rate of 1.0% of the price paid or the market value of the shares acquired, if higher. Because our ordinary shares are traded on a recognized stock exchange in the U.S., an exemption from this stamp duty is available in respect of transfers by shareholders who hold our ordinary shares beneficially through brokers which in turn hold those shares through the Depository Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by or to a record holder who holds our ordinary shares directly in his, her or its own name could be subject to this stamp duty. We, in our absolute discretion and insofar as the Irish Companies Act 2014 or any other applicable law permits, may, or may provide that a subsidiary of ours will, pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of our ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of our subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

Dividends paid by us may be subject to Irish dividend withholding tax.

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to our shareholders. Shareholders that are resident in the U.S., EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish dividend withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or us or our transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

Until recently, our auditor, like other independent registered public accounting firms operating in Ireland and a number of other European countries, was not subject to inspection by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, our investors have not had the benefits of PCAOB oversight.

As an auditor of companies that are publicly-traded in the U.S. and as a firm registered with the PCAOB, our independent registered public accounting firm is required by the laws of the U.S. to undergo regular inspections by the PCAOB to assess its compliance with the laws of the U.S. and the professional standards of the PCAOB. However, because our auditor is located in Ireland, a jurisdiction where until recently the PCAOB was unable to conduct regular inspections, our auditor has not been subject to inspection by the PCAOB. In October 2017, the PCAOB entered into a cooperative agreement with the Irish Auditing and Accounting Supervisory Authority, permitting the PCAOB to conduct inspections of auditors in Ireland, effective immediately.

Inspections of other auditors conducted by the PCAOB outside of Ireland have at times identified deficiencies in those auditor's audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections in Ireland historically had prevented the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. In addition, the inability of the PCAOB to conduct auditor inspections in Ireland had made it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors located outside of Ireland that are subject to regular PCAOB inspections. As a result, our investors have been deprived of the benefits of PCAOB inspections, including with respect to our reported financial information and procedures and the quality of our financial statements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

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 Securities Exchange Act of 1934, as amended, during each fiscal month during the three-month period ended September 30, 2017:

	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)
July 1 - July 31, 2017	58,000	$ 156.21	58,000	$ 241,612,487
August 1 - August 31, 2017	51,000	$ 149.98	51,000	$ 233,964,552
September 1 - September 30, 2017	59,000	$ 150.13	59,000	$ 225,108,062
Total	168,000	$ 152.18	168,000	

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

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

(3) The ordinary shares reported in the table 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. This authorization has no expiration date.

(4) The dollar amount shown represents, as of the end of each period, 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. Exhibits

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 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.
4.2	Rights Agreement, dated as of April 5, 2017, by and between Jazz Pharmaceuticals plc and Computershare Trust Company, N.A., which includes the Form of Ownership Statement as Exhibit A and the Summary of Rights to Purchase Ordinary Shares as Exhibit B (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 April 5, 2017).
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 year 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 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.5A	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. 001-033500), 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 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on August 23, 2017).
10.1†	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)
10.2	Commercial Lease, dated as of September 28, 2017, by and between Jazz Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the SEC.

* The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q 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.

SIGNATURES

Pursuant to the requirements 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: November 7, 2017

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Registrant)

/s/ Bruce C. Cozadd

Bruce C. Cozadd

Chairman and Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Matthew P. Young

Matthew P. Young

Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

/s/ Karen J. Wilson

Karen J. Wilson

Senior Vice President, Finance
(Principal Accounting Officer)

COMMERCIAL LEASE

THIS LEASE is entered into as of September 22, 2017 (the ***"Effective Date"***), by and between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, a body having corporate powers under the laws of the State of California (***"Landlord"***), and JAZZ PHARMACEUTICALS, INC., a Delaware corporation (***"Tenant"***).

1. BASIC LEASE INFORMATION. The following is a summary of basic lease information. Each item in this Article 1 incorporates all of the terms set forth in this Lease pertaining to such item and to the extent there is any conflict between the provisions of this Article 1 and any other provisions of this Lease, the other provisions of this Lease shall control. Any capitalized term not defined in this Lease shall have the meaning set forth in the Glossary that appears at the end of this Lease.

Premises:	That certain space within a two-story building to be constructed by Landlord, consisting of a minimum of 99,000 square feet of Rentable Area and a maximum of 100,000 square feet of Rentable Area, which includes the Amenity Space (as defined in Section 2.1), is estimated to be 99,415 square feet, and is located on the property commonly known as 3181 Porter Drive, Palo Alto, California, as particularly described on the attached **Exhibit A**
Scheduled Access Date:	January 7, 2019
Term:	Twelve (12) years, commencing as of the Commencement Date, but subject to Sections 5.2 and 5.3
Commencement Date:	The earlier of (a) Tenant's occupancy of the Premises for the conduct of business, and (b) two hundred forty (240) days after the Actual Access Date, as may be extended by any Tenant Unavoidable Delays, but in no event earlier than the date on which Landlord achieves Substantial Completion of the Base Building Work (as such terms are defined in **Exhibit D**)
Expiration Date:	The day before the twelfth (12th) anniversary of the Commencement Date, subject to Sections 5.2 and 5.3
Base Rent:	$6.20 per square foot of Rentable Area per calendar month, subject to adjustment pursuant to Section 6.1

Abated Rent:	Base Rent (but not Additional Rent) shall be abated for one (1) full calendar month after the Commencement Date, which is estimated to be the sum of $616,373 ($6.20 x 99,415), subject to adjustment based on actual Rentable Area
Letter of Credit Amount:	$1,232,746, subject to reduction as provided in Section 6.5(a)
Parking:	One (1) parking space per Three Hundred (300) square feet of Rentable Area (excluding any Rentable Area considered by the City to be Amenity Space), and including those parking spaces located in the garage
Permitted Use:	Research and development, including pharmaceutical and biotech research and development, and ancillary general office uses, and including laboratories, warehousing and full service kitchen/cafeteria, to the extent permitted under City ordinances and subject to Landlord's reasonable approval
Tenant Improvement Allowance:	$50 per square foot of Rentable Area, based on the actual Rentable Area of Premises, as certified by Landlord's architect and as determined in accordance with Section 10.3 and **Exhibit D**
Addresses for Notice:	
Landlord:	The Board of Trustees of the Leland Stanford Junior University Office of Land, Buildings and Real Estate 3160 Porter Drive, Suite 200 Palo Alto, CA 94304 Attention: Associate Vice President, Real Estate E-Mail: stanfordresearchpark@stanford.edu and tgriego@stanford.edu
with a copy to:	Carol K. Dillon, Esq. Morgan Lewis & Bockius LLP 1400 Page Mill Road Palo Alto, CA 94304 E-Mail: carol.dillon@morganlewis.com

Tenant:	
	3170 Porter Drive Palo Alto, CA 94304 Attention: Ron Malouf E-mail: ronald.malouf@jazzpharma.com
with a copy to:	3180 Porter Drive Palo Alto, CA 94304 Attention: Legal Department E-mail: Jazz_Notices@jazzpharma.com
with a copy to:	
Landlord's Lockbox Instructions:	Hines AAF Stanford University Bank: Bank of America – Global ACH ABA: 111000012 Fed Wire ABA: 026009593
Brokers:	Landlord's Broker: Cushman & Wakefield Tenant's Broker: CBRE

2. PREMISES.

2.1 Premises. Subject to the terms, covenants and conditions set forth in this Lease, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. The Premises shall include certain traffic-mitigating amenity space (i.e. an on-site cafeteria, fitness center or otherwise approved by the City) to be constructed by Tenant, subject to the City's approvals (the ***"Amenity Space"***). The parties anticipate that the Amenity Space shall consist of approximately Three Thousand (3,000) feet of Rentable Area, which shall be included in the Rentable Area of the Premises for all purposes other than the calculation of parking spaces. Tenant acknowledges that the size and use of the Amenity Space, if any, is granted at the City's discretion. The building in which the Premises will be located is sometimes referred to in this Lease as the "***Building***". Notwithstanding anything to the contrary in this Lease (other than Section 9.8 and Schedule 9.8), Landlord hereby reserves the exclusive right to the exterior of all walls and the roof of the Building. The Building, which will include a below-grade parking garage, and certain improvements in the Common Area will be constructed by Landlord in accordance with the provisions of Article 1 above and the Work Letter attached to this Lease as **Exhibit D**. Together, the Premises, the Building, and the Common Area are sometimes referred to in this Lease as the ***"Property"***, and the construction of the Building and related improvements in the Common Area by Landlord is sometimes referred to as the ***"Project"***.

2.2 Common Area. Landlord hereby grants to Tenant and its officers, employees, agents, contractors, invitees, permitted subtenants and any other permitted occupants of the Premises (collectively, ***"Tenant's Agents"***) a non-exclusive license to

reasonably use the exterior areas, sidewalks, driveways, Parking Area and other public amenities that Landlord will construct on the Property (the ***"Common Area"***) during the Term. Tenant's rights to the Common Area shall be subject to the Rules and Regulations described in Section 24.1, to Landlord's reserved rights described in Article 17 and to other applicable provisions of this Lease.

2.3 Parking. Subject to the terms and conditions of this Section 2.3, during the Term, Tenant and Tenant's Agents, at no additional cost, shall have the exclusive right to all surface and underground parking within the Building and all other parking areas on the Property (the ***"Parking Area"***) for parking operable motor vehicles and for ingress to and egress from the Property in connection with Tenant's use of the Premises. Tenant's right to use the Parking Area shall be subject to the following terms and conditions:

(a) Tenant agrees that neither Tenant nor Tenant's Agents shall park in areas not designated as parking spaces, or in parking spaces on other properties owned by Landlord or its affiliates.

(b) Tenant's parking license shall not be assigned, sublet or otherwise transferred separately from the Premises.

(c) Tenant shall not at any time park, or permit the parking of commercial trucks or vehicles of Tenant or Tenant's Agents in any portion of the Common Area not designated by Landlord for such use by Tenant. Tenant shall not park nor permit to be parked any inoperative vehicles or store any materials or equipment on any portion of the Parking Area or other areas of the Common Area other than temporary storage in connection with moving and remodeling; provided however, Tenant may install, subject to Article 10, lockers in the underground portions of the Parking Area for bicycles and motorcycles, subject to all Applicable Laws and so long as Tenant does not reduce the number of parking spaces below the amount required by Applicable Laws.

(d) Tenant agrees to assume responsibility for compliance by Tenant's Agents with the parking provisions contained in this Section. Tenant hereby authorizes Landlord at Tenant's expense to attach violation stickers or notices to such vehicles not parked in compliance with this Section, and, following reasonable notice to Tenant, to tow away any such vehicles. In addition, one or more specific sections of the Parking Area may be set aside by Landlord from time to time for visitor parking for the Property, for loading purposes, for car or van pool parking for the Property, or for other specific uses for the Property as designated by Landlord.

3. ACCEPTANCE.

3.1 Lease Subject to Certain Matters. This Lease shall be subject to (a) all Applicable Laws and all zoning and other governmental regulations, requirements and conditions of approval now or hereafter in effect; (b) all liens, assessments, encumbrances, restrictions, rights and conditions of law or of record existing as of the Commencement Date; (c) any access and easement agreements and/or other agreements relating to the Pre-Existing Environmental Condition that have been entered into by Landlord, or that Landlord is required by prior agreement or governmental requirements to enter into during the Term, provided Tenant is given written notice of such agreements or requirements by Landlord; and (d) all other matters affecting title to or use of the Premises either known to Tenant or ascertainable by survey or investigation. Tenant hereby acknowledges that Landlord intends to develop and

operate a transportation hub, which may include retail and other amenities, in the vicinity of the Premises and may apply for entitlements or otherwise endeavor to negotiate agreements with the City and other governmental entities in connection with the potential development of the transportation hub. Tenant will cooperate fully with Landlord's efforts to entitle, construct and operate such transportation hub and Tenant shall not publicly oppose or object to the transposition hub or any related development efforts by Landlord. Landlord shall pay Tenant's reasonable, actual, out-of-pocket expenses related to such cooperation; provided that Tenant notifies Landlord in writing in advance of the expenditure.

3.2 Acceptance; AS-IS. The Premises as furnished by Landlord will consist of the Base Building Work (as defined in **Exhibit D**) to be provided by Landlord pursuant to **Exhibit D**, and Landlord shall have no obligation for any other construction work or improvement on or to the Property. Prior to entering into this Lease, Tenant has made a thorough and independent examination of all matters related to Tenant's decision to enter into this Lease. Except as expressly set forth in this Lease, Tenant does not rely on, and Landlord does not make, any express or implied representations or warranties as to any matters including, without limitation, (a) the physical condition of the Property, (b) the quality or adequacy of utilities serving the Property, (c) the size of the Premises, the Building or the Property (d) the use, habitability, merchantability, fitness or suitability of the Premises for the Permitted Use, (e) the likelihood of deriving business from Tenant's location or the economic feasibility of Tenant's business, (f) Hazardous Substances in the Premises, or on, in, under or around the Property (including those that may impact indoor air quality), (g) zoning, entitlements or any Applicable Laws which may apply to Tenant's use of the Premises or business operations, or the Property's compliance with Applicable Laws, or (h) any other matter. Tenant has satisfied itself as to such suitability and other pertinent matters by Tenant's own inquiries and tests into all matters relevant in determining whether to enter into this Lease. Upon Substantial Completion of the Base Building Work (as defined in **Exhibit D**), Tenant shall acknowledge that the Premises is in good, condition and repair, and accept (or by occupying the Premises be deemed to have accepted) the physical condition of the Premises and the Building in their then-existing "as-is" condition, subject to any punch-list items as provided in **Exhibit D,** and Landlord's delivery, maintenance and restoration obligations set forth in this Lease. Further, it is understood that the acceptance of the Premises by Tenant in its then-existing "as-is" condition shall not limit Landlord's obligation to complete any Base Building Work and to enforce all third-party warranties pertaining to the Base Building Work as provided in **Exhibit D**.

3.3 Access. Without limiting the foregoing provisions of this Article 3, in accordance with California Civil Code Section 1938, Landlord notifies Tenant that neither the Premises nor the Property have been inspected by a Certified Access Specialist (***"CASp"***). Landlord and Tenant agree and acknowledge, as required by California Civil Code Section 1938, the following:

> "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of

making any repairs necessary to correct violations of construction-related accessibility standards within the premises."

Landlord and Tenant agree and acknowledge that Tenant shall be solely responsible for the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Premises identified by the CASp inspection, subject to Landlord's obligations with respect to the Base Building Work and any contrary provisions set forth in this Lease.

3.4 Energy. Landlord and Tenant acknowledge that, notwithstanding California Public Resources Code Section 25402.10, because the Building is not yet constructed and Tenant will be its first occupant, Landlord will be unable to provide Tenant with electricity and gas usage benchmarking data and ratings for the Premises. After the Commencement Date, if Tenant is billed directly by a utility company with respect to Tenant's electricity and gas usage at the Premises, then, promptly upon request, Tenant shall provide monthly electricity and gas usage data for the Premises to Landlord for the period of time requested by Landlord (in electronic or paper format) or, at Landlord's option, provide any written authorization or other documentation required for Landlord to request information regarding Tenant's electricity and gas usage data with respect to the Premises directly from the utility company. Tenant acknowledges and consents to Landlord's use and disclosure of such information to the extent required to comply with California Public Resources Code Section 25402.10.

4. CONTINGENCIES.

4.1 Failure to Achieve Substantial Completion. If Landlord has not achieved Substantial Completion (as further defined and described in **Exhibit D**) of the Base Building Work, pursuant to Section 2.7 of **Exhibit D**, by March 1, 2019 (the ***"Outside Completion Date"***), as such date is extended due to Landlord's Unavoidable Delay (as defined in **Exhibit D**) and Landlord's failure causes a delay in Tenant's completion of Tenant's Improvement Work (approved by Landlord as set forth in **Exhibit D**) resulting in delay in Tenant's occupancy of the Premises past September 4, 2019, (a) the validity of this Lease and the obligations of Tenant under this Lease shall not be affected by any such delay, (b) Tenant shall have no claim against Landlord arising out of Landlord's failure to achieve Substantial Completion, and (c) Tenant's sole remedy shall be Tenant's receipt of a credit of one (1) additional day free Base Rent for every day from the Outside Completion Date to the date Landlord achieves Substantial Completion of the Base Building Work. By way of example, if Landlord achieves Substantial Completion twenty-five (25) days after the Outside Completion Date, then the Rental Abatement Period, as defined in Section 6.2 below, shall increase by twenty-five (25) days.

4.2 Tenant Delay. Notwithstanding the foregoing, if Landlord is delayed in the delivery of access beyond the Scheduled Access Date because of Tenant Delays (as defined in **Exhibit D**), then (a) the Actual Access Date shall be deemed to have occurred on the date on which Landlord could have delivered access to the Premises to Tenant but for such Tenant Delays, (b) the time period for the determination of the Commencement Date shall commence, and (c) to the extent Landlord is delayed in achieving Substantial Completion of the Base Building Work due to any Tenant Delays, the Outside Completion Date shall be delayed by one day for each day of delay caused by Tenant Delays. If Tenant has not satisfied the requirements to obtain Landlord's approval of Tenant's plans for the Tenant Improvement Work as set forth in Section 3.3 of **Exhibit D** or any construction requirements with respect to Tenant

Improvement Work as set forth in Section 4 of **Exhibit D** in the timeframes set forth therein, Tenant shall not be eligible for the credit of Base Rent described in Section 4.1.

5. TERM.

5.1 Term. Subject to the contingencies set forth in Article 4, the Premises are leased for a term (the ***"Term"***) commencing on the Commencement Date and ending on the Expiration Date, unless it is earlier terminated in accordance with this Lease. As of the Effective Date, the parties anticipate that the Premises will be delivered to Tenant for the construction of the Tenant Improvement Work on or before the Scheduled Access Date set forth in Article 1. As of the Effective Date, the parties anticipate that the Base Building Work (as defined in **Exhibit D**) shall be Substantially Complete on or before the date estimated for Substantial Completion set forth as Item #10 in the Schedule (the actual date being the ***"Substantial Completion Date"***). The Term shall end on the Expiration Date, or such earlier date on which this Lease terminates pursuant to its terms. The date upon which this Lease actually terminates, whether by expiration of the Term or earlier termination pursuant to the terms of this Lease, is sometimes referred to in this Lease as the ***"Termination Date"***. After the Commencement Date has been determined, Landlord shall specify in a written notice to Tenant, substantially in the form of **Exhibit B**, the Commencement Date and Expiration Date of this Lease, the actual Rentable Area and the Base Rent and Tenant Improvement Allowance, and other terms herein based upon Rentable Area (based on the actual Rentable Area of the Premises as determined in accordance with Section 10.3). Such notice shall be delivered promptly after all of the information set forth in the notice has been determined; provided that Landlord's failure to do so shall not in any way affect either party's rights or obligations under this Lease.

5.2 Renewal Option. Tenant shall have two (2) options (each, a ***"Renewal Option"***) to extend the Term of the Lease for the entire Premises then being leased to Tenant for terms of five (5) years each (each, a ***"Renewal Term"***). If the first Renewal Option is exercised, the first Renewal Term shall commence on the day after the Expiration Date. If the second renewal term is exercised, the second Renewal Term shall commence on the day after the Expiration Date of the first Renewal Term. Each Renewal Option shall be void if an Event of Default by Tenant exists, either at the time of exercise of such Renewal Option or the time of commencement of such Renewal Term. The second Renewal Term shall be void if Tenant fails to exercise the first Renewal Option. Each Renewal Option must be exercised, if at all, by written notice from Tenant to Landlord given not more than eighteen (18) months and not less than twelve (12) months prior to the expiration of the Term (as previously extended, if applicable). Each Renewal Term shall be upon the same terms and conditions as the original Term, except that (a) the Base Rent payable pursuant to Section 6.1 with respect to each Renewal Term shall be equal to ninety-five percent (95%) of the Prevailing Market Rent as of the commencement of the Renewal Term, as determined pursuant to **Exhibit C**, (b) Tenant shall not be entitled to any Tenant Improvement Allowance during the Renewal Term, (c) the L-C Amount shall remain as the amount determined in accordance with Section 6.5(a) below; and (d) from and after the exercise of a Renewal Option, (i) all references to "Expiration Date" shall be deemed to refer to the last day of the Renewal Term, and (ii) all references to "Term" shall be deemed to include the Renewal Term. The Renewal Options are personal to Tenant and shall be inapplicable and null and void if Tenant assigns its interest under this Lease to any Transferee other than a Permitted Transferee. Landlord shall not be responsible for any commissions or fees related to Tenant's exercise of the Renewal Option.

5.3 Early Termination. So long as Tenant has not assigned its interest in the 3170 Porter Lease (other than to a Permitted Transferee) or extended the term of the 3170 Porter Lease, Tenant shall have a one-time right to terminate this Lease (the ***"Early Termination Option"***) as of the expiration date of the 3170 Porter Lease at the end of its initial twelve (12) year term (and not the date of an earlier voluntary or involuntary termination of the 3170 Porter Lease) (the ***"Termination Option Date"***). In order to exercise the Early Termination Option, Tenant must deliver written notice to Landlord no later than twelve (12) months prior to the Termination Option Date. The Early Termination Option shall have no force or effect, and this Lease shall not terminate unless at least sixty (60) days prior to the Termination Option Date Tenant pays to Landlord (a) reimbursement of all unamortized costs incurred by Landlord in connection with this Lease for brokers' commissions and the Tenant Improvement Allowance (amortized over the Term using straight-line amortization with no interest) calculated as of the date that is three (3) months after the Termination Option Date (the ***"Termination Reimbursement Amount"***); plus (b) a termination fee equal to three (3) months' of Base Rent in the amount that would otherwise have been due for the three (3) months of the Term following the Termination Option Date (together with the Termination Reimbursement Amount, the ***"Termination Fee"***). For the purposes of the Termination Reimbursement Amount calculation, the parties agree that the Termination Option Date shall be presumed to have occurred on the first day of the month in which the Termination Option Date occurred. Upon Tenant's written request, Landlord shall promptly provide the amount and formula for the Termination Reimbursement Amount. Tenant's failure to deliver the Termination Fee (or a reasonable estimate in the event Landlord fails to timely provide the amount and formula for the Termination Reimbursement Amount) at least sixty (60) days prior to the Termination Option Date shall render Tenant's termination notice null and void. The Early Termination Option shall, at Landlord's option, be void if an Event of Default by Tenant exists, at the time of exercise of such Early Termination Option, on the date the Termination Fee is paid, or on the Termination Option Date. If for any reason Tenant's exercise of its Early Termination Option is not effective, this Lease shall remain in full force and effect as if the Early Termination Option had not been exercised by Tenant and the Termination Fee shall be held by Landlord and applied against Rent as it becomes due hereunder.

6. RENT.

6.1 Base Rent. Commencing on the Commencement Date (but subject to Section 6.2 below), and thereafter during the Term, Tenant shall pay to Landlord the monthly Base Rent specified in Article 1 on or before the first day of each month, in advance, without any prior notice or demand and without any deductions or offset whatsoever (except as otherwise expressly provided in this Lease). Base Rent shall be paid by wire transfer pursuant to the instructions set forth in Article 1 or, if requested by Landlord, at the address specified for Landlord in Article 1 or at such other place as Landlord designates in writing. If the Commencement Date occurs on a day other than the first day of a calendar month, or the Termination Date occurs on a day other than the last day of a calendar month, then the Base Rent for such fractional month will be prorated on the basis of the actual number of days in such month. Base Rent shall be increased on the first day of the thirteenth (13th) month following the first anniversary of the Commencement Date and on the anniversary of such date thereafter (each, an ***"Adjustment Date"***) by three percent (3%) over the Base Rent for the immediately preceding twelve (12) month period.

6.2 Abated Rent. Tenant's payment of Base Rent (but not including payment of Additional Rent, as defined in Section 6.3), shall be abated for one (1) full calendar month after the Commencement Date (the ***"Rent Abatement Period"***), so long as no Event of

Default occurs during the Rent Abatement Period. If an Event of Default occurs during the Rent Abatement Period, Tenant shall not be entitled to any abatement of Base Rent under this Section 6.2, unless during the Rent Abatement Period, Tenant cures the Event of Default, in which case Tenant shall be entitled to prorated abatement of Base Rent based on the number of days during the Rent Abatement Period in which there was no Event of Default.

6.3 Additional Rent. All sums due from Tenant to Landlord or to any third party under the terms of this Lease (other than Base Rent) shall be additional rent (***"Additional Rent"***), including without limitation the charges for Operating Expenses (described in Article 8), TDM Fees (described in Section 7.3), and all sums incurred by Landlord due to Tenant's failure to perform its obligations under this Lease. Tenant's obligation to pay Additional Rent shall commence on the Commencement Date. All Additional Rent that is payable to Landlord shall be paid at the time and place that Base Rent is paid, unless otherwise specifically provided in this Lease. Landlord will have the same remedies for a default in the payment of any Additional Rent as for a default in the payment of Base Rent. Together, Base Rent and Additional Rent are sometimes collectively referred to in this Lease as ***"Rent"***.

6.4 Late Fee. Any unpaid Rent shall bear interest from the date due until paid at the Interest Rate. In addition, Tenant recognizes that late payment of any Rent will result in administrative expense to Landlord, the extent of which expense is difficult and economically impracticable to determine. Therefore, Tenant agrees that if Tenant fails to pay any Rent within five (5) days after its due date, a one-time late fee for the applicable month of five percent (5%) of the overdue Rent for the applicable month shall become immediately due and payable. Notwithstanding the foregoing, if Tenant is late in payment of Rent and it is Tenant's first late payment in that calendar year, then provided there have been no more than three (3) late payments during the Term, Landlord agrees not to charge a late charge if Tenant has delivered the Rent payment within five (5) Business Days after written notice from Landlord to Tenant that the Rent payment has not been received. Tenant agrees that the late fee is a reasonable estimate of the additional administrative costs and detriment that will be incurred by Landlord as a result of such failure by Tenant. In the event of nonpayment of interest or late fees on overdue Rent, Landlord shall have, in addition to all other rights and remedies, the rights and remedies provided in this Lease and by law for nonpayment of Rent.

6.5 Letter of Credit. Within fifteen (15) Business Days following the full execution of this Lease, Tenant shall deliver to Landlord a letter of credit as described in this Section 6.5.

(a) The letter of credit (***"L-C"***) shall be a clean, unconditional irrevocable letter of credit in the initial amount set forth in the Basic Lease Information, to be delivered concurrently with the execution of this Lease. Provided there is no outstanding Event of Default under this Lease, the L-C shall be reduced to one (1) month's Base Rent (based on the initial Base Rent as determined upon certification of the actual Rentable Area of the Premises) on the third (3rd) anniversary of the Commencement Date. The amount of the L-C from time to time is sometimes referred to in this Lease as the ***"L-C Amount"***. Tenant shall not replace or substitute the L-C without Landlord's prior written consent, which Landlord may withhold in its sole and absolute discretion.

(b) If (i) there is an Event of Default by Tenant with respect to any provisions of this Lease (including but not limited to the payment of Rent); (ii) Tenant files a petition in bankruptcy, insolvency, reorganization, dissolution or liquidation under any law; (iii) Tenant makes an assignment for the benefit of its creditors; (iv) Tenant consents to or

acquiesces in the appointment of a receiver of itself or the Premises; (v) if a court of competent jurisdiction enters an order or judgment appointing a receiver of Tenant or the Premises; or (vi) if a court of competent jurisdiction enters an order or judgment approving a petition filed against Tenant under any bankruptcy, insolvency or liquidation law (individually and collectively, an ***"L-C Event"***), then in any such case Landlord may, without waiving any of Landlord's other rights or remedies under this Lease, draw down the L-C Amount in whole or in part to remedy any failure by Tenant to pay any sums due under this Lease, to repair or maintain the Premises, to perform any other terms, covenants or conditions contained in this Lease, to compensate Landlord for any loss or damages which Landlord may suffer as a result thereof, including without limitation any lost rent to which Landlord is entitled in the event the Lease terminates or is rejected as a result of any of the foregoing, and the cost of reletting the Premises upon any termination of this Lease. Should Landlord so apply any portion of the L-C Amount, Tenant shall replenish the L-C to the original L-C Amount within fifteen (15) Business Days after written demand by Landlord.

(c) The L-C shall be issued by a money-center bank (a solvent, nationally recognized bank with a long term rating of BBB, or higher, under the supervision of the Superintendent of Banks of the State of California, or a national banking association, which accepts deposits, maintains accounts, has a local California office which will negotiate the L-C, and whose deposits are insured by the FDIC) reasonably approved by Landlord (the ***"Bank"***) and shall be in a form that is reasonably acceptable to Landlord in Landlord's reasonable discretion. The Bank shall be a bank that accepts deposits, maintains accounts, has a local Santa Clara County office that will negotiate the L-C, or if no local office then the L-C shall provide for draws by Landlord upon delivery of the written draw request by courier or by fax (to be confirmed by telephone and with original to follow by overnight courier) and payment to be made by wire transfer to Landlord's account as directed by Landlord upon receipt of the original or fax request. If Landlord notifies Tenant in writing that the Bank that issued the L-C has become financially unacceptable in Landlord's reasonable opinion, then Tenant shall have thirty (30) days to provide Landlord with a substitute L-C complying with all of the requirements hereof and issued by a Bank reasonably approved by Landlord. If Tenant does not so provide Landlord with a substitute L-C within such time period, then Landlord shall have the right to draw upon the current L-C and shall hold the proceeds as provided in Section 6.5(f) below. Tenant shall pay all expenses, points, or fees incurred by Tenant in obtaining or extending the L-C. The L-C shall be available by draft at sight, subject only to receipt by the Bank of a statement from Landlord certifying that a matter allowing Landlord to draw upon the L-C Amount under the terms of this Lease has occurred. The L-C shall: (i) name Landlord as beneficiary; (ii) allow Landlord to make partial and multiple draws thereunder up to the face amount, as determined by Landlord in its sole discretion, upon an L-C Event by Tenant, or in the event Tenant fails to deliver a substitute L-C as provided in this paragraph; and (iii) provide that Landlord can freely transfer it in its entirety upon an assignment or other transfer of its interest in this Lease to the assignee or transferee, without charge to Landlord and without recourse, and without having to obtain the consent of Tenant or the Bank. If transfer fees are assessed as a result of any transfer of the L-C by Landlord, Tenant shall pay such fees. Tenant shall cooperate as required by Landlord and Bank to cause Bank to transfer the L-C to Landlord's assignee or transferee within fifteen (15) Business Days after Landlord's written request, subject to Landlord surrendering the original L-C if a replacement L-C will need to be obtained. Tenant shall maintain in effect the L-C, which shall by its terms expire not less than one (1) year from the date issued and shall provide for automatic one (1) year extensions continuing until the date that is one hundred twenty (120) days after the Termination Date. If the L-C will not be renewed or extended through this period, Tenant shall notify Landlord in writing not less than ninety (90) days prior to the expiration of the L-C. Upon receipt of such notice, Landlord shall have the right

to immediately draw upon the current L-C in an amount up to the face amount of the L-C and shall hold the proceeds as provided in Section 6.5(f) below. If after receipt of notice that the L-C will not be renewed or extended through the date that is one hundred twenty (120) days after the Termination Date and Landlord does not in its sole and absolute discretion draw down upon the current L-C, Tenant, subject to Landlord's written approval (which may be withheld in Landlord's sole and absolute discretion, shall deliver a new L-C or certificate of renewal or extension to Landlord at least sixty (60) days before the expiration of the L-C then held by Landlord. Tenant's failure to so deliver, renew (including specifically but not limited to the delivery to Landlord of such renewal not less than sixty (60) days prior to expiration of the L-C) and maintain such L-C, shall entitle Landlord to fully draw the L-C. If any portion of the L-C is drawn upon as permitted herein and not held by Landlord as a cash security deposit as provided in Section 6.5(f) below, Tenant shall, within fifteen (15) Business Days after written demand therefor from Landlord, reinstate the L-C to the full L-C Amount, and Tenant's failure to do so shall be an Event of Default. The L-C shall not be mortgaged, assigned or encumbered in any manner whatsoever by Tenant.

(d) Landlord and Tenant (i) acknowledge and agree that in no event or circumstance shall the L-C or any renewal thereof or substitute therefor be deemed to be or treated as a "security deposit" under any law applicable to security deposits in the commercial context, including, but not limited to, Section 1950.7 of the California Civil Code, as such Section now exists or as it may be hereafter amended or succeeded (the "***Security Deposit Laws***"), (ii) acknowledge and agree that the L-C (including any renewal thereof or substitute therefor) is not intended to serve as a security deposit, and the Security Deposit Laws shall have no applicability or relevancy thereto, and (iii) waive any and all rights, duties and obligations that any such party may now, or in the future will, have relating to or arising from the Security Deposit Laws. Tenant hereby irrevocably waives and relinquishes the provisions of Section 1950.7 of the California Civil Code and any successor statute, and all other provisions of law, now or hereafter in effect, which (A) establish the time frame by which a landlord must refund a security deposit under a lease, and/or (B) provide that a landlord may claim from a security deposit only those sums reasonably necessary to remedy defaults in the payment of rent, to repair damage caused by a tenant or to clean the premises, it being agreed that Landlord may, in addition, claim those sums specified in this Section, and/or those sums reasonably necessary to (y) compensate Landlord for any loss or damage caused by Tenant's breach of this Lease, including any damages Landlord suffers following termination of this Lease, and/or (z) compensate Landlord for any and all damages arising out of, or incurred in connection with, the termination of this Lease, including, without limitation, those specifically identified in Section 1951.2 of the California Civil Code.

(e) On the date that is one hundred twenty (120) days after the Termination Date, Landlord shall return the L-C to Tenant, and/or any cash L-C Amount that Landlord holds due to Landlord having drawn the L-C pursuant to this Section 6.5; provided that during such one hundred twenty (120) days Landlord has not determined that Tenant failed to surrender the Premises in the condition required pursuant to this Lease and there has been an L-C Event hereunder, in which case Landlord may deduct only those L-C proceeds the amounts that Landlord may deduct legally from a cash security deposit, as modified herein.

(f) In the event at any time Landlord draws on the L-C, and to the extent any portion of the L-C Amount is not used by Landlord to cure a breach by Tenant, compensate for non-payment of Rent or the like, the cash L-C Amount shall be delivered to Landlord, in which case Landlord shall hold the cash as a security deposit, but shall not be required to keep the cash L-C Amount separate from its general funds, and Tenant shall not be

entitled to interest on the cash L-C Amount. If Tenant has fully complied with all of the terms, covenants and conditions of this Lease, the cash L-C Amount (less any amount applied to cleaning, repairing damage to the Premises caused by Tenant or otherwise applied in accordance with the provisions of this Lease) shall be returned to Tenant after the Termination Date and after delivery of possession of the Premises to Landlord in the manner required by this Lease. In the event of any Assignment of this Lease by Tenant, such Assignment shall be deemed to include an assignment of Tenant's rights to recover the L-C Amount, and Landlord's agreement to return the L-C Amount shall run only to Tenant's assignee and not to the original Tenant. Tenant hereby expressly waives the provisions of California Civil Code Section 1950.7 or under any similar law, statute or ordinance now or hereafter in effect.

7. USE OF PREMISES AND CONDUCT OF BUSINESS.

7.1 Permitted Use. Tenant may use and occupy the Premises during the Term solely for the Permitted Use, unless Landlord consents to any other use in Landlord's sole discretion. Tenant's use of the Property shall in all respects comply with all Applicable Laws.

7.2 Prohibited Uses. Tenant shall not use the Premises or allow the Premises to be used for any illegal purpose, or so as to create waste, or constitute a private or public nuisance. Tenant shall use reasonable efforts to maintain cooperative relations with Landlord and the occupants of neighboring buildings in the vicinity of the Property. Such cooperation shall include, as reasonably requested by Landlord (a) responding to complaints regarding operational issues (i.e., lighting, parking, noise, etc.), (b) designating a representative to handle any issues that may arise, and (c) advising Tenant's employees regarding issues of concern to Tenant's neighbors. Tenant shall not place any loads upon the floors, walls, or ceiling that endanger the structure, or overload existing electrical or other mechanical systems. Tenant shall not use any machinery or equipment which causes any substantial noise or vibration. Tenant shall not engage in any action or inaction that (i) jeopardizes the Building's LEED or Energy Star ratings, or (ii) compromises Landlord's sustainability goals for the Building as communicated in writing to Tenant. No waste materials or refuse shall be dumped upon or permitted to remain upon any part of the Premises or outside of the Premises except in trash containers placed inside exterior enclosures designated by Landlord for that purpose or inside of the Premises where approved by Landlord. No materials, supplies, equipment, finished products or semi-finished products, raw materials or articles of any nature shall be stored upon or permitted to remain outside the Premises or on any portion of the Common Area unless otherwise approved by Landlord in its reasonable discretion. No loudspeaker or other device, system or apparatus which can be heard outside the Premises shall be used in or at the Premises without the prior written consent of Landlord. No explosives or firearms shall be brought into the Premises. Landlord shall have the right to enter and conduct an inspection of the Premises, at any reasonable time and upon reasonable advance notice, to determine whether Tenant is complying with the terms of this Section 7.2. In the event such inspection identifies any deficiencies in Tenant's compliance with the terms of this Section 7.2, Tenant shall promptly correct such deficiency and shall reimburse Landlord within ten (10) days after written demand as Additional Rent for any reasonable third-party costs incurred by Landlord in connection with such inspection.

7.3 Transportation Demand Management Operational Obligations. Tenant shall (and shall cause any and all occupants and subtenants to) cooperate with Landlord in facilitating and coordinating the Transportation Demand Management programs implemented in the Stanford Research Park by Landlord. Tenant's obligations with respect to such program shall include without limitation, designating a Transportation Demand Management liaison for

Tenant and for each subtenant under a permitted sublease, supporting a transportation management association approved by Landlord, responding to and collecting responses from subtenants, employees and visitors to transportation related surveys, distributing information related to the program to subtenants, employees, and visitors, and encouraging subtenants, employees, contractors, and visitors to cooperate with and participate in such programs. Tenant shall provide to Landlord on each anniversary of the Commencement Date a reasonably detailed report regarding the number of persons working at the Premises and how such persons typically commute to the Premises. Tenant shall (or cause each employer located in the Premises to) use reasonable efforts to cause its employees to cooperate in the completion and return of transportation related surveys at a response rate of 70% or higher, when and as requested by Landlord or its designated transportation coordinator or independent consultant, but no more often than twice per calendar year. Cooperation with the Transportation Demand Management programs shall include Tenant's paying Tenant's proportionate share of the reasonable cost of any current or future Transportation Demand Management program serving the Stanford Research Park, whether implemented by Landlord, City or any other governmental agency, including without limitation fees imposed by Landlord, fees imposed by a transportation management association that Landlord has joined or similar program, and any fees imposed by any governmental agencies (collectively, ***"TDM Fees"***). TDM Fees may be based on the costs of on-going monitoring as well as the costs of Transportation Demand Management measures. Tenant's share of TDM Fees imposed by Landlord or by a transportation management association shall be assessed pro rata and on a non-discriminatory basis, based on a reasonable standard applied in a non-discriminatory manner (for example, based on the rentable area of the Improvements as compared to the total rentable area of the Stanford Research Park (or the area being served, if less than the entire Stanford Research Park), or based on the average employee headcount in the Premises as compared to the overall employee density of the Stanford Research Park). In the event a TDM Fee is assessed specifically for Premises or Tenant's building(s) and/or business operations on the Premises by the City or other governmental agency, and Tenant pays such fee directly to the City or other governmental agency, the direct payment shall fully satisfy Tenant's liability under this Section 7.3, unless Landlord adopts an additional Transportation Demand Management Program for the Stanford Research Park that funds services or programs that are different from those funded through the TDM Fee assessed by the City or other governmental agency. For the avoidance of doubt, any City-imposed tax based on gross receipts, payroll or employee head count would not be considered a TDM Fee, and Tenant's payment of such tax would not exempt Tenant from its obligation to pay TDM Fees or any other requirements of this Section 7.3.

8. OPERATING EXPENSES.

8.1 Net Lease. This Lease is intended to be a net lease, and the Base Rent and all Additional Rent are to be paid by Tenant absolutely net of all costs and expenses relating to Landlord's ownership, operation and maintenance of the Property during the Term of this Lease, except as specifically provided in this Lease. The provisions of this Article 8 for the payment of Operating Expenses are intended to make Tenant responsible for all such costs and expenses that are incurred by Landlord in connection with the ownership, operation and maintenance of the Property during the Term of this Lease, subject to the limitation and amortization provisions set forth below.

8.2 Operating Expenses. ***"Operating Expenses"*** means the total actual costs and expenses paid or incurred by Landlord in connection with the ownership, management, operation, maintenance, repair and replacement of the Property, including,

without limitation, all costs of:

(a) taxes, assessments and charges levied upon or with respect to the Property or any personal property of Landlord used in the operation of the Property, or on Landlord's interest in the Property or its personal property (***"Real Estate Taxes"***). Real Estate Taxes shall include, without limitation, all general real property taxes and general and special assessments, charges, fees, or assessments for transit, housing, police, fire, or other governmental services or purported benefits to the Property or the occupants thereof, service payments in lieu of taxes that are now or hereafter levied or assessed against Landlord by the United States of America, the State of California or any political subdivision thereof, or any other political or public entity, and shall also include any other tax, assessment or fee, however described, that may be levied or assessed as a substitute for, or as an addition to, in whole or in part, any other Real Estate Taxes, whether or not now customary or in the contemplation of the parties as of the Commencement Date, including any general or supplemental real property taxes assessed as a result of a change in the assessed value of the Property following or in connection with any transfer of the Property by Landlord. Real Estate Taxes shall also include reasonable legal fees, costs, and disbursements incurred in connection with proceedings to contest, determine, or reduce Real Estate Taxes; provided that Landlord shall return to Tenant Tenant's proportionate share of such reduction in Real Estate Taxes, net of such fees, costs and disbursements. Real Estate Taxes shall not include franchise, transfer, succession, gift, inheritance, gross receipts or capital stock taxes or income taxes measured by the net income of Landlord unless, due to a change in the method of taxation, any of such taxes is levied or assessed against Landlord as a substitute for, or as an addition to, in whole or in part, any other tax that would otherwise constitute a Real Estate Tax. Without limiting the generality of the foregoing, Landlord shall have the right, in its sole discretion, but not the obligation, to cause all Real Estate Taxes applicable to the Property to be segregated from other real property owned by Landlord, and to have such Real Estate Taxes billed directly to Tenant by the Santa Clara County Assessor. In the event Landlord exercises such right, Tenant shall be liable for and shall pay before delinquency all such Real Estate Taxes and shall deliver satisfactory evidence of such payment to Landlord before delinquency;

(b) repair, maintenance, replacement and supply of any air conditioning, electricity, steam, water, heating, ventilating, mechanical, lighting, solar panels, automobile charging stations, elevator systems, sanitary and storm drainage systems and all other utilities and mechanical systems (the ***"Building Systems"***) provided that the cost of any capital improvements, repairs and replacements shall be subject to subsection (o) below;

(c) lighting, landscaping and gardening of the Common Area;

(d) cleaning, lighting, repaving, resealing, repairing, maintaining and restriping of the Parking Area, sidewalks, loading areas, driveways and vehicular entrances and exits at or serving the Property; provided that the cost of any capital improvements, repairs and replacements shall be subject to subsection (o) below;

(e) repair, maintenance and replacement of the Common Area; provided that the cost of any capital improvements, repairs and replacements shall be subject to subsection (o) below;

(f) repair, maintenance and replacement of any building access systems and fire protection systems installed in the Premises; provided that the cost of any capital improvements, repairs and replacements shall be subject to subsection (o) below;

(g) general maintenance, janitorial services, window cleaning, trash removal, cleaning and service contracts and the cost of all supplies, tools and equipment required in connection therewith;

(h) the costs of all utilities and services furnished to or used at the Premises and not paid for directly by Tenant, including the cost of renewable and green energy resources.

(i) all premiums, premium equivalents, and other costs for insurance carried by Landlord on the Premises, the Common Area and the Property, or in connection with the use or occupancy thereof (including all amounts paid as a result of loss sustained that would be covered by such policies but for deductibles or self-insurance retentions and all amounts not covered by insurance proceeds), including, but not limited to, the premiums and costs of fire and extended coverage, earthquake, flood, vandalism and malicious mischief, commercial liability and property damage, worker's compensation insurance, rental income insurance and any other insurance commonly carried by prudent owners of comparable buildings; provided, however, that the Landlord may, but shall not be obligated to carry earthquake insurance;

(j) wages, salaries, payroll taxes and other labor costs and employee benefits for all on-site and off-site persons engaged in the operation, management, maintenance and security of the Property, equitably allocated by Landlord to the extent one or more employees do not work full time at or on behalf of the Premises;

(k) a management fee equal to two percent (2%) of then-current Base Rent (whether or not Landlord employs a third party manager);

(l) fees, charges and other costs of all independent contractors and consultants engaged by Landlord to assess the Property or to insure compliance with Applicable Laws (storm water regulations, TDM reporting and ADA compliance) and LEED or Energy Star certification criteria;

(m) license, permit and inspection fees;

(n) the cost of supplies, tools, machines, materials and equipment used in operation and maintenance of the Common Area;

(o) the cost of any capital repairs, improvements or replacements to the Property, including without limitation those that are required by Applicable Laws (other than those required in connection with the Base Building Work), or that are made by Landlord to reduce energy or other utility costs or requirements (including LEED certification); provided that the cost of any such capital improvements, repairs and replacements shall be amortized over the useful life of the improvement, repair or replacement in question (determined in accordance with GAAP), together with interest on the unamortized balance at the rate of seven and one-quarter percent (7.25%) until fully paid;

(p) the cost of reasonably contesting the validity or applicability of any governmental enactments that may affect Operating Expenses;

(q) audit and bookkeeping fees, legal fees and expenses incurred in connection with the operation or management of the Property;

(r) reasonable allocation of costs for an off-site or on-site property management office and office operation;

(s) legal and accounting services related to the general management of the Property;

(t) the TDM Fees and/or similar assessments, fees or other charges levied by an association against the Property; and

(u) any other expenses of any kind whatsoever reasonably incurred in connection with the management, operation, maintenance, repair and replacement of the Property and typically included in pass-through expenses charged to triple net tenants in the vicinity of the Premises.

Notwithstanding anything in the definition of Operating Expenses to the contrary, Operating Expenses shall not include the following:

(i) costs actually reimbursed to Landlord by any insurer, tenant, condemnor or other third party;

(ii) costs incurred in connection with the sale, financing or refinancing (or attempted sale, financing or refinancing) of the Property including, without limitation, commissions, marketing costs, interest, principal, points and fees on debts or amortization on any mortgage or mortgages or any other debt instrument encumbering the Property or planned to encumber the Property;

(iii) legal fees, leasing commissions, allowances, buy-out amounts, tenant improvement costs, advertising expenses, promotional expenses, and other costs incurred in the leasing of space at the Property;

(iv) ground rent or any other payments paid under any present or future ground or overriding or underlying lease and/or grant affecting the Property and/or the Premises (other than payments which, independent of such lease, would constitute an Operating Expense hereunder);

(v) costs incurred due to a breach of this Lease by Landlord or any violation of any Applicable Laws by Landlord or Landlord's employees, agents or contractors with respect to the Property;

(vi) costs arising from the presence of any Hazardous Substances or violation of Environmental Requirements as of or prior to the Commencement Date or caused by Landlord or Landlord's employees, agents or contractors;

(vii) Any costs for the design or construction of the Base Building Work, and any costs associated with the correcting of any design or construction defects and/or the enforcement of warranties related to the design, materials or workmanship of any portion of the Base Building Work;

(viii) costs associated with damage or repairs to the Property necessitated by the breach of this Lease, Active Negligence or willful misconduct of Landlord or Landlord's Agents;

(ix) reserves for Landlord's repair, replacement or improvement of the Property or any portion thereof;

(x) charitable or political contributions or fees paid to trade associates;

(xi) Landlord's general overhead expenses and costs associated with operation of the business of the ownership of the Property or entity that constitutes Landlord or Landlord's property manager, as distinguished from the cost of Property operations, including the costs of partnership or corporate accounting and legal matters; defending or prosecuting any lawsuit with any mortgagee, lender, ground lessor, broker, tenant, occupant, or prospective tenant or occupant; selling or syndicating any of Landlord's interest in the Property; and disputes between Landlord and Landlord's property manager;

(xii) any costs, fines, or penalties incurred due to the late payment of Real Estate Taxes or any other items that comprise Operating Expenses;

(xiii) costs incurred in connection with Hazardous Substances not payable by Tenant under this Lease; and

(xiv) any costs that are solely Landlord's responsibility pursuant to any express provisions of this Lease.

8.3 Payment of Operating Expenses. Commencing on the Commencement Date, Tenant shall pay to Landlord as Additional Rent one twelfth (1/12) of the estimated Operating Expenses for each calendar year or portion thereof during the Term, in advance, on or before the first day of each month in an amount estimated by Landlord and stated in a written notice to Tenant; provided, further, that with respect to the Real Estate Taxes, in addition to the right to have Tenant billed directly by the County of Santa Clara for the Real Estate Taxes pursuant to Section 8.2(a), Landlord shall have the right to bill Tenant for, and require Tenant to pay to Landlord the entire amount of Real Estate Taxes for the Premises not more than thirty (30) days before the date by which such installment would be deemed delinquent by the County of Santa Clara. Prior to the Commencement Date, and the beginning of each calendar year thereafter, or as soon thereafter as practicable, Landlord shall deliver to Tenant a reasonable estimate of the Operating Expenses for the then current calendar year. Landlord may by written notice to Tenant revise such estimates from time to time (but not more than once per year) and Tenant shall thereafter make payments on the basis of such revised estimates. With reasonable promptness after the expiration of each calendar year, Landlord will furnish Tenant with a statement (***"Landlord's Expense Statement"***) setting forth in reasonable detail the actual Operating Expenses for the prior calendar year. If the actual Operating Expenses for such year exceeds the estimated Operating Expenses paid by Tenant for such year, Tenant shall pay to Landlord (whether or not this Lease has terminated) the difference between the amount of estimated Operating Expenses paid by Tenant and the actual Operating Expenses within thirty (30) days after the receipt of Landlord's Expense Statement. If the total amount paid by Tenant for any year exceeds the actual Operating Expenses for that year, the excess shall be credited against the next installments of Base Rent due from Tenant to Landlord, or, if after the Termination Date, the excess shall first be credited against any unpaid Base Rent or Additional Rent due and any remaining excess shall be refunded to Tenant concurrently with the furnishing of Landlord's Expense Statement. Notwithstanding anything to the contrary set forth above, Tenant shall not be responsible for any Operating Expense not billed by Landlord to Tenant within three (3) years after the year in which such Operating

Expense was incurred by Landlord. Further, all calculations, determinations, allocations and decisions to be made hereunder with respect to Operating Expenses shall be made in accordance with the good faith determination of Landlord applying sound accounting and property management principles consistently applied which are consistent with institutional owner practices. All discounts, reimbursements, rebates, refunds, or credits attributable to Operating Expenses received by Landlord in a particular year shall be deducted from Operating Expenses in the year the same are received;

8.4 Audit. Each Landlord's Expense Statement shall be conclusive and binding upon Tenant unless, within three (3) months after receipt thereof, Tenant shall give Landlord notice that Tenant disputes the correctness of the Landlord's Expense Statement, specifying the particular respects in which the Landlord's Expense Statement is claimed to be incorrect. Tenant shall not have the right to withhold payment of Operating Expenses in the event of a dispute. Landlord shall maintain books and records appropriate for the computation and verification of Operating Expenses and shall permit Tenant's accountants, consultants and/or employees to examine Landlord's books and records, during Landlord's regular business hours at Landlord's place of business and with at least ten (10) Business Days prior written notice, in order to verify the accuracy of the relevant Landlord's Expense Statement. The records and any related information obtained from Landlord shall be treated as confidential, and as applicable only to the Premises, by Tenant, its accountants, consultants, and any other parties reviewing the same on behalf of Tenant. Before making any records available for review, Landlord may require Tenant and Tenant's accountants, consultants and employees to execute a reasonable confidentiality agreement, in which event Tenant shall cause the same to be executed and delivered to Landlord within thirty (30) days after receiving it from Landlord, and if Tenant fails to do so, the three (3) month objection period referred to in the first sentence of this paragraph shall be reduced by one day for each day by which such execution and delivery follows the expiration of such 30-day period. If it shall be finally determined by an independent accountant engaged by Tenant and reasonably approved by Landlord that Landlord's Expense Statement was incorrect or commercially unreasonable, then either (a) Landlord shall at its election reimburse Tenant for any overpayment or credit the amount of such overpayment against the next monthly installment of Operating Expenses payable under this Lease, or (b) Tenant shall within fifteen (15) days after such determination pay any amounts due to Landlord. Tenant agrees to pay the cost of such audit, provided that, if the audit reveals that Landlord's determination of Operating Expenses was overstated by more than five percent (5%), Landlord shall pay the cost of such audit. Notwithstanding any contrary provision hereof, Tenant may not examine Landlord's records or dispute any Landlord's Expense Statement if any Rent remains unpaid past its due date.

8.5 Proration. If either the Commencement Date or the Termination Date occurs on a date other than the first or last day, respectively, of a calendar year, Operating Expenses for the year in which the Commencement Date or Termination Date occurs shall be prorated based on a 365-day year.

8.6 Taxes on Tenant's Property and Business. Tenant shall pay prior to delinquency all taxes levied or assessed by any local, state or federal authority upon the conduct of Tenant's business in the Premises or upon Tenant's Property and shall deliver satisfactory evidence of such payment to Landlord. If the assessed value of the Property is increased by the inclusion of a value placed upon Tenant's Property, Tenant shall pay to Landlord, upon written demand, the taxes so levied against Landlord, or the portion of Landlord's taxes resulting from said increase in assessment, as determined from time to time by Landlord.

9. REPAIRS, MAINTENANCE, UTILITIES AND SERVICES.

9.1 Landlord's Repair Obligations. Landlord shall have the obligation to repair, replace and maintain only the structural portions of the Premises, including, without limitation, the foundation, footings, floor/ceiling slabs, roof (including roof structure), curtain wall, exterior glass and mullions, load bearing walls, columns, beams, shafts (including elevator shafts), stairs, building standard stairwells (but not stairs or stairwells installed by the Tenant or any former tenant) and elevators (collectively, the ***"Building Structure"***), and the Building Systems and Common Area. Landlord shall repair, replace and maintain the Building Structure, the Building Systems and Common Area in good working order and in a clean, safe and sanitary condition, consistent with the maintenance and repair of first class buildings of similar age and quality located in the Stanford Research Park in Palo Alto. The costs of such repair, replacement and maintenance shall be included in Operating Expenses to the extent permitted by Section 8 of this Lease; provided that, Tenant shall reimburse Landlord in full and within thirty (30) days after written demand for the cost of any repair to the Common Area, Building Structure or Building Systems attributable to misuse by Tenant or Tenant's Agents. Such reimbursement shall be Additional Rent. Except as specifically provided in this Section 9.1 or elsewhere in this Lease, Landlord shall not be required to furnish any services, facilities or utilities to the Premises or to Tenant, and Tenant assumes full responsibility for paying for all services, facilities and utilities to the Premises. Tenant shall notify Landlord in writing when it becomes aware of the need for any repair, replacement or maintenance which is Landlord's responsibility under this Section of which it becomes aware. Except as otherwise provided in Section 16.7 below, Tenant hereby waives and releases any right it may have under any Applicable Laws to make any repairs that are Landlord's obligation under this Section.

9.2 Services to be Provided by Landlord. Landlord shall provide the following services to the Premises:

(a) hot and cold water, gas and electricity service in amounts sufficient for normal office operations as provided in similar buildings in the Stanford Research Park; provided that Landlord shall have the right to purchase green or renewable utilities;

(b) heating and air conditioning, at such temperatures and in such amounts as are reasonably determined by Tenant and customary for research and development uses, subject to the requirements of Applicable Law;

(c) sewer service and non-hazardous waste pick-up; and

(d) exterior window washing services.

Except as otherwise provided in Section 16.7 below, Tenant hereby waives and releases any right it may have under any Applicable Laws to make any repairs that are Landlord's obligation under this Section.

9.3 Tenant's Obligations. Except as provided in Section 9.1 and Article 19, Tenant assumes full responsibility for the condition, repair, replacement and maintenance of the Premises on and after the Commencement Date, including, without limitation, all electrical, steam, water, heating, ventilating and mechanical systems and all other utilities, systems and equipment installed in the Premises by Tenant in connection with its use and occupancy of the Premises as permitted by this Lease (***"Tenant Systems"***). Tenant shall be responsible for arranging for and supplying security services and telephone and other electronic communication

services to the Premises and shall pay the costs of such utilities and services directly. Tenant shall take good care of the Premises and the Tenant Systems and keep the Premises (other than the Common Area, Building Structure and Building Systems that are the responsibility of Landlord to the extent expressly provided in Section 9.1) and the Tenant Systems in good working order and in a clean, safe and sanitary condition. All repairs and replacements by Tenant for which Tenant is responsible are collectively referred to as the ***"Tenant Obligations"*** and shall be made and performed: (a) at Tenant's cost and expense, and in such manner as Landlord may reasonably designate, (b) by licensed and reputable contractors or mechanics reasonably approved by Landlord, (c) so that the same shall be at least equal in quality, value and utility to the original work or installation, (d) in a manner and using equipment and materials that will not interfere with or impair the operation of or damage the Building Systems, and (e) in accordance with Article 10 (if applicable) and all Applicable Laws. Tenant shall cooperate fully and in good faith with Landlord and Landlord's property manager in the performance of all such repairs and replacements by Tenant, and shall perform all such work and activities diligently and expeditiously to completion, and in a manner consistent with the repair and maintenance of first class buildings of similar age and quality located in the Stanford Research Park in Palo Alto. Tenant shall reimburse Landlord within ten (10) Business Days after written demand as Additional Rent for any actual out-of-pocket expenses incurred by Landlord in connection with any repairs or replacements required to be made by Tenant, including without limitation, any reasonable fees charged by Landlord's contractors to review plans and specifications prepared by Tenant.

9.4 Utility Costs. Subject to Tenant's right to contract directly with the providers of certain utilities, as provided in Section 9.3, Landlord shall arrange for water, electrical, gas, non-hazardous waste collection and sewer service to the Premises as are generally provided in similar research and development buildings in the Stanford Research Park. Tenant shall be responsible for arranging for hazardous waste collection, telephone and other electronic communications services at the Premises. Tenant shall pay, either through Operating Expenses, as a reimbursement to Landlord, or directly the cost of all utilities provided to the Premises. If Tenant is billed directly by Landlord for any utilities, Tenant shall deliver payment to Landlord within thirty (30) days after receipt of an invoice. If Tenant is billed directly by a utility company with respect to Tenant's electricity and gas usage at the Premises, then, promptly upon request, Tenant shall provide monthly electricity and gas usage data for the Premises to Landlord for the period of time requested by Landlord (in electronic or paper format) or, at Landlord's option, provide any written authorization or other documentation required for Landlord to request information regarding Tenant's electricity and gas usage data with respect to the Premises directly from the utility company. Tenant acknowledges and consents to Landlord's use and disclosure of such information to the extent required to comply with California Public Resources Code Section 25402.10.

9.5 Security. Tenant shall be solely responsible for the security of the Premises and Tenant and Tenant's Agents while in or about the Premises. Landlord shall not be obligated to provide any security services, facilities or equipment for the Premises, the Building, the Common Area or the Property. Any security services provided to the Property by Landlord shall be at Landlord's sole discretion and Landlord shall not be liable to Tenant or Tenant's Agents for any failure to provide security services or any loss, injury or damage suffered as a result of a failure to provide security services.

9.6 Assumption of Additional Tenant Obligations. In addition to the Tenant Obligations set forth in Section 9.3, Tenant may upon written notice to Landlord assume specific items included in Landlord's repair and maintenance obligations as Tenant Obligations,

subject to Landlord's prior written consent, which consent shall not be unreasonably withheld or conditioned. Notwithstanding the foregoing, in the event Tenant fails to perform or adequately perform any of Tenant's Obligations as reasonably determined by Landlord, Landlord, in its sole and absolute discretion, and upon fifteen (15) Business Days written notice to Tenant, may terminate Tenant's right to perform such Tenant's Obligations, and Landlord shall then assume for itself or assign to Landlord's property manager all responsibility for the performance of all such Tenant's Obligations for the remainder of the Term, the cost of which shall be included within the definition of Operating Expenses.

9.7 Special Services. If Tenant requests any services from Landlord other than those for which Landlord is obligated under this Lease, Tenant shall make its request in writing and Landlord may elect in its sole discretion whether to provide the requested services. If Landlord provides any special services to Tenant, Landlord shall charge Tenant for such services and Tenant shall pay the cost of such services as Additional Rent within thirty (30) days after receipt of Landlord's invoice.

9.8 Additional Equipment. Tenant shall have the right to install a back-up generator to supply emergency power to the Premises, and rooftop communication systems on the Building; provided that the installation and operation of such equipment shall be subject to the terms and conditions set forth in ***Schedule 9.8***.

9.9 Sustainability. Tenant shall use commercially reasonable efforts to incorporate sustainable products, components and supplies in its operation and maintenance of the Premises; provided that this Section 9.9 shall not require Tenant to incorporate sustainable products in its research and development activities.

10. INITIAL IMPROVEMENT WORK; ALTERATIONS.

10.1 Base Building Work. Landlord shall construct the Base Building Work specified in, and in accordance with, the provisions of attached **Exhibit D**. Landlord shall provide certain construction cost and related information to Tenant as set forth in the attached **Exhibit D**.

10.2 Entitlement Efforts. Tenant acknowledges that Landlord has received approvals from the City's Architectural Review Board (***"ARB"***) and the Planning and Community Environment Director for the Base Building Work (as defined and described in **Exhibit D**) and has received applicable demolition, grading and building permits from the City. Accordingly, Tenant has no right to modify the Base Building Construction Drawings, except as set forth in Section 2.5 of **Exhibit D**. Landlord shall have the right to determine all aspects of the strategy and timing for any additional submissions to and correspondence with governmental authorities regarding the development of the Building.

10.3 Rentable Area. The maximum Rentable Area to be developed by Landlord is specified in Article 1. The actual Rentable Area of the Premises will be certified by Landlord's architect upon Substantial Completion of the Base Building Work (as defined in **Exhibit D**). Landlord shall provide Tenant the certified Rentable Area of the Premises in writing, together with reasonable and appropriate documentation (the ***"Certification"***). The final size of the Building, including any Amenity Space, will be determined by City Zoning Code requirements and the City approval process, with input from Landlord and Tenant regarding the Amenity Space. Consistent with the City's approval of the inclusion of Amenity Space, pursuant to the City Zoning Code Landlord will be permitted to construct square footage in excess of the

floor area ratio square footage otherwise permitted by and defined in the City Zoning Code. Any Amenity Space shall be included in the calculation of Rentable Area for the purposes of determining the Base Rent and the Tenant Improvement Allowance to be paid hereunder. Tenant shall have ten (10) Business Days after receipt of the Certification to object to the actual Rentable Area of the Premises in the Certification, in which case Tenant shall provide Landlord with its good faith and reasonable basis for objecting, together with reasonable and appropriate documentation for the estimated Rentable Area. If Landlord's architect disagrees with Tenant's estimate, Landlord's architect and Tenant's architect shall meet and confer regarding the dispute, but Landlord's architect's final determination of the Rentable Area shall be binding on both parties. Once the Rentable Area is finally determined by Landlord's architect, the Base Rent and Tenant Improvement Allowance shall be recalculated to reflect the actual Rentable Area.

10.4 Tenant Improvement Work. Tenant shall construct the Tenant Improvement Work specified in, and in accordance with, the provisions of **Exhibit D**.

10.5 Tenant Improvements and Alterations by Tenant. Tenant's construction of the Tenant Improvement Work shall comply with the requirements of this Article 10, except to the extent inconsistent with **Exhibit D**, in which case the terms and conditions of **Exhibit D** shall control. After completion of the Tenant Improvement Work, Tenant shall not make or permit any alterations to the Building Systems, and shall not make or permit any alterations, installations, additions or improvements, structural or otherwise (collectively, ***"Alterations"***) in or to the Premises or the Building without Landlord's prior written consent, which Landlord shall not unreasonably withhold, condition or delay. Notwithstanding the foregoing, in no event shall Tenant be permitted to make any Alterations that affect the exterior appearance of the Building without Landlord's prior written consent, which Landlord may withhold in its sole discretion.

(a) Tenant's request for Landlord's consent shall include copies of all plans and specifications for the proposed Alterations, and Tenant shall promptly supply any additional information reasonably requested by Landlord. Landlord shall either approve, disapprove or request more information within ten (10) Business Days after receipt of such request for consent from Tenant.

(b) Notwithstanding the foregoing, Landlord's consent shall not be required (i) in the case of interior, cosmetic non-structural Alterations that do not require a permit, or affect the Building Systems, or (ii) in the case of other Alterations that do not exceed a total price of Fifty Thousand Dollars ($50,000) per project and do not affect the Building Systems, the structural integrity of the Building or the exterior appearance of the Building.

(c) All Alterations shall be done at Tenant's sole cost and expense, including without limitation the cost and expense of obtaining all permits and approvals required for any Alterations. Further, to the extent any of Tenant's permitted Tenant Improvement Work and Alterations cause the Property or any portion thereof to be in violation of the ADA or to become subject to any compliance obligations of, or any enforcement actions under, the ADA (which obligations or actions were not triggered by Landlord's Base Building Work), Tenant shall correct, perform or resolve such violations, obligations or enforcement actions at Tenant's sole cost and expense.

10.6 Project Requirements. The following provisions of this Section 10.6 shall apply to the Tenant Improvement Work and all Alterations, whether or not requiring

Landlord's approval (unless otherwise noted):

(a) Prior to entering into a contract for any Tenant Improvement Work or Alterations requiring Landlord's approval, Tenant shall obtain Landlord's written approval, which approval shall not be unreasonably withheld, conditioned or delayed, of the identity of each of the design architect and the general contractor. Tenant shall not be required to use union labor in connection with the Tenant Improvement Work.

(b) Before commencing the construction of any Tenant Improvement Work or Alterations, Tenant shall procure or cause Tenant's contractor to procure the insurance coverage described below and provide Landlord with certificates of such insurance in form reasonably satisfactory to Landlord. All such insurance shall comply with the following requirements of this Section and of Section 14.2.

(i) During the course of construction, to the extent not covered by property insurance maintained by Tenant pursuant to Section 14.2, comprehensive special form builder's risk insurance, covering all improvements in place on the Premises, all materials and equipment stored at the site and furnished under contract, and all materials and equipment that are in the process of fabrication at the premises of any third party or that have been placed in transit to the Premises when such fabrication or transit is at the risk of, or when title to or an insurable interest in such materials or equipment has passed to, Tenant or its construction manager, contractors or subcontractors (excluding any contractors', subcontractors' and construction managers' tools and equipment, and property owned by the employees of the construction manager, any contractor or any subcontractor), such insurance to be written on a completed value basis in an amount not less than the full estimated replacement cost of the Alterations.

(ii) Commercial general liability insurance covering Tenant, Landlord and each construction manager, contractor and subcontractor engaged in any work on the Premises, which insurance may be effected by endorsement, if obtainable, on the policy required to be carried pursuant to Section 14.2, including insurance for completed operations, for three (3) years after the date of acceptance of the work by Tenant, contractual liability, property damage and personal injury (including but not limited to bodily injury), covering the performance of all work at or from the Premises by Tenant, its construction manager, contractors and subcontractors, and with a liability limit not less than the amount at the time carried by prudent owners of comparable construction projects, but in any event not less than Five Million Dollars ($5,000,000) per occurrence, which policy shall include thereunder for the mutual benefit of Landlord and Tenant, bodily injury liability and property damage liability, and automobile insurance on any non-owned, hired or leased automotive equipment used in the construction of any work. Such insurance shall include Landlord as an additional insured.

(iii) Commercial auto liability insurance for all owned, non-owned and hired autos used in the construction of any work with liability limits not less than Five Million Dollars ($5,000,000) combined single limit per accident. Such insurance shall name Landlord and Tenant as additional insureds.

(iv) Workers' compensation insurance approved by the State of California, covering all employees of the contractor and any subcontractors, in the amounts and coverages required under workers' compensation, disability and similar employee benefit laws applicable to the Premises, and employer's liability insurance with limits not less than Two Million Dollars ($2,000,000) each accident and each disease, or such higher amounts as may

be required by Applicable Law. Such insurance shall include a waiver of subrogation in favor of Landlord.

(c) All construction and other work shall be done at Tenant's sole cost and expense and in a prudent and first class manner. Tenant shall cause all work to be performed in accordance with all Applicable Laws, and with plans and specifications that are in accordance with the provisions of this Article 10 and all other provisions of this Lease.

(d) Prior to the commencement of any Alteration in excess of Ten Thousand Dollars ($10,000), Landlord shall have the right to post in a conspicuous location on the Premises and to record in the public records a notice of Landlord's nonresponsibility. Tenant covenants and agrees to give Landlord at least ten (10) Business Days prior written notice of the commencement of any such Alteration in order that Landlord shall have sufficient time to post such notice.

(e) Tenant shall reimburse Landlord within thirty (30) days after written demand as Additional Rent for any out-of-pocket expenses incurred by Landlord in connection with the Tenant Improvement Work or Alterations and/or any repairs or replacements required to be made by Tenant, including, without limitation, any reasonable fees charged by Landlord's contractors and/or consultants to review plans and specifications or working drawings prepared by Tenant and to inspect or supervise any work performed by or on behalf of Tenant. Other than the foregoing, Landlord shall not charge a supervisory or management fee in connection with the construction of any Tenant Improvement Work or Alterations. Tenant acknowledges and agrees that Landlord and Landlord's contractors and consultants, in reviewing Tenant's plans and specifications or working drawings, in granting approval for them, and in approving any work done by Tenant, owe no duty and assume no responsibility to Tenant for the design and construction of the Tenant Improvement Work or Alterations, it being expressly understood and agreed that Landlord, its contractors and consultants may, in their sole discretion, limit the scope of its review to only such matters as may appear appropriate or necessary in the interests of Landlord.

(f) Tenant and Tenant's Agents shall take all necessary safety precautions during any construction, including, without limitation, compliance with the California Division of Occupational Safety and Health.

(g) Tenant shall take all necessary and prudent measures to secure the Premises, all of the materials and equipment stored on the Property in connection with Tenant's Alterations and any components of the Building or the Property exposed as a result of Tenant's Alterations. Tenant shall be solely responsible for any loss, injury or damage suffered as a result of a failure to provide such security measures.

(h) Tenant shall prepare and maintain (i) on a current basis during construction, annotated plans and specifications showing clearly all changes, revisions and substitutions during construction, and (ii) upon completion of construction, as-built drawings showing clearly all changes, revisions and substitutions during construction, including, without limitation, field changes and the final location of all mechanical equipment, utility lines, ducts, outlets, structural members, walls, partitions and other significant features. These as-built drawings and annotated plans and specifications shall be kept at the Premises and Tenant shall update them as often as necessary to keep them current. The as-built drawings and annotated plans and specifications shall be made available for copying and inspection by Landlord at all reasonable times. Within sixty (60) days after the Tenant Improvement Work with respect to the

Premises has been substantially completed, Tenant shall, at its cost, deliver copies of the as-built drawings and annotated plans to Landlord in Adobe Acrobat and AutoCAD formats.

(i) Upon completion of the construction of the Tenant Improvement Work and any Alterations in excess of Ten Thousand Dollars ($10,000) during the Term, Tenant shall file for recordation, or cause to be filed for recordation, a notice of completion and shall deliver to Landlord evidence satisfactory to Landlord of payment of all costs, expenses, liabilities and liens arising out of or in any way connected with such construction (except for liens that are contested in the manner provided herein).

10.7 Communications and Computer Lines. Tenant may install, maintain, replace, remove or use any communications or computer wires and cables serving the Premises (collectively, the ***"Lines"***), provided that (a) Tenant shall obtain Landlord's prior written consent, not to be unreasonably withheld, conditioned or delayed, use an experienced and qualified contractor approved in writing by Landlord, and comply with all provisions of Article 10; (b) the Lines (including riser cables) shall be appropriately insulated to prevent excessive electromagnetic fields or radiation and shall be surrounded by a protective conduit reasonably acceptable to Landlord; (c) the Lines shall be clearly marked at end points; (d) any new Lines installed in the Premises shall comply with all Applicable Laws; and (e) Tenant shall pay all costs in connection therewith. Unless otherwise instructed by Landlord in writing, Tenant shall, at its expense, before the expiration or earlier termination of this Lease, remove any Lines located in or serving the Premises and repair any resulting damage.

10.8 Ownership of Improvements. Except as provided in Section 10.9, all Tenant Improvement Work, Alterations, and any other appurtenances, fixtures, improvements, equipment, additions and property permanently attached to or installed in the Premises at the commencement of or during the Term, shall at the end of the Term become Landlord's property without compensation to Tenant, or be removed in accordance with this Section. Landlord shall notify Tenant in writing at the time of Landlord's approval of the Tenant Improvement Work or any Alterations, as applicable, whether or not the proposed Tenant Improvement Work or Alterations will be required to be removed by Tenant at the end of the Term, and Tenant shall not be required to remove any such Tenant Improvement Work or Alterations unless so notified by Landlord. With respect to any Tenant Improvement Work or Alterations that Landlord has reserved the right to require be removed at the end of the Term, Tenant shall request in writing no earlier than six (6) months prior to the Termination Date that Landlord notify Tenant in writing whether or not Tenant will be required to remove such Tenant Improvement Work or Tenant Alterations installed by Tenant at the end of the Term. If Landlord fails to respond to Tenant's request, no Tenant Improvement Work and Alterations installed by Tenant shall be required to be removed by Tenant prior to the end of the Term. Any Alterations made by Tenant that required Landlord's consent under this Lease that Tenant makes without requesting and receiving Landlord's consent shall be removed at the end of the Term without any requirement that Landlord give Tenant notice of such removal. Tenant shall repair or pay the cost of repairing any damage to the Property caused by the removal of Tenant Improvement Work or Alterations. If Tenant fails to perform its repair or removal obligations, without limiting any other right or remedy, Landlord may on five (5) Business Days prior written notice to Tenant perform such obligations at Tenant's expense without liability to Tenant for any loss or damage, and Tenant shall reimburse Landlord within thirty (30) days after demand for all out-of-pocket costs and expenses incurred by Landlord in connection with such repair or removal. Tenant's obligations under this Section shall survive the termination of this Lease.

10.9 Tenant's Personal Property. All furniture, trade fixtures, furnishings, equipment and articles of movable personal property installed in the Premises by or for the account of Tenant (except for ceiling and related fixtures, HVAC equipment and floor coverings, which shall become the property of Landlord at the end of the Term), and which can be removed without structural or other material damage to the Property (collectively, ***"Tenant's Property"***) shall be and remain the property of Tenant and may be removed by it at any time during the Term. Tenant shall remove from the Premises all Tenant's Property on or before the Termination Date, except such items as the parties have agreed pursuant to the provisions of this Lease or by separate agreement are to remain and to become the property of Landlord. Tenant shall repair or pay the cost of repairing any damage to the Property resulting from such removal, and the provisions of Section 10.8 above shall apply in the event Tenant fails to do so. Any items of Tenant's Property which remain in the Premises after the Termination Date may, on five (5) Business Days prior written notice to Tenant, at the option of Landlord, be deemed abandoned and in such case may either be retained by Landlord as its property or be disposed of, without accountability, at Tenant's expense in such manner as Landlord may see fit. In no event shall Tenant's failure to remove Tenant's Property prior to the Termination Date constitute a holdover as described in Section 21.2 of this Lease.

11. LIENS.

Tenant shall keep the Premises free from any liens arising out of any work performed, material furnished or obligations incurred by or for Tenant. If Tenant shall not, within ten (10) days after notice of the imposition of any such lien, cause the lien to be released of record by payment or posting of a proper bond, Landlord shall have, in addition to all other remedies provided in this Lease and by law, the right but not the obligation to cause any such lien to be released by such means as it shall deem proper, including payment of the claim giving rise to such lien. All such sums paid by Landlord and all expenses incurred by it in connection therewith (including, without limitation, reasonable counsel fees) shall be payable to Landlord by Tenant upon demand with interest from the date incurred at the Interest Rate. Landlord shall have the right at all times to post and keep posted on the Premises any notices permitted or required by Applicable Laws or that Landlord shall deem proper for the protection of Landlord, the Premises and the Property from mechanics' and materialmen's liens, as more specifically provided in Section 10.6(d).

12. COMPLIANCE WITH LAWS AND INSURANCE REQUIREMENTS.

12.1 Applicable Laws. Subject to Landlord's obligation to deliver the Base Building Work to Tenant as required by **Exhibit D**, and further excluding any of Landlord's obligations to monitor, test, contain or otherwise remediate any Pre-Existing Environmental Condition, Tenant, at Tenant's cost and expense, shall comply with all applicable laws, statutes, codes, ordinances, orders, directives, resolutions, zoning restrictions, rules, regulations, conditions of approval, and requirements, of all federal, state, county, municipal and other governmental authorities (including but not limited to the City, the County of Santa Clara, the Regional Water Quality Control Board, Department of Toxic Substances Control, California Department of Fish and Wildlife, California Environmental Protection Agency, United States Environmental Protection Agency, United States Fish and Wildlife Services and Army Corps of Engineering) and the departments, commissions, boards, bureaus, instrumentalities, and officers thereof, and all administrative or judicial orders or decrees and all permits, licenses, approvals and other entitlements issued by governmental entities, and rules of common law, whether now existing or hereafter enacted, including without limitation all Environmental Requirements (collectively, ***"Applicable Laws"***), relating to or affecting Tenant's use, alteration,

operation or occupancy of the Premises. Except as provided in **Exhibit D**, Tenant shall be solely responsible for compliance with and shall make or cause to be made all such improvements and alterations to and within the Premises (including, without limitation, removing barriers and providing alternative services) as shall be required to comply with all Applicable Laws relating to public accommodations, including the Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12111 et seq. (the ***"ADA"***), and the ADA Accessibility Guidelines promulgated by the Architectural and Transportation Barriers Compliance Board, the public accommodations title of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000a et. seq., the Architectural Barriers Act of 1968, 42 U.S.C. §§ 4151 et. seq., as amended, Title V of the Rehabilitation Act of 1973, 29 U.S.C. §§ 790 et. seq., the Minimum Guidelines and Requirements for Accessible Design, 36 C.F.R. Part 1190, the Uniform Federal Accessibility Standards, and Title 24 of the California Code of Regulations, as the same may be amended from time to time, or any similar or successor laws, ordinances and regulations, now or hereafter adopted. Tenant's liability for compliance with Applicable Laws as provided in this Section shall be primary and Tenant shall indemnify Landlord in accordance with Section 14.1 in the event of any failure or alleged failure of Tenant to comply with Applicable Laws as required pursuant to this Lease. Any work or installations made or performed by or on behalf of Tenant or any person or entity claiming through or under Tenant pursuant to the provisions of this Section shall be made in conformity with and subject to the provisions of Article 10. Tenant shall deliver to Landlord within five (5) Business Days of receipt, a copy of any notice from any governmental authority relating to any violation or alleged violation of any Applicable Law pertaining to the Premises or the Property or activities in, on or about the Premises or the Property. Tenant shall deliver to Landlord within five (5) Business Days after receipt a copy of any notice from any governmental authority relating to any violation or alleged violation of any Applicable Laws pertaining to the Premises or Tenant's activities in, on or about the Premises or the Property. Landlord shall be responsible for compliance with Applicable Laws with respect to its construction and operation of the Base Building Work. Notwithstanding the foregoing, Tenant shall not be required to correct any non-compliance with Applicable Law for which Tenant is responsible hereunder unless (a) the non-compliance arises, directly or indirectly, from work performed by or on behalf of Tenant for Tenant's Alterations or (b) Tenant is required to do so by a government authority.

12.2 Insurance Requirements. Tenant shall not do anything, or permit anything to be done, in or about the Premises that would: (a) invalidate or be in conflict with the provisions of or cause any increase in the applicable rates for any fire or other insurance policies covering the Property or any property located therein (unless Tenant pays for such increased costs), or (b) result in a refusal by fire insurance companies of good standing to insure the Property or any such property in amounts reasonably satisfactory to Landlord (which amounts shall be comparable to the amounts required by comparable landlords of comparable buildings, or (c) subject Landlord to any liability or responsibility for injury to any person or property by reason of any business operation being conducted in the Premises.

13. HAZARDOUS SUBSTANCES.

13.1 Except as provided in this Section 13.1, no Hazardous Substance shall be used, treated, kept, stored, transported, handled, sold or Released at, on, under or from the Premises by Tenant or Tenant's Agents. Notwithstanding the foregoing, (a) Tenant and Tenant's Agents may use small quantities of standard janitorial and office products, and also such products as are incorporated into the functioning of building systems (e.g., HVAC units and elevators) that are necessary to the Permitted Use of the Premises, and then only in compliance with all Applicable Laws; and (b) Tenant and Tenant's Agents shall also be permitted to use, keep and store reasonable quantities of the Hazardous Substances required in connection with

the operation of Tenant's or Tenant's assignees' or subtenants' business in the Premises for the Permitted Use as of the Commencement Date, as set forth on ***Schedule 13.1***. Any change in use, type or quantities of Hazardous Substances at the Premises shall require Landlord's prior written consent and the submittal of an amended ***Schedule 13.1***, which consent shall not be unreasonably withheld, conditioned or delayed. Tenant shall in all respects handle, treat, deal with and manage any and all Tenant's Hazardous Substances in total conformity with all Environmental Requirements, other Applicable Laws, and prudent industry practices regarding Hazardous Substances management. Tenant's completed hazard substances questionnaire is attached as ***Schedule 13.1***, which Tenant shall update upon written request by Landlord.

13.2 Permits; Inventories. Tenant shall, at its own expense, procure, maintain in effect and comply with all conditions of any and all permits, licenses, and other governmental and regulatory approvals required for Tenant's use of Hazardous Substances at the Premises, including, without limitation, discharge of appropriately treated materials or wastes into or through any sanitary sewer serving the Premises, or for the use or storage of radiological materials. If Tenant uses Hazardous Substances in the operation of its business other than those found in standard janitorial and office products, Tenant shall, promptly following the Commencement Date, provide Landlord copies of the following for Landlord's review and approval, as applicable:

(a) Bay Area Air Quality Management District air permits for generators and for volatile organic compounds;

(b) Radiological license from Department of Health Services;

(c) A complete hazardous materials business plan or hazardous material inventory form for all Hazardous Substances to be used or stored by Tenant or any of Tenant's Agents at the Premises, excluding standard janitorial and office products; and

(d) All other permits, licenses and approvals required for Tenant's use of Hazardous Substances at the Premises.

Throughout the Term, Tenant shall update the hazardous materials business plan or hazardous material inventory form annually, or as required by permit, license or regulatory requirements, so that it remains current. If required by Applicable Laws, Tenant shall obtain and retain during the Term manifests for the transport of all Hazardous Substances, and all such Hazardous Substances shall be disposed of using Tenant's hazardous waste generator number.

13.3 No Lien. Tenant shall not suffer any lien to be recorded against the Premises or other property in which Landlord has an interest as a consequence of any Tenant Environmental Activity or off-site disposal, including any so-called state, federal or local Superfund lien related to the remediation of any Hazardous Substances in, on, under or about the Premises, except to the extent that such lien is related to the existence of a Pre-Existing Environmental Condition and is not the result of Exacerbation by Tenant or Tenant's Agents.

13.4 Tenant's Indemnity for Environmental Claims. Tenant (on behalf of itself and its successors and assigns) shall indemnify, protect, defend, reimburse, and save and hold harmless Landlord and Landlord's trustees, directors, officers, agents, employees, contractors, representatives, property managers, students and volunteers, and their respective successors and assigns (collectively, the ***"Landlord Parties"***) from and against any and all Environmental Claims to the extent arising from or related to (a) Tenant Environmental Activity,

(b) any non-compliance by Tenant or Tenant's Agents with Environmental Requirements at the Premises, (c) any other acts or omissions of Tenant or Tenant's Agents in, on, under or about the Premises which result in the Release of Hazardous Substances, (d) Tenant's failure to pay and Added Costs, or (e) Tenant's failure to comply with the requirements of this Article 13. Tenant's obligations hereunder shall include, but not be limited to, the reimbursement of Landlord's reasonable costs and expenses related to the defense of all claims, suits and administrative proceedings (with counsel selected by Landlord and approved by Tenant), even if such claims, suits or proceedings are groundless, false or fraudulent; participating in all negotiations of any description; and promptly paying and discharging when due any and all judgments, penalties, fines or other sums due against or from Landlord or the Premises.

13.5 Obligation to Remediate.

(a) Notwithstanding the obligation of Tenant to indemnify Landlord pursuant to this Lease, Tenant shall, upon demand by Landlord, and at Tenant's sole cost and expense, promptly take all actions to remediate the Premises from the effects of any Tenant Environmental Activity (which includes the Pre-Existing Environmental Condition only to the extent that it is caused by or results from Exacerbation by Tenant Environmental Activity), and to obtain "no further action" letters from all governmental authorities asserting jurisdiction over the Premises. Such "no further action" letters shall apply solely to the effects of any Tenant Environmental Activity. If it is not the custom or practice of such governmental authority to issue a "no further action" letter under such circumstances, Tenant shall deliver documentation from its consultant evidencing the completion of the remediation in compliance with Environmental Requirements. By receiving documents from Tenant's consultants, however, Landlord is not deemed to have agreed with any statements from such consultant or waived any rights to dispute their accuracy. Notwithstanding any provision of this Lease to the contrary, in no event shall Tenant be responsible for obtaining "no further action" letters with respect to any Pre-Existing Environmental Condition, nor shall Tenant be required to remediate any Pre-Existing Environmental Condition, except to the extent it was the result of Exacerbation due to Tenant Environmental Activity. With regard only to Tenant Environmental Activity that is not an Added Cost, Tenant shall be responsible for all reporting obligations under applicable Environmental Requirements, and Tenant agrees to be named on any remediation orders as the sole primarily responsible party. Landlord shall have the right to report any Release to governmental authorities, and to participate in all negotiations with the governmental authorities having jurisdiction over any remediation. With regard only to Tenant Environmental Activity that is not an Added Cost, Tenant's remediation obligations shall include, but not be limited to, the investigation of the environmental condition of the Premises, the preparation of any feasibility studies, reports or remedial plans, and the performance of any cleanup, remediation, containment, operation, maintenance, monitoring or restoration work, whether on or off of the Premises. Tenant shall take all actions necessary to remediate such contamination on the Premises and any other real property owned by Landlord from the effects of such Tenant Environmental Activity to a condition allowing Unrestricted Use of the Premises, notwithstanding any lesser standard of remediation allowable under Applicable Laws, and Tenant agrees that the foregoing remediation standard with respect to Tenant Environmental Activity shall be included in any remediation orders; provided that (i) Tenant's obligation to remediate to such standard is only with respect to any Tenant Environmental Activity and not due to the Pre-Existing Environmental Condition. All such remediation work, including without limitation the contractor(s) performing the work and the work plan for the remediation, shall be disclosed in advance in writing to Landlord and Landlord shall have the right to approve or disapprove any such work. Tenant shall proceed continuously and diligently with such investigatory and remedial actions, provided that in all cases such actions shall be in accordance with all

Applicable Laws. Any such actions shall be performed in a good, safe and workmanlike manner. Tenant shall pay all costs in connection with such investigatory and remedial activities, including but not limited to all power and utility costs, and any and all taxes or fees that may be applicable to such activities.

(b) Landlord's environmental consultant or contractor shall have the right to be present during any testing or investigation on the Premises, and Tenant shall promptly provide to Landlord copies of testing results and reports that are generated in connection with the above activities, including, without limitation, any that are submitted to any governmental entity. Promptly upon completion of such investigation and remediation, Tenant shall permanently close all monitoring wells and test holes in accordance with sound engineering practice and in compliance with Applicable Laws, remove all associated equipment, and restore the Premises to the maximum extent possible, which shall include, without limitation, the repair of any surface damage, including paving, caused by such investigation or remediation.

(c) If Tenant uses Hazardous Substances in the operation of its business other than those found in standard janitorial and office products, at least one (1) year before expiration or earlier termination of the Lease, Tenant shall prepare and deliver to Landlord a plan for facility closure activities. Prior to the expiration or earlier termination of this Lease (and in addition to Landlord's rights pursuant to Sections 13.8 and 13.9 below), Landlord shall have the right to engage a consultant to perform an environmental assessment, including sampling of soil or groundwater, of the Property to verify that Tenant has fully complied with the requirements of this Article 13 and to determine the need for any further remediation. Tenant shall cooperate with the consultants performing the assessment and comply with Landlord's then-current policies and requirements generally applicable to the Stanford Research Park regarding the environmental condition of the Property and full facility closure of any facility permits upon surrender, unless Landlord agrees in its sole discretion to allow partial facility closure, in which case Tenant shall be responsible for all Added Costs relating to such partial facility closure, as described in subsection (d) below. Facility closure shall be at Tenant's sole cost and expense. Tenant shall make its employees reasonably available for interviews by Landlord and Landlord's Agents regarding the use of Hazardous Substances and Tenant's end-of-Term obligations hereunder. In the event the end-of-Term assessment identifies any deficiencies in the compliance of the Property with Environmental Requirements which the consultant determines arose from or are related to any Tenant Environmental Activity, Tenant shall promptly correct any such deficiencies identified in the assessment, and document to Landlord that corrective action has been taken. In such event, Tenant shall also reimburse Landlord for the reasonable cost of the assessment.

(d) In the event that there are Hazardous Substances remaining in or under the Property (including those that may be identified in the components of any tenant improvements) as a result of any Tenant Environmental Activity that are not removed due to a Landlord-permitted partial facility closure, or that cannot be removed without material damage to or demolition of some or all of the improvements (the ***"Remaining Substances"***), Tenant shall pay to Landlord an amount equal to the estimated Added Costs associated with such Remaining Substances on or before the later of thirty (30) days after receipt of the estimate described in the following sentence and the expiration date of the Term. Landlord and Tenant shall mutually agree upon a third-party consultant or neutral third-party arbitrator who, prior to the end of the Term, will provide the parties with an estimate of the Added Costs, based on a commercially reasonable method of remediation (based on the costs associated with the prospective demolition of the structure at the end of the Term) and an industry-standard

contingency amount. Landlord shall have no obligation to refund to Tenant any sums paid by Tenant that are not expended in the remediation of the Premises. With respect to any work undertaken by Landlord to remediate the Premises from the effects of Tenant's Environmental Activity, Tenant shall be named as generator of all Hazardous Substances that are disposed of in connection with the remediation and shall sign all manifests and bills of lading, and all such Hazardous Substances shall be disposed of using Tenant's hazardous waste generator number.

13.6 Obligation to Notify. If either Landlord or Tenant becomes aware of or receive notice or other communication in writing concerning any actual, alleged, suspected or threatened violation of Environmental Requirements, Release of Hazardous Substances, or liability for Environmental Claims in connection with the Property or in connection with other property that is reasonably expected to affect the Property, including but not limited to, notice or other communication concerning any actual or threatened investigation, inquiry, lawsuit, claims, citation, directive, summons, proceeding, complaint, notice, order, writ, or injunction, relating to same, then such party shall deliver to the other a written description of said notice or other communication immediately, but in no event later than five (5) Business Days after becoming aware. If such notice or other communication is received by Landlord, and if the notice relates to Tenant Environmental Activity, Landlord shall have the right to tender such notice or communication to Tenant for response and action.

13.7 Periodic Audits. If Tenant uses Hazardous Substances in the operation of its business other than those found in standard janitorial and office products, Tenant shall establish and maintain, at its sole cost and expense, a system to assure and monitor continued compliance on the Premises with Environmental Requirements related to Tenant Environmental Activity. No more than once per calendar year, or at any time Landlord has a reasonable basis for belief that Tenant is in breach of its obligations under this Article 13, Landlord may retain a consultant selected by Landlord to undertake a detailed review of such compliance (the **"*Environmental Audit*"**). A copy of the Environmental Audit report shall be promptly supplied to Landlord and Tenant when it becomes available. In the event the Environmental Audit identifies any deficiencies in the compliance of the Premises with Environmental Requirements (other than those relating to the Pre-Existing Environmental Condition), Tenant shall promptly correct any such deficiencies, and document to Landlord that corrective action has been taken. In such event, Tenant shall also reimburse Landlord for the reasonable cost of the Environmental Audit. If the Environmental Audit identifies any such deficiency in compliance of the Premises with Environmental Requirements due to any Tenant Environmental Activity, then, within two-hundred seventy (270) days of the date of the Environmental Audit, Landlord may request a detailed review of the status of such violation by a consultant selected by Landlord (the **"*Supplemental Audit*"**). Tenant shall pay for the reasonable cost of any Supplemental Audit. A copy of the Supplemental Audit shall be promptly supplied to Landlord and Tenant when it becomes available.

13.8 Right to Inspect. In addition to Landlord's rights under Section 13.7 above, Landlord shall have the right to enter and conduct an inspection of the Premises, including invasive tests, at any reasonable time and upon reasonable advance notice, to determine whether Tenant is complying with the terms of this Lease, including but not limited to the compliance of the Premises and the activities thereon with Environmental Requirements and the existence of Environmental Claims as a result of the condition of the Premises or surrounding properties and activities thereon. Landlord shall have the right, but not the obligation, to retain at its expense any independent professional consultant or contractor to enter the Premises to conduct such an inspection, and to review any report prepared by or for

Tenant concerning such compliance. Tenant hereby grants to Landlord and Landlord's Agents the right to enter the Premises and to perform such tests on the Premises as are reasonably necessary in the opinion of Landlord to conduct such review and inspections. Except to the extent of Landlord's gross negligence or willful misconduct in the exercise of its rights under this Section 13.8, Tenant hereby waives and releases any claims for damages for any injury or inconvenience to or interference with Tenant's business at the Premises, any loss of occupancy or quiet enjoyment of the Premises or any other loss, damage, liability or cost occasioned by Landlord's exercise of the rights reserved to Landlord under, or granted to Landlord pursuant to this Section 13.8. In no event shall Tenant be entitled to terminate this Lease as a result of Landlord's exercise of such rights, notwithstanding any possible liability of Landlord for damages as a result of its gross negligence or willful misconduct.

13.9 Right to Remediate. Should Tenant fail to perform or observe any of its obligations or agreements pertaining to Hazardous Substances or Environmental Requirements as set forth herein within thirty (30) days after receipt of written notice from Landlord, then Landlord shall have the right, but not the obligation, without limitation of any other rights of Landlord hereunder, to enter the Premises personally or through Landlord's Agents and perform the same. Tenant agrees to indemnify Landlord for the actual costs thereof and liabilities therefrom as set forth above in this Article 13. With respect to any work undertaken by Landlord to remediate the Premises from the effects of Tenant Environmental Activity pursuant to this Section 13.9, Tenant shall be named as generator of all Hazardous Substances that are disposed of in connection with the remediation, shall sign all manifests and bills of lading and all such Hazardous Substances shall be disposed of using Tenant's hazardous waste generator number.

13.10 Statute of Limitations. Tenant hereby agrees that no statute of limitations relating to Tenant Environmental Activity, or any other matter covered by this Article 13 shall commence to run unless and until Landlord obtains actual knowledge of the foregoing in the course of any inspection or assessment conducted by Landlord or by written notice from a governmental agency with jurisdiction over the environmental condition of the Premises (each, a **"*Triggering Event*"**). In the event of a Triggering Event, Landlord and Tenant shall enter into a commercially reasonable agreement to toll all applicable statutes of limitation, which the parties shall renew periodically during or after the Term; provided that by entering into such agreement Landlord shall not be deemed to have waived any rights, and Tenant shall not be deemed to have waived any substantive defenses, available pursuant to this Lease or any Applicable Laws.

13.11 Release of Landlord. Tenant represents and acknowledges that it is aware that, prior to the Effective Date, detectable amounts of Hazardous Substances and any byproducts thereof may have been Released to air, soil and groundwater beneath and/or in the vicinity of the Premises as described in the documents listed on the attached ***Schedule 13.11*** (the ***"Pre-Existing Environmental Condition"***). Tenant further represents and acknowledges that it has made such investigations and inquiries as it deems appropriate to ascertain the effects, if any, of the Pre-Existing Environmental Condition on the Premises and on persons using the Premises. Landlord makes no representation or warranty with regard to the Pre-Existing Environmental Condition or with regard to any aspect of the environmental condition of the Premises. Landlord does not guaranty or warrant the accuracy of any of the information contained within the documents listed on ***Schedule 13.11***. Tenant, on behalf of itself and its successors and assigns, hereby releases Landlord and the Landlord Parties from any and all claims, demands, debts, liabilities, and causes of action of whatever kind or nature, whether known or unknown or suspected or unsuspected which Tenant may have, claim to have, or

which may hereafter accrue, arising out of or relating to or in any way connected with the Pre-Existing Environmental Condition or the presence, suspected presence, Release or suspected Release of any Hazardous Substances in or into the air, soil, groundwater, surface water or improvements at, on, about, under or within the Premises or any portion thereof, or elsewhere in connection with the transportation of Hazardous Substances to or from the Premises, in each case prior to the Effective Date. In connection with such release, Tenant hereby waives any and all rights conferred upon it by the provisions of Section 1542 of the California Civil Code, which reads as follows:

> "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."

or by the provisions of any similar statute. Nothing in the foregoing shall be deemed to release Landlord from its indemnity obligations set forth in Section 13.13.

13.12 Release of Tenant. Landlord hereby releases Tenant from any and all claims, demands, debts, liabilities, and causes of action of whatever kind or nature, whether known or unknown or suspected or unsuspected which Landlord may have, claim to have, or which may hereafter accrue against Tenant, arising out of or relating to or in any way connected with the Pre-Existing Environmental Condition, except to the extent related to Tenant Environmental Activity. In connection with such release, Landlord hereby waives any and all rights conferred upon it by the provisions of Section 1542 of the California Civil Code, which reads as follows:

> "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."

or by the provisions of any similar statute.

13.13 Landlord Indemnity. Landlord shall indemnify, defend (by counsel reasonably acceptable to Tenant), protect and hold Tenant and Tenant's directors, officers, agents, and employees and their respective successors and assigns (not including any subtenants), free and harmless from and against (i) any government-required investigations and remediation costs incurred by Tenant and (ii) any third party claims brought against Tenant (other than those brought by Tenant's employees), in either event only to the extent caused by a Pre-Existing Environmental Condition (except to the extent caused by the exacerbation of any Pre-Existing Environmental Condition arising out of or resulting from the acts or negligent omissions of Tenant or Tenant's Agents or subtenants on or about the Premises). Landlord's obligations hereunder shall include, but not be limited to, the burden and expense of defending all such claims, suits and administrative proceedings (with counsel reasonably approved by Tenant), even if such claims, suits or proceedings are groundless, false or fraudulent; conducting all negotiations of any description; and promptly paying and discharging when due any and all judgments, penalties, fines or other sums due against or from Tenant or the Premises. Landlord's indemnification obligations with respect to claims under Subsection 13.13(i) above hereunder shall extend only to Tenant's investigations and remediation costs.

13.14 General Provisions.

(a) The obligations of Tenant under this Article 13 shall not be affected by any investigation by or on behalf of Landlord, or by any information which Landlord may have or obtain as a result of any such investigation.

(b) The provisions of this Article 13 shall survive any termination of this Lease.

(c) The provisions of Article 14 (Insurance) shall not limit in any way Tenant's obligations under this Article 13.

(d) Except as required by Applicable Laws, Tenant shall maintain the confidentiality of all information, reports and assessments regarding the environmental condition of the Premises, whether received by or prepared for Tenant, Landlord or any third party. Tenant shall have the right to disclose any such information only to Tenant's employees, consultants, prospective or actual lenders and other persons or entities having a reasonable need to know such information in connection with this Lease; provided that Tenant has first obtained a written agreement from the third party to keep the information confidential. Tenant shall be responsible for any breaches of confidentiality by persons to whom Tenant discloses information. If Tenant is confronted with, or is otherwise subject to, government compulsion, regulatory requirement, or legal action to disclose information received under this Agreement, Tenant shall promptly notify Landlord. In the event disclosure is not required by Applicable Laws, Tenant shall reasonably assist Landlord in obtaining a protective order requiring that any portion of the information required to be disclosed be used only for the purpose for which a court issues an order.

14. INDEMNITY; INSURANCE.

14.1 Indemnity. Tenant shall indemnify, protect, defend and save and hold Landlord and the Landlord Parties harmless from and against any and all losses, costs, liabilities, claims, judgments, liens, damages and expenses, including, without limitation, reasonable attorneys' fees and costs (including Landlord's in-house counsel), and reasonable investigation costs (collectively, ***"Claims"***), incurred in connection with or arising from: (a) any default by Tenant in the observance or performance of any of the terms, covenants or conditions of this Lease on Tenant's part to be observed or performed, or (b) the use or occupancy or manner of use or occupancy of the Premises and the Property by Tenant and Tenant's Agents, except to the extent any Claim arises due to the Active Negligence or willful misconduct of Landlord or any of Landlord's Agents, (c) the condition of the Premises, and any occurrence on the Premises (including injury to or death of any person, or damage to property) or the Property from any cause whatsoever occurring after the Actual Access Date, except to the extent arising due to the Active Negligence or willful misconduct of Landlord or any of Landlord's Agents, and (d) any acts or omissions or negligence of Tenant or of Tenant's Agents, in, on or about the Premises or the Common Area. In case any action or proceeding be brought, made or initiated against Landlord relating to any matter covered by Tenant's indemnification obligations under this Section or under Section 13.4, Landlord will provide prompt written notice of such action or proceeding and Tenant, upon notice from Landlord, shall at its sole cost and expense, resist or defend such claim, action or proceeding by counsel approved by Landlord, such approval not to be unreasonably withheld; provided that Landlord shall not disapprove any counsel designated by Tenant's insurance carrier. Notwithstanding the foregoing, in the event Landlord is reasonably concerned about Tenant's solvency or a claim

under this indemnity is not fully covered (less a reasonable deductible) by Tenant's insurance, Landlord may retain its own counsel to defend or assist in defending any claim, action or proceeding involving potential liability of Five Million Dollars ($5,000,000) or more, and Tenant shall pay the reasonable fees and disbursements of such counsel. The indemnity in this Section 14.1 shall include indemnification by Tenant for all Claims against Landlord and the Landlord Parties under any theory of landowner premises liability, except to the extent of Landlord's Active Negligence or willful misconduct. Tenant's obligations under this Section shall survive the expiration or earlier termination of this Lease.

14.2 Tenant Insurance. At all times during the Term and at its sole cost and expense, Tenant shall obtain and keep in force for the benefit of Tenant and Landlord the following insurance:

(a) Commercial general liability insurance (ISO occurrence form CG0001 or its equivalent) through one or more primary and umbrella liability policies covering the use and occupancy of the Premises and insuring against claims for bodily injury and property damage occurring on the Premises during the policy term. Such coverage shall be written on an "occurrence" form, with such limits of not less than Five Million Dollars $5,000,000 per occurrence. Any combination of primary general liability insurance and umbrella liability insurance limits can satisfy the per occurrence limit shown above. All such general and umbrella liability insurance shall include as additional insureds Landlord, and such other parties as Landlord reasonably may request.

(i) Such insurance shall (A) include employees as insureds; (B) provide standard contractual liability coverage (for Tenant); and (C) include a cross liability endorsement (or provision) permitting recovery with respect to claims of one insured against another. Such insurance shall insure against claims for bodily injury, including death resulting therefrom, and damage to or destruction of property.

(b) Plate glass insurance with coverage against breakage.

(c) Boiler and machinery insurance (if applicable).

(d) As respects owned, non-owned and hired autos, Tenant shall maintain commercial auto liability coverage with liability limits not less than Five Million Dollars ($5,000,000) combined single limit per accident.

(e) Commercial property insurance, including sprinkler leakages, vandalism and malicious mischief and plate glass damage covering all property of every description including stock-in-trade, furniture, fittings, installations, alterations, additions, partitions and fixtures or anything in the nature of a leasehold improvement made or installed by or on behalf of the Tenant in an amount of not less than one hundred percent (100%) of the full replacement cost thereof as shall from time to time be determined by Tenant in form satisfactory to Landlord.

(f) Business interruption insurance with extra expense insurance in an amount sufficient to insure payment of Rent for a period of not less than twelve (12) months during any interruption of Tenant's business by reason of the Premises being damaged by casualty.

(g) Workers' Compensation Insurance in the amounts and coverages

required in accordance with Applicable Laws, and employer's liability insurance in an amount not less than Two Million Dollars ($2,000,000) each accident and each disease, or such higher amounts as may be required by law.

(h) All other insurance that Tenant is required to maintain under Applicable Laws.

14.3 Landlord Insurance. Landlord shall maintain at a minimum the following insurance, together with such other insurance or self-insurance coverage as Landlord, in its reasonable judgment, may elect to maintain: (a) commercial general liability insurance or self-insurance applicable to the Premises, Building and Property providing, on an occurrence basis, combined primary and excess/umbrella limits of at least Five Million Dollars ($5,000,000) each occurrence and Five Million Dollars ($5,000,000) annual aggregate; (b) special cause of loss or "all risk" insurance or self-insurance on the Building and improvements within the Common Area at replacement cost value as reasonably estimated by Landlord; and (c) worker's compensation insurance to the extent required by Applicable Law.

14.4 Policy Form and General.

(a) All of the insurance policies required under this Lease, and all renewals thereof shall be issued by one or more companies of recognized responsibility, authorized to do business in California with a financial rating of at least a Class A-VIII (or its equivalent successor) status, as rated in the most recent edition throughout the Term of Best's Insurance Reports (or its successor, or, if there is no equivalent successor rating, otherwise reasonably acceptable to Landlord). All deductibles shall be paid by Tenant. All insurance of Tenant shall be primary coverage to Landlord. Any insurance maintained by Landlord shall be excess of, and shall not contribute with, Tenant's insurance.

(b) All commercial general liability and property damage policies shall contain a provision that Landlord and any other additional insured, although named as loss payees or additional insureds, shall nevertheless be entitled to recover under said policies for a covered loss occasioned by it, its servants, agents and employees, by reason of Tenant's negligence. Landlord shall be named as a loss payee on Tenant's business interruption insurance policy. As often as any policy shall expire or terminate, renewal or additional policies shall be procured and maintained by Tenant in like manner and to like extent. Tenant will give to Landlord not less than thirty (30) days' notice in writing in advance of any cancellation of the policy and not less than ten (10) days' notice in writing in advance of any failure to pay the premium of the policy. All commercial general liability and property damage shall be written on an occurrence basis. Landlord's coverage shall not be contributory. No policy shall have a deductible in excess of Two Hundred Fifty Thousand Dollars ($250,000) for any one occurrence. Tenant shall furnish Landlord with original certificates and amendatory endorsements effecting coverage required by this clause. All certificates and endorsements are to be received and approved by Landlord before work commences. Landlord reserves the right to require complete, certified copies of all required insurance policies, including endorsements affecting the coverage required by the specifications at any time.

(c) Each policy, or a certificate of the policy executed by the insurance company's representative evidencing that the required insurance coverage is in full force and effect, shall be deposited with Landlord on or before the Actual Access Date, shall be maintained throughout the Term, and shall be renewed not less than ten (10) days before the expiration of the term of the policy.

(d) No approval by Landlord of any insurer, or the terms or conditions of any policy, or any coverage or amount of insurance, or any deductible amount shall be construed as a representation by Landlord of the solvency of the insurer or the sufficiency of any policy or any coverage or amount of insurance or deductible, and Tenant assumes full risk and responsibility for any inadequacy of insurance coverage or any failure of insurers.

(e) Should Tenant fail to take out and keep in force each insurance policy required under this Section, or should such insurance not be reasonably approved by Landlord and should Tenant not rectify the situation within ten (10) Business Days after written notice from Landlord to Tenant, Landlord shall have the right, without assuming any obligation in connection therewith, to purchase such insurance at the sole cost of Tenant, and all costs incurred by Landlord shall be payable to Landlord by Tenant within thirty (30) days after demand as Additional Rent and without prejudice to any other rights and remedies of Landlord under this Lease.

(f) Notwithstanding anything to the contrary contained herein, to the extent permitted by their respective policies of insurance and to the extent of insurance proceeds received (or which would have been received had the party carried the insurance required by this Lease) with respect to the loss, Landlord and Tenant each hereby waives any right of recovery against the other party and against any other party maintaining a policy of insurance with respect to the Property or any portion thereof, or the contents of the Premises or any Alterations in the Premises for any loss or damage sustained by such party with respect to this Lease, the Property, the Premises, the Alterations, or any portion thereof, or the contents of the same or any operation therein (including for Tenant with respect to workers' compensation insurance), whether or not such loss is caused by the fault or negligence of such other party. Each party shall notify the other party if the policy of insurance carried by it does not permit the foregoing waiver.

15. ASSIGNMENT AND SUBLETTING.

15.1 Consent Required. Except as provided in Section 15.7 below, Tenant shall not directly or indirectly, voluntarily or by operation of law, sell, assign, encumber, pledge or otherwise transfer or hypothecate all or any part of its interest in or rights with respect to the Premises or its leasehold estate (collectively, ***"Assignment"***), or permit a Change of Control (as defined below) or permit all or any portion of the Premises to be occupied by anyone other than itself or sublet all or any portion of the Premises (collectively, ***"Sublease"***) without Landlord's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed (subject to Landlord's rights as described in Section 15.5). As used in this Lease, ***"Change of Control"*** means any sale or other transfer of voting stock, partnership interests or membership interests, or any consolidation, merger or reorganization that results in a change in control of Tenant. For this purpose, "control" shall mean any of the following: (a) the sale or other transfer of more than forty-nine percent (49%) of the beneficial interest in Tenant, whether directly or by sales or transfers of underlying corporate, partnership or membership interests, and whether in a single transaction or a series of transactions, (b) the effective transfer of management or operational control of the Premises, whether or not more than 49% of the beneficial interest has transferred, or (c) any other transaction that modifies the source of funding of the Tenant entity or gives an entity other than the Tenant entity the ability to determine, directly or indirectly, how funds are expended.

15.2 Notice. If Tenant desires to enter into a Sublease of all or any portion of the Premises or Assignment of this Lease (other than a Permitted Transfer under Section 15.7),

it shall give written notice (the ***"Transfer Notice"***) to Landlord of its intention to do so, which notice shall contain (a) the name and address of the proposed assignee, subtenant or occupant (the ***"Transferee"***), (b) the nature of the proposed Transferee's business to be carried on in the Premises, (c) the terms and provisions of the proposed Assignment or Sublease, (d) such financial information as Landlord may reasonably request concerning the proposed Transferee, and (e) all other documents reasonably requested by Landlord. Without limitation of any other provision hereof, it shall not be unreasonable for Landlord to withhold its consent if (i) an Event of Default is then in existence, (ii) the use of the Premises would not comply with the provisions of this Lease, (iii) any complaints or claims (whether by regulators, entities or individuals) have been asserted, or any civil or administrative judgments have been entered, involving fraud or dishonesty, or criminal convictions of any kind, against the proposed Transferee or its key people, or (iv) in Landlord's reasonable judgment, the proposed Transferee (for an Assignment only) does not have the financial capability to perform its obligations with respect to the Premises which are the subject of the Assignment.

15.3 Terms of Approval. Landlord shall respond to Tenant's request for approval within fifteen (15) Business Days after receipt of the Transfer Notice. If Landlord approves the proposed Assignment or Sublease, Tenant may, not later than ninety (90) days thereafter, enter into the Assignment or Sublease with the proposed Transferee upon the terms and conditions set forth in the Transfer Notice.

15.4 Excess Rent. For any Assignment or Sublease (other than a Permitted Transfer under Section 15.7), fifty percent (50%) of the Excess Rent received by Tenant shall be paid to Landlord as and when received by Tenant. ***"Excess Rent"*** means the gross rent received by Tenant from the Transferee during the Sublease term or consideration received from the Transferee with respect to the Assignment, less (a) the gross rent received by Landlord from Tenant during the period of the Sublease term or concurrently with or after the Assignment; (b) any reasonably documented tenant improvement costs or allowance or other economic concession (planning allowance, moving expenses, abated rent, etc.), paid by Tenant to or on behalf of the Transferee; (c) customary and reasonable external brokers' commissions to the extent paid and documented; (d) reasonable and documented attorneys' fees; and (e) reasonable and documented costs of advertising the space for Sublease or Assignment (collectively, ***"Transfer Costs"***). Tenant shall not be required to pay to Landlord any Excess Rent until Tenant has recovered its Transfer Costs.

15.5 Right of First Refusal. Except for Permitted Transfers, if Tenant desires to assign Tenant's interest in the Premises or to sublease fifty percent (50%) or more of the Premises for more than three (3) years or for the balance of the Term (collectively, a ***"Transfer"***), Tenant's Transfer Notice shall also include a written offer that includes all of the substantial business terms that Tenant has offered to a Transferee and shall offer to Transfer to Landlord, Tenant's interest in the portion of the Premises offered to the Transferee on such terms and conditions (the ***"Offer"***). Landlord shall have ten (10) Business Days from Landlord's receipt of the Offer to accept the Offer by written notice to Tenant or to approve or disapprove the Transfer as provided in Section 15.3. If Landlord accepts the Offer, Landlord and Tenant shall consummate the Transfer within fifteen (15) Business Days after Landlord's written notice of acceptance. Notwithstanding the above, Tenant may, by delivering written notice to Landlord within ten (10) Business Days after its receipt of Landlord's acceptance, rescind the Transfer Notice, in which event Landlord's acceptance shall be of no force and effect. The Transfer shall be consummated by Tenant's delivery to Landlord of a good and sufficient assignment of lease or sublease. If Landlord does not accept the Offer, but approves the Transfer, then in the event the terms of the Transfer are materially changed during

subsequent negotiations to be more favorable to the Transferee, Tenant shall again deliver to Landlord an Offer in accordance with this Section, offering the interest to Landlord on such more favorable terms. Landlord shall then have another period of fifteen (15) Business Days after receipt of such Offer to accept such Offer. The forgoing notwithstanding, Landlord's rights under this Section 15.5 shall not apply to (a) Tenant's subleasing to one or more sublessees, subject to the other provisions of this Article 15, of no more than sixty percent (60%) of the actual Rentable Area of the Premises, with initial sublease terms expiring within the first four (4) years of the Term (the ***"Initial Subleases"***), and (b) any subsequent subleases, subject to the other provisions of this Article 15, of all or a portion of the Premises that was subleased under the Initial Subleases to one or more Transferees, for an additional four (4) years after the expiration of the Initial Subleases.

15.6 No Release. No Sublease or Assignment by Tenant nor any consent by Landlord thereto shall relieve Tenant of any obligation to be performed by Tenant under this Lease. Any Sublease or Assignment that is not in compliance with this Article shall be null and void and, at the option of Landlord, shall constitute an Event of Default by Tenant under this Lease, and Landlord shall be entitled to pursue any right or remedy available to Landlord under the terms of this Lease or under the laws of the State of California. The acceptance of any Rent or other payments by Landlord from a proposed Transferee shall not constitute consent to such Sublease or Assignment by Landlord or a recognition of any Transferee, or a waiver by Landlord of any failure of Tenant or other Transferor to comply with this Article.

15.7 Permitted Transfers. Notwithstanding anything in this Article 15 to the contrary, but subject to the provisions of Section 15.8 below, Landlord's prior written consent shall not be required for any assignment of this Lease or sublease to, or Change of Control involving the following: (a) a successor entity that acquires Tenant or combines with Tenant through a merger or purchase of substantially all of the assets or equity of Tenant, or (b) an Affiliate of Tenant; provided that after such assignment or transfer the operation of the business conducted in the Premises shall be in the manner required by this Lease and, in the event of a transfer under Section 15.7(a) above, the Transferee shall have a net worth at least equivalent to the lesser of the Tenant's net worth at the Commencement Date or the net worth of the Tenant immediately prior to the consummation of the Assignment or Sublease. Any such transfer shall be deemed a ***"Permitted Transfer"***, and the Transferee shall be deemed a ***"Permitted Transferee"***. As used in this Lease, the term "***Affiliate***" shall mean an individual, partnership, corporation, unincorporated association or other entity controlling, controlled by or under common control with Tenant and for the purposes of the foregoing, "control" shall mean ownership of 50% or more of the legal and beneficial interest in such corporation or other entity coupled with the power to direct the management and affairs thereof.

15.8 Assumption of Obligations by Assignees. Any Transferee pursuant to an Assignment shall, from and after the effective date of the Assignment, assume all obligations of Tenant under this Lease with respect to the Premises and shall be and remain liable jointly and severally with Tenant for the payment of Base Rent and Additional Rent, and for the performance of all of the terms, covenants, conditions and agreements herein contained on Tenant's part to be performed for the Term. No Assignment shall be binding on Landlord unless Tenant delivers to Landlord a counterpart of the Assignment and an instrument that contains a covenant of assumption reasonably satisfactory in substance and form to Landlord, and consistent with the requirements of this Section. In the event of an Assignment (irrespective of whether Landlord's consent is required), the acceptance of any replacement or substitute L-C by Landlord from the Transferee shall be subject to Landlord's prior written approval, in

Landlord's sole and absolute discretion, and any attorneys' fees incurred by Landlord in connection with such determination shall be payable by Tenant to Landlord upon demand.

16. DEFAULT.

16.1 Event of Default. The occurrence of any of the following shall be an ***"Event of Default"*** on the part of Tenant:

(a) Failure to pay any part of the Base Rent or Additional Rent, or any other sums of money that Tenant is required to pay under this Lease where such failure continues for a period of five (5) Business Days after written notice of default has been delivered by Landlord to Tenant. Landlord's notice to Tenant pursuant to this subsection shall be deemed to be the notice required under California Code of Civil Procedure Section 1161.

(b) Failure to perform any other covenant, condition or requirement of this Lease when such failure shall continue for a period of thirty (30) days after written notice thereof from Landlord to Tenant; provided that if the nature of the default is such that more than thirty (30) days are reasonably required for its cure, then an Event of Default shall not be deemed to have occurred if Tenant shall commence such cure within said thirty (30) day period and thereafter diligently and continuously prosecute such cure to completion. Landlord's notice to Tenant pursuant to this subsection shall be deemed to be the notice required under California Code of Civil Procedure Section 1161.

(c) The abandonment of the Premises by Tenant.

(d) Tenant shall admit in writing its inability to pay its debts generally as they become due, file a petition in bankruptcy, insolvency, reorganization, dissolution or liquidation under any law or statute of any government or any subdivision thereof either now or hereafter in effect, or Tenant shall make an assignment for the benefit of its creditors, consent to or acquiesce in the appointment of a receiver of itself or of the whole or any substantial part of the Premises.

(e) A court of competent jurisdiction shall enter an order, judgment or decree appointing a receiver of Tenant or of the whole or any substantial part of the Premises and such order, judgment or decree shall not be vacated, set aside or stayed within sixty (60) days after the date of entry of such order, judgment, or decree, or a stay thereof shall be thereafter set aside.

(f) A court of competent jurisdiction shall enter an order, judgment or decree approving a petition filed against Tenant under any bankruptcy, insolvency, reorganization, dissolution or liquidation law or statute of the federal or state government or any subdivision of either now or hereafter in effect, and such order, judgment or decree shall not be vacated, set aside or stayed within sixty (60) days from the date of entry of such order, judgment or decree, or a stay thereof shall be thereafter set aside.

16.2 Remedies. Upon the occurrence of an Event of Default, Landlord shall have the following rights and remedies:

(a) The right to terminate this Lease upon written notice to Tenant, in which event Tenant shall immediately surrender possession of the Premises in accordance with Article 21.

(b) The right to bring a summary action for possession of the Premises.

(c) The rights and remedies described in California Civil Code Section 1951.2, pursuant to which Landlord may recover from Tenant upon a termination of the Lease, (i) the worth at the time of award of the unpaid rent which has been earned at the time of termination; (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; (iii) the worth at the time of the award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that Tenant proves could be reasonably avoided; and (iv) any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of events would be likely to result therefrom. The "worth at the time of award" of the amounts referred to in (i) and (ii) above is computed by allowing interest at the Interest Rate. The "worth at the time of award" of the amount referred to in (iii) above shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%). The detriment proximately caused by Tenant's failure to perform its obligations under this Lease or which in the ordinary course of events would be likely to result therefrom includes, without limitation, (A) the unamortized portion of any brokerage or real estate agent's commissions paid in connection with the execution of this Lease, (B) any direct costs or expenses incurred by Landlord in recovering possession of the Premises, maintaining or preserving the Premises after such default, (C) preparing the Premises for reletting to a new tenant, (D) any repairs or alterations to the Premises for such reletting, (E) leasing commissions, architect's fees and any other costs necessary or appropriate either to relet the Premises or, if reasonably necessary in order to relet the Premises, to adapt them to another beneficial use by Landlord and (F) such amounts in addition to or in lieu of the foregoing as may be permitted from time to time by Applicable Law to the extent that such payment would not result in a duplicative recovery.

(d) The rights and remedies described in California Civil Code Section 1951.4 which allow Landlord to continue this Lease in effect and to enforce all of Landlord's rights and remedies under this Lease, including the right to recover Base Rent, Additional Rent and other charges payable hereunder as they become due. Acts of maintenance or preservation, efforts to relet the Premises or the appointment of a receiver upon Landlord's initiative to protect its interest under this Lease shall not constitute a termination of Tenant's right to possession.

(e) The right and power, as attorney-in-fact for Tenant, to sublet the Premises, to collect rents from all subtenants and to provide or arrange for the provision of all services and fulfill all obligations of Tenant under any permitted subleases. Landlord is hereby authorized on behalf of Tenant, but shall have absolutely no obligation, to provide such services and fulfill such obligations and to incur all such expenses and costs as Landlord deems necessary. Landlord is hereby authorized, but not obligated, to relet the Premises or any part thereof on behalf of Tenant, to incur such expenses as may be necessary to effect a relet and make said relet for such term or terms, upon such conditions and at such rental as Landlord in its reasonable discretion may deem proper. Tenant shall be liable immediately to Landlord for all costs and expenses Landlord incurs in reletting the Premises including, without limitation, brokers' commissions, expenses of remodeling the Premises required by the reletting, and the cost of collecting rents and fulfilling the obligations of Tenant to any subtenant. If Landlord relets the Premises or any portion thereof, such reletting shall not relieve Tenant of any

obligation hereunder, except that Landlord shall apply the rent or other proceeds actually collected by it as a result of such reletting against any amounts due from Tenant hereunder to the extent that such rent or other proceeds compensate Landlord for the nonperformance of any obligation of Tenant hereunder. Such payments by Tenant shall be due at such times as are provided elsewhere in this Lease, and Landlord need not wait until the termination of this Lease, by expiration of the Term or otherwise, to recover them by legal action or in any other manner. Landlord may execute any sublease made pursuant to this Section in its own name, and the tenant thereunder shall be under no obligation to see to the application by Landlord of any rent or other proceeds, nor shall Tenant have any right to collect any such rent or other proceeds. Landlord shall not by any reentry or other act be deemed to have accepted any surrender by Tenant of the Premises or Tenant's interest therein, or be deemed to have otherwise terminated this Lease, or to have relieved Tenant of any obligation hereunder, unless Landlord shall have given Tenant express written notice of Landlord's election to do so as set forth herein.

(f) The right to enjoin, and any other remedy or right now or hereafter available to a Landlord against a defaulting tenant under the laws of the State of California or the equitable powers of its courts, and not otherwise specifically reserved herein.

16.3 Cumulative Remedies. The various rights and remedies reserved to Landlord, including those not specifically described herein, shall, to the extent that the exercise of such right and/or remedy does not result in a duplicative recovery, be cumulative and shall be in addition to every other right or remedy provided for in this Lease or now or hereafter existing at law or in equity and the exercise of the rights or remedies provided for in this Lease or now or hereafter existing at law or in equity shall not preclude the simultaneous or later exercise by Landlord of any or all other rights and remedies.

16.4 Waiver of Redemption by Tenant. Tenant hereby waives any right to relief against forfeiture of this Lease pursuant to California Code of Civil Procedure Section 1179.

16.5 Landlord's Right to Cure. If Tenant shall fail or neglect to do or perform any covenant or condition required under this Lease and such failure shall not be cured within any applicable grace period, Landlord may, on five (5) days' notice to Tenant, but shall not be required to, make any payment payable by Tenant hereunder, discharge any lien, take out, pay for and maintain any insurance required hereunder, or do or perform or cause to be done or performed any such other act or thing (entering upon the Premises for such purposes, if Landlord shall so elect), and Landlord shall not be or be held liable or in any way responsible for any loss, disturbance, inconvenience, annoyance or damage resulting to Tenant on account thereof. Tenant shall repay to Landlord within fifteen (15) days after demand all reasonable out-of-pocket cost and expense incurred by Landlord in connection with the cure, including, without limitation, compensation to the agents, consultants and contractors of Landlord and reasonable attorneys' fees and expenses. Landlord may act upon shorter notice or no notice at all if necessary in Landlord's reasonable judgment to meet an emergency situation or governmental or municipal time limitation or to protect Landlord's interest in the Premises. Landlord shall not be required to inquire into the correctness of the amount of validity or any tax or lien that may be paid by Landlord and Landlord shall be duly protected in paying the amount of any such tax or lien claimed and in such event Landlord also shall have the full authority, in Landlord's sole judgment and discretion and without prior notice to or approval by Tenant, to settle or compromise any such lien or tax. Any act or thing done by Landlord pursuant to the provisions of this Section shall not be or be construed as a waiver of any such failure by Tenant, or as a waiver of any term, covenant, agreement or condition herein contained or of the performance

thereof.

16.6 Landlord's Default. Landlord shall be in default under this Lease if Landlord fails to perform obligations required of Landlord within thirty (30) days after written notice by Tenant to Landlord and to the holder of any first mortgage or deed of trust covering the Property whose name and address shall have heretofore been furnished to Tenant in writing, specifying wherein Landlord has failed to perform such obligations; provided, however, that if the nature of Landlord's obligations is such that more than thirty (30) days are required for performance, then Landlord shall not be in default if Landlord commences performance within such thirty (30) day period and thereafter diligently prosecutes the same to completion. Tenant shall be entitled to actual (but not consequential) damages in the event of an uncured default by Landlord and shall be entitled to injunctive relief, but the provisions of Article 17 shall apply to any Landlord default and Tenant shall not have the right to terminate this Lease as a result of a Landlord default.

16.7 Tenant's Right to Cure. If Landlord shall fail to perform any maintenance or repair required by this Lease, which if not performed will materially and adversely affect Tenant's operations within the Premises, and such failure gives rise to a Landlord default after expiration of all applicable cure periods pursuant to Section 16.6, Tenant may, on five (5) Business Days' notice to Landlord, but shall not be required to, make or pay for any such maintenance or repair; provided that Tenant shall not perform any repair or maintenance that could be reasonably expected to void any applicable warranties covering such repair or maintenance. In the event Tenant exercises its rights under this Section 16.7, Tenant shall utilize the services of a qualified contractor who normally and regularly performs similar work in Class A buildings. Within thirty (30) days after receipt of a reasonably detailed invoice from Tenant of its costs of taking action which Tenant claims should have been taken by Landlord, Landlord shall reimburse Tenant the amount set forth in such invoice; provided, that Tenant shall not be entitled to reimbursement of any amounts that would otherwise be payable by Tenant to Landlord hereunder, including without limitation charges for Operating Expenses and TDM Fees. If Landlord delivers to Tenant within thirty (30) days after receipt of Tenant's invoice, a written objection to the payment of such invoice, setting forth in reasonable detail Landlord's reasons for its claim that such action did not have to be taken by Landlord pursuant to the terms of this Lease or that the charges are excessive (in which case Landlord shall pay the amount it contends would not have been excessive), then Tenant shall not be entitled to such reimbursement (except pursuant to a court order), but as Tenant's sole remedy, Tenant may proceed to claim a default by Landlord under this Lease.

17. LANDLORD'S RESERVED RIGHTS.

17.1 Control of Building and Common Area. Landlord reserves the right, at any time and from time to time, to make alterations, additions, repairs, replacements or improvements to all or any part of the Building (including the Building Structure and Building Systems), the Common Area and the Property; provided such changes do not materially interfere with Tenant's access to or use of the Building or the parking to which Tenant is entitled under this Lease, Landlord may make changes at any time and from time to time in the size, shape, location, use and extent of the Common Area, and no such change shall entitle Tenant to any abatement of rent or damages. Landlord shall at all times during the Term have the sole and exclusive control of the Building Systems, Building Structure and the Common Area. Landlord may temporarily close any portion of the Common Area for repairs, maintenance, replacements or alterations, to prevent a dedication or the accrual of prescriptive rights, or for any other reasonable purpose; provided, however, that Landlord shall use

reasonable efforts not to materially adversely affect Tenant's use of or access to the Premises. Tenant's rights in and to the Common Area shall at all times be subject to the rights of Landlord and Tenant shall keep the Common Area free and clear of any obstructions created or permitted by Tenant or resulting from Tenant's operations.

17.2 Access.

(a) Landlord reserves (for itself and its agents, consultants, contractors and employees) the right to enter the Premises at all reasonable times, subject to Tenant's reasonable security procedures, and, except in cases of emergency, after giving Tenant reasonable notice (which such notice may be by electronic mail provided such electronic mail is acknowledged by Tenant), to inspect the Premises (including, without limitation, environmental testing); to supply any service to be provided by Landlord hereunder; to show the Premises to prospective purchasers or mortgagees; to show the Premises to prospective tenants during the last year of the Term; to post notices of non-responsibility; and to repair or maintain the Premises and the Building as required by Section 9.1, without abatement of Rent, and may for that purpose erect, use and maintain necessary structures in and through the Premises and the Building where reasonably required by the character of the work to be performed. Notwithstanding the above, Landlord may not access any controlled document rooms, patient records or other secured area (i) without prior written notice to Tenant, except in the event of an emergency, (ii) unless accompanied by a Tenant designated representative. When entering the Premises, Landlord agrees to comply with Tenant's rules and policies intended to protect the privacy of its patients' protected health information as required by law, including without limitation The Health Insurance Portability and Accountability Act of 1996, as amended from time to time. Tenant hereby waives any claim for damages for any injury or inconvenience to or interference with Tenant's business, any loss of occupancy or quiet enjoyment of the Premises or any other loss occasioned thereby, except to the extent caused by the Active Negligence or willful misconduct of Landlord in the exercise of its rights, or its failure to comply with the security requirements of this Section 17.2(a); and provided that Landlord shall use reasonable efforts not to materially adversely affect Tenant's use of the Premises. All locks for all of the doors in, upon and about the Premises, excluding Tenant's vaults and safes or special security areas (designated in advance in writing by Tenant) shall at all times be keyed to a master system and Landlord shall at all times have and retain a key with which to unlock all of said doors. Landlord shall have the right to use any and all means that Landlord may deem necessary or proper to open said doors in an emergency in order to obtain entry to any portion of the Premises, and any such entry to the Premises or portions thereof obtained by Landlord by any of said means, or otherwise, shall not under any circumstances be construed or deemed to be a forcible or unlawful entry into, or a detainer of, the Premises, or an eviction, actual or constructive, of Tenant from the Premises or any portion thereof.

(b) Landlord hereby reserves the right of Landlord, at all reasonable times and, following reasonable advance notice to Tenant, to permit the City, the County of Santa Clara, the Santa Clara Valley Water District, the Regional Water Quality Control Board, Department of Toxic Substances Control, or other governmental bodies, public or private utilities and any other persons or entities authorized by Landlord to enter upon the Premises for the purposes of the following: (i) installing, using, operating, maintaining, removing, relocating and replacing (A) underground wells, (B) water, oil, gas, steam, storm sewer, sanitary sewer and other pipe lines, and (C) telephone, electric, power and other lines, conduits, and facilities; (ii) flood control; (iii) maintenance of rights of way, (iv) performing any work, testing or monitoring in connection with any Regional Water Quality Control Board, Department of Toxic Substances Control, or other governmental requirements, including, without limitation, indoor air monitoring);

and (v) remediation of Hazardous Substances in, on, or under, the Premises or any other property in the neighborhood of the Premises, whether related to the Pre-Existing Environmental Condition or otherwise.

17.3 Easements. Landlord reserves the right to grant or relocate all easements and rights of way which Landlord in its sole discretion may deem necessary or appropriate; provided that Tenant's rights to use the Property is not materially impeded.

17.4 Use of Additional Areas. Landlord reserves the exclusive right to use any air space above the Property, and the land beneath the Premises; provided that such use shall not materially impede Tenant's use of and access to the Premises.

17.5 Subordination. This Lease shall be subject and subordinate at all times to: (a) all reciprocal easement agreements, and any ground leases or underlying leases which may now exist or hereafter be executed affecting the Property, (b) the lien of any mortgage or deed of trust that may now exist or hereafter be executed in any amount for which the Property, or any ground leases or underlying leases, or Landlord's interest or estate in any of said items, is specified as security, and (c) any access agreements which may now exist or hereafter be executed affecting the Property. Notwithstanding the foregoing, Landlord shall have the right to subordinate or cause to be subordinated to this Lease any of the items referred to in clause (a) or (b) above, subject to compliance with the condition precedent set forth below. In the event that any ground lease or underlying lease terminates for any reason or any mortgage or deed of trust is foreclosed or a conveyance in lieu of foreclosure is made for any reason, (i) no person or entity which as a result of the foregoing succeeds to the interest of Landlord under this Lease, (a "***Successor"***) shall be liable for any default by Landlord or any other matter that occurred prior to the date the Successor succeeded to Landlord's interest in this Lease, and (ii) Tenant shall, notwithstanding any subordination, attorn to and become the tenant of the Successor, at the option of the Successor; provided that Tenant shall have received a Non-Disturbance Agreement from Successor. Tenant covenants and agrees, however, to execute and deliver, upon demand by Landlord and in the form reasonably requested by Landlord (which form shall include the non-disturbance protections for Tenant described below), any additional documents evidencing the priority or subordination of this Lease with respect to any such ground leases, underlying leases, reciprocal easement agreements or similar documents or instruments, or with respect to the lien of any such mortgage or deed of trust and Tenant's failure to execute and deliver any such document within ten (10) Business Days after such demand by Landlord shall constitute an Event of Default without further notice. Landlord shall use commercially reasonable efforts to obtain the written agreement (a ***"Non-Disturbance Agreement"***) of the mortgagee or trustee named in any mortgage, deed of trust or other encumbrance, and any landlord under any ground lease or underlying lease, that so long as an Event of Default by Tenant is not in existence, neither this Lease nor any of Tenant's rights hereunder shall be terminated or modified, nor shall Tenant's possession of the Premises be disturbed or interfered with, by any trustee's sale or by an action or proceeding to foreclose said mortgage, deed of trust or other encumbrance. Landlord represents and warrants that, as of the Effective Date, there is no mortgage, ground lease or other such encumbrance on the Property.

18. LIMITATION OF LANDLORD'S LIABILITY.

18.1 Limitation. Landlord shall not be responsible for or liable to Tenant and Tenant hereby releases Landlord, waives all claims against Landlord and assumes the risk for any injury, loss or damage to any person or property in or about the Property by or from any cause whatsoever (other than Landlord's or the Landlord Parties' Active Negligence or willful

misconduct or Landlords' breach of its obligations under this Lease) including, without limitation, (a) acts or omissions of persons occupying adjoining premises, (b) theft or vandalism, (c) burst, stopped or leaking water, gas, sewer or steam pipes, (d) loss of utility service, (e) accident, fire or casualty, (f) nuisance, and (g) work done by Landlord in the Property. There shall be no abatement of Rent and no liability of Landlord by reason of any injury to or interference with Tenant's business arising from the making of any repairs, alterations or improvements to any portion of the Property or to fixtures, appurtenances and equipment in the Property or arising from the provision of (or interruption of or failure to provide) any utilities or services to the Premises or any inability for Tenant to access the Premises; provided, however, that in the event Landlord fails to perform its obligations to make repairs, alterations or improvements or provide any access, utilities or services or performs such obligations in a negligent manner in each case which results in Tenant being unable to operate its business at the Premises for a period of more than five (5) consecutive Business Days, then Tenant shall be entitled to an abatement of Rent commencing on the sixth (6th) Business Day Tenant is unable to operate and continuing until the Premises are again available for operation of Tenant's business. Such Rent abatement shall be Tenant's only remedy in the event of a negligent interference with Tenant's business and Tenant shall not be entitled to damages or to termination of this Lease arising from Landlord's repairs, alterations, improvements or provision of access, utilities or services. Tenant hereby waives and releases any right it may have to make repairs at Landlord's expense under Sections 1941 and 1942 of the California Civil Code, or under any similar law, statute or ordinance now or hereafter in effect.

18.2 Sale of Property. It is agreed that Landlord may at any time sell, assign or transfer its interest as landlord in and to this Lease, and may at any time sell, assign or transfer its interest in and to the Property. In the event of any transfer of Landlord's interest in this Lease or in the Property, the transferor shall be automatically relieved of any and all of Landlord's obligations and liabilities accruing from and after the date of such transfer; provided that the transferee assumes all of Landlord's obligations under this Lease. Tenant hereby agrees to attorn to Landlord's assignee, transferee, or purchaser from and after the date of notice to Tenant of such assignment, transfer or sale, in the same manner and with the same force and effect as though this Lease were made in the first instance by and between Tenant and the assignee, transferee or purchaser.

18.3 No Personal Liability. In the event of any default by Landlord hereunder, Tenant shall look only to Landlord's interest in the Property and rents therefrom and any available insurance proceeds for the satisfaction of Tenant's remedies, and no other property or assets of Landlord or any trustee, partner, member, officer or director thereof, disclosed or undisclosed, shall be subject to levy, execution or other enforcement procedure for the satisfaction of Tenant's remedies under or with respect to this Lease.

19. DESTRUCTION.

19.1 Landlord's Repair Obligation. If the Property or any portion thereof is damaged by fire or other casualty, Landlord shall repair the same (including the Base Building Work but not any Tenant Improvement Work and not any Tenant's Alterations); provided that (a) such repairs can be made under the laws and regulations of the federal, state and local governmental authorities having jurisdiction within eighteen (18) months after the date of such damage (or in the case of damage occurring during the last twelve (12) months of the Term, provided that such repairs can be made within ninety (90) days after the date of such damage), (b) such repairs are substantially covered (except for any deductible) by the proceeds of insurance maintained by Landlord or required to be maintained by Landlord under Section 14.3

of this Lease, and (c) the estimate cost of repairing such damage does not exceed fifty percent (50%) of the then replacement cost of the Building.

19.2 Notice. Landlord shall notify Tenant within sixty (60) days after the date of damage whether or not the conditions requiring Landlord's to reconstruct and repair as described in Section 19.1 are met. If such requirements are not met, Landlord shall have the option, exercisable within sixty (60) days after the date of such damage either to: (a) notify Tenant of Landlord's intention to repair such damage and Landlord's reasonable estimate of the date upon which such repairs shall be completed, in which event this Lease shall continue in full force and effect (unless terminated by Tenant pursuant to Section 19.3 below), or (b) notify Tenant of Landlord's election to terminate this Lease as of the date of the damage. If such notice to terminate is given by Landlord, this Lease shall terminate as of the date of such damage. If within ten (10) days after receipt of a notice from Landlord electing to terminate this Lease because of the unavailability of insurance proceeds (provided such unavailability is not due to Landlord's failure to secure and maintain the insurance required by this Lease), Tenant sends Landlord a notice electing to reimburse Landlord for the total cost of such repairs in excess of Landlord's available insurance proceeds, this Lease shall not terminate, and Landlord shall complete such repairs; provided that Landlord shall have the right to invoice Tenant on a monthly basis for Tenant's share of the repair costs, which Tenant shall pay within thirty (30) days after receipt. Further, in the event Landlord elects to terminate this Lease as provided in Section 19.1, Tenant shall have the right within thirty (30) days of receipt of Landlord's notice of termination to notify Landlord of Tenant's election to pay for the restoration of the Building and Premises, in which event this Lease shall continue in full force and effect, Landlord shall proceed to make such repairs as soon as reasonably possible, and Tenant shall pay to Landlord all costs of the repairs in excess of any insurance proceeds actually received by Landlord within thirty (30) days after written demand by Landlord. If Tenant does not give such notice within the thirty (30) day period, this Lease shall be cancelled and terminated as of the date of the occurrence of such damage.

19.3 Termination by Tenant. If Landlord elects to repair or is required to repair the damage and any such repair (a) is not commenced by Landlord within one hundred twenty (120) days after the occurrence of such damage or destruction, or (b) is not or cannot practicably be substantially completed by Landlord within eighteen (18) months after the occurrence of such damage or destruction (or in the case of damage occurring in the last twelve (12) months of the Term, within ninety (90) days), all as reasonably determined by Landlord's Contractor, then in either such event Tenant may, at its option, upon written notice to Landlord to be delivered within fifteen (15) days after receipt of Landlord's notice or the expiration of the 120-day commencement period, elect to terminate this Lease as of the date of the occurrence of such damage or destruction.

19.4 Rent Adjustment. In case of termination pursuant to Sections 19.2 or 19.3 above, the Base Rent and Operating Expenses shall be reduced by a proportionate amount based upon the extent to which such damage interferes with Tenant's ability to operate in the Premises, and Tenant shall pay such reduced Base Rent and Operating Expenses up to the date of vacation of the Premises; provided that Landlord receives all proceeds of Tenant's business interruption insurance up to the amount by which Base Rent and Operating Expenses are so reduced, less any rental loss insurance proceeds payable to Landlord from Landlord's insurance coverage on account of such casualty. If Landlord is required or elects to make repairs, and Tenant does not terminate this Lease pursuant to Section 19.3, this Lease shall remain in full force and effect except that Tenant shall be entitled to a proportionate reduction of Base Rent and Operating Expenses from the date of such casualty and during the period such

repairs are being made by a proportionate amount based upon the extent to which such damage interferes with Tenant's ability to operate in the Premises; provided that Landlord receives all proceeds of Tenant's business interruption insurance up to the amount by which Base Rent and Operating Expenses are so reduced less any rental loss insurance proceeds payable to Landlord from Landlord's insurance coverage on account of such casualty. The full amount of Base Rent and Operating Expenses shall again become payable immediately upon the completion of such work of repair, reconstruction or restoration that Landlord is obligated to complete; provided however that, if the damage includes Tenant Improvement Work that Tenant is obligated to repair or replace, the full amount of Base Rent and Operating Expenses shall again become payable on the earlier of (i) when Tenant completes Tenant's repairs or replacements, or (ii) ninety (90) days after the completion by Landlord of such work of repair, reconstruction or restoration that Landlord is obligated to complete and the delivery of the Premises to Tenant for its repair and restoration work. The repairs to be made by Landlord under this Article shall not include, and Landlord shall not be required to repair, any casualty damage to the Tenant Improvement Work, Tenant's Property or any Alterations.

19.5 Tenant Obligations. If Landlord elects or is required to repair, reconstruct or restore the Premises after any damage or destruction, and Tenant does not elect to terminate this Lease as provided herein, Tenant shall be responsible at its own expense for the repair and replacement of any of the Tenant Improvement Work, Tenant's Property and any Alterations which Tenant elects to replace.

19.6 No Claim. Tenant shall have no interest in or claim to any portion of the proceeds of any property insurance or self-insurance maintained by Landlord in connection with the damage. If Landlord is entitled and elects not to rebuild the Premises, Landlord shall relinquish to Tenant such claim as Landlord may have for any part of the proceeds of any insurance maintained by Tenant under Section 14.2 of this Lease.

19.7 No Damages. If Landlord is required or elects to make any repairs, reconstruction or restoration of any damage or destruction to the Premises under any of the provisions of this Article 19, Tenant shall not be entitled to any damages by reason of any inconvenience or loss sustained by Tenant as a result thereof. Except as expressly provided in Section 19.4, there shall be no reduction, change or abatement of any rental or other charge payable by Tenant to Landlord hereunder, or in the method of computing, accounting for or paying the same. Tenant hereby waives the provisions of Section 1932(2) and Section 1933(4) of the California Civil Code, or any other statute or law that may be in effect at the time of a casualty under which a lease is automatically terminated or a tenant is given the right to terminate a lease due to a casualty.

20. EMINENT DOMAIN.

20.1 Taking. If all or any part of the Premises shall be taken as a result of the exercise of the power of eminent domain or any transfer in lieu thereof, this Lease shall terminate as to the part so taken as of the date of taking or as of the date of final judgment, whichever is earlier, and, in the case of a partial taking of at least twenty-five percent (25%) of the Rentable Area of the Premises or parking areas servicing the Premises, either Landlord or Tenant shall have the right to terminate this Lease as to the balance of the Premises by written notice to the other within thirty (30) days after such date, provided, however, that a condition to the exercise of such right to terminate shall be that the portion of the Premises taken shall be of such extent and nature as substantially to handicap, impede or impair Tenant's use of the balance of the Premises. If any material part of the Common Area shall be taken as a result of

the exercise of the power of eminent domain or any transfer in lieu thereof, whether or not the Premises are affected, Landlord shall have the right to terminate this Lease by written notice to Tenant within thirty (30) days of the date of taking. If any material part of the Common Area shall be taken as a result of the exercise of the power of eminent domain or any transfer in lieu thereof, such that Tenant's access to or use of the Premises is materially adversely affected, Tenant shall have the right to terminate this Lease by written notice to Landlord within thirty (30) days of the date of taking.

20.2 Award. In the event of any taking of the Property, Landlord shall be entitled to any and all compensation, damages, income, rent, awards, or any interest therein whatsoever which may be paid or made in connection therewith. Nothing contained herein shall be deemed to prohibit Tenant from making a separate claim against the condemning authority for the taking of Tenant's Property, the unamortized cost of Tenant Improvement Work, the cost of removing Tenant's trade fixtures and removable property, and relocation expenses.

20.3 Partial Taking. In the event of a partial taking of the Premises which does not result in a termination of this Lease, the Base Rent and Operating Expenses shall be adjusted as follows:

(a) In the event of a partial taking, if this Lease is not terminated pursuant to this Article 20, Landlord shall repair, restore or reconstruct the Premises to a useable state; provided that Landlord shall not be required to expend any sums other than those received pursuant to Section 20.2;

(b) During the period between the date of the partial taking and the completion of any necessary repairs, reconstruction or restoration, Tenant shall be entitled to a reduction of Base Rent and Operating Expenses by a proportionate amount based upon the extent of interference with Tenant's operations in the Premises; and

(c) Upon completion of said repairs, reconstruction or restoration, and thereafter throughout the remainder of the Term, the Base Rent and Operating Expenses shall be recalculated based on the remaining total number of square feet of Rentable Area of the Premises.

20.4 Temporary Taking. Notwithstanding any other provision of this Article, if a taking occurs with respect to all or any portion of the Premises for a period of six (6) months or less, this Lease shall remain unaffected thereby and Tenant shall continue to pay Base Rent and Additional Rent and to perform all of the terms, conditions and covenants of this Lease, provided that Tenant shall have the right to terminate this Lease if the taking continues beyond six (6) months by giving Landlord notice of such termination within twenty (20) days following the expiration of such six-month period. If Tenant exercises such termination right, this Lease and the estate hereby granted shall terminate as of the thirtieth (30th) day following the giving of such notice. In the event of any such temporary taking, and if this Lease is not terminated, Tenant shall be entitled to receive that portion of any award which represents compensation for the use or occupancy of the Premises during the Term up to the total Base Rent and Additional Rent owing by Tenant for the period of the taking, and Landlord shall be entitled to receive the balance of any award.

20.5 Sale in Lieu of Condemnation. A voluntary sale by Landlord of all or any part of the Property to any public or quasi-public body, agency or person, corporate or otherwise, having the power of eminent domain, either under threat of condemnation or while

condemnation proceedings are pending, shall be deemed to be a taking under the power of eminent domain for the purposes of this Article.

20.6 Waiver. Except as provided in this Article, Tenant hereby waives and releases any right it may have under any Applicable Law to terminate this Lease as a result of a taking, including without limitation Sections 1265.120 and 1265.130 of the California Code of Civil Procedure, or any similar law, statute or ordinance now or hereafter in effect.

21. SURRENDER.

21.1 Surrender. On or before the ninetieth (90th) day preceding the Expiration Date, Tenant shall notify Landlord in writing of the estimated date (the ***"Move-Out Date"***) upon which Tenant plans to surrender the Premises to Landlord. At least sixty (60) days prior to the Move-Out Date, Landlord and Tenant shall walk through the Premises to identify any repair and removal work to be performed by Tenant, provided that failure by any party to participate in the walk-through shall not relieve Tenant of any of its obligations hereunder. Prior to the Termination Date, Tenant shall repair at Tenant's sole cost, all damage caused by removal of Tenant's Property and any Alterations as required under this Lease, and shall leave the floor broom clean and the walls patched and paint-ready. Upon the Termination Date, Tenant shall surrender the Premises to Landlord in good order and repair, reasonable wear and tear and damage by casualty excepted, free and clear of all letting and occupancies and free of Tenant's Hazardous Substances as required pursuant to Article 13, with all applicable closure requirements satisfied and completed, and with all of Tenant's Property (including all movable equipment, furniture, trade fixtures and other personal property) removed from the Premises. Subject to Article 10, upon any termination of this Lease all improvements, except for Tenant's Property, shall automatically and without further act by Landlord or Tenant, become the property of Landlord, free and clear of any claim or interest therein by Tenant, and without payment therefore by Landlord.

21.2 Holding Over.

(a) If Tenant remains in possession of all or any part of the Premises after the Termination Date with Landlord's prior written consent: (i) Tenant's occupancy of the Premises shall be deemed a month-to-month tenancy (not a renewal or extension of the Term), terminable by either party upon 30 days' written notice to the other; (ii) the Base Rent during the holdover period shall be 125% of the greater of (x) the Base Rent in effect during the last month of the Term; and (y) Prevailing Market Rent; and (iii) Tenant's occupancy of the Premises otherwise shall be subject to all applicable terms and conditions of this Lease as if the Term had not expired or this Lease had not been terminated, as the case may be. Landlord's acceptance of Rent without all or any part of the increase due pursuant to clause (ii) above shall not be deemed or construed as a waiver by Landlord of its right to the entire increase in Base Rent due pursuant to clause (ii). Nothing in this Section 21.2(a) shall be deemed or construed as a consent by Landlord to any holding over by Tenant.

(b) If Tenant remains in possession of all or any part of the Premises after the Termination Date without Landlord's written consent: (i) the Base Rent during the holdover period shall be the greater of (x) 150% of the Base Rent in effect during the last month of the Term; and (y) the Prevailing Market Rent; (ii) Tenant's occupancy of the Premises shall be solely as a tenant at sufferance and no notice of termination shall be necessary in order to recover possession; (iii) Tenant's occupancy of the Premises otherwise shall be subject to all applicable terms and conditions of this Lease; and (iv) in addition to such other remedies as

may be available to Landlord at law or in equity, Tenant shall indemnify, defend and hold Landlord harmless from and against any and all claims, damages, liabilities and costs arising from or related to Landlord's continued possession, including without limitation claims, damages or losses incurred in connection with prospective or actual successor tenants, lost rents, lost development opportunities and reasonable attorneys', brokers' and consultants' fees, costs and expenses. Landlord's acceptance of Rent without all or any part of the increase due pursuant to clause (i) above shall not be deemed or construed as a waiver by Landlord of its right to the entire increase in Rent due pursuant to clause (ii). Without limiting the foregoing, if Tenant fails to remediate the Property from the effects of any Tenant Environmental Activity and complete full facility closure on or prior to the Termination Date and provide Landlord with satisfactory evidence of the same, then, from and after the Termination Date, then whether or not Tenant has vacated the Premises, Tenant shall be deemed to be holding over without the consent of Landlord and shall be subject to the provisions of this Section 21.2(b).

21.3 Notice of Lease Termination. At the expiration or earlier termination of this Lease, Tenant shall execute, acknowledge and deliver to Landlord, within ten (10) days after written demand from Landlord to Tenant, a notice of lease termination in the form attached as **Exhibit E** required by any reputable title company, licensed to operate in the State of California, to remove the cloud or encumbrance created by this Lease from the Property.

22. FINANCIAL STATEMENTS.

If Tenant's (or Tenant's parent's) financial statements are not publicly available through the S.E.C. or other regulatory agency in the United States or elsewhere, Tenant shall tender to Landlord within ten (10) Business Days after receipt of a written request any information reasonably requested by Landlord regarding the financial stability, credit worthiness or ability of Tenant to pay the Rent due under this Lease. Landlord shall be entitled to rely upon the information provided in determining whether or not to enter into this Lease or for the purpose of any financing or other transaction subsequently undertaken by Landlord. Tenant hereby represents and warrants to Landlord the following: (a) that all documents provided by Tenant to Landlord in connection with the negotiation of this Lease are true and correct copies of the originals, (b) Tenant has not withheld any information from Landlord that is material to Tenant's credit worthiness, financial condition or ability to perform its obligations hereunder, (c) all information supplied by Tenant to Landlord is true, correct and accurate, and (d) no part of the information supplied by Tenant to Landlord contains any misleading or fraudulent statements. A default under this Article shall be a non-curable default by Tenant and Landlord shall be entitled to pursue any right or remedy available to Landlord under the terms of this Lease or available to Landlord under the laws of the State of California. Landlord shall a be entitled to disclose Tenant's financial information to (i) its agents, employees and consultants, (ii) potential purchasers of an interest in the Property, and (iii) lenders contemplating making a loan to the Landlord to be secured by the Property, provided that such recipients are advised of the confidential nature of such information and agree to maintain such confidentiality provided that Landlord first execute a commercially reasonable non-disclosure agreement. Landlord shall also be entitled to disclose Tenant's confidential financial information to (i) its agents, employees and consultants, (ii) potential purchasers of an interest in the Property, and (iii) lenders contemplating making a loan to the Landlord to be secured by the Property, provided that such recipients are advised of the confidential nature of such information and agree to maintain such confidentiality. Nothing herein, however, shall require Tenant to disclose to Landlord any proprietary or confidential non-public information in violation of Applicable Laws and Tenant shall not be deemed in default under this Section 22 on account of withholding any

proprietary or confidential nonpublic information as required by Applicable Laws or as advised by Tenant's legal counsel.

23. TENANT CERTIFICATES.

Tenant, at any time and from time to time within ten (10) Business Days after receipt of written notice from Landlord, shall execute, acknowledge and deliver to Landlord or to any party designated by Landlord (including prospective lenders, purchasers, ground lessees and others similarly situated), a certificate of Tenant stating, to the best of Tenant's knowledge: (a) that Tenant has accepted the Premises, (b) the Commencement Date and Expiration Date of this Lease, (c) that this Lease is unmodified and in full force and effect (or, if there have been modifications, that same is in full force and effect as modified and stating the modifications), (d) whether or not there are then existing any defenses against the enforcement of any of the obligations of Tenant under this Lease (and, if so, specifying same), (e) whether or not there are then existing any defaults by Landlord in the performance of its obligations under this Lease (and, if so, specifying same), (f) the dates, if any, to which the Base Rent and Operating Expenses have been paid, and (g) any other factual information relating to the rights and obligations under this Lease that may reasonably be required by any of such persons. Failure to deliver such certificate after receipt of a second five (5) Business Day notice shall constitute an Event of Default. At the request of Tenant, Landlord shall execute, acknowledge and deliver to Tenant a certificate with similar types of information and in the time period set forth above. Failure by either Landlord or Tenant to execute, acknowledge and deliver such certificate shall be conclusive evidence that this Lease is in full force and effect and has not been modified except as may be represented by the requesting party.

24. RULES AND REGULATIONS; SIGNS.

24.1 Rules and Regulations. Tenant shall faithfully observe and comply with all reasonable rules and regulations attached to this Lease as **Exhibit F**, and all reasonable modifications relating to Tenant's use of the Common Area and additions thereto from time to time put into effect by Landlord (the ***"Rules and Regulations"***) and provided in writing to Tenant. Landlord shall not enforce such Rules and Regulations in an unreasonable or discriminatory manner. In the event of any conflict between the terms of this Lease and the terms, covenants, agreements and conditions of the Rules and Regulations, this Lease shall control. Landlord shall not adopt any Rules or Regulations or modify the existing Rules and Regulations in such a way as to materially interfere with Tenant's use and enjoyment of the Premises or with the conduct of Tenant's business within the Premises. Landlord shall administer the Rules and Regulations in a fair and non-discriminatory manner.

24.2 Signs. Tenant shall have the exclusive right, at Tenant's sole cost and expense, to install Tenant's name on a monument sign approved by Landlord. Tenant shall also have the right to place a sign on the entrance doors to Tenant's Premises identifying Tenant. All signage to be installed by Tenant pursuant to the foregoing shall meet the requirements of Landlord's signage program for the Property (e.g., aesthetic appearance, size, etc.) and shall be subject to the prior written consent of Landlord, not to be unreasonably withheld, and, if required, the approval of the City.

25. INABILITY TO PERFORM.

If Landlord is unable to fulfill or is delayed in fulfilling any of Landlord's obligations under this Lease, by reason of acts of God, accidents, breakage, repairs, strikes, lockouts, other

labor disputes, inability to obtain utilities or materials or by any other reason beyond Landlord's reasonable control, then such inability or delay by Landlord shall excuse the performance of Landlord for a period equal to the duration of such prevention, delay or stoppage, and no such inability or delay by Landlord shall constitute an actual or constructive eviction, in whole or in part, or entitle Tenant to any abatement or diminution of Base Rent or Additional Rent, or relieve Tenant from any of its obligations under this Lease, or impose any liability upon Landlord or Landlord's Agents by reason of inconvenience, annoyance, interruption, injury or loss to or interference with Tenant's business or use and occupancy or quiet enjoyment of the Premises or any loss or damage occasioned thereby. If Tenant is unable to fulfill or is delayed in fulfilling any of Tenant's obligations under this Lease (other than the payment of Rent), by reason of acts of God, accidents, breakage, repairs, strikes, lockouts, other labor disputes, inability to obtain utilities or materials or by any other reason beyond Tenant's reasonable control, then such inability or delay by Tenant shall excuse the performance of Tenant for a period equal to the duration of such prevention, delay or stoppage. Tenant hereby waives and releases any right to terminate this Lease under Section 1932(1) of the California Civil Code, or any similar law, statute or ordinance now or hereafter in effect.

26. NOTICES.

Any notice, consent or other communication required or permitted under this Lease shall be in writing and shall be delivered by hand, sent by expedited courier, sent by prepaid registered or certified mail with return receipt requested, or sent by facsimile or electronic mail, and shall be deemed to have been given on the earliest of (a) receipt or refusal of receipt; (b) one Business Day after delivery to an air courier or reputable over-night delivery service (e.g., FedEx) for overnight expedited delivery service; (c) five (5) Business Days after the date deposited in the United States mail, registered or certified, with postage prepaid and return receipt requested (provided that such return receipt must indicate receipt at the address specified); or (d) on the day of its transmission by facsimile or electronic mail if transmitted during the business hours of the place of receipt, otherwise on the next Business Day, and in the case of electronic mail, upon the sender's receipt of an acknowledgement from the intended recipient (such as by the "return receipt requested" function, as available, or return e-mail or other written acknowledgement from such recipient confirming receipt) provided that in either case a copy of such notice, consent or other communication is also delivered pursuant to clause (b) or (c) above. All notices shall be addressed as appropriate to the addresses given in the Basic Lease Information (or to such other or further addresses as the parties may designate by notice given in accordance with this Section).

27. QUIET ENJOYMENT.

Landlord covenants that subject to the other terms and conditions of this Lease, upon paying the Base Rent and Additional Rent and performing all of its obligations under this Lease, Tenant shall peaceably and quietly enjoy the Premises, subject to the terms and provisions of this Lease.

28. AUTHORITY.

28.1 Tenant's Authority. Tenant represents and warrants as follows: Tenant is an entity as identified in the introductory paragraph, duly formed and validly existing and in good standing under the laws of the state of organization specified in the introductory paragraph and qualified to do business in the State of California. Tenant has the power, legal capacity and authority to enter into and perform its obligations under this Lease and no approval or consent

of any third party is required in connection with the execution and performance hereof, other than the approval of Tenant's parent, which approval has been duly obtained. The execution and performance of Tenant's obligations under this Lease will not result in or constitute any default or event that would be, or with notice or the lapse of time would be, a default, breach or violation of the organizational instruments governing Tenant or any agreement or any order or decree of any court or other governmental authority to which Tenant is a party or to which it is subject. Tenant has taken all necessary action to authorize the execution, delivery and performance of this Lease and this Lease constitutes the legal, valid and binding obligation of Tenant. Upon Landlord's request, Tenant shall provide Landlord with evidence reasonably satisfactory to Landlord confirming the foregoing representations and warranties.

28.2 Landlord's Authority. Landlord represents and warrants as follows: Landlord has the power, legal capacity and authority to enter into and perform its obligations under this Lease and no approval or consent of any person is required in connection with the execution and performance hereof. The execution and performance of Landlord's obligations under this Lease will not result in or constitute any default or event that would be, or with notice or the lapse of time would be, a default, breach or violation of the organizational instruments governing Landlord or any agreement or any order or decree of any court or other governmental authority to which Landlord is a party or to which it is subject. Landlord has taken all necessary action to authorize the execution, delivery and performance of this Lease and this Lease constitutes the legal, valid and binding obligation of Landlord.

29. BROKERS.

Tenant and Landlord warrant that they have had dealings with only the real estate brokers or agents listed in Article 1 (the "***Brokers***") in connection with the negotiation of this Lease and that they know of no other real estate broker or agent who is entitled to a commission in connection with this Lease. The brokerage commissions earned in connection with this transaction shall be paid by Landlord pursuant to a separate written agreement between Landlord and each of the Brokers. Tenant and Landlord shall indemnify, defend and hold the other harmless from and against all liabilities arising from any other claims of brokerage commissions or finder's fees based on Tenant's or Landlord's, as applicable, dealings or contacts with brokers or agents other than those listed in Article 1.

30. DISPUTE RESOLUTION.

30.1 Meet and Confer. The parties shall endeavor to resolve any disputes relating to this Lease through reasonable business-like dispute resolution procedures without resort to litigation. Accordingly, if a dispute arises regarding any matter other than the Tenant defaults described in Section 16.1, either party may call a special meeting of the parties by written request specifying the nature of the matter to be addressed. The meeting shall be held at the Premises, and shall be attended by representatives of Landlord and Tenant who have authority to resolve the dispute. Such representatives shall confer in a good faith attempt to resolve the dispute until they either succeed or one or both parties concludes that the dispute will not be resolved through one or more special meetings.

30.2 Mediation. If a matter in dispute is not resolved through the special meeting process, either party may initiate mediation by delivering written notice to the other. Both parties shall attend and participate in the mediation, which shall be non-binding and without prejudice to any other rights or remedies that either party may have. Unless the parties agree otherwise, the mediation proceeding shall be conducted in the San Francisco Bay Area,

by an independent mediator from the San Francisco office of JAMS (or any successor or mutually acceptable alternative, referred to hereafter as the "JAMS") in accordance with JAMS procedures, within thirty (30) days after the notice initiating mediation is delivered. The costs of the mediation shall be shared equally by both parties to the mediation, except that each party shall pay the fees, costs and expenses of its own legal counsel and consultants in connection with such mediation. Any voluntary settlement reached as a result of the mediation proceeding shall be reduced to writing. All mediation proceedings shall be subject to the provisions of California Evidence Code sections 1152 and 1152.5, and any amended, similar or successor laws.

30.3 General. The foregoing dispute resolution procedures shall not in any way affect any statutes of limitation relating to any dispute relating to this Lease. This dispute resolution procedure may be conducted before or during the pendency of any other legal proceedings, and either party shall be entitled to bring any legal or judicial action to enjoin an act or proposed act by the other party which is in dispute, or seek any other ancillary relief to preserve the status quo or protect the rights of either party, pending the commencement or completion of any mediation process.

31. MISCELLANEOUS.

31.1 Entire Agreement. This Lease, including the exhibits which are incorporated herein and made a part of this Lease, contains the entire agreement between the parties and all prior negotiations and agreements are merged herein. Tenant hereby acknowledges that neither Landlord nor Landlord's Agents have made any representations or warranties with respect to the Premises, the Property, or this Lease except as expressly set forth herein, and no rights, easements or licenses are or shall be acquired by Tenant by implication or otherwise unless expressly set forth herein.

31.2 No Waiver. No failure by Landlord or Tenant to insist upon the strict performance of any obligation of Tenant or Landlord under this Lease or to exercise any right, power or remedy consequent upon a breach thereof, no acceptance of full or partial Base Rent or Additional Rent during the continuance of any such breach by Landlord, or payment of Base Rent or Additional Rent by Tenant to Landlord, and no acceptance of the keys to or possession of the Premises prior to the expiration of the Term by any employee or agent of Landlord shall constitute a waiver of any such breach or of such term, covenant or condition or operate as a surrender of this Lease. No waiver of any breach shall affect or alter this Lease, but each and every term, covenant and condition of this Lease shall continue in full force and effect with respect to any other then-existing or subsequent breach thereof. The consent of Landlord or Tenant given in any instance under the terms of this Lease shall not relieve Tenant or Landlord, as applicable, of any obligation to secure the consent of the other in any other or future instance under the terms of this Lease.

31.3 Amendments, Modifications or Waivers. This Lease may only be amended, changed, terminated or modified by a written instrument signed by both Landlord and Tenant. Neither this Lease nor any term or provisions hereof may be changed, waived, discharged or terminated orally. A breach of this Lease shall not be waived except by a written instrument signed by the party against which the change, waiver, discharge or termination is sought.

31.4 Successors and Assigns. The terms, covenants and conditions contained in this Lease shall bind and inure to the benefit of Landlord and Tenant and, except

as otherwise provided or limited herein, their respective personal representatives and successors and assigns.

31.5 Validity. If any provision of this Lease or the application thereof to any person, entity or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such provision to persons, entities or circumstances other than those as to which it is invalid or unenforceable, shall not be affected thereby, and each provision of this Lease shall be valid and be enforced to the full extent permitted by law.

31.6 Jurisdiction. This Lease shall be construed and enforced in accordance with the laws of the State of California. Any action that in any way involves the rights, duties and obligations of the parties under this Lease may (and if against Landlord, shall) be brought in the courts of the State of California or the United States District Court for the District of California, and the parties hereto hereby submit to the personal jurisdiction of said courts.

31.7 Attorneys' Fees. In the event that either Landlord or Tenant fails to perform any of its obligations under this Lease or in the event a dispute arises concerning the meaning or interpretation of any provision of this Lease, the defaulting party or the party not prevailing in such dispute, as the case may be, shall pay any and all costs and expenses incurred by the other party in enforcing or establishing its rights hereunder, including, without limitation, court costs, costs of arbitration and reasonable attorneys' fees.

31.8 Intentionally Omitted.

31.9 Light and Air. Tenant covenants and agrees that no diminution of light, air or view by any structure that may hereafter be erected (whether or not by Landlord) shall entitle Tenant to any reduction of the Base Rent or Additional Rent under this Lease, result in any liability of Landlord to Tenant, or in any other way affect this Lease or Tenant's obligations hereunder.

31.10 Lease Memorandum. Neither Landlord nor Tenant shall record this Lease or a short form memorandum hereof without the consent of the other.

31.11 Confidentiality. The parties agree that neither of them shall make public the terms and conditions of this Lease or the fact that they have entered into this Lease to any person other than a party's accountants, attorneys, lenders, brokers, prospective ground lessees, investors, consultants or financial advisors without first obtaining the written permission from the other party, except to the extent otherwise required by Applicable Law, including without limitation the securities laws of the United States and other jurisdictions. The foregoing notwithstanding, Tenant hereby grants Landlord the right to include Tenant's name and logo on any list of Stanford Research Park tenants posted on its website or included in other published materials.

31.12 Terms. The term "Premises" includes the space leased hereby and any improvements now or hereafter installed therein or attached thereto. The words "Landlord" and "Tenant" as used herein shall include the plural as well as the singular. If there is more than one Tenant or Landlord, the obligations under this Lease imposed on Tenant or Landlord shall be joint and several. The captions preceding the articles of this Lease have been inserted solely as a matter of convenience and such captions in no way define or limit the scope or intent of any provision of this Lease.

31.13 Review and Approval. The review, approval, inspection or examination by Landlord of any item to be reviewed, approved, inspected or examined by Landlord under the terms of this Lease or the exhibits attached hereto shall not constitute the assumption of any responsibility by Landlord for either the accuracy or sufficiency of any such item or the quality of suitability of such item for its intended use. Any such review, approval, inspection or examination by Landlord is for the sole purpose of protecting Landlord's interests in the Property and under this Lease, and no third parties, including, without limitation, Tenant or any person or entity claiming through or under Tenant, or the contractors, agents, servants, employees, visitors or licensees of Tenant or any such person or entity, shall have any rights hereunder with respect to such review, approval, inspection or examination by Landlord.

31.14 No Beneficiaries. This Lease shall not confer or be deemed to confer upon any person or entity other than the parties hereto, any right or interest, including without limitation, any third party status or any right to enforce any provision of this Lease.

31.15 Time of the Essence. Time is of the essence in respect of all provisions of this Lease in which a definite time for performance is specified. In the event the time for performance of any obligation under this Lease shall fall on a Saturday, Sunday or holiday, such time for performance shall be extended to the next Business Day.

31.16 Modification of Lease. In the event of any ruling or threat by the Internal Revenue Service, or opinion of counsel, that all or part of the Rent paid or to be paid to Landlord under this Lease will be subject to the income tax or unrelated business taxable income, Tenant agrees to modify this Lease to avoid such tax; provided that such modifications will not result in any increase in Rent, or any increased obligations of Tenant under this Lease. Landlord will pay all Tenant's reasonable costs incurred in reviewing and negotiating any such lease modification, including reasonable attorneys' and accountants' fees.

31.17 Construction. This Lease has been negotiated extensively by Landlord and Tenant with and upon the advice of their respective legal counsel, all of whom have participated in the drafting hereof. Consequently, Landlord and Tenant agree that no party shall be deemed to be the drafter of this Lease and in the event this Lease is ever construed by a court of law, such court shall not construe this Lease or any provision of this Lease against any party as the drafter of the Lease.

31.18 Use of Name. Tenant acknowledges and agrees that the names ***"The Leland* Stanford *Junior University," "Stanford"*** and ***"Stanford University,"*** and all variations thereof, are proprietary to Landlord. Tenant shall not use any such name or any variation thereof or identify Landlord in any promotional advertising or other promotional materials to be disseminated to the public or any portion thereof or use any trademark, service mark, trade name or symbol of Landlord or that is associated with it, without Landlord's prior written consent, which may be given or withheld in Landlord's sole discretion. Notwithstanding the foregoing, Tenant may use the term "Stanford Research Park" only to identify the location of the Premises.

31.19 Blocked Person. Tenant represents and warrants that neither Tenant nor any person or entity owning any direct or indirect membership interest or other equity ownership interest in Tenant is now, or ever has been, named on (or now is or ever has been acting directly or indirectly for or on behalf of any person or entity named on) the list of "Specially Designated Nationals and Blocked Persons" published by the Office of Foreign Assets Control of the United States Department of the Treasury or any similar list maintained by

the United States government or any other government (any person so named, a ***"Blocked Person"***). If Tenant, or any person or entity owning any direct or indirect membership interest or other equity ownership interest in Tenant, at any time becomes a Blocked Person or acts directly or indirectly for or on behalf of any Blocked Person, such event shall constitute an Event of Default under this Lease, unless within thirty (30) days after Tenant becomes aware of such Blocked Person or aware of actions taken directly or indirectly for or on behalf of such Blocked Person, Tenant initiates and diligently pursues steps to cause such Blocked Person to be removed from owning a direct or indirect membership or other equity ownership interest in Tenant or removed from the list of "Specially Designated Nationals and Blocked Persons."

31.20 Survival. The obligations of this Lease shall survive the expiration of the Term to the extent necessary to implement any requirement for the performance of obligations or forbearance of an act by either party hereto which has not been completed prior to the termination of this Lease. Such survival shall be to the extent reasonably necessary to fulfill the intent thereof, or if specified, to the extent of such specification, as same is reasonably necessary to perform the obligations and/or forbearance of an act set forth in such term, covenant or condition. Notwithstanding the foregoing, in the event a specific term, covenant or condition is expressly provided for in such a clear fashion as to indicate that such performance of an obligation or forbearance of an act is no longer required, then the specific shall govern over this general provisions of this Lease.

31.21 Counterparts. This Lease may be executed in counterparts, each of which shall be an original, and all of which together shall constitute one original of the Lease. Signature pages may be detached from the counterparts and attached to a single copy of this Agreement to physically form one document. Counterparts sent by fax or email shall be deemed originals for all purposes.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease as of the Effective Date.

LANDORD:	TENANT:
THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY	JAZZ PHARMACEUTICALS, INC., a Delaware corporation
By: /s/ Tiffany Griego	
Tiffany Griego	By: /s/ Bruce C. Cozadd
Its: Managing Director, Asset Management	Bruce C. Cozadd
	Its: CEO

GLOSSARY

As used in this Lease, the following terms shall have the following meanings, applicable, as appropriate, to both the singular and plural form of the terms defined below:

"3170 Porter Lease" is that certain Commercial Lease by and between Landlord and Tenant dated January 7, 2015 pursuant to which Tenant leases from Landlord certain space within the building constructed on property commonly known as 3170 Porter Drive in Palo Alto, California.

"Active Negligence" means the want of care in performing an act, as distinguished from inaction, which in a proper case may be negligence. Active Negligence occurs when a party has individually participated in an affirmative act of negligence.

"Actual Access Date" is defined in Section 2.4(a) of **Exhibit D**.

"ADA" is defined in Section 12.1.

"Added Costs" means the extra, incremental out-of-pocket costs to redevelop, upgrade, renovate, repair, rehabilitate, or remodel the existing improvements or construct new improvements at the Premises, or to make the Premises suitable for sale or tenant use, to the extent due to Tenant Environmental Activity, including the presence of residual Hazardous Substances after remediation. Added Costs may include, but is not limited to, the costs of any studies or risk assessments required by any government authority with jurisdiction, or those that are technically warranted and reasonably requested by subsequent lessee of the Premises or any portion thereof, including without limitation, the costs of any hazardous material contractor to perform work at the Premises, the costs for handling and disposal of any Hazardous Substances at the Premises, and the costs of any special requirements to control soil vapors or dewater the Premises as a means to remediate the Premises. Added Costs shall not include ordinary costs to redevelop, upgrade, renovate, repair, rehabilitate, or remodel the existing improvements or construct new improvements at the Premises, or to make the Premises suitable for use by another occupant, that would have been incurred absent the Tenant Environmental Activity.

"Additional Rent" is defined in Section 6.3.

"Adjustment Date" is defined in Section 6.1.

"Affiliate" is defined in Section 15.7.

"Alterations" are defined in Section 10.5.

"Amenity Space" is defined in Section 2.1.

"Applicable Laws" are defined in Section 12.1.

"ARB" is defined in Section 10.2.

"Assignment" is defined in Section 15.1.

"Bank" is defined in Section 6.5(c).

"Base Building Architect" means the architect for the Base Building Work, who shall be designated by Landlord.

"Base Building Construction Drawings" are defined in Section 2.1 of **Exhibit D**.

"Base Building Contractor" means the general contractor for the Base Building Work, who shall be designated by Landlord.

"Base Building Work" means the improvement work described in ***Attachment 1*** to **Exhibit D**. ***Attachment 1*** is comprised of ***Attachment 1A*** (Base Building Work Description) and ***Attachment 1B*** (Construction Responsibility Matrix), and references to ***Attachment 1*** shall be deemed to refer to both such components. The Base Building Work consists of (a) the Shell Components, (b) the Core Components, and (c) the Common Area Improvements.

"Base Rent" means the amount stated in Article 1, to be adjusted and payable in accordance with Article 6.

"Blocked Person" is defined in Section 31.19.

"Brokers" is defined in Article 29.

"Building" is defined in Section 2.1.

"Building Structure" is defined in Section 9.1.

"Building Systems" are defined in Section 8.2(b).

"Business Days" means Monday through Friday, excluding federal and state legal holidays.

"CASp" is defined in Section 3.3.

"Certification" is defined in Section 10.3.

"Change of Control" is defined in Section 15.1.

"City" means the City of Palo Alto.

"Code Requirements" are defined in ***Attachment 1A*** to **Exhibit D**.

"Common Area Improvements" are described in ***Attachment 1*** to **Exhibit D**.

"Common Area" is defined in Section 2.2.

"Commencement Date" means the date specified in Article 1.

"Core" and/or ***"Core Components"*** are described in ***Attachment 1*** to **Exhibit D**.

"Early Termination Option" is defined in Section 5.3.

"Environmental Audit" is defined in Section 13.7.

"Environmental Claims" means all claims, demands, suits, actions (including, without limitation, notices of noncompliance, charges, directives, and requests for information), causes of action, orders, judgments, settlements, damages, losses, diminutions in value, penalties, fines, actions, proceedings, obligations, liabilities (including strict liability), encumbrances, liens, costs (including, without limitation, costs of investigation and defense of any claim (including, Landlord's in-house counsel), whether or not such claim is ultimately defeated, and costs of any good faith settlement or judgment), and expenses of whatever kind or nature, contingent or otherwise, matured or unmatured, foreseeable or unforeseeable, including without limitation reasonable attorneys' and

consultants' fees and disbursements, any of which are incurred at any time, arising out of or related to Environmental Requirements, including, without limitation:

(a) Damages for personal injury, or injury to property or natural resources occurring upon the Premises or off the Premises, foreseeable or unforeseeable, including, without limitation, consequential damages, lost profits, lost rents, the cost of demolition and rebuilding of any improvements on real property, interest and penalties;

(b) Claims brought by or on behalf of employees of Tenant;

(c) Fees incurred for the services of attorneys, consultants, contractors, experts, laboratories and all other costs incurred in connection with the investigation or remediation of Releases of Hazardous Substances (whether or not performed voluntarily) or violation of Environmental Requirements, including, but not limited to, preparation of feasibility studies or reports, or the performance of any cleanup, remediation, removal, response, abatement, containment, closure, restoration or monitoring work required by any federal, state or local governmental agency or political subdivision, reasonably necessary to restore full economic use of the Premises or any other property, or otherwise expended in connection with such conditions, and including without limitation any attorneys' fees, costs and expenses incurred in enforcing this Lease or collecting any sums due hereunder;

(d) Liability to any third person or governmental agency to indemnify such person or agency for costs expended in connection with the items referenced above; and

(e) Diminution in the value of the Premises, and damages for the loss of business and restriction on the use of, or adverse impact on the marketing of, rentable or usable space or any amenity of the Premises.

"Environmental Requirements" means all applicable present and future statutes, regulations, rules, ordinances, codes, common law, licenses, permits, orders, approvals, plans, authorizations, concessions, franchises, and similar items, and all amendments thereto, of all governmental agencies, departments, commissions, boards, bureaus or instrumentalities of the United States, California, and political subdivisions thereof, including but not limited to City, the County of Santa Clara, the Regional Water Quality Control Board, Department of Toxic Substances Control, California Department of Fish and Wildlife, United States Environmental Protection Agency, United States Fish and Wildlife Service, and Army Corps of Engineers, and all applicable judicial, administrative and regulatory decrees, judgments, orders and written directives relating to the protection of human health, safety, wildlife or the environment, including, without limitation, (a) all requirements pertaining to reporting, licensing, permitting, investigation and/or remediation of emissions, discharges, Releases, or threatened Releases of Hazardous Substances, whether solid, liquid, or gaseous in nature, into the air, surface water, groundwater, or land, or relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport, or handling of Hazardous Substances; and (b) all requirements pertaining to occupational health, the health and safety of employees or the public. Environmental Requirements include, but are not limited to, the Comprehensive Environmental Response, Compensation and Liability Act; the Emergency Planning and Community Right-to-Know Act; the Hazardous Substances Transportation Act; the Resource Conservation and Recovery Act; the Solid Waste Disposal Act; the Clean Water Act; the Clean Air Act; the Toxic Substances Control Act; the Safe Drinking Water Act; the California Medical Waste Management Act and Radiation Control Law; the Occupational Safety and Health Act; the Federal Water Pollution Control Act; the Federal Insecticide, Fungicide and Rodenticide Act; the Endangered Species Act and the National Environmental Policy Act and any and all state or local law counterparts.

"Event of Default" is defined in Section 16.1.

"Exacerbation" means any direct, material adverse impact on a Pre-Existing Environmental Condition. Exacerbation includes, without limitation, actions which speed, redirect or enhance the migration of groundwater contamination at the Premises in a fashion that causes a material adverse impact (for example, by causing Hazardous Substances to migrate to deeper aquifers), actions which cause damage to or limit the effectiveness of any existing remediation systems or equipment, and actions which give rise to Environmental Claims.

"Excess Rent" is defined in Section 15.4.

"Expiration Date" means the date specified in Article 1.

"Final Plans" are defined in Section 3.3(b) of **Exhibit D**.

"Hazardous Substance" means any substance, material or waste:

(a) the presence of which requires investigation or remediation under any Environmental Requirement;

(b) which is or becomes listed, regulated or defined as a "hazardous waste," "hazardous substance," "hazardous material", "toxic substance", "hazardous air pollutant", "pollutant," "infectious waste," "bio-hazardous waste", "medical waste", "radioactive material", "radioactive waste", or "contaminant" under any Environmental Requirement;

(c) which is toxic, explosive, corrosive, flammable, infectious, radioactive, carcinogenic, mutagenic, or otherwise hazardous to human health, safety, wildlife or the environment and is or becomes regulated under any Environmental Requirement;

(d) the presence or Release of which at, on, under or from the Premises causes or threatens to cause a nuisance upon the Premises or to surrounding properties or poses or threatens to pose a hazard to the environment or the health or safety of persons on or about the Premises; or

(e) the presence of which on adjacent properties could constitute a trespass by Tenant.

Without limitation of the foregoing, Hazardous Substances shall include gasoline, diesel fuel and other petroleum hydrocarbons and the additives and constituents thereto, including MTBE; polychlorinated biphenals (PCBs); asbestos and asbestos-containing material; lead; urea formaldehyde foam insulation; radon gas and microbial material (including mold).

"Interest Rate" means the annual compounded interest rate equal to a 400 basis points spread over the prime rate of interest published in the Wall Street Journal as of the first date any applicable interest accrues. The Interest Rate shall be reset each month that it is invoked such that the Interest Rate shall be the greater of the Interest Rate owed on the outstanding amount or the current Interest Rate as calculated by the preceding sentence. For the purpose of converting the Interest Rate into a daily compound interest rate, Landlord shall divide the Interest Rate by 365 days.

"Initial Sublease" is defined in Section 15.5.

"Landlord" is defined in the introductory paragraph to this Lease.

"Landlord Parties" is defined in Section 13.4.

"Landlord's Agents" means Landlord's agents, employees and contractors.

"Landlord's Expense Statement" is defined in Section 8.3.

"Landlord's Unavoidable Delay" means any actual delay in the completion of the Base Building Work caused by: (a) Acts of God (including without limitation, lightning, earthquake, fire, storm, hurricane, tornado, flood, washout or rain affecting the job site, access to the site or the supply chain), explosion, strikes, lock-outs, inability to obtain necessary equipment, supplies or materials through ordinary sources by reason of regulation or order of any government or regulatory body, civil disturbance, act of a public enemy, war, riot, sabotage, blockade; (b) delays in obtaining any required entitlements, permits, inspections, approvals and final signoffs from governmental authorities; (c) the construction of the Tenant Improvement Work to the extent such construction is performed in a manner which is inconsistent with this Work Letter and impedes or damages the Base Building Work; (d) delay in the completion of the Final Plans and/or the construction of the Base Building Work to the extent caused by unforeseen changes in any Applicable Laws after the Effective Date (including, without limitation, the ADA); (e) Tenant's failure to meet the deadlines and schedules described in this Work Letter; (f) any interruption in Landlord's access to or utilities available to the Premises on account of Tenant Improvement Work or otherwise caused by Tenant or Tenant's Agents; or (g) any other similar cause beyond the reasonable control of Landlord, or any of its contractors or other representatives.

"L-C" is defined in Section 6.5(a)

"L-C Amount" is defined in Section 6.5(a).

"L-C Event" is defined in Section 6.5(b).

"Lines" is defined in Section 10.7.

"Milestone Schedule" means the schedule for the design, approval and construction of the Base Building Work and the Tenant Improvement Work, as amended from time to time in accordance with **Exhibit D**. The initial Milestone Schedule is attached hereto as ***Attachment 2*** to **Exhibit D**.

"Modification Costs" are defined in Section 2.5 of **Exhibit D**.

"Move-Out Date" is defined in Section 21.1.

"Non-Disturbance Agreement" is defined in Section 17.5.

"Offer" is defined in Section 15.5.

"Operating Expenses" are defined in Section 8.2.

"Outside Completion Date" is defined in Section 4.1.

"Parking Area" is defined in Section 2.3.

"Permitted Transfer" is defined in Section 15.7.

"Permitted Transferee" is defined in Section 15.7.

"Permitted Use" is defined in Article 1.

"Pre-Existing Environmental Condition" is defined in Section 13.11.

"Premises" is defined in Section 1.

"Prevailing Market Rent" is defined in Exhibit C.

"Project" is defined in Section 2.1.

"Property" is defined in Section 2.1.

"Punch List Items" means any incomplete items, items requiring correction, or defective items in the construction of the Base Building Work that do not materially interfere with the ability of the Tenant Improvement Contractor to complete and perform the Tenant Improvement Work or for Tenant to legally occupy the Premises upon completion of the Tenant Improvement Work.

"Real Estate Taxes" are defined in Section 8.2(a).

"Release" with respect to Hazardous Substances, means any release, deposit, discharge, emission, leaking, spilling, seeping, migrating, injecting, pumping, pouring, emptying, escaping, dumping, disposing, or other movement of Hazardous Substances into the environment; provided that "Release" shall not include the migration, seepage or discharge on, over or across the Premises of any Hazardous Substance that originates off of the Premises.

"Remaining Substances" is defined in Section 13.5(d).

"Renewal Option" is defined in Section 5.2.

"Renewal Term" is defined in Section 5.2.

"Rent" is defined in Section 6.3.

"Rent Abatement Period" is defined in Section 6.2.

"Rentable Area" means the Gross Floor Area of the Building, as defined in Chapter 18 of the City's Zoning Ordinance. The definition includes, but is not limited to, calculating the total area of all floors of a building measured to the outside surfaces of exterior walls, and includes all of the following: (i) halls, (ii) stairways, (iii) elevators shafts, (iv) service and mechanical equipment rooms, (v) basement, cellar or attic areas deemed usable by the Director of Planning and Community Environment, (vi) open or roofed porches, arcades, plazas, balconies, courts, walkways, breezeways or porticos if located above the ground floor and used for required access, and (vii) permanently roofed, but either partially enclosed or unenclosed, building features used for sales, service, display, storage or similar uses. Rentable Area shall also include any Amenity Space in the Building.

"Rules and Regulations" is defined in Section 24.1.

"Security Deposit Laws" is defined in Section 6.5(d).

"Scheduled Access Date" means the date specified in Article 1, subject to extension for a Landlord's Unavoidable Delay.

"Shell" and/or ***"Shell Components"*** are described in ***Attachment 1*** to **Exhibit D**.

"Space Plan" is defined in Section 3.3(a) of **Exhibit D**.

"Sublease" is defined in Section 15.1.

"Substantial Completion" or ***"Substantially Complete"*** means the substantial completion of the Shell Components, Core Components and Common Area Improvements, as certified by the Base Building Architect by a factually correct notice to Tenant confirming that the Shell Components, Core Components and Common Area Improvements have been substantially completed in all material respects in accordance with Section 2 of **Exhibit D,** such that the only

additional work to be completed by the Base Building Contractor is Punch List Items. Substantial Completion and Tenant's acceptance of the Premises shall not be conditioned upon completion of all Common Area Improvements or Punch List Items unless such Common Area Improvements or Punch List Items materially adversely affect the construction of the Tenant Improvement Work or Tenant's ability to obtain permits, permit sign-offs, or a certificate of occupancy.

"Substantial Completion Date" is defined in Section 5.1.

"Substantial Completion Inspection" is defined in Section 2.7 of **Exhibit D**.

"Successor" is defined in Section 17.5.

"Supplemental Audit" is defined in Section 13.7.

"TDM Fees" is defined in Section 7.3.

"Tenant" is defined in the introductory paragraph to this Lease.

"Tenant Delay" means any delay in the completion of the Base Building Work to the extent caused or contributed to by (i) any failure of Tenant to comply with the approval schedules set forth herein; (ii) any Tenant Modification; or (iii) Tenant's failure to make any payment as and when required under **Exhibit D**; provided that no act or omission by Tenant or Tenant's Agents shall be deemed to cause a Tenant Delay unless Landlord provides Tenant with written notice of the specific act or omission and Tenant fails to cure the same within five (5) Business Days thereafter.

"Tenant Environmental Activity" means (a) any use, treatment, keeping, handling, storage, transport, sale or Release at, on, under or from the Premises of any Hazardous Substance during the Term by Tenant or any Tenant Agent; (b) the Exacerbation of any Pre-Existing Environmental Condition, as defined in Section 13.11, to the extent such Exacerbation is the result of, or is related to the acts or omissions of Tenant or Tenant's Agents, subtenants or invitees on or about the Premises during the Term; or (c) any violation of any Environmental Requirements by Tenant or Tenant's Agents on or about the Premises during the Term.

"Tenant Improvement Allowance" is specified in Article 1.

"Tenant Improvement Contract" means the contract with the Tenant Improvement Contractor for the construction of the Tenant Improvement Work.

"Tenant Improvement Contractor" means the general contractor for the construction of the Tenant Improvement Work, who shall be selected by Tenant and approved by Landlord, which approval shall not be unreasonably withheld, conditioned or delayed. Subject to Landlord's foregoing approval right, Tenant shall have the right to solicit multiple bids prior to selection of the Tenant Improvement Contractor.

"Tenant Improvement Costs" means the actual costs of the Tenant Improvement Work, including the fees and expenses payable to Tenant's Architect, consultants and third party managers, design and development costs, fees for the Tenant Improvement Permits and construction costs. Tenant Improvement Costs shall not include, and the Tenant Improvement Allowance shall not be spent on, furniture, demountable partitions or other personal property.

"Tenant Improvement Permits" means all permits, licenses and other approvals necessary to construct the Tenant Improvement Work in compliance with all Applicable Laws.

"Tenant Improvement Plans" are defined in Section 3.3(b) of **Exhibit D**.

"Tenant Improvement Work" means all work required to finish the Premises to a condition acceptable for the conduct of Tenant's business and not specifically included in the Base Building Work.

"Tenant Modifications" are defined in Section 2.5 of **Exhibit D**.

"Tenant Obligations" is defined in Section 9.3.

"Tenant Systems" is defined in Section 9.3.

"Tenant's Agents" is defined in Section 2.2.

"Tenant's Architect" means the licensed architect engaged by Tenant, and approved by Landlord in its reasonable discretion, to develop the Space Plan and working drawings for, and to oversee the construction of, the Tenant Improvement Work.

"Tenant's Architect Agreement" means the agreement between Tenant and Tenant's Architect for the design and oversight of the Tenant Improvement Work.

"Tenant's Property" is defined in Section 10.9.

"Tenant's Unavoidable Delay" means any actual delay in the completion of the Tenant Improvement Work caused by: (a) Acts of God (including without limitation, lightning, earthquake, fire, storm, hurricane, tornado, flood, washout or rain affecting the job site, access to the site or the supply chain), explosion, strikes, lock-outs, inability to obtain necessary equipment, supplies or materials through ordinary sources by reason of regulation or order of any government or regulatory body, civil disturbance, act of a public enemy, war, riot, sabotage, blockade; (b) the construction of the Shell Components and Core Components to the extent such construction is performed in a manner which is inconsistent with this Work Letter, and impedes or damages the Tenant Improvement Work; (c) delay in the construction of the Tenant Improvement Work to the extent caused by unforeseen changes in any Applicable Laws after the Effective Date (including, without limitation, the ADA); (d) Landlord's failure to meet the Scheduled Access Date; (e) any defects in the Shell Components and Core Components that materially adversely affect the construction of the Tenant Improvement Work, including without limitation Tenant's ability to obtain building permits, permit sign-offs and/or a certificate of occupancy; (f) any interruption in Tenant's access to or utilities available to the Premises on account of the Base Building Work or otherwise caused by Landlord or Landlord's Agents; or (g) any other similar cause beyond the reasonable control of Tenant, or any of its contractors or other representatives. Tenant's Unavoidable Delay shall not include (i) Tenant's financial inability; (ii) economic downturn; (iii) delays in Tenant's obtaining any required entitlements, permits, inspections, approvals and final signoffs from governmental authorities, except to the extent arising due to Landlord's failure to complete construction of the Shell Components and Core Components.

"Term" is defined in Article 1 and Section 5.1.

"Termination Date" is defined in Section 5.1.

"Termination Option Date" is defined in Section 5.3.

"Transfer" is defined in Section 15.5.

"Transfer Costs" is defined in Section 15.4.

"Transfer Notice" is defined in Section 15.2.

"Transferee" is defined in Section 15.2.

"Transportation Demand Management" is a set of programs and policies that respond to real and perceived barriers to taking trips by transit, bicycling, walking or carpooling/vanpooling, and that use market signals to reduce drive-alone trips. Transportation Demand Management strategies include information and education, incentives, physical and infrastructure changes, technology and pricing. Transportation Demand Management programs may be implemented by Landlord, the City or other governmental agency.

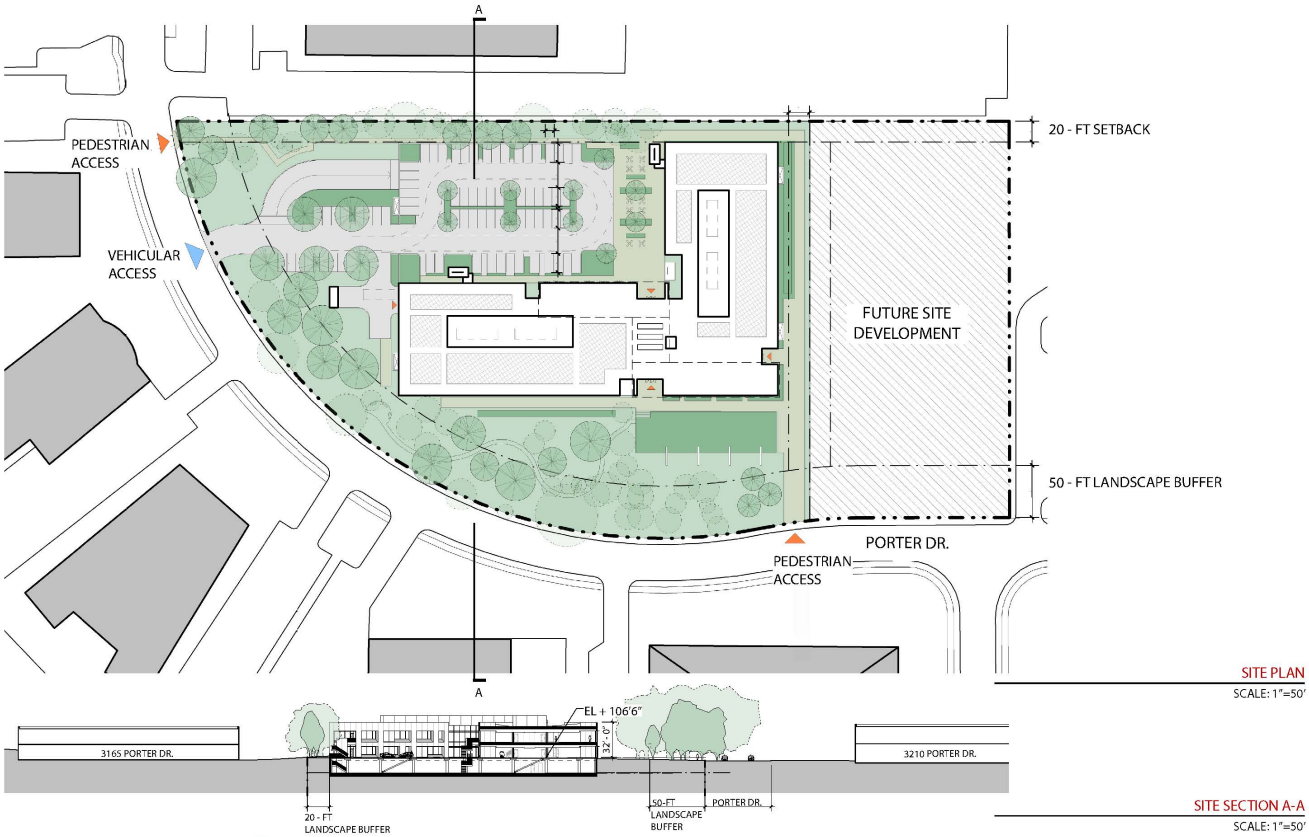
"Triggering Event" is defined in Section 13.10.

"Unrestricted Use" means a condition allowing any use of real property, including without limitation residential, hospital or day care, without any engineering controls or deed restrictions.

EXHIBIT A

SITE PLAN

[Attached]



SITE PLAN
SCALE: 1"=50'

SITE SECTION A-A
SCALE: 1"=50'

SMITHGROUP JJR

Stanford University

SITE CONTEXT PLAN
3181 PORTER
05/06/2016

EXHIBIT B

NOTICE OF COMMENCEMENT DATE,
EXPIRATION DATE, BASE RENT AND RENTABLE AREA

_____, 201_

_____
_____

Attention:_____

Re: Lease between The Board of Trustees of the Leland Stanford Junior University (Landlord), and Jazz Pharmaceuticals, Inc. (Tenant), for premises located at 3181 Porter Drive, Palo Alto, California

Gentlemen/Ladies:

This letter will confirm the following for all purposes under the Lease:

The Tenant Improvement Allowance is $_____
The Commencement Date is _____
The Expiration Date is _____
The Rentable Area of the Premises is _____
The Base Rent for the initial Term is as follows:

Period During Lease Term	Monthly Base Rent per sq. ft. of Rentable Area	Monthly Base Rent
_____ - _____	$6.20	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____
_____ - _____	$_____	$_____

Please acknowledge your acceptance of this letter by signing and returning two copies of this letter.

Very truly yours,

The Board of Trustees of the
Leland Stanford Junior University

By: _____

Its: _____

EXHIBIT C

DETERMINATION OF PREVAILING MARKET RENT

The term ***"Prevailing Market Rent"*** means the base monthly rent per rentable square foot (net of all expenses) for direct leases from the landlord (as opposed to subleases) of space of comparable size and location to the Premises and in buildings similar in age and quality to the Premises for a comparable term, taking into account any additional rent and all other payments or escalations then being charged and allowances and economic concessions being given in the Stanford Research Park for such comparable space over a comparable term. The Prevailing Market Rent shall be determined by Landlord and Landlord shall give Tenant written notice of such determination not later than thirty (30) days after delivery by Tenant of Tenant's notice of exercise of the Renewal Option. If Tenant disputes Landlord's determination of the Prevailing Market Rent, Tenant shall so notify Landlord within ten (10) Business Days following Landlord's notice to Tenant of Landlord's determination and, in such case, the Prevailing Market Rent shall be determined as follows:

(a) Within thirty (30) days following Tenant's notice to Landlord that it disputes Landlord's determination of the Prevailing Market Rent, Landlord and Tenant shall meet no less than two (2) times, at a mutually agreeable time and place, to attempt to agree upon the Prevailing Market Rent.

(b) If within this 30-day period Landlord and Tenant cannot reach agreement as to the Prevailing Market Rent, they shall each select one appraiser to determine the Prevailing Market Rent. Each such appraiser shall arrive at a determination of the Prevailing Market Rent and submit his or her conclusions to Landlord and Tenant within thirty (30) days after the expiration of the 30-day consultation period described in (a) above.

(c) If only one appraisal is submitted within the requisite time period, it shall be deemed to be the Prevailing Market Rent. If both appraisals are submitted within such time period, and if the two appraisals so submitted differ by less than ten (10) percent of the higher of the two, the average of the two shall be the Prevailing Market Rent. If the two appraisals differ by more than ten (10) percent of the higher of the two, then the two appraisers shall immediately select a third appraiser who will within thirty (30) days of his or her selection make a determination of the Prevailing Market Rent and submit such determination to Landlord and Tenant. This third appraisal will then be averaged with the closer of the previous two appraisals and the result shall be the Prevailing Market Rent.

(d) All appraisers specified pursuant hereto shall be members of the American Institute of Real Estate Appraisers with not less than five (5) years' experience appraising office, research and development and industrial properties in the San Francisco/Peninsula/South Bay area. Each party shall pay the cost of the appraiser selected by such party and one-half of the cost of the third appraiser plus one-half of any other costs incurred in the determination.

EXHIBIT D

WORK LETTER

The purpose of this **Exhibit D** is to delineate the responsibilities of Landlord and Tenant with respect to the design and construction of the Base Building Work and the Tenant Improvement Work, subject to the satisfaction of the contingencies set forth in Section 4 of the Lease.

1. Definitions. Terms defined in the Lease, including without limitation, the exhibits thereto, and not otherwise defined in this **Exhibit D** shall have the meanings assigned in the Lease. As used herein, the following terms shall have the following meanings:

"Actual Access Date" is defined in Section 2.4(a) below.

"Base Building Architect" means the architect for the Base Building Work, who shall be designated by Landlord.

"Base Building Construction Drawings" are defined in Section 2.1 below.

"Base Building Contractor" means the general contractor for the Base Building Work, who shall be designated by Landlord.

"Base Building Work" means the improvement work described in ***Attachment 1*** to this **Exhibit D**. ***Attachment 1*** is comprised of ***Attachment 1A*** (Base Building Work Description) and ***Attachment 1B*** (Construction Responsibility Matrix), and references to ***Attachment 1*** shall be deemed to refer to both such components. The Base Building Work consists of (a) the Shell Components, (b) the Core Components, and (c) the Common Area Improvements.

"Code Requirements" are defined in ***Attachment 1A*** to this **Exhibit D**.

"Common Area Improvements" are described in ***Attachment 1*** to this **Exhibit D**.

"Core" and/or ***"Core Components"*** are described in ***Attachment 1*** to this **Exhibit D**.

"Final Plans" are defined in Section 3.3(b) below.

"Landlord's Unavoidable Delay" means any actual delay in the completion of the Base Building Work caused by: (a) Acts of God (including without limitation, lightning, earthquake, fire, storm, hurricane, tornado, flood, washout or rain affecting the job site, access to the site or the supply chain), explosion, strikes, lock-outs, inability to obtain necessary equipment, supplies or materials through ordinary sources by reason of regulation or order of any government or regulatory body, civil disturbance, act of a public enemy, war, riot, sabotage, blockade; (b) delays in obtaining any required entitlements, permits, inspections, approvals and final signoffs from governmental authorities; (c) the construction of the Tenant Improvement Work to the extent such construction is performed in a manner which is inconsistent with this Work Letter and impedes or damages the Base Building Work; (d) delay in the completion of the Final Plans and/or the construction of the Base Building Work to the extent caused by unforeseen changes in any Applicable Laws after the Effective Date (including, without limitation, the ADA); (e) Tenant's failure to meet the deadlines and schedules described in this Work Letter; (f) any interruption in Landlord's access to or utilities available to the Premises on account of Tenant Improvement Work or otherwise caused by Tenant

or Tenant's Agents; or (g) any other similar cause beyond the reasonable control of Landlord, or any of its contractors or other representatives.

"Milestone Schedule" means the schedule for the design, approval and construction of the Base Building Work and the Tenant Improvement Work, as amended from time to time in accordance with this **Exhibit D**. The initial Milestone Schedule is attached hereto as ***Attachment 2*** to this **Exhibit D**.

"Modification Costs" are defined in Section 2.5 below.

"Punch List Items" means any incomplete items, items requiring correction, or defective items in the construction of the Base Building Work that do not materially interfere with the ability of the Tenant Improvement Contractor to complete and perform the Tenant Improvement Work or for Tenant to legally occupy the Premises upon completion of the Tenant Improvement Work.

"Scheduled Access Date" means the date specified in Article 1 of the Lease, subject to extension for a Landlord's Unavoidable Delay.

"Shell" and/or ***"Shell Components"*** are described in ***Attachment 1*** to this **Exhibit D**.

"Space Plan" is defined in Section 3.3(a) below.

"Substantial Completion" or ***"Substantially Complete"*** means the substantial completion of the Shell Components, Core Components and Common Area Improvements, as certified by the Base Building Architect by a factually correct notice to Tenant confirming that the Shell Components, Core Components and Common Area Improvements have been substantially completed in all material respects in accordance with Section 2 of this **Exhibit D,** such that the only additional work to be completed by the Base Building Contractor is Punch List Items. Substantial Completion and Tenant's acceptance of the Premises shall not be conditioned upon completion of all Common Area Improvements or Punch List Items unless such Common Area Improvements or Punch List Items materially adversely affect the construction of the Tenant Improvement Work or Tenant's ability to obtain permits, permit sign-offs, or a certificate of occupancy.

"Substantial Completion Inspection" is defined in Section 2.7 below.

"Tenant Delay" means any delay in the completion of the Base Building Work to the extent caused or contributed to by (i) any failure of Tenant to comply with the approval schedules set forth herein; (ii) any Tenant Modification; or (iii) Tenant's failure to make any payment as and when required under this **Exhibit D**; provided that no act or omission by Tenant or Tenant's Agents shall be deemed to cause a Tenant Delay unless Landlord provides Tenant with written notice of the specific act or omission and Tenant fails to cure the same within five (5) Business Days thereafter.

"Tenant Improvement Allowance" means the amount set forth in Article 1 of the Lease, as adjusted pursuant to Section 5.1 below.

"Tenant Improvement Contract" means the contract with the Tenant Improvement Contractor for the construction of the Tenant Improvement Work.

"Tenant Improvement Contractor" means the general contractor for the construction of the Tenant Improvement Work, who shall be selected by Tenant and approved by Landlord, which approval shall not be unreasonably withheld, conditioned or delayed. Subject to Landlord's foregoing approval right, Tenant shall have the right to solicit multiple bids prior to selection of the Tenant Improvement Contractor.

"Tenant Improvement Costs" means the actual costs of the Tenant Improvement Work, including the fees and expenses payable to Tenant's Architect, consultants and third party managers, design and development costs, fees for the Tenant Improvement Permits and construction costs. Tenant Improvement Costs shall not include, and the Tenant Improvement Allowance shall not be spent on, furniture, demountable partitions or other personal property.

"Tenant Improvement Permits" means all permits, licenses and other approvals necessary to construct the Tenant Improvement Work in compliance with all Applicable Laws.

"Tenant Improvement Plans" are defined in Section 3.3(b) below.

"Tenant Improvement Work" means all work required to finish the Premises to a condition acceptable for the conduct of Tenant's business and not specifically included in the Base Building Work. Tenant Improvement Work shall include the Amenity Space.

"Tenant Modifications" are defined in Section 2.5 below.

"Tenant's Architect" means the licensed architect engaged by Tenant, and approved by Landlord in its reasonable discretion, to develop the Space Plan and working drawings for, and to oversee the construction of, the Tenant Improvement Work.

"Tenant's Architect Agreement" means the agreement between Tenant and Tenant's Architect for the design and oversight of the Tenant Improvement Work.

"Tenant's Unavoidable Delay" means any actual delay in the completion of the Tenant Improvement Work caused by: (a) Acts of God (including without limitation, lightning, earthquake, fire, storm, hurricane, tornado, flood, washout or rain affecting the job site, access to the site or the supply chain), explosion, strikes, lock-outs, inability to obtain necessary equipment, supplies or materials through ordinary sources by reason of regulation or order of any government or regulatory body, civil disturbance, act of a public enemy, war, riot, sabotage, blockade; (b) the construction of the Shell Components and Core Components to the extent such construction is performed in a manner which is inconsistent with this Work Letter, and impedes or damages the Tenant Improvement Work; (c) delay in the construction of the Tenant Improvement Work to the extent caused by unforeseen changes in any Applicable Laws after the Effective Date (including, without limitation, the ADA); (d) Landlord's failure to meet the Scheduled Access Date; (e) any defects in the Shell Components and Core Components that materially adversely affect the construction of the Tenant Improvement Work, including without limitation Tenant's ability to obtain building permits, permit sign-offs and/or a certificate of occupancy; (f) any interruption in Tenant's access to or utilities available to the Premises on account of the Base Building Work or otherwise caused by Landlord or Landlord's Agents; or (g) any other similar cause beyond the reasonable control of Tenant, or any of its contractors or other representatives. Tenant's Unavoidable Delay shall not include (i) Tenant's financial inability; (ii) economic downturn; (iii) delays in Tenant's obtaining any required entitlements, permits, inspections, approvals and final signoffs from

governmental authorities, except to the extent arising due to Landlord's failure to complete construction of the Shell Components and Core Components.

2. Design and Construction of Base Building Work. Landlord shall diligently prosecute the development and construction of the Base Building Work and cause the Base Building Work to be performed in a first class manner (in consideration of the prominence of the location of the Property in the Stanford Research Park), in compliance in all material respects with the Base Building Construction Drawings, and all Applicable Laws (including, without limitation, the ADA). Tenant acknowledges that Landlord intends to construct the Base Building Work so that the Shell Components and Core Components are reasonably equivalent to LEED Gold status version 3.

2.1 Base Building Construction Drawings. Within thirty (30) days after the Effective Date, Landlord shall deliver to Tenant the final City-approved working drawings for the construction of the Base Building Work (the ***"Base Building Construction Drawings"***), which will include changes made in response to City plan check comments.

2.2 Schedule; Coordination. During the development and construction of the Base Building Work, and when certain milestones are achieved, Landlord shall distribute to Tenant updates to the Milestone **Schedule** that are prepared in connection with the Base Building Work, and Landlord and Tenant shall participate in regularly scheduled meetings to coordinate the Base Building Work with the Tenant Improvement Work. Landlord shall keep Tenant informed of all material changes in the Milestone Schedule so that Tenant may coordinate its construction work accordingly.

2.3 Tenant's Project Manager. Tenant shall enter into a contract with a third-party project manager reasonably approved by Landlord, and shall use commercially reasonable efforts to do so within sixty (60) days **after** the Effective Date of the Lease. Tenant's project manager will participate in meetings when requested to do so by Landlord, and otherwise provide project management services to Tenant. If Tenant's project manager is not granted decision-making authority on behalf of Tenant, Tenant shall also designate a representative who does have decision-making authority, and such representative shall also participate in any requested meetings. Tenant's designated project manager or other representative shall be the only person authorized to communicate with Landlord or to request Tenant Modifications.

2.4 Early Access and Joint Construction. Landlord shall allow Tenant early access to the Premises for the construction of the Tenant Improvement Work as early in the process of constructing the Base Building Work as is reasonably possible; provided that (a) such early access will not interfere with the timely completion of the Base Building Work, and (b) such early access will not delay any critical dates for the Substantial Completion of the Base Building Work. As of the Effective Date, the parties anticipate that Tenant will be permitted early access to the Premises for the construction of the Tenant Improvement Work on or before the Scheduled Access Date set forth in Article 1 of the Lease.

(a) Landlord shall use commercially reasonable efforts to provide Tenant with at least thirty (30) days prior written notice of the date that the Tenant Improvement Contractor may commence and proceed with construction of the Tenant Improvement Work (the ***"Actual Access Date"***), but in no event shall the Actual Access Date occur until Tenant has received written notice of such date. Landlord shall use reasonable efforts to complete installation of communications vault and conduit from MPOE to Premises at least ninety (90) days prior to the

Actual Access Date. Representatives of Landlord and Tenant shall accompany the Base Building Contractor and the Tenant Improvement Contractor on a walk-through and inspection of the Premises to determine if the Tenant Improvement Contractor may commence and proceed with construction of the Tenant Improvement Work, which shall occur no later than three (3) Business Days prior to the Actual Access Date. Tenant shall have three (3) Business Days after the walk-through to deliver written notice to Landlord if Tenant disagrees that the Tenant Improvement Contractor may commence and proceed with construction of the Tenant Improvement Work, and to provide a reasonably detailed list of all items that it considers insufficiently complete. In the event of such disagreement, (i) Landlord shall use commercially reasonable efforts to complete its work with respect to the unfinished items set forth on Tenant's list, (ii) on or prior to completion of such work, Landlord shall notify Tenant in writing of a proposed date for a subsequent walk-through and inspection of the Premises and (iii) on that date, or such other date as may be mutually agreed between Landlord and Tenant, representatives of Landlord and Tenant shall accompany the Base Building Contractor and the Tenant Improvement Contractor on a subsequent walk-through and inspection of the Premises to determine if the Tenant Improvement Contractor may commence and proceed with construction of the Tenant Improvement Work. If Tenant disagrees that the Tenant Improvement Contractor may commence and proceed with construction of the Tenant Improvement Work after such subsequent walk-through then, within three (3) Business Days thereafter, the parties and their respective contractors shall meet and confer in good faith regarding such disagreement. Neither party shall delay or suspend the construction process hereunder on account of such disagreement, and shall continue to perform the Base Building Work or Tenant Improvement Work as provided in this **Exhibit D**. Notwithstanding anything to the contrary set forth in the Lease or this **Exhibit D**, the Actual Access Date shall not occur until the parties have agreed that the Tenant Improvement Contractor may commence and proceed with construction of the Tenant Improvement Work.

(b) As of the Actual Access Date, Tenant shall deliver to Landlord evidence of the insurance that Tenant is required to maintain pursuant to the Lease, and Tenant's indemnity obligations shall become effective. Tenant and Tenant's Agents shall comply with all requirements of the Lease that are applicable during the early access period (e.g. no waste or nuisance, liability for Tenant Environmental Activity, Tenant's indemnity obligations, etc.). Tenant and Landlord shall use commercially reasonable efforts to avoid interference with the work that will be occurring by each party concurrently on the Property and shall cause their respective contractors, sub-contractors and suppliers to reasonably coordinate and cooperate so that neither party's work unreasonably interferes with the construction of the other party's work.

2.5 Tenant Modifications. Any changes to the exterior appearance of the Building are within the sole discretion of the Landlord. Any modifications to the Shell Components and Core Components requested by Tenant and approved by Landlord in its sole discretion prior to or during the course of construction pursuant to this Section 2.5 (collectively, ***"Tenant Modifications"***) shall be designed and constructed at Tenant's sole cost and expense. If Tenant desires any Tenant Modifications to the Shell Components and Core Components from the Base Building Construction Drawings in order to accommodate the Tenant Improvement Work, Tenant shall deliver a request in writing to Landlord for Landlord's review and approval. Landlord's construction representative shall review such Tenant Modification request and approve or deny such request within ten (10) Business Days after receipt of such request, and if such request is denied, shall state in writing the reason for such denial. If such request is denied, then Landlord and Tenant shall meet and confer within five (5) Business Days to attempt to resolve any issues which they have as to such requested Tenant Modification; provided that Landlord shall have the

final decision in its sole discretion whether or not to proceed with the proposed Tenant Modification. If Landlord approves Tenant's request for Tenant Modifications, Landlord shall prepare and deliver to Tenant an estimate of the incremental increased cost of designing and constructing such modifications, if any (the ***"Modification Costs"***). Tenant shall have five (5) Business Days after receipt of such estimate to revoke its request for the proposed Tenant Modifications by written notice to Landlord or to request that Landlord modify such Tenant Modification to reduce the Modification Costs. Actual Modification Costs paid to third parties shall be deducted from the Tenant Improvement Allowance, such that the Tenant Improvement Allowance shall be reduced by the total amount of all Modification Costs. Tenant shall have no right to any further Tenant Modifications once the Tenant Improvement Allowance has been fully paid by Landlord unless Tenant agrees to pay Landlord for such costs as and when invoices for such costs are delivered to Tenant by Landlord or the Base Building Contractor. If Tenant Modifications delay Substantial Completion of the Base Building Work, Substantial Completion shall be deemed to have occurred on the date Substantial Completion would have occurred but for the Tenant Modifications.

2.6 Landlord Changes. During construction of the Base Building Work, Landlord shall deliver to Tenant copies of any proposed changes to the Base Building Work from the Base Building Construction Drawings that Landlord reasonably determines could have a material adverse impact on the design and construction of the Tenant Improvement Work. Tenant shall review such proposed change within five (5) Business Days after receipt of notice, and if the Tenant reasonably objects to the proposed change, shall state in writing the reason for such denial. Failure to deliver notice of objections by 5:00 p.m. local time on the fifth (5th) Business Day shall constitute Tenant's approval of same. If Landlord intends to proceed with the change despite Tenant's objection, Landlord and Tenant shall meet within five (5) Business Days to attempt to resolve Tenant's objection; provided that Landlord shall have the final decision in its sole discretion whether or not to proceed with the proposed change.

2.7 Substantial Completion. Landlord shall diligently prosecute the construction of the Base Building Work and use diligent efforts to achieve Substantial Completion of the Base Building Work by the dates identified in the Milestone Schedule, subject to Landlord's Unavoidable Delays. Landlord shall notify Tenant in writing when Landlord believes that Substantial Completion of the Base Building Work has occurred (or will occur on a specified date). Representatives of Landlord and Tenant shall accompany the Base Building Architect and the Base Building Contractor on a walk-through and inspection of the Premises (the ***"Substantial Completion Inspection"***) when the Base Building Architect and Base Building Contractor determine if Substantial Completion of the Base Building Work has occurred. The Base Building Architect shall certify in writing the date of Substantial Completion, and Landlord shall cause a copy of such certification to be delivered to Tenant. Within five (5) Business Days after the Substantial Completion Inspection, Landlord shall send to Tenant a written list of Landlord's Punch List Items identified during the Substantial Completion Inspection. Tenant shall have five (5) Business Days after receipt to send a written notice to Landlord requesting that additional Punch List Items be added, which Landlord shall approve or disapprove in its reasonable discretion. The final list of Punch List Items shall be attached to ***Attachment 3*** to this **Exhibit D** and sent to Tenant, at which time, Tenant shall sign ***Attachment 3***. Tenant's failure to notify Landlord in writing of any reasonable grounds for not executing ***Attachment 3*** within five (5) Business Days after receipt of ***Attachment 3*** and the attached Punch List Items shall be deemed to be acceptance of the work whether or not Tenant executes ***Attachment 3***. Substantial Completion and Tenant's acceptance of the Premises shall not be conditioned upon completion of all Common Area Improvements or Punch List Items unless such Common Area Improvements or Punch List Items materially adversely

affect the construction of the Tenant Improvement Work or Tenant's ability to obtain permits, permit sign-offs, or a certificate of occupancy.

2.8 Punch List Items and Final Completion. Landlord shall use commercially reasonable efforts to cause the completion of the Punch List Items within ninety (90) days after Substantial Completion of the Base Building Work, subject to Landlord's Unavoidable Delay. Completion of the Punch List Items shall be undertaken so as to minimize any material interference with Tenant's construction of the Tenant Improvement Work and Tenant's occupancy of the Premises. Landlord shall notify Tenant upon receipt by Landlord of notice from the Base Building Contractor that final completion has occurred. Representatives of Landlord and Tenant shall accompany the Base Building Architect and the Base Building Contractor on a walk-through and inspection of the Premises to determine if final completion has occurred. If there are any remaining Punch List Items, Landlord shall cause the diligent and prompt completion of such items and the parties shall conduct an additional walk through and inspection to determine if final completion has occurred.

2.9 Warranties. Landlord shall enforce all warranties pertaining to the Base Building Work at Landlord's sole cost and expense.

3. Design and Construction of the Tenant Improvement Work.

3.1 Tenant Responsibility. Tenant shall be responsible for the design and construction of the Tenant Improvement Work and shall cause the construction of the Tenant Improvement Work in a first class manner and in compliance with all Applicable Laws. Tenant will use commercially reasonable efforts to incorporate sustainable features in the Tenant Improvement Work, unless Tenant determines in its reasonable discretion the cost of such sustainable features will have a material adverse economic impact on Tenant's operating costs.

3.2 Integration with Lease. Without limitation of any other provision of the Lease or this **Exhibit D**, all of the provisions of Article 10 (Alterations by Tenant) and Article 11 (Liens) shall apply to the Tenant Improvement Work, to the extent not inconsistent with the provisions of this **Exhibit D**.

3.3 Development **of Plans - Tenant.**

(a) No later than one hundred twenty (120) days after Landlord has delivered to Tenant the Base Building Construction Drawings, Tenant shall submit to Landlord, for Landlord's approval, a basic space plan (the ***"Space Plan"***) prepared by Tenant's Architect for the layout of the Tenant Improvement Work consistent with the design of the Base Building Work. The Space Plan shall include at a minimum, the interior improvement layouts and location of the wall and partition structures for the Tenant Improvement Work (including the Amenity Space), the location and size of the generator pad, and the location, type and weight of all rooftop equipment. Within fifteen (15) Business Days after Landlord receives the Space Plan, Landlord shall either approve the Space Plan or disapprove the Space Plan and, in the event of disapproval, furnish to Tenant a reasonably detailed written statement outlining the reasons for such disapproval. Landlord and Tenant shall then meet together to explore and identify reasonable alternatives and to agree to mutually acceptable changes to the Space Plan during the five (5) Business Days after delivery of Landlord's notice of disapproval. In the event of such disapproval, or if the parties agree upon mutually acceptable changes, Tenant shall make the changes necessary in order to resolve

Landlord's objections and shall return the Space Plan to Landlord. Landlord shall approve or reasonably disapprove such changes within ten (10) Business Days after Landlord receives the revised Space Plan. This procedure shall be repeated until the Space Plan is finally approved by Landlord and written approval has been received by Tenant.

(b) No later than two hundred seventy (270) days after Landlord has delivered to Tenant the Base Building Construction Drawings, Tenant shall submit to Landlord complete plans and specifications for the Tenant Improvement Work for the entire Premises, based upon the approved Space Plan, including, without limitation, mechanical and electrical drawings (collectively the ***"Tenant Improvement Plans"***), for Landlord's approval. The Tenant Improvement Plans shall be in a form sufficient to secure necessary Tenant Improvement Permits. Tenant shall use diligent efforts to obtain, on a timely basis, all Tenant Improvement Permits. Landlord shall, within twenty (20) Business Days after receipt of the Tenant Improvement Plans, approve the same or designate by written notice to Tenant the specific changes reasonably required to be made to the Tenant Improvement Plans. Tenant shall promptly within ten (10) Business Days make the necessary changes and shall return the revised Tenant Improvement Plans to Landlord. Landlord shall approve or disapprove the revised Tenant Improvement Plans within ten (10) Business Days after receipt by Landlord. This procedure shall be repeated until the Tenant Improvement Plans are finally approved by Landlord and Tenant has received Landlord's written approval thereof. The Tenant Improvement Plans may be submitted by Tenant in one or more stages and at one or more times, and the time periods for Landlord's approval shall apply with respect to each such portion submitted; provided that Landlord may withhold approval if in Landlord's reasonable judgment the portion submitted is not sufficient for Landlord to approve or disapprove such portion. The final Tenant Improvement Plans approved by Landlord, including any changes, additions or alterations thereto approved by Landlord and Tenant as provided in Section 3.5 below, are herein referred to as the ***"Final Plans"***.

(c) Landlord's approval of the Space Plan, Tenant Improvement Plans or Final Plans shall not be deemed to be a representation or warranty by Landlord as to the adequacy or accuracy of such plans, and Landlord shall have no liability therefor. If Landlord fails to deliver to Tenant written notice of its approval or disapproval hereunder within the applicable time periods set forth above, Tenant shall have the right to send Landlord a written request for approval, and if Landlord fails to respond to such written request within ten (10) Business Days after receipt of the request, Landlord shall be deemed to have approved the item for which request was sought.

3.4 Landlord Consultants. Landlord shall have the right to engage third-party consultants to review the Space Plan and Tenant Improvement Plans, and Tenant shall reimburse Landlord for the cost of such consultants within twenty (20) days after receipt of one or more invoices from Landlord reasonably detailing such costs; provided that in no event shall such costs exceed the sum of Twelve Thousand Dollars ($12,000) and at Tenant's request, such costs shall be deducted from the Tenant Improvement Allowance. Other than the foregoing, Landlord shall not charge a supervisory or management fee in connection with the construction of the Tenant Improvement Work.

3.5 Tenant Changes. If Tenant requests any change, addition or alteration in the Tenant Improvement Plans or Final Plans, Tenant's Architect shall prepare plans and specifications with respect to such change, addition or alteration, which plans and specifications shall be submitted to Landlord for Landlord's review and approval. The procedure set forth in

Section 3.3(a) above shall apply to any such change, addition or alteration, except Landlord shall be required to approve or reject such change, addition or alteration within five (5) Business Days.

4. Construction of the Tenant Improvement Work.

4.1 Construction of Tenant Improvement Work. Tenant shall construct the Tenant Improvement Work in accordance with all Applicable Laws and the Final Plans and the requirements of Article 10 of the Lease, to the extent not inconsistent with the provisions of this **Exhibit D**. Tenant must fully complete all Landlord-approved Tenant Improvement Work in the Premises and may not leave any portion of the Premises unfinished. Tenant shall also install all fixtures required for Tenant's operations.

(a) Tenant shall promptly commence the construction of the Tenant Improvement Work after the Actual Access Date, and thereafter diligently prosecute construction of the Tenant Improvement Work to completion.

(b) Landlord's written approval shall be obtained prior to undertaking any work that deviates in any material respect from the Final Plans approved by Landlord.

(c) Subject to any Tenant's Unavoidable Delays and Substantial Completion of all Base Building Work by Landlord, Tenant shall use commercially reasonable efforts to complete the Tenant Improvement Work and obtain a temporary certificate of occupancy from the City no later than two hundred seventy (270) days after the Actual Access Date. Tenant shall promptly deliver to Landlord a copy of the temporary certificate of occupancy, along with the permit card showing additional work needed to obtain a final certificate of occupancy. Tenant shall secure a final certificate of occupancy from the City with respect to the Premises within sixty (60) days after receipt of the temporary certificate of occupancy. If Tenant fails to occupy at least forty percent (40%) of the Premises, not including the Initial Sublease, for the conduct of Tenant's business by the first anniversary of the Commencement Date (subject to Tenant's Unavoidable Delays), Landlord shall have the right to terminate the Lease by written notice to Tenant delivered within ten (10) days following such anniversary date, and Landlord shall promptly return to Tenant the Letter of Credit.

(d) Commencing no later than the Actual Access Date, Landlord shall permit Tenant to deliver and store within the Premises and Common Area in the locations identified by Landlord such construction equipment, tools and materials reasonably required in connection with the Tenant Improvement Work.

4.2 Evidence of Insurance. Prior to commencement of construction of the Tenant Improvement Work, Tenant shall obtain and deliver to Landlord certificates of insurance for all policies of insurance required to be maintained by Tenant under the Lease.

5. Payment of Tenant Improvement Costs.

5.1 Tenant Improvement Allowance. Landlord shall provide to Tenant the Tenant Improvement Allowance (as defined in Article 1 of the Lease), which shall be applied to the payment of the Tenant Improvement Costs as provided herein. Regardless of the status of completion of the Tenant Improvement Work, any balance of the Tenant Improvement Allowance not expended by Tenant as provided in the following provisions of this Section 5 by the first (1st) anniversary of the Actual Access Date shall be forfeited.

5.2 Tenant Improvement Costs. Any Tenant Improvement Costs in excess of the Tenant Improvement Allowance shall be paid by Tenant. Any portion of the Tenant Improvement Allowance that is expended by Tenant for the Tenant Improvement Work shall be disbursed as provided below.

5.3 Use of Tenant Improvement Allowance. The Tenant Improvement Allowance may be used for commercially reasonable architectural, engineering, and project management fees, a LEED consultant engaged by Tenant, construction and installation of the Tenant Improvement Work, and cabling and signage, but not for any items of personal property, including, without limitation, furniture, demountable partitions, fixtures or equipment. The Tenant Improvement Allowance may not be used to fund overtime costs. The Tenant Improvement Allowance shall be expended on the Tenant Improvements for the entire Premises (and not a portion of the Premises).

5.4 Conditions to First Disbursement. As a condition to the first disbursement of the Tenant Improvement Allowance, Tenant shall have satisfied all of the following conditions:

(a) Tenant shall have delivered to Landlord a duly executed copy of the contract with Tenant's Architect and the Tenant Improvement Contract;

(b) The Final Plans shall have been completed and approved as provided above;

(c) Tenant shall have obtained, delivered to Landlord, and be in compliance with all Tenant Improvement Permits;

(d) Tenant shall have delivered to Landlord the total budget, which shall become the basis for calculating Landlord's pro rata contribution towards the Tenant Improvement Work draws, and construction schedule for the Tenant Improvement Work, including an estimated cash flow schedule that describes the timing and amounts of Tenant's projected Tenant Improvement Allowance draw requests and each party's pro rata contribution towards the draw requests; and

(e) Tenant shall have provided Landlord with any other information reasonably requested by Landlord.

Notwithstanding anything to the contrary in this Work Letter, upon the parties' approval of the Tenant Improvement Plans and Tenant's delivery of reasonably detailed invoices, Landlord shall disburse up to $250,000 of the Tenant Improvement Allowance to reimburse Tenant for design, project management, permitting fees and any other pre-construction costs and activities without any requirement for Tenant to satisfy the requirements set forth in Section 5.4 (a) – (e) above.

5.5 Disbursements of Tenant Improvement Allowance. Disbursements of installments of the Tenant Improvement Allowance will be made by check payable to Tenant within thirty (30) days after receipt by Landlord of the Construction Draw Certificate required under Section 5.6 below, but not more frequently than monthly. Landlord's disbursements shall be conditioned upon the following: (a) all contingencies for the benefit of Tenant pursuant to Article 4 of the Lease shall have been satisfied or waived; (b) no Event of Default by Tenant shall exist under the Lease; (c) no lien shall have been filed with respect to the Tenant Improvement Work that has not been released or bonded over; (d) Tenant shall be in compliance with the Tenant Improvement Permits,

(e) all insurance required of Tenant under the Lease shall be in full force and effect; and (f) Tenant shall have paid its pro rata portion of the Tenant Improvement Costs to be funded, such that Landlord's payment of the Tenant Improvement Allowance installment is not in excess of its share of the total Tenant Improvement Costs. By way of example, if the Tenant Improvement Allowance is $1,000,000 and the total Tenant Improvement Costs are $3,000,000, each payment by Landlord of an installment of the Tenant Improvement Allowance shall be one third (1/3) of the total Improvement Costs being paid for each disbursement during the construction of the Tenant Improvement Work. Landlord shall also have the right to hold back five percent (5%) of the Tenant Improvement Allowance pending Tenant's delivery of the items set forth in Section 5.7, which amount shall be paid to Tenant within ten (10) Business Days after Landlord's acceptance of the Tenant Improvement Work.

5.6 Documentation. As a condition to each funding, Tenant shall deliver to Landlord all of the following:

(a) Tenant's Construction Draw Certificate in the form of ***Attachment 4*** to this **Exhibit D** (with capitalized terms used therein without definition having the meanings ascribed to them in the Lease);

(b) The Tenant Improvement Contractor's Certificate in the form of ***Attachment 5*** hereto;

(c) Conditional and unconditional lien releases, as applicable, in the form required under California Civil Code Section 3262 from all contractors, subcontractors and materialmen who shall have furnished materials or supplies or performed work or services in connection with the Tenant Improvement Work.

5.7 Final Certification. Upon final completion of the Tenant Improvement Work, and as a condition to Landlord's obligation to make its final payment and acceptance of the Tenant Improvement Work as completed, Tenant shall provide Landlord with the following:

(a) certifications from the Tenant Improvement Contractor and Tenant's Architect that the Tenant Improvement Work throughout the entire Premises has been finally completed in accordance with the Final Plans;

(b) copies of final lien releases from all contractors and subcontractors;

(c) all operating permits and hazardous material permits issued with respect to Tenant's use and occupancy of the Premises;

(d) the final certificate of occupancy issued by the City;

(e) copies of all warranties for the Tenant Improvement Work and any components thereof;

(f) a copy of Tenant's punch list for the Tenant Improvement Work;

(g) the as-built drawings and annotated plans described in Section 10.6(h) of the Lease; and

(h) a copy of the recorded notice of completion of described in Section 10.6(i) of the Lease.

6. Notices; Time of the Essence. All notices to be delivered pursuant to this Work Letter shall be delivered in the manner set forth in Article 26 of the Lease. Time is of the essence in respect of all provisions of this Work Letter in which a definite time for performance is specified.

7. Landlord's Reporting Obligation. Landlord shall provide certain construction cost information that Tenant has represented that it is required to disclose in order to comply with its accounting reporting obligations as a public company as set forth in Tenant's "2015-Q1-8 Tech Memorandum" dated April 14, 2015, as may be reasonably updated and supplemented by Tenant from time to time (but not more often than once per year) by Tenant's delivery of such updates and supplements to Landlord. Subject to the following limitations, Landlord shall provide the information:

(a) Landlord will provide quarterly reporting of the costs incurred to the date of each report with respect to the Base Building Work. Quarterly reports will be delivered no later than five (5) business days after the close of each calendar quarter commencing as of the quarter ending on September 30, 2017 and ending as of the end of the quarter during which Landlord has both completed all Punch List Items and concluded its final accounting for the Base Building Work. Landlord's quarterly reports will be delivered on the form attached as ***Attachment 6*** to this **Exhibit D**, and in no event shall additional detail be required from Landlord.

(b) Landlord's financial reporting shall include only the "Landlord's Costs" described in the attached ***Attachment 7*** to this **Exhibit D**.

(c) Landlord will use commercially reasonable efforts to provide accurate financial information, but shall not make any representation or warranty regarding the accuracy or completeness of any report, and shall not be liable for any errors contained in such information. Tenant shall have no right to audit Landlord's financial records.

(d) Landlord acknowledges that the information to be provided pursuant to this Section will be disclosed to Tenant's accountants and used in connection with mandatory reporting to the Securities and Exchange Commission. Other than the foregoing disclosures, Tenant agrees to keep all information provided by Landlord strictly confidential. Tenant shall be permitted to disclose on its financial statements the fact that these costs are associated with the construction of a new facility in Palo Alto, California, but in no event shall Tenant disclose on its financial statements the fact that the costs are associated with construction of a facility in the Stanford Research Park or for a construction project built by Landlord, "Stanford University" or "Stanford Real Estate." The provisions of Sections 31.11 and 31.18 of the Lease are incorporated herein by this reference.

(e) As reasonably requested by Tenant or its auditors to the extent necessary for Tenant to comply with its financial reporting required by lease accounting requirements applicable to Tenant, but no more frequently than quarterly, Landlord will cause its representative to discuss information provided by Landlord with Tenant and/or its auditors.

(f) Tenant shall indemnify, protect, defend and save and hold Landlord, Landlord's Agents and the Landlord Parties harmless from and against any Claims incurred in connection with or arising from (i) the information delivered to Tenant pursuant to this Section, (ii) any breach of the confidentiality provisions set forth above, or (iii) Tenant's use of the information provided by Landlord.

Attachment 1A to Exhibit D

BASE BUILDING WORK DESCRIPTION

The components and systems described herein will be included in the design of the Building. Landlord shall design and construct the Base Building Work (consisting of the Shell Components, the Common Area Improvements and the Core Components listed below) in compliance with Applicable Laws, including without limitation all City and uniform building codes (collectively, "***Code Requirements***").

A. Shell Components

1. Structure

a) The foundation and structural frame and all metal work

b) The foundation and structural framing are to be designed to support a live load of 100 psf reducible; exit facilities and stairways designed to support a live load of 100 psf non-reducible. Any structural upgrades required for vibration sensitive equipment shall be a Tenant Modification. The design shall include fireproofing pursuant to Code Requirements. The slab to underside of steel structure height within the Premises shall accommodate a minimum 10' finished ceiling height on the first floor and a minimum 9' 6" finished ceiling height on the second floor, with a minimum interstitial space of 24" predominately, with exception for occasional rainwater leaders or other critical utilities.

c) Stairs shall meet Code Requirements; exit stairs will be concrete filled metal pan stairs; steel to be prime painted only. Floor finishes on stairs shall be Tenant Improvement Work. The Building's handrails and guardrails during construction will be temporary; permanent handrails are part of Core Components. A lobby stair is being provided with handrails. Stairs will be located to provide egress to meet Code Requirements for a typical Tenant Modification.

d) The Building's Shell will be constructed to be water-tight.

e) Landlord shall coordinate with Tenant to allow for reasonable access through window sections on each floor of the Building which Tenant can use to move large items (e.g. furniture) into the Building. Tenant will be responsible to complete the windows after access is no longer required.

2. Exterior Facade

a) Base design intent includes inoperable windows. Windows shall include dual glazing, low-e emissive, and/or tinted glass as may be required to meet Title 24 requirements for the Building's envelope. Glazing materials may include, but not be limited to, ceramic frit, spandrel glass, or translucent glass. A storefront entry shall be provided.

b) The exterior doors and hardware shall be configured pursuant to Code Requirements. Hardware modifications and/or upgrades to be compatible with Tenant's security system shall be a Tenant Modification or Tenant Improvement Work. Exterior doors shall include two main entrance (storefront) from street and one secondary entrance/egress doors (also storefront) for the Building.

c) Drywall adaptors are not included with the curtain wall system. Landlord will coordinate with tenant to incorporate adaptors if requested as part of the Tenant Modification.

3. Roof

a) The roof membrane system shall consist of either a TPO roofing system or a 4-ply built-up roof (cap sheet plus 3-ply) and insulation on metal deck over rolled steel members. Membrane system will be constructed equal to a 15-year bondable product. Landlord will provide a 15-year manufacturer's warranty.

b) The roof supporting structural steel shall be designed to allow for structural modifications included in Core Components.

c) Roof access will be provided for the building by a ship's ladder up to a roof hatch.

4. Fire and Life Safety

a) The fire and life safety shall be designed in accordance with Code Requirements. A building fire alarm panel which will monitor water flow shall include panel, PIV flow switch and tamper switch. In addition, one manual pull station and one bell as well as a phone line connection to a central station monitoring service will be included. All other alarm system modifications shall be Tenant Improvement Work, unless otherwise specified as a Core Component below.

b) The Shell Components shall include an overhead fire sprinkler system throughout the Building's interior (ordinary hazard, group 2: 0.2 gpm over 1,500 square feet). Upright heads and plugged tees shall be provided in a standard grid pattern. The system shall be designed to NFPA 13.

5. Garage

a) Garage will be constructed as part of the Shell Components to meet Code Requirements.

b) Bike lockers will be provided to meet Code Requirements.

c) Electric car charging stations will be provided to meet Code Requirements.

d) Garage entry will include overhead roll-up door with open grate material required to provide for fresh air intake.

e) Garage entry will include conduit rough-in for use by Tenant card reader.

B. Common Area Improvements

1) All soft and hard landscaping and irrigation shall be designed to meet Code Requirements and shall include bike racks and bike lockers pursuant to Code Requirements. All site furnishings that are not required by Code Requirements or are not of a permanent nature shall be part of the Tenant Improvement Work.

2) Monument and up-lighting shall be provided for the Tenant-provided sign. Sign shall be Tenant Improvement Work.

3) One roofed trash enclosure shall be provided to service the Building, which will house required dumpsters and recycling bins.

4) One transformer pad provided by Landlord with enclosure as required by city code, path and conduit to run power into the building electric room will be provided. One generator, ATS is being provided for code-required loads. Any additional emergency loads will require generator upgrade/replacement by Tenant. Generator, ATS, and wiring shall be included in the Tenant Improvement Work.

5) Water, sewer, and gas shall be provided and sized for standard office loads. The domestic water shall be terminated within the Building at the inside face of the exterior wall. A sewer gut line and related venting shall be provided at a depth to accept remote fixtures and terminated at each restroom core location. The natural gas meter and piping for Core heating equipment will be provided and sized only for standard office building heating requirements. Additional piping connections or upsized distribution of natural gas piping shall be a Tenant Modification. Extensions to the utilities and additional piping, conduit, wire and equipment are part of the Tenant Improvement Work.

6) Electrical service shall be provided typical of an office building in the Silicon Valley. Office building load shall be designed to accommodate 98.9 watts/sf, based on 2013 CEC: 0.9 watts/sf for lighting; 3.0watts/sf for general receptacles; 5.0 watts/sf for HVAC. A 1600A, 277/480V, 3PH electrical service consisting of underground pull section, City of Palo Alto Electrical metering provisions, 80% rated main breaker (maximum amperage 1280A), and Core/Shell/tenant improvement distribution provisions. In addition, house panel for the Shell will be included with circuits for site lighting, landscape lighting, and irrigation controllers. Service conduits shall be run from City electric vaults to main electrical room for new service. Any additional conduit and/or wiring inside and outside the Building are part of Tenant Improvement Work.

7) Two 4” conduits shall be provided from existing telecommunications vault to the electrical room MPOE.

8) A storm drain system shall be provided in compliance with Code Requirements.

9) Roof drainage, excluding canopies, shall be piped to storm drainage system. Overflow drainage shall be piped to face of wall or provided in overflow scuppers in compliance with Code Requirements and the design intent of the Building.

10) Parking lot and garage lighting in compliance with Code Requirements with time clock and photocell. All fixtures that occur adjacent to property lines to have proper cut-off of light spillover.

11) Exterior lighting will be provided along entry/egress to/from the Building as per Code Requirements. Site landscape, and monument sign lighting will also be provided. Additional lighting shall be a Tenant Modification.

12) An asphaltic concrete parking lot will be provided in compliance with Code Requirements.

13) Exterior handrails will be provided in compliance with Code Requirements where required.

14) Landlord to provide the greater of (a) six (6) or (b) the minimum number required by Code Requirements double headed charging stations for vehicles all of which will be located in the garage if allowed by City of Palo Alto.

15) At grade receiving area will be provided with aluminum roll up door and single man door.

16) Drive ways, required ramps as per ADA, pathways, shrubs, all painting including parking lots including signs disabled parking and outside of the building to be completed as part of base work

C. Core Components

1. Elevator and Stairs

a) The Building will include one passenger elevator adjacent to the main entry of the Building. The elevator shall be designed to Code Requirements and have a 3,500 pound load capacity. The elevator cab shall be large enough to accommodate a City-approved emergency gurney/stretcher. The base cab finish shall be from the standard selection of elevator company, including plastic laminate wall panels, lighting/ceiling, steel tubular ADA compliant handrail, protective blanket pads, and ADA compliant telephone. Passenger elevator flooring shall be stone or comparable. Upgraded finishes shall be a Tenant Modification. Elevator shall return to first floor upon power failure. Landlord will provide certification by the State for elevator operation. If feasible (in Landlord's sole discretion), an additional freight elevator may be included as part of the Core, and if included, such elevator will be a Tenant Modification for the incremental cost of the elevator subcontract.

b) Stairways between floors shall be provided to meet Code Requirements for office occupancy. Stair enclosures will be provided for stairways between garage and 1st floor. Finish at interior stair will be Level 4 sheetrock and painted. Floor finishes on the interior

stairs and paint on the risers shall be Tenant Improvement Work. A 2 ½ inch standard painted steel piperail shall be included in the Core, as per Code Requirements.

c) Exterior stairs shall be painted to match exterior design.

2. Mechanical (HVAC)

a) Core HVAC system shall be provided typical of a sustainable office building in the Silicon Valley. Core HVAC installed capacity shall include tenant contributions to the cooling load based on: 1.2 watts/sf for lighting; 2.5 watts/sf for equipment and plug loads; 200 sf/person occupancy density; 0.15 CFM/sf outdoor ventilation air.

b) The Core shall include two (2) AC units (Trane, Carrier, McQuay, Johnson Controls or equivalent) to serve the Building, total installed cooling capacity of approximately 240 tons. The AC units will have variable air volume capability including variable speed supply air fans and supply air temperature control, 100% outside air capability with integrated air-side economizers and power exhaust, and building static pressure control capability. The units shall comply with the requirements of all current State and local Codes and ordinances. All necessary components in rooftop AC units shall be internally isolated on engineered 2-inch deflection seismic isolation systems.

c) Heating for the Building shall be provided by a rooftop hydronic heating system including a high-efficiency boiler and pumps, and shall be sized to provide the heating indoor design temperature of 70°F on a 30°F design heating day with design ventilation air supply.

d) The Core HVAC systems will be equipped with pre-installed, pre-wired, self-contained factory controls. A building management system will be provided and installed as part of Tenant's Base Building Improvement Work and shall include all necessary hardware and software interface components and control wiring to fully integrate the pre-installed unit controls with the Building's management system.

e) Exhaust and make-up air systems shall be provided for each restroom core to meet Code Requirements. Exhaust systems shall be comprised of rooftop exhaust fans, exhaust ductwork and ceiling-mounted exhaust grilles. Make-up air systems shall be comprised of ceiling-mounted make-up air grilles and make-up air duct from the grilles to the perimeter of the restroom core for future connection to tenant improvement HVAC work.

f) The Core Components shall include necessary ductwork and piping above the roof from the HVAC systems, stubbed through the roof to serve the second floor, and installed down a duct shaft and stubbed into the first floor to provide points of connection for Tenant distribution ductwork and piping.

g) All medium and low pressure distribution ductwork, variable air volume terminal units, hot water reheat piping, air distribution devices, zone temperature controls, duct and

piping insulation, fire and fire/smoke dampers, air and water balancing, and other mechanical devices and services as necessary to provide complete, operable HVAC systems shall be Tenant Improvement Work.

h) Modification to the Shell structural steel to support HVAC equipment is included as a Core Component Incremental loads and upgrade to structure to carry those loads beyond normal code-required roof live load shall be a Tenant Modification.

i) Plumbing services provided as part of the Core construction shall include natural gas and condensate drain piping as required for Base Building rooftop HVAC systems.

3. Electrical / Telephone / Data

a) One electrical service shall be provided as part of Common Area Improvements (see Section B.6 in this Attachment 1A).

b) House panels and transformers shall be provided as required for the Core with feeders for (1) elevator and two (2) HVAC units, generator and building sump pits and water heaters. Electrical connections beyond stairwell lighting and restroom core power and lighting will be considered Tenant Improvement Work. All other distribution wiring panels, and breakers shall be considered Tenant Improvement Work.

c) Tele/Data Room shall accommodate tele/data service entrance as part of the Shell construction (see Section B.7 in this Attachment 1A). All other tele/data closets, conduit, cabling, and equipment shall be considered Tenant Improvement Work.

4. Plumbing & Toilet Core

a) Plumbing will be designed to accommodate the Core fixtures. The plumbing system gutline will be designed to accept a Tenant fixture at remote locations.

b) The Building’s plumbing shall include plumbing fixtures for all Core facilities. Domestic water service shall be roughed-in and completed to all necessary plumbing fixtures to meet Code Requirements. In addition to the Core facilities, the domestic water service shall have a capacity sufficient to add supplemental tenant facilities within office environment standard loads (e.g. coffee pantries and lunchrooms).

c) The Core Components shall include men's rooms, women’s rooms, shower facilities, and janitor's sinks to meet Code Requirements. The base finishes shall consist of ceramic tile on the wet walls, a ceramic tile floor (American Olean or equivalent), granite, engineered stone or comparable countertops and backsplash, and plastic laminate or painted metal toilet partitions. Tenant shall be allowed to review the proposed restroom and shower finishes and provide suggestions for any changes; Landlord will consider changes but maintain the final determination of finishes. Any upgraded finishes shall be a Tenant Modification. The Core Components shall include water and sanitary sewer service plumbing roughed-in and fully finished to Core facilities including fixtures, toilets,

automatic water and soap dispensers in sink, air hand dryers showers, floor drains, and hose bibs as required.

d) Exhaust air shall be provided for the toilet core as per Section 2.f above. Tenant to tie-in the Building's HVAC system to the supply air grilles constructed with the Core.

e) Lighting shall consist of recessed downlights or other similar quality lighting for toilet core with wiring provided to a junction box in an adjacent space for future connection to the Tenant Improvement Work.

f) Convenience outlets shall be provided pursuant to Code Requirements with wiring provided to a junction box in an adjacent space for future connection to the Tenant Improvement Work.

g) All Core elements shall be provided in taped, textured and painted finish (Level 4) at the Core side of the wall. Tenant side of the wall will be provided with Level 2 finish.

h) Water pressure will be provided to meet Code Requirements and to meet the pressure requirements of equipment in the building or on the roof that would be typical of a standard office.

5. Others

a) All code-required graphics and signs installed in the Shell and Core as per Code Requirements.

b) The Core area fire and life safety fire sprinkler system shall include dropped tees with semi-recessed heads Adjustments to head locations triggered by Tenant's interior design shall be Tenant Improvement Work. All other drops and heads for concealed spaces and interior improvements shall be Tenant Improvement Work.

c) Roof screen and roof screen supports shall be a Core Component. Roof screens will be sized to accommodate base HVAC system. Additional roof screen required by tenant shall be a Tenant Modification and will need to be coordinated with the aesthetic design of the Building.

Attachment 1B to Exhibit D

CONSTRUCTION RESPONSIBILITY MATRIX

		ITEM DESCRIPTION	Design Cost Responsibility	Construction Responsibility	Cost Type	Design Responsibility	Dwg. Package Where Shown
1	**GRADING & PAVING**						
	A	SITE DEMOLITION	OWNER	OWNER	SHELL	CIVIL	SHELL
	B	STRIP SITE OF ORGANIC MATERIAL & STORAGE	OWNER	OWNER	SHELL	CIVIL	SHELL
	C	ROUGH/FINISH GRADING - PARKING LOT AREA	OWNER	OWNER	SHELL	CIVIL	SHELL
	D	ROUGH/FINISH GRADING - LANDSCAPE/HARDSCAPE AREA	OWNER	OWNER	SHELL	CIVIL/LAND	SHELL
	E	ROUGH/FINISH GRADING - SIDEWALK AREAS	OWNER	OWNER	SHELL	CIVIL/LAND	SHELL
	F	CONSTRUCT BUILDING PAD	OWNER	OWNER	SHELL	CIVIL	SHELL
	G	ASPHALT PATCH / PAVE / SEAL COAT EXISTING AS REQUIRED	OWNER	OWNER	SHELL	CIVIL	SHELL
	H	SPEED BUMPS	NONE	NONE	NONE	NONE	NONE
	I	TENANT REVISIONS TO SITE (e.g. Exit Walks; Loading Dock)	TENANT	OWNER	T.I.	CIVIL/LAND	SHELL
2	**PARKING LOT & GARAGE STRIPING/ SIGNAGE**						
	A	PARKING STALL STRIPING (INCLUDING ADA)	OWNER	OWNER	SHELL	CIVIL	SHELL
	B	DIRECTIONAL ARROW STRIPING	OWNER	OWNER	SHELL	CIVIL	SHELL
	C	RED CURB AT FIRE LANE	OWNER	OWNER	SHELL	CIVIL	SHELL
	D	VISITOR STALL STRIPING	OWNER	OWNER	SHELL	CIVIL	SHELL
	E	HANDICAP STALL SIGNAGE	OWNER	OWNER	SHELL	CIVIL	SHELL
	F	"NO PARKING" AT FIRE LANE DRIVEWAY SIGNAGE	OWNER	OWNER	SHELL	CIVIL	SHELL
	G	OTHER STRIPING / SIGNAGE	TENANT	OWNER	T.I.	CIVIL	SHELL
3	**STORM DRAINAGE**						
	A	OFFSITE STORM FROM MAIN TO PROPERTY LINE	OWNER	OWNER	SHELL	CIVIL	SHELL
	B	STANDARD ONSITE STORM DRAINAGE	OWNER	OWNER	SHELL	CIVIL	SHELL
	C	LANDSCAPE / AREA DRAINS	OWNER	OWNER	SHELL	CIVIL	SHELL
	D	ROOF DRAIN PIPING FROM BLDG TO STORM SYSTEM	OWNER	OWNER	SHELL	CIVIL	SHELL
	E	DRAINAGE REVISIONS DUE TO T.I. REVISIONS	TENANT	OWNER	T.I.	CIVIL	SHELL
4	**SANITARY SEWER - SITE**						
	A	SEWER CONNECTION FROM OFFSITE MAIN TO PROPERTY LINE	OWNER	OWNER	SHELL	CIVIL	SHELL
	B	ONSITE SANITARY PIPING FROM PROPERTY LINE TO BUILDING	OWNER	OWNER	SHELL	CIVIL	SHELL
	C	ONSITE SANITARY CODE REQUIRED CLEAN OUTS	OWNER	OWNER	SHELL	CIVIL	SHELL
	D	ONSITE SANITARY MONITORING MAN HOLE (IF REQUIRED)	OWNER	OWNER	SHELL	CIVIL	SHELL
	E	ONSITE/OFFSITE REV. DUE TO T.I. SPECIALTIES (e.g. Cafeteria)	TENANT	OWNER	T.I.	CIVIL	SHELL

		ITEM DESCRIPTION	Design Cost Responsibility	Construction Responsibility	Cost Type	Design Responsibility	Dwg. Package Where Shown
5		**UNDERGROUND FIRE PROTECTION**					
	A	WATER CONNECTION FROM OFFSITE MAIN TO FIRE SERVICE	OWNER	OWNER	SHELL	CIVIL	SHELL
	B	FIRE SERVICE BACKFLOW DEVICE	OWNER	OWNER	SHELL	CIVIL	SHELL
	C	ONSITE FIRE SERVICE PIPING INTO BUILDING (6" A.F.F.)	OWNER	OWNER	SHELL	CIVIL	SHELL
	D	ONSITE FIRE HYDRANTS (AS REQUIRED)	OWNER	OWNER	SHELL	CIVIL	SHELL
	E	FIRE DEPARTMENT CONNECTIONS / P.I.V.	OWNER	OWNER	SHELL	CIVIL	SHELL
	F	CATHODIC PROTECTION (IF REQUIRED)	OWNER	OWNER	SHELL	CIVIL	SHELL
6		**DOMESTIC WATER SERVICE**					
	A	OFFSITE WATER FROM OFFSITE MAIN TO PROPERTY LINE	OWNER	OWNER	SHELL	CIVIL	SHELL
	B	DOMESTIC WATER SERVICE METER	OWNER	OWNER	SHELL	CIVIL	SHELL
	C	DOMESTIC WATER SERVICE BACKFLOW PREVENTER	OWNER	OWNER	SHELL	CIVIL	SHELL
	D	ONSITE DOMESTIC WATER PIPING STUBBED INTO BUILDING	OWNER	OWNER	SHELL	CIVIL	SHELL
7		**LANDSCAPING**					
	A	LANDSCAPE PLANTINGS	OWNER	OWNER	SHELL	LAND	SHELL
	B	TREE PROTECTION	OWNER	OWNER	SHELL	LAND	SHELL
	C	TREE RELOCATION	OWNER	OWNER	SHELL	LAND	SHELL
	D	REVISIONS TO PLANTINGS/TREES DUE TO TENANT SCOPE	TENANT	OWNER	T.I.	CIVIL	SHELL
8		**IRRIGATION SYSTEM**					
	A	OFFSITE WATER FROM OFFSITE MAIN TO METER (Near Property Line)	OWNER	OWNER	SHELL	CIVIL/LAND	SHELL
	B	IRRIGATION WATER METER	OWNER	OWNER	SHELL	CIVIL/LAND	SHELL
	C	IRRIGATION WATER SERVICE BACKFLOW PREVENTER	OWNER	OWNER	SHELL	LAND	SHELL
	D	IRRIGATION WATER PIPING	OWNER	OWNER	SHELL	LAND	SHELL
	E	POWER TO IRRIGATION CONTROLLER	OWNER	OWNER	SHELL	LAND/ELEC	SHELL
	F	REVISIONS TO IRRIGATION DUE TO TENANT SCOPE	TENANT	OWNER	T.I.	CIVIL	SHELL
9		**SITE CONCRETE**					
	A	OFFSITE CONCRETE WORK (IF REQUIRED)	OWNER	OWNER	SHELL	CIVIL	SHELL
	B	DRIVEWAY APPROACHES (IF REQUIRED)	OWNER	OWNER	SHELL	CIVIL	SHELL
	C	CITY SIDEWALKS (IF REQUIRED)	OWNER	OWNER	SHELL	CIVIL	SHELL
	D	PARKING LOT CURB & GUTTERS (WHERE APPLICABLE)	OWNER	OWNER	SHELL	CIVIL	SHELL
	E	SIDEWALKS LEADING TO SHELL DOORS	OWNER	OWNER	SHELL	ARCH/LAND	SHELL
	F	EXTERIOR CONCRETE STAIRS/STEPS (SHELL SCOPE ONLY)	OWNER	OWNER	SHELL	ARCH/LAND	SHELL
	G	ADA RAMPS (SHELL SCOPE ONLY)	OWNER	OWNER	SHELL	ARCH/LAND	SHELL
	H	TRANSFORMER PAD	OWNER	OWNER	SHELL	ARCH/LAND	SHELL
	I	UTILITY PADS (ACCESSORY AREAS FOR TENANT EQUIPMENT)	TENANT	TENANT	T.I.	(TENANT)	TBD
	J	SIDEWALKS/RAMPS/STEPS/RAILS FOR ADDTL. TENANT WALKS	TENANT	TENANT	T.I.	ARCH/LAND	SHELL

		ITEM DESCRIPTION	Design Cost Responsibility	Construction Responsibility	Cost Type	Design Responsibility	Dwg. Package Where Shown
10	**SITE ACCESSORIES**						
	A	BICYCLE RACKS	OWNER	OWNER	SHELL	CIVIL/LAND	SHELL
	B	BICYCLE LOCKERS	OWNER	OWNER	SHELL	CIVIL/LAND	SHELL
	C	ASH URNS	TENANT	TENANT	T.I.	ARCH/LAND	SHELL
	D	TRASH RECEPTACLES	TENANT	TENANT	T.I.	ARCH/LAND	SHELL
	E	SITE FURNITURE	TENANT	TENANT	T.I.	(TENANT)	T.I.
	F	BUS STOPS AND SHELTERS (IF REQUIRED)	OWNER	OWNER	SHELL	CIVIL/LAND	SHELL
	G	EXTERIOR HANDRAILS (SHELL SCOPE ONLY)	OWNER	OWNER	SHELL	ARCH/LAND	SHELL
11	**TRASH ENCLOSURE**						
	A	TRASH ENCLOSURE FOUNDATION, WALLS, ROOF	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	B	TRASH ENCLOSURE GATES / DOORS	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	C	TRASH ENCLOSURE FIRE PROTECTION	OWNER	OWNER	SHELL	ARCH	SHELL
	D	ADDITIONAL TRASH ENCLOSURES AND RELATED ITEMS	TENANT	OWNER	T.I.	ARCH/LAND	SHELL
12	**NATURAL GAS PIPING**						
	A	UNDERGROUND GAS PIPING FROM OFFSITE MAIN TO METER	OWNER	OWNER	SHELL	CIVIL	SHELL
	B	GAS METER	OWNER	OWNER	SHELL	CIVIL	SHELL
	C	GAS PIPING - METER TO CORE EQUIPMENT	OWNER	OWNER	CORE	PLUMB/HVAC	CORE
13	**SITE ELECTRICAL WORK**						
	A	TELECOMM. CONDUITS FROM STREET TO TELE/ELEC ROOM	OWNER	OWNER	SHELL	ELEC	SHELL
	B	PRIMARY POWER CONDUITS FROM STREET TO TRANSFORMER	OWNER	OWNER	SHELL	ELEC	SHELL
	C	PRIMARY POWER CONDUITS FROM TRANSFORMER TO BLDG.	OWNER	OWNER	SHELL	ELEC	SHELL
	D	GARAGE LIGHTING	OWNER	OWNER	SHELL	ELEC	SHELL
	E	PARKING LOT LIGHTING	OWNER	OWNER	SHELL	ELEC/LAND	SHELL
	F	EXTERIOR BUILDING LIGHTING	OWNER	OWNER	SHELL	ELEC/ARCH	SHELL
	G	PEDESTRIAN LIGHTING (SHELL ONLY)	OWNER	OWNER	SHELL	ELEC/LAND	SHELL
	H	IRRIGATION CONTROLLER POWER (SEE #8-E)					
	I	MONUMENT SIGN CONDUIT / J-BOX FOR UPLIGHTS	OWNER	OWNER	SHELL	ELEC	SHELL
	J	MONUMENT SIGN LIGHT FIXTURES & WIRE	OWNER	OWNER	T.I.	ELEC	SHELL
	K	PANELS / BREAKERS FOR SITE ELECTRICAL ITEMS	OWNER	OWNER	SHELL	ELEC	SHELL
	L	TIME CLOCKS / PHOTOCELLS FOR SITE LIGHTING	OWNER	OWNER	SHELL	ELEC	SHELL
	M	TENANT LIGHTING REVISIONS	TENANT	OWNER	T.I.	ELEC	SHELL
	N	TELEPHONE SERVICE, CABLE, WIRE, EQUIP. (From Street to Bldg.)	TENANT	TENANT	T.I.	(TENANT)	T.I.
	O	LANDSCAPE LIGHTING	OWNER	OWNER	SHELL	ELEC/LAND	SHELL
14	**BUILDING FOUNDATIONS**						
	A	SHELL CONSTRUCTION	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	B	TENANT REVISIONS	TENANT	OWNER	T.I.	ARCH/STRUCT	SHELL

		ITEM DESCRIPTION	Design Cost Responsibility	Construction Responsibility	Cost Type	Design Responsibility	Dwg. Package Where Shown
15	**FLOOR SLABS**						
	A	STANDARD SLAB-ON-GRADE CONSTRUCTION	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	B	STANDARD 2ND FLOOR SLAB CONSTRUCTION	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	C	SLAB DEPRESSIONS FOR T.I. FEATURES	TENANT	OWNER	T.I.	ARCH/STRUCT	SHELL
	D	ADDTL. 2ND FLOOR SLAB LOAD, DEFLECT., VIBRATION CRITERIA	TENANT	OWNER	T.I.	ARCH/STRUCT	SHELL
	E	SLAB OPENINGS FOR T.I. FEATURES	TENANT	OWNER	T.I.	ARCH/STRUCT	SHELL
16	**ROOF CONSTRUCTION**						
	A	STANDARD ROOF CONSTRUCTION (ROLLED STEEL MEMBERS)	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	B	UNDER ROOF HVAC EQUIPMENT SUPPORT MEMBERS	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	C	ROOF OPENING FOR HVAC SYSTEM	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	D	UNDER ROOF SUPPORT MEMBERS FOR T.I. SPECIALTIES	TENANT	TENANT	T.I	(TENANT)	TBD
	E	ROOF OPENING FOR T.I. SPECIALTIES	TENANT	TENANT	T.I.	(TENANT)	TBD
17	**EXTERIOR ARCHITECTURAL SHEET METAL**						
	A	FLASHING / SHEET METAL FOR SHELL ITEM	OWNER	OWNER	SHELL	ARCH	SHELL
	B	FLASHING / SHEET METAL FOR T.I. ITEM	TENANT	TENANT	T.I.	ARCH	SHELL
18	**ROOFING MEMBRANE**						
	A	CRICKETS FOR SHELL PURPOSES	OWNER	OWNER	SHELL	ARCH	SHELL
	B	CRICKETS FOR T.I. PURPOSES	TENANT	TENANT	T.I.	(TENANT)	TBD
	C	UNDERLAYMENT BOARDS/BARRIERS	OWNER	OWNER	SHELL	ARCH	SHELL
	D	ROOFING MEMBRANE	OWNER	OWNER	SHELL	ARCH	SHELL
	E	ROOFING OF BASE HVAC EQUIPMENT	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	F	SKYLIGHTS / ROOFING OF SKYLIGHTS (SHELL SCOPE ONLY)	OWNER	OWNER	SHELL	ARCH	TBD
	G	ROOFING OF ROOF SCREEN SUPPORTS	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	H	ROOFING OF OTHER T.I. PENETRATIONS	TENANT	TENANT	T.I.	(TENANT)	TBD
	I	ROOF INSULATION	OWNER	OWNER	SHELL	ARCH	SHELL
19	**ROOF SCREEN**						
	A	UNDER-ROOF STRUCTURAL SUPPORT	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	B	CONNECTION OF FRAME TO SHELL STRUCTURE	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	C	SCREEN MATERIAL, FRAMING, BRACING	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	D	PAINTING OF SCREENING MEMBERS	OWNER	OWNER	CORE	ARCH	SHELL
	E	ROOFING /FLASHING OF ATTACHMENT OF ROOF SCREEN	OWNER	OWNER	CORE	ARCH	SHELL
20	**EXTERIOR WALLS**						
	A	EXTERIOR GLASS & GLAZING	OWNER	OWNER	SHELL	ARCH	SHELL
	B	GYP. BOARD ADAPTERS TO EXTERIOR GLASS SYSTEM	TENANT	TENANT	T.I.	ARCH	SHELL

		ITEM DESCRIPTION	Design Cost Responsibility	Construction Responsibility	Cost Type	Design Responsibility	Dwg. Package Where Shown
	C	EXTERIOR PRECAST CONCRETE AND/OR GFRC PANELS	OWNER	OWNER	SHELL	ARCH	SHELL
	D	FIRE CAULKING OF 2ND FL. SLAB/PANEL JOINT	OWNER	OWNER	SHELL	ARCH	OWNER
	E	GYP. BOARD & METAL STUDS ON INTERIOR FACE OF PERIMETER	TENANT	TENANT	T.I.	(TENANT)	T.I.
	F	INSULATION @ EXTERIOR PERIMETER WALLS	OWNER	OWNER	SHELL	ARCH	OWNER
	G	PREP. & PAINTING OF INTERIOR FACE OF PERIMETER WALLS	TENANT	TENANT	T.I.	(TENANT)	T.I.
21	**EXTERIOR DOORS AND HARDWARE**						
	A	SHELL PERIMETER DOORS WITH OWNER'S STD. HARDWARE	OWNER	OWNER	SHELL	ARCH	SHELL
	B	T.I. PERIMETER DOORS & HARDWARE	TENANT	TENANT	T.I.	ARCH	SHELL
	C	T.I. UPGRADES TO SHELL PERIMETER DOOR HARDWARE	TENANT	TENANT	T.I.	ARCH	SHELL
22	**INTERIOR STAIRS & RELATED OPENINGS**						
	A	STAIR FOUNDATION	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	B	STEEL PAN STAIR	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	C	CONCRETE FILL IN PANS AND LANDING	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	D	STRUCTURAL STEEL SYSTEM FOR STAIR OPENING	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	E	CONNECTION OF THE STAIR TO THE STRUCTURAL STEEL SYSTEM	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	F	TEMPORARY GUARD RAILS (COURSE OF CONSTRUCTION)	OWNER	OWNER	SHELL	ARCH/STRUCT	SHELL
	G	HANDRAILS/ GUARDRAILS FOR STAIRS & OPENINGS (PERMANENT)	TENANT	TBD	T.I.	ARCH	TBD
	H	STAIRWELL ENCLOSURE (GARAGE TO 1ST FLOOR ONLY)	OWNER	OWNER	CORE	ARCH	SHELL
	I	PAINTING OF STAIRS, RAILS AND WALLS	TENANT	TENANT	T.I.	(TENANT)	T.I.
	J	FLOOR FINISHES ON STAIRS	TENANT	TENANT	T.I.	(TENANT)	T.I.
23	**PASSENGER ELEVATOR - BASE = ONE (1)**						
	A	ELEVATOR PIT, LADDER, WATERPROOFING	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	B	ELEVATOR PIT SUMP / SUMP DRAINAGE (AS REQUIRED)	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	C	ELEVATOR SHAFT	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	D	MOD. TO STRUCTURAL STEEL SYSTEM FOR 2ND FLOOR OPENING	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	E	ELEVATOR GUIDE RAIL SUPPORTS	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	F	ELEVATOR CAB (STANDARD FINISHES)	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	G	ELEVATOR TELEPHONE (INCL. MONITORING SERVICE), ADA COMPLIANT	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	H	ELEVATOR CAB UPGRADES	TENANT	OWNER	T.I.	ARCH	SHELL
	I	ADDITIONAL ELEVATOR = ONE FREIGHT (1)	OWNER	OWNER	T.I.	ARCH/STRUCT	SHELL
24	**RESTROOM CORE CONSTRUCTION**						
	A	INTERIOR WALLS	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	B	INTERIOR DOORS/FRAMES/HARDWARE, PARTITIONS, ACCESSORIES	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	C	INTERIOR CEILINGS	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	D	FLOOR COVERINGS - CERAMIC TILE	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	E	WALL COVERINGS (CERAMIC TILE ON WET WALLS ONLY; PAINT)	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL

		ITEM DESCRIPTION	Design Cost Responsibility	Construction Responsibility	Cost Type	Design Responsibility	Dwg. Package Where Shown
25	**LOBBY CONSTRUCTION**						
	A	INTERIOR WALLS	TENANT	TENANT	T.I.	(TENANT)	T.I.
	B	INTERIOR DOORS, FRAMES & HARDWARE	TENANT	TENANT	T.I.	(TENANT)	T.I.
	C	INTERIOR CEILINGS	TENANT	TENANT	T.I.	(TENANT)	T.I.
	D	FLOOR COVERINGS	TENANT	TENANT	T.I.	(TENANT)	T.I.
	E	WALL COVERINGS	TENANT	TENANT	T.I.	(TENANT)	T.I.
26	**MILLWORK**						
	A	RESTROOM COUNTERTOPS	OWNER	OWNER	CORE	ARCH	SHELL
	B	BALANCE T.I. CASEWORK & MILLWORK	TENANT	TENANT	T.I.	(TENANT)	T.I.
27	**OVERHEAD FIRE SPRINKLER SYSTEM**						
	A	RISER AND MAIN DRAIN PIPING	OWNER	OWNER	SHELL	FIRE	SHELL
	B	OVERHEAD PIPING AND HEADS (DENSITY - 0.2 GPM / 1,500 SF)	OWNER	OWNER	SHELL	FIRE	SHELL
	C	CEILING DROPS FOR CORE RESTROOM	OWNER	OWNER	CORE	ARCH	SHELL
	D	SPRINKLER HEADS FOR BASE CORE RESTROOMS - FULL HT WALLS	OWNER	OWNER	CORE	ARCH	SHELL
	E	CEILING DROPS T.I.	TENANT	TENANT	T.I.	(TENANT)	T.I.
	F	SPRINKLER HEADS FOR T.I. FULL HT WALLS	TENANT	TENANT	T.I.	(TENANT)	T.I.
	G	SPRINKLER HEADS FOR EXTERIOR SOFFITED AREAS	OWNER	OWNER	SHELL	ARCH/FIRE	SHELL
28	**PLUMBING**						
	A	ROOF DRAINS	OWNER	OWNER	SHELL	ARCH/PLUMB	SHELL
	B	UNDERSLAB SANITARY SEWER GUT LINE (CORE ONLY)	OWNER	OWNER	SHELL	PLUMB	SHELL
	C	TOILET ROOM PLUMBING ROUGH-IN	OWNER	OWNER	CORE	ARCH/PLUMB	SHELL
	D	TOILET ROOM PLUMBING FIXTURES (STANDARD)	OWNER	OWNER	CORE	ARCH	SHELL
	E	ROUGH-IN FOR ALL OTHER UNDERSLAB PLUMBING	TENANT	TENANT	T.I.	(TENANT)	TBD
	F	PLUMBING FOR OTHER INTERIOR ITEMS	TENANT	TENANT	T.I.	(TENANT)	T.I.
	G	BASE HVAC SYSTEM ROOFTOP CONDENSATE PIPING	OWNER	OWNER	CORE	HVAC/PLUMB	SHELL
	H	PROCESS PIPING	TENANT	TENANT	T.I.	(TENANT)	T.I.
29	**HVAC SYSTEMS**						
	A	HVAC SYSTEM HEATING / COOLING EQUIPMENT (BASE SYSTEM)	OWNER	OWNER	CORE	HVAC	SHELL
	B	PENETRATION FOR VERTICAL DUCT FROM UNIT TO 1ST FLOOR	OWNER	OWNER	CORE	ARCH/STRUCT	SHELL
	C	HORIZONTAL DUCT DISTRIBUTION FROM RISER	TENANT	TENANT	T.I.	(TENANT)	T.I.
	D	INTERFACE CARD FOR HVAC UNITS TO OPERATE WITH TENANT BMS	TENANT	TENANT	T.I.	(TENANT)	T.I.
	E	HVAC SYSTEM CONTROLS, BMS SYSTEM	TENANT	TENANT	T.I.	(TENANT)	T.I.
	F	HVAC SYSTEM BALANCING	TENANT	TENANT	T.I.	(TENANT)	T.I.
	G	DISTRIBUTION FOR RESTROOM CORE HVAC	TENANT	TENANT	T.I.	(TENANT)	T.I.

		ITEM DESCRIPTION	Design Cost Responsibility	Construction Responsibility	Cost Type	Design Responsibility	Dwg. Package Where Shown
30		**ELECTRICAL & DATA**					
	A	SITE ELECTRICAL (SEE #13)					
	B	U.G. PULL SECTION; HOUSE PANEL; TENANT METER SECTIONS	OWNER	OWNER	SHELL	ELEC	TBD
	C	DISTRIBUTION SECTION (ONLY FOR HVAC UNITS & ELEVATOR)	OWNER	OWNER	CORE	ELEC	SHELL
	D	INTENTIONALLY DELETED	N/A	N/A	N/A	N/A	N/A
	E	LIGHT FIXTURES FOR TOILET CORE & STAIRWELLS	OWNER	OWNER	CORE	ELEC	SHELL
	F	POWER FOR TOILET CORE & STAIRWELLS (COORD. W/T.I.)	TENANT	TENANT	T.I.	ELEC	TBD
	G	INTERIOR POWER DISTRIBUTION/SUB-PANELS & TRANSFORMERS	TENANT	TENANT	T.I.	ELEC	T.I.
	H	TELEPHONE & DATA CABLING	TENANT	TENANT	T.I.	ELEC	T.I.
	I	PAGING SYSTEMS	TENANT	TENANT	T.I.	ELEC	T.I.
	J	SECURITY SYSTEMS	TENANT	TENANT	T.I.	ELEC	T.I.
	K	FIRE ALARM SYSTEMS (RISER & PIV MONITORING ONLY)	OWNER	OWNER	SHELL	ELEC	SHELL
	L	SPECIAL GROUNDING REQUIREMENTS	TENANT	TENANT	T.I.	ELEC	T.I.
	M	ELEVATOR & HVAC POWER	OWNER	OWNER	CORE	ELEC	SHELL
31		**SPECIAL INSPECTION COSTS**					
	A	SHELL ITEMS	OWNER	OWNER	SHELL	N/A	N/A
	B	CORE ITEMS	OWNER	OWNER	CORE	N/A	N/A
	C	T.I. ITEMS	TENANT	TENANT	T.I.	N/A	N/A
32		**G.C., SUPERVISION, CLEAN-UP & OTHER JOB OVERHEAD COSTS**					
	A	SHELL ITEMS	OWNER	OWNER	SHELL	N/A	N/A
	B	CORE ITEMS	OWNER	OWNER	CORE	N/A	N/A
	C	T.I. ITEMS	TENANT	TENANT	T.I.	N/A	N/A
33		**PLAN CHECK AND BUILDING PERMIT FEES**					
	A	PLAN CHECK & BUILDING PERMIT FEES - SHELL VALUE	OWNER	OWNER	SHELL	N/A	N/A
	B	PLAN CHECK & BUILDING PERMIT FEES - CORE VALUE	OWNER	OWNER	CORE	N/A	N/A
	C	PLAN CHECK & BUILDING PERMIT FEES - TENANT DRAWINGS	TENANT	TENANT	T.I.	N/A	N/A
	D	FIRE DEPARTMENT PLAN CHECK FEES - SHELL	OWNER	OWNER	SHELL	N/A	N/A
	E	FIRE DEPARTMENT PLAN CHECK FEES - CORE	OWNER	OWNER	CORE	N/A	N/A
	F	FIRE DEPARTMENT PLAN CHECK FEES - T.I.	TENANT	TENANT	T.I.	N/A	N/A
34		**MISCELLANEOUS FEES**					
	A	SANITARY, STORM SEWER SHELL FEES	OWNER	OWNER	SHELL	N/A	N/A
	B	UTILITY SHELL FEES (GAS; ELEC.; DOM. WATER; FIRE WATER)	OWNER	OWNER	SHELL	N/A	N/A
	C	UTILITY/ PLANT FEES ASSOC. W/ T.I. PLUMBING	TENANT	TENANT	T.I.	N/A	N/A
	D	SCHOOL FEE - SHELL (OFFICE OCCUPANCY)	OWNER	OWNER	SHELL	N/A	N/A
	E	TRAFFIC FEE - SHELL (OFFICE OCCUPANCY)	OWNER	OWNER	SHELL	N/A	N/A
	F	HOUSING FEE - SHELL (OFFICE OCCUPANCY)	OWNER	OWNER	SHELL	N/A	N/A

		ITEM DESCRIPTION	Design Cost Responsibility	Construction Responsibility	Cost Type	Design Responsibility	Dwg. Package Where Shown
	G	SCHOOL, TRAFFIC, HOUSING, OTHER FEES (SPECIAL TI OCCUPANCY)	TENANT	TENANT	T.I.	N/A	N/A
35	**DRAWING PACKAGE DESIGN FEES**						
	A	SHELL COST ITEMS (INCLUDING ARCH., STRUCT., MEP ENG.)	OWNER	OWNER	SHELL	N/A	N/A
	B	CORE COST ITEMS (INCLUDING ARCH., STRUCT., MEP ENG.)	OWNER	OWNER	CORE	N/A	N/A
	C	T.I. COST ITEMS	TENANT	TENANT	T.I.	N/A	N/A

ABBREVIATIONS USED:

(TENANT)	=	TENANT DESIGNATED CONSULTANT
ARBO	=	ARBORIST
ARCH	=	ARCHITECT
BLDG	=	BUILDING
CIVIL	=	CIVIL ENGINEER
CONST.	=	CONSTRUCTION
CORE	=	CORE ITEM
ELEC	=	ELECTRICAL ENGINEER
FIRE	=	FIRE SPRINKLER ENGINEER
HVAC	=	HEATING VENTING & AIR-COND. ENGR
LAND	=	LANDSCAPE ARCHITECT
N/A	=	NOT APPLICABLE
P.L.	=	PROPERTY LINE
PLUMB	=	PLUMBING MECHANICAL ENGINEER
SHARED	=	COST SHARED 50/50 - TENANT/OWNER
SOIL	=	GEOTECNICAL ENGINEER
SOUND	=	SOUND ENGINEER
STRUCT	=	STRUCTURAL ENGINEER
TEMP.	=	TEMPORARY
T.I.	=	TENANT IMPROVEMENT
TBD	=	TO BE DETERMINED
ARCH/CIVIL	=	ARCH AND CIVIL (TYPICAL)

Attachment 2 to Exhibit D

MILESTONE SCHEDULE

In the event of any conflict between this Schedule and the Lease/Work Letter, the Lease/Work letter shall control.

Milestone	**Target Date** (Estimated, Non-binding)	**Milestone Date**
1. Landlord's delivery of Base Building Construction Drawings to Tenant. (Exhibit D, Section 2.1)	October 27, 2017	Within 30 days after the Effective Date
2. Tenant's Project Manager. (Exhibit D, Section 2.3)	November 27, 2017	Within 60 days after the Effective Date
3. Tenant's delivery of Space Plan to Landlord. (Exhibit D, Section 3.3(a))	February 26, 2018	No later than 120 days after Landlord delivers Base Building Construction Drawings
4. Landlord's comments to or approval of Tenant's Space Plan. (Exhibit D, Section 3.3 (a))	March 12, 2018	Within 15 Business Days after Landlord's receipt of Tenant's Space Plan
5. Tenant's delivery of Tenant Improvement Plans to Landlord. (Exhibit D, Section 3.3(b))	July 25, 2018	No later than 270 days after Landlord delivers Base Building Construction Drawings
6. Landlord's approval of Tenant Improvement Plans. (Exhibit D, Section 3.3 (b))	August 22, 2018	Within 20 Business Days after Landlord's receipt of Tenant Improvement Plans
7. Landlord to use reasonable efforts to complete installation of communications vault and conduit from MPOE to Premises.	October 9, 2018 (estimate)	At least 90 days prior to the Actual Access Date
8. Landlord's notice of Actual Access Date to Tenant. (Exhibit D, Section 2.4(a))	December 8, 2018 (estimate)	At least 30 days prior to Actual Access Date
9. Scheduled Access Date. (Article 1 and Exhibit D, Section 2.4(a))	January 7, 2019	Subject to change as set forth in Exhibit D, Section 2.5
10. Tenant's delivery of evidence of insurance. (Section 10.6, 14.2 and Exhibit D, Section 2.4(b))	January 7, 2019 (estimate)	As of the Actual Access Date

Milestone	Target Date (Estimated, Non-binding)	Milestone Date
11. Substantial Completion – Base Building Work. (Exhibit D, Section 2.7)	March 1, 2019	
12. Landlord's completion of Punch List. (Exhibit D, Section 2.8)	May 30, 2019	Within 90 days after Substantial Completion of Base Building Work
13. Initial Disbursement of Tenant Improvement Allowance. (Exhibit D, Section 5.4, 5.5 and 5.6)		Subject to Tenant's fulfillment of all requirements set forth in Exhibit D, Section 5.4, 5.5 and 5.6
14. Final Disbursement of Tenant Improvement Allowance. (Exhibit D, Section 5.7)		Subject to Tenant's fulfillment of all requirements set forth in Exhibit D, Section 5.7
15. Tenant's anticipated occupancy. (Exhibit D, Section 4.1(c))	September 4, 2019 (estimate)	240 days after Actual Access Date Tenant shall deliver items required under Section 13.2 and any other relevant sections
16. Commencement Date. (Articles 1 and 5)	September 4, 2019 (estimate)	The earlier of (a) Tenant's occupancy of the Premises for the conduct of business, and (b) 240 days after the Actual Access Date as defined in the Lease, but in no event earlier than the date which Landlord achieves Substantial Completion of the Base Building Work.
17. Abated Rent period ends. (Article 1 and Section 6.2)	October 3, 2019	Base Rent (but not Additional Rent) shall be abated for a total of 1 full calendar month after the Commencement Date, subject to Section 4.1.
18. Expiration of Tenant Improvement Allowance. (Exhibit D, Section 5.1)	January 7, 2020 (estimate)	1st Anniversary of the Actual Access Date

Milestone	**Target Date** (Estimated, Non-binding)	**Milestone Date**
19. Tenant's Failure to Achieve Occupancy (Exhibit D, Section 4.1(c))	September 4, 2020	Landlord shall have the right to terminate the Lease if Tenant does not achieve occupancy by the first anniversary of the Commencement Date, subject to Tenant's Unavoidable Delays.

Attachment 3 to Exhibit D

ACCEPTANCE FORM

This Acceptance Form is executed with reference to that certain Lease dated as of _____, 201_ by and between by and between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY (***"Landlord"***), and _____ (***"Tenant"***). Terms defined in the Lease and the exhibits thereto shall have the same meaning when used herein.

Tenant hereby certifies to Landlord that Tenant has inspected the Premises as of _____ (the ***"Date of Substantial Completion Inspection"***) and that the Base Building Work is Substantially Complete except only for Punch List Items listed in Base Building Architect's Certificate of Substantial Completion as supplemented by the Tenant's punch list for the Tenant Improvement Work showing the Punch List Items a copy of which is attached hereto. Tenant further acknowledges that Tenant hereby accepts the Premises in its existing AS-IS condition, in accordance with and subject to the provisions of the Lease, and subject only to the completion of any Punch List Items.

The person executing this Acceptance Form on behalf of Tenant represents and warrants to Landlord that such person is duly authorized to execute this Acceptance Form and that this Acceptance Form has been duly authorized, executed and delivered on behalf of Tenant.

THIS ACCEPTANCE FORM is executed by Tenant as of the Date of Inspection.

TENANT

_____

By: _____
Its: _____

By: _____
Its: _____

Attachment 4 to Exhibit D

TENANT'S CONSTRUCTION DRAW CERTIFICATION

General Contractor: _____

Design Architect: _____

1. Original Contract Amount:	$_____
2. Additions to Contract:	$_____
3. Deductions from Contract:	$_____
4. Adjusted Amount of Contract:	$_____
5. Total Completed or Stored to Date:	$_____
6. Total Retainage:	$_____
7. Total Earned Less Retainage:	$_____
8. Previous Payments:	$_____
9. Current Payment Due:	$_____

TENANT CERTIFICATION

To induce Landlord to disburse proceeds of the Tenant Improvement Work pursuant to the Lease, Tenant hereby certifies to Landlord as follows:

A. The amount shown on Line 9 above as Current Payment Due is the actual amount presently payable to the General Contractor.

B. No Event of Default presently exists.

C. Tenant has no knowledge of and has received no notices of liens or claims of lien either filed or threatened against the premises, except:

_____

_____

D. All amounts shown on Line 8 above and in the column entitled "Previous Payments" in the Disbursement Request Summary for this Draw Request have been paid by Tenant.

E. Tenant approves all work and materials for which payment is due (as shown on Line 9 above) and confirms that to Tenant's knowledge and belief such work and materials conform with the Tenant Improvement Plans, as defined in the Lease, as they may be modified by written change orders in compliance with the requirements of the Lease.

F. The following list identifies those change order requests or proposals which have been submitted by the Tenant Improvement Contractor but are pending approval:

_____

_____

G. All permits, approvals and authorizations required by all governmental authorities for the work covered by this draw request, the work which was the subject of previous draw requests, and the work that is currently ongoing have been obtained.

H. Approximately ____% of the Tenant Improvement Work has been completed as of this date.

TENANT:

_____

By: _____

Its: _____

Date: _____

PAYMENT REQUEST

(Attached to and forming a part of Tenant's Construction Draw Certification)

DISBURSEMENT NO. _____

DATE: _____

Item No.	Description	Original Estimate	Revised Estimate Date	Disbursed to Date	This Request	Total Disbursed	% Est. Disb.	% Comp

Total:
Contingencies Reserve:
Total Funds Available:

Attachment 5 to Exhibit D

CONTRACTOR'S CONSTRUCTION DRAW CERTIFICATION

Project Name: _____
Date: _____
Location: _____
Draw No. _____

Landlord: The Board of Trustees of the Leland Stanford Junior University

Tenant: _____

General Contractor: _____

Design Architect: _____

1.	Original Contract Amount	$	_____
2.	Additions to Contract	$	_____
3.	Deductions from Contract	$	_____
4.	Adjusted Amount of Contract	$	_____
5.	Total Completed or Stored to Date	$	_____
6.	Total Retainage	$	_____
7.	Total Earned Less Retainage	$	_____
8.	Previous Payments	$	_____
9.	Current Payment Due	$	_____

GENERAL CONTRACTOR CERTIFICATION

To induce Landlord to make a disbursement of the Tenant Improvement Allowance pursuant to its Lease with Tenant, the undersigned (General Contractor) certifies to Landlord as follows:

(a) The information contained in all documents and supporting papers prepared or signed by General Contractor and submitted to Landlord are true and correct.

(b) The amount shown on Line 9 of the Draw Request Certification is the amount presently due and payable under the contract with Tenant.

(c) The amount shown on Line 8 of the Draw Request Certification has been received by the General Contractor and applied to the amount due under the contract with Tenant.

(d) All work performed to date conforms with the contract with Tenant and the Plans and Specifications prepared and coordinated by the Design Architect.

(e) There have been no change orders to the contract, proposed or approved, except: _____.

(f) All subcontracted items and material/equipment items are shown in the Application for Payment breakdown accompanying this Draw Request.

(g) All subcontractors and materialmen have been paid all amounts due to them to date, as described in Line 8 above.

_____

By: _____

Its: _____

Attachment 6 to Exhibit D

FORM OF QUARTERLY REPORTS

[Stanford Letterhead]

Date: [DUE DATE]

To: Jazz Pharmaceuticals, Inc.

From: [XXX, Stanford Real Estate Group]

Re: Commercial Lease dated September 22, 2017 ("Lease") by and between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY ("Landlord") and JAZZ PHARMACEUTICALS, INC. ("Tenant")

Quarterly Financial Reporting - 3181 Porter Drive, Palo Alto, California:

Estimated Landlord Costs incurred through [QUARTER END]	$[X.X Million]
Estimated Total Budget of Landlord Costs as of [QUARTER END]	$[X.X Million]

OR:

Final Financial Reporting - 3181 Porter Drive, Palo Alto, California:

Total Landlord Costs incurred through completion: $[XX,XXX,XXX]

[NOTE: LANDLORD TO FORMAT NUMBERS AS DESCRIBED ABOVE, EXCEPT FINAL REPORT WILL INCLUDE NUMBERS TO THE THOUSANDS.]

Attachment 7 to Exhibit D

LANDLORD'S COSTS

Included in Landlord's Costs:

- Landlord's costs for Base Building Work as described in Attachment 1 to Exhibit D of the Lease. [Attachment 1 is comprised of Attachment 1A (Base Building Work Description) and Attachment 1B (Construction Responsibility Matrix). The Base Building Work consists of (a) the Shell Components, (b) the Core Components, and (c) the Common Area Improvements.]
- Landlord's property tax and insurance during construction
- Landlord's project and contract management costs

Excluded from Landlord's Costs:

- Leasing commissions and marketing/promotion costs paid in connection with the Lease
- Interest expense and finance charges
- Legal fees related to the Lease
- Tenant Improvement Allowance and Tenant reimbursements
- Litigation

EXHIBIT E

NOTICE OF LEASE TERMINATION

Recording Requested by and When Recorded, Return to: The Board of Trustees of the Leland Stanford Junior University Land, Buildings and Real Estate 3160 Porter Drive, Suite 200 Palo Alto, CA 94304 Attn: Managing Director, Real Estate	

Space above this line for Recorder's use)

NOTICE OF LEASE TERMINATION

The Board of Trustees of the Leland Stanford Junior University (***"Landlord"***) and _____, a _____ (***"Tenant"***), entered into that certain Commercial Lease dated as of September 22, 2017 (the **"*Lease*"**).

Pursuant to the Lease, Landlord leased to Tenant, and Tenant leased from Landlord, that certain property commonly known as 3181 Porter Drive, Palo Alto, California 94304 described on the attached **Exhibit A**. By signing below, Tenant certifies that the Lease expired pursuant to its terms on _____, 20__.

TENANT:

_____,
a _____

By: _____

Its: _____

[ACKNOWLEDGEMENT AND EXHIBIT A TO BE ATTACHED]

EXHIBIT F

RULES AND REGULATIONS

Tenant shall comply with the following rules and regulations (as modified or supplemented from time to time, the *"**Rules and Regulations**"*). Landlord shall not be responsible to Tenant for the nonperformance of any of the Rules and Regulations by any other tenants or occupants of the Project. In the event of any conflict between the Rules and Regulations and the other provisions of this Lease, the latter shall control.

1. Tenant shall not alter any lock or install any new or additional locks or bolts on any doors or windows of the Premises without obtaining Landlord's prior consent (which consent shall not be unreasonably withheld, conditioned or delayed). Tenant shall bear the cost of any lock changes or repairs required by Tenant. Upon the termination of this Lease, Tenant shall restore to Landlord all keys of stores, offices and toilet rooms furnished to or otherwise procured by Tenant, and if any such keys are lost, Tenant shall pay Landlord the cost of replacing them or of changing the applicable locks if Landlord deems such changes necessary.

2. Employees of Landlord shall not perform any work or do anything outside their regular duties unless under special instructions from Landlord.

3. The toilet rooms, urinals, wash bowls and other apparatus shall not be used for any purpose other than that for which they were constructed, and no foreign substance shall be thrown therein. Notwithstanding Sections 8 and 9.1 of this Lease, Tenant shall bear the expense of any breakage, stoppage or damage resulting from any violation of this rule by Tenant or any of its employees, agents, contractors, invitees or licensees.

4. Tenant shall not overload the floor of the Premises or deface the Premises, without Landlord's prior consent.

5. Except for vending machines intended for the sole use of Tenant's employees and invitees, no vending machines or machines other than typical office machines, including computers, shall be installed, maintained or operated in the Premises without Landlord's prior consent.

6. Tenant shall not, without Landlord's prior consent, use any method of heating or air conditioning other than that supplied by Landlord.

7. Tenant shall store all its trash and garbage inside the Premises or in areas designated by Landlord for such storage in the Common Area. No material shall be placed in the trash or garbage receptacles if, under Law, it may not be disposed of in the ordinary and customary manner of disposing of trash and garbage in the vicinity of the Building. All trash, garbage and refuse disposal shall be made only through entryways and elevators provided for such purposes at such times as Landlord shall designate. Tenant shall comply with Landlord's recycling program, if any.

8. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any governmental agency.

9. Tenant must comply with the State of California “No-Smoking” law set forth in California Labor Code Section 6404.5 and with any local “No-Smoking” ordinance that is not superseded by such law.

Schedule 9.8

Additional Equipment

1. **Additional Equipment**. Landlord and Tenant acknowledge and agree that during the Term of this Lease, Tenant shall be permitted to access, install, replace, remove, operate and maintain the following equipment (the "***Additional Equipment***") subject to the provisions of this Schedule 9.8:

(a) a backup generator and related appurtenances (collectively, the "***Generator Equipment***"), such Generator Equipment to be located within an enclosed equipment area (the "***Generator Equipment Area***") as designated by Landlord; and

(b) a satellite antenna not exceeding three (3) feet in height or microwave dish not exceeding two (2) feet in diameter (the "***Antenna***") on the rooftop of the Building at a location reasonably determined by Landlord (the "***Rooftop Equipment Area***"), including the cabling and connecting equipment (collectively, the "***Connecting Equipment***" and, together with the Antenna, the "***Rooftop Equipment***").

2. **Design Considerations**. The Additional Equipment shall be properly screened from view for aesthetic reasons, and must not be visible from street level. Tenant, at Tenant's sole cost and expense, shall install and maintain such fencing and other protective equipment and/or visual screening on or about the Additional Equipment as Landlord may reasonably determine. The Additional Equipment shall be clearly marked to show the name, address, telephone number of the person to contact in case of emergency.

3. **Approval of Plans.** Prior to the commencement of any work in relation to the Additional Equipment, Tenant shall, at its sole cost and expense, prepare and deliver to Landlord construction drawings and specifications, detailing the location and size of the Additional Equipment and specifically describing the proposed construction and work. No such work shall commence until Landlord has given its written consent to the applicable location, construction or installation drawings, which consent shall not be unreasonably withheld or delayed. In no event shall Landlord's consent be deemed a representation that the Additional Equipment will not cause interference with other systems in the Building or that the work shown on Tenant's drawings complies with Applicable Laws.

4. **Disturbance of Existing Surfaces.** Tenant shall in no event cut, drill, or bore through any structural components of the Building, and shall patch, fill and cover with approved materials to match surrounding surfaces wherever Tenant has cut, drilled or bored in the Building or Common Area with Landlord's prior written consent. Landlord reserves the right to require that Tenant use construction contractors of Landlord's choice whenever Tenant cuts, drills or bores into the Building's or Common Area's existing surfaces, all at Tenant's sole cost and expense.

5. **Manner of Construction.** Tenant agrees that installation and construction of the Additional Equipment shall be performed in accordance by licensed contractors approved by Landlord and otherwise in accordance with Article 10 of this Lease. Tenant shall ensure that the Additional Equipment is secured firmly to the Building or Common Area, where applicable, and engineered to withstand reasonably anticipated winds, storms and earth movements, as applicable. Tenant shall, at its sole cost and expense, repair or refinish any surface of the Building or Common

Area that is damaged by or during the installation of the Additional Equipment. If Tenant fails to repair or refinish any such damage within ten (10) Business Days following notice from Landlord (or three (3) Business Days if such failure impacts other tenants of the Property), Landlord may, in its sole discretion, repair or refinish such damage and Tenant shall reimburse Landlord for all costs and expenses incurred in such repair or refinishing.

6. **Permits and Licenses.** Tenant shall obtain, at its sole cost and expense, prior to construction and work, all permits, licenses, approvals, zoning variances and the like, as necessary to install and operate the Additional Equipment, including but not limited to approvals from the Federal Communications Commission, Federal Aviation Administration, and state and local entities having jurisdiction ("***Governmental Approvals***"). Copies of all Governmental Approvals shall be delivered to Landlord prior to commencement of construction and work. The Additional Equipment and Tenant's use, operation and maintenance thereof shall comply with all Applicable Laws (including OSHA requirements, applicable building and fire codes and any required conditional use permit). Landlord makes no representation that any such Laws permit such installation and operation, and Tenant shall be solely responsible to determine the feasibility and legality of installing the Additional Equipment.

7. **No Interference.** Tenant shall not during construction or otherwise, in Landlord's sole judgment, in any way obstruct access to any portion of the Property by Landlord or other tenants or licensees of Landlord or any other occupant of the Property. If such conditions shall occur, Tenant shall take corrective action as promptly as feasible, but in no event more than twenty-four (24) hours following notice by Landlord of such conditions. Tenant shall not use the Additional Equipment in any way which interferes with the use of the Property by Landlord, or other tenants or licensees of Landlord. Such interference shall be deemed a material breach by the Tenant under this Lease, and Tenant shall, within five (5) days of written notice from Landlord, be responsible for terminating said interference. In the event any such interference does not cease within five (5) days of Landlord's written notice, Tenant acknowledges that continuing interference may cause irreparable injury and Tenant shall immediately cease all operation of the applicable Additional Equipment.

8. **Changes.** Tenant may only amend the drawings and specifications approved by Landlord, or modify the Additional Equipment as installed, with Landlord's prior written consent, which consent shall not unreasonably be conditioned, withheld or delayed. Following Landlord's consent to such amendments, all terms and conditions of this Schedule 9.8 shall apply.

9. **Utilities.** Landlord shall have no responsibility and shall not be obligated to provide any utilities, including, but not limited to, electricity or other power for the operation of the Additional Equipment. If Landlord elects not to provide such utilities, Tenant shall procure utility services to be used in connection with the Additional Equipment with the appropriate local utility companies, which arrangements, other than the cost and expense, shall be subject to the prior written approval of Landlord which approval shall not unreasonably be conditioned, withheld or delayed. Tenant shall pay for the cost of all utility services in connection with the Additional Equipment, or shall reimburse Landlord for the cost of any such services that are not separately metered.

10. **Insurance; Maintenance**. Tenant shall be responsible for insuring the Additional Equipment pursuant to Article 14 of this Lease and Landlord shall have no responsibility therefor. Tenant shall be solely responsible for and shall pay all costs, expenses and taxes incurred in connection

with the ownership, installation, operation, maintenance, use and removal of the Additional Equipment and the appurtenant equipment located in or on the Building, including all installation or “hook-up” costs. Tenant shall keep and maintain the Additional Equipment in good condition and repair, promptly making all necessary repairs and replacements, whether ordinary or extraordinary, in accordance with the applicable provisions of Section 9.3 of this Lease, and to the reasonable satisfaction of Landlord including, but not limited to, repairing any damage (and replacing any property so damaged) caused by Tenant or any of Tenant's Agents. Tenant's repair responsibilities shall include the requirement that Tenant keep in full force and effect, during the Term of the Lease, a contract for preventative maintenance meeting, at a minimum, the manufacturer's recommended standards of service. Tenant shall promptly repair any damage to the Building or the Property caused by Tenant or the use, operation, repair, maintenance, or alteration of the Additional Equipment.

11. **Health Hazard.** If Landlord, in its reasonable judgment, believes that any Additional Equipment poses a human health or environmental hazard that cannot be remediated or has not been remediated within ten (10) days after Tenant has been notified thereof, then Tenant shall immediately cease all operation of such Additional Equipment. To the best of Tenant's knowledge, Tenant represents to Landlord that the use of the Additional Equipment will not pose a human health or environmental hazard.

12. **Books and Records.** Tenant shall maintain all reports, inventory and other records, test results, permits and all other data and information required under Applicable Laws for the installation, use and operation of the Additional Equipment, and upon request of Landlord, shall provide a copy of all such reports, records, test results and other information without cost or expense to Landlord.

13. **Removal.** Upon termination of the Lease by expiration of time or otherwise, Tenant, at its sole cost and expense, shall remove the Additional Equipment and shall restore the Property to its condition existing prior to the installation of the Additional Equipment, ordinary wear and tear excepted. Tenant shall further repair, at its sole cost and expense, any damage or destruction caused by the removal of the Additional Equipment. Restoration and repair required to be performed by Tenant shall be completed under the supervision of a representative of Landlord at such time and in such manner that is reasonably satisfactory to Landlord. Landlord, at Landlord’s option, exercised by written notice given to Tenant, shall have the right to perform any repairs, removal and restoration required hereunder at Tenant’s sole cost and expense and such expense shall be reimbursed to Landlord promptly upon demand by Landlord. Notwithstanding anything contained herein, Tenant shall not remove, and shall not be reimbursed for the cost of, any Additional Equipment which is affixed to, embedded in or permanently attached in or to the Building, including, but not limited to, cables and other wiring, unless Landlord directs otherwise.

14. **Limitation of Liability; Indemnity.** Neither Landlord nor the Landlord Parties shall be liable or responsible to Tenant for (a) any loss or damage to the Additional Equipment (b) interference with Tenant’s operations or any loss of business or profits or (c) any interference with Tenant’s operation of the Additional Equipment caused by Landlord’s repair, maintenance or replacement of any structural elements of the Building (including the roof), except in each case to the extent arising out of Landlord’s or Landlord’s Agents’ gross negligence or willful misconduct. Landlord shall be entitled to suspend operation of any Additional Equipment temporarily if such temporarily suspended operation is reasonably necessary for the performance of Landlord’s

repair, maintenance or replacement activities. Tenant hereby agrees to indemnify, defend and hold Landlord and the Landlord Parties harmless from and against any and all claims, costs, damages, expenses and liabilities (including reasonable attorneys' fees) arising out of or related to the installation, operation, use, maintenance or removal of the Additional Equipment, except to the extent arising out of Landlord's or Landlord's Agents' Active Negligence or willful misconduct.

15. **No Assignment.** Tenant may not assign, lease, rent, sublet or otherwise transfer any of its interest in the Additional Equipment except together with the remainder of all of the Premises in accordance with Article 15 of this Lease.

16. **Termination of Lease**. If this Lease terminates or expires for any reason, Tenant's rights with respect to the Additional Equipment shall also terminate concurrently therewith unless otherwise agreed in writing by Landlord in its sole and absolute discretion.

17. **Provisions Applicable to Generator Equipment:**

a. The Generator Equipment shall not cause excessive noise or unreasonably disturb other occupants of the Property and, in the event the Generator Equipment is unreasonably noisy or unreasonably disturbs other occupants of the Property, then such noise and/or disturbance shall be deemed an interference with Landlord's use of the Property that must be eliminated within five (5) days after written notice from Landlord, as provided above.

b. If requested by Landlord, Tenant shall obtain for the benefit of Landlord a separate policy of environmental insurance to provide coverage against any and all damage to property or injury or death to persons as a result of the Generator Equipment, and Tenant shall provide written evidence of such coverage within ten (10) days after request by Landlord.

18. **Provisions Applicable to Rooftop Equipment:**

a. The Rooftop Equipment shall be used and operated solely by Tenant.

b. The Antenna may not protrude above a height equal to the highest point of the Building structure. The weight of the Rooftop Equipment shall not exceed the load limits of the Building. Use of a non-penetrating load frame mount with ballast will ordinarily be used for any Rooftop Equipment, although a penetrating mount may be approved by Landlord on a case-by-case basis. Tenant shall use only non-rusting hardware with respect to the installation of the Rooftop Equipment, such as stainless steel or hot-dipped galvanized bolts, nuts, washers and clamps.

c. Tenant, at Tenant's sole cost and expense, shall be responsible for any modifications to the rooftop, risers, utility areas or other facilities or portions of the Building which may be necessary to accommodate the Rooftop Equipment.

d. It is expressly understood that Landlord retains the right to use the roof of the Building for any purpose whatsoever (including granting rights to third parties to utilize any portion of the roof not utilized by Tenant).

e. Tenant covenants and agrees that the Rooftop Equipment (i) shall not cause or create any unreasonable interference with the operation or use by any occupant of the Property

whatsoever, of other transmitting and receiving devices, antennae, televisions, radios and stereo equipment in place as of the date of installation of the Rooftop Equipment, (ii) shall comply with all non-interference rules of the Federal Communications Commission ("FCC") and (iii) shall not preclude the installation and operation by other tenants of the Property of similar equipment on their buildings or create any interference with the operation, access to, or the servicing of, the Building's HVAC equipment. If in the future equipment is installed at the Property which interferes with the operation of the Rooftop Equipment, Tenant agrees to reasonably cooperate with such other user to resolve such interference in a mutually acceptable manner, subject to and in accordance with the rules of the FCC. If any testing, sampling or disclosures relating to the Rooftop Equipment are required to satisfy OSHA or other governmental agencies (including for radio frequency [RF] or electromagnetic field [EMF] emissions), Tenant shall pay the costs of any such required tests and studies (or its prorata share thereof if the cost is properly shared by other rooftop users). Landlord shall have no liability or responsibility for the maintenance or compliance with laws of any towers, antennas or structures, including, without limitation, compliance with Part 17 of the FCC Rules.

f. Tenant shall promptly pay all taxes and license fees imposed by any federal, state or local governmental agency or authority in connection with the installation, operation and maintenance of the Rooftop Equipment.

g. Tenant understands and agrees that the structural integrity of the load bearing capability of the roof of the Building, the moisture resistance of the Building membrane, and the ability of Landlord to use all parts of the Property are of critical importance to Landlord. Tenant, therefore, agrees that the specifications and drawings that it will provide shall be of sufficient specificity to ensure that these concerns are addressed, and Tenant further agrees and commits that the actual installation of the Rooftop Equipment shall be in accordance with those approved specifications and drawings. Tenant warrants that the installation of the Rooftop Equipment shall not impair, adversely affect, or void any roofing warranty benefiting the Building. No manner of construction will be approved if it has the effect of impairing the Building's existing roof warranty.

h. Tenant shall secure the approval of Landlord's fire insurance underwriter prior to installation of any Rooftop Equipment, shall provide copies of the same to Landlord and shall comply with all requirements issued by said fire insurance underwriter. Landlord shall cooperate with Tenant in attempting to obtain the approval of Landlord's fire insurance underwriter and shall submit such documentation to the underwriter as Tenant may reasonably request. Tenant shall provide all installation specifications and drawings required for the securing of said approvals.

i. Landlord agrees that Tenant's authorized representatives and contractors shall have reasonable access to the rooftop of the Building for the purposes of installing, maintaining, operating and repairing the Rooftop Equipment. Only authorized engineers, employees or properly authorized contractors, subcontractors, and agents of Tenant, other authorized regulatory inspectors, or persons under their direct supervision and control will be permitted to enter the Building, and only upon conditions set forth herein. In exercising its right of access to the roof, Tenant agrees to cooperate and comply with any reasonable security procedures, access requirements and rules and regulations utilized by Landlord for the Building and further agrees not to unduly disturb or interfere with the business or other activities of Landlord or of other tenants or occupants of the Property.

j. Except in the event of an emergency, Tenant shall give at least twenty-four (24) hours' notice to Landlord of its intent to enter the rooftop of the Building. At the time that such notice is given, Tenant shall inform Landlord of the identity of contractors who will be accessing the rooftop, the reasons for entry, and the expected duration of the work to be performed. In the event of an emergency, Tenant shall give to Landlord as much advance notice as reasonably possible of its intent to enter the rooftop and, within twenty-four (24) hours following such entry, shall provide to Landlord a written report detailing the nature of such emergency, the corrective actions taken, and other such information as may reasonably be requested by Landlord.

k. Landlord shall have the right, at its option and from time to time, upon not less than thirty (30) days prior notice to Tenant, to relocate the Rooftop Equipment to another location in the Building adequate to afford equivalent service to Tenant. Landlord shall pay the costs of relocation reasonably incurred by Tenant in connection with such substituted location, subject to adequate substantiation of such costs.

l. Landlord shall have the right to terminate Tenant's rights with respect to the Rooftop Equipment and the Rooftop Equipment Area upon three (3) months prior written notice in the event Landlord determines that (i) Tenant's use unreasonably interferes with an essential Building system or function, which interference cannot be remedied; or (ii) the operation of the Rooftop Equipment unreasonably interferes with the equipment or operations of any of the existing tenants, licensees, or occupants of the Property with prior rights to use rooftop equipment. In connection with such termination, no amounts will be refunded or otherwise paid to Tenant and Tenant shall remain responsible for removing Tenant's Rooftop Equipment and restoring the Building in accordance with the terms hereof.

Schedule 13.1

ENVIRONMENTAL MANAGEMENT PRE-LEASE QUESTIONNAIRE

Company Name:
Jazz Pharmaceuticals, Inc.

Main Address(es) of Proposed Facility:
3181 Porter Drive, Palo Alto, CA 94304

Address of Existing Facility(ies):
3180 Porter Drive, Palo Alto, CA 94304

Contact Name (person who completed this form)/Position:
Ron Malouf

Telephone/Fax/Nos:
650-496-2704; 650-823-6858 (mobile)

Email:
Ronald.malouf@jazzpharma.com

1) GENERAL INFORMATION:

Please describe the intended activities to be conducted at the proposed facility:

Research and Development of pharmacological products

1a) Business type: (identify by Subtenant if applicable):

X	Administrative/Office	___	Computer (Software/Hardware)
___	Aerospace	___	Utilities
___	Electronics	___	Transportation
___	Biotechnology	___	(Pharmaceutical
___	Medical	___	Other describe) ___

Please describe proposed on-site operations. (Indicate whether manufacturing, research, administrative, etc.)

Research and Development administrative functions

1b) Do you anticipate that future activities conducted at the proposed facility might change significantly from initial operations? YES___ NO_X_ If YES, please describe: ___

2) CHEMICAL PROCESS OR USAGE:

Will the intended activities (initial and future) involve chemical process or usage? YES__ NO X_

If YES, check all that apply:

___	Product Forming (e.g., plastic extrusion; tableting)				
___	Painting and Coating	___	Vehicle Maintenance and Fueling	___	Cooling
___	Photography or Printing	___	Degreasing/Cleaning	___	Laboratory
___	Warehousing and Distribution	___	Synthesis	___	Component
___	Electroplating/Metal Finishing	___	Assembly	___	Sterilization
___	Heating	___	Machining	___	Soldering
___	Mixing/Compounding/Formulating	___	Extraction	___	Research
___	Other (describe below) ___				

3) ON-SITE ACTIVITIES:

Will intended operations at the proposed facility involve any of the following (check as appropriate):

YES__ NO X Waste or wastewater discharge

YES__ NO X Emissions of any air contaminant (including asbestos containing material)

YES__ NO X Manufacturing, generation, storage, or use of Hazardous Materials or Waste

YES__ NO X Installation of aboveground or underground storage tanks

If the response is NO to all of the questions in Section 3, go to Question 5. Otherwise, continue to Question 4.

4) PERMITS AND REGULATIONS:

Please check all that apply or will apply for and/or at the intended facility (identify by Subtenant if applicable).

4a) Discharge:

____ National Pollutant Discharge Elimination System (NPDES) point source type discharge permit

____ NPDES general storm water discharge permit

____ Sanitation System/Publicly-Owned Treatment Works (POTW) discharge permit

____ Other _____

Briefly describe source of waste stream, constituents of waste stream, estimated volume/day gallons, and permitting agency:

Has your existing facility been out of compliance within the last 5 years with regard to the above (4a)?
YES __ NO __ If you answered YES, attach a brief summary.

Has the compliance issue(s) since been resolved? YES___ NO___ If you answered NO, attach a brief summary.

4b) Emissions:

_____Bay Area Air Quality Management District (BAAQMD) air permit

Would the air permit be required for any of the following air contaminants:

___ Volatile Organic Compounds	___ Sulfur Dioxide	___ Carbon Monoxide
___ Lead	___ Nitrogen Oxides	___ Particulate Matter
Removal of Asbestos-Containing Material	___ Hazardous air pollutants listed under Section 112 of the federal Clean Air Act	___ Toxic air contaminants regulated by the California Air Resources Board

___ Other _____

Has your existing facility been out of compliance within the last 5 years with regard to the above (4b)?

YES___ NO___ If you answered YES, attach a brief summary.

Has the compliance issue(s) since been resolved? YES___ NO___ If you answered NO, attach a brief summary.

4c) Hazardous Materials Use, Storage, and Production:

____ Hazardous Materials Business Plan
____ Above-ground storage tank (AGST) permit
____ Underground storage tank (UST) permit
____ Other

List hazardous material type (i.e. solvents, gases, acids, fuels, etc.); estimated volume (gallons); and storage type (AGT, UST, drums, etc.):

_____

_____

_____

Has your existing facility been out of compliance within the last 5 years with regard to the above (4c)?

YES___ NO___ If you answered YES, attach a brief summary.

Has the compliance issue(s) since been resolved? YES___ NO___ If you answered NO, attach a brief summary.

4d) Hazardous Waste Generation (RCRA or California Code of Regulations, Title 22)

_____ Hazardous Waste Treatment, Storage, or Disposal (TSD) Facility permit
_____ California Code of Regulations, Title 22 Tiered Permit
check one: _____ Full _____ Standard ____ Permit-By-Rule
_____ Conditional Authorization _____ Conditional Exemption ____ Variance
_____ Other _____

List waste stream; waste type (RCRA or CA), estimated volume generated/month, and storage method

_____

_____

_____

Is the ultimate disposal destination of hazardous wases an off-site location? YES ___ NO ___
Identify the proposed location of each Tiered-permitted unit:

_____

_____

_____

Has your existing facility been out of compliance within the last 5 years with regard to the above (4d)?
YES _____ NO _____ If you answered YES, attach a brief summary.
Has the compliance issue(s) since been resolved? YES ____ NO ___ If you answered NO, attach a brief summary.

4e) _____ Uniform Hazardous Material/Waste Registration Form
4f) _____ Radioactive Storage Permit
4g) _____ Risk Management Prevention Plan

5) <u>COMPLIANCE & HAZARDOUS MATERIAL RELEASES AND SPILLS AT EXISTING FACILITIES:</u>

5a) Has your existing facility or company received any of the following regarding environmental matters?

___ formal complaints ___ citations from any governmental agencies
___ environmental claims ___ odor or other air emission nuisance complaints
___ notices of violation ___ cleanup & abatement orders
___ other: _____

If you checked any of the above (5a), please describe below:

_____

_____

_____

_____

5b) Has there ever been an occasion in any existing facility in the past 5 years when a liquid or solid waste material or any fuel or other Hazardous Material was accidentally or intentionally spilled or released? YES ___ NO <u>X</u>
If YES, please check appropriate type(s) and describe below:

____inside facility building ____on-site/outside facility building ____off-site/outside of facility

_____

_____

_____

5c) Has your company ever received any notice or demand in kind from the EPA or any other governmental agency or third party to the effect that the company must contribute to the cost of any Hazardous Material investigation or remediation at or emanating from an existing facility?
YES ___ NO X

If YES, please describe suit in question, appropriate number of PRPs, identity of the primary PRP(s), and any insurance coverage available to the company for the liability.

_____

_____

_____

_____

6) WORKING CONDITIONS:

Has your company ever been subject to or party to the following (check as appropriate):

YES ___ NO X Any citation from any governmental agency (e.g., OSHA) or grievance from a collective bargaining unit for alleged unsafe working conditions at existing facilities or any prior facilities in the last 5 years.

YES ___ NO X Any inspection or tests conducted by or at the request of OSHA or a comparable state or federal agency, any employee group, or your company in connection with Hazardous Materials at any existing facility in the last 3 years.

YES ___ NO X Any claims by employees for injury due to the work environment at any existing facilities.

YES ___ NO X A litigation in which allegations have been made regarding intentional or unintentional releases of air contaminants or Hazardous Materials that allegedly harmed or threatened to harm persons in the vicinity of such a facility.

If you answered YES to any of the above, please attach summary or description.

Will intended operations at the proposed facility have or require the following (check as appropriate):

YES ___ NO X Employees' use of facemasks or other protective equipment.

YES ___ NO X Compliance with federal or state work place "hazard communication" standards or other "right-to-know" Laws (such as California Proposition 65 or SARA Title III).

YES ___ NO X A training program for employees who work with Hazardous Materials when such materials are present at an existing facility.

YES ___ NO X An emergency plan to respond to fires, explosions, or releases of Hazardous Materials.

If you answered YES to any of the above, please attach summary or description.

7) INSURANCE:

Please check as appropriate:

YES ___ NO X “Environmental impairment” insurance will be acquired for the proposed facility.

YES ___ NO X An insurance company has refused to cover your existing facility under environmental impairment insurance.

YES ___ NO X An insurance company has canceled environmental impairment insurance coverage for your existing facility.

If you answered YES to any of the above, please attach summary or description.

Stanford Real Estate (SRE) reserves the right to request supporting documentation to your responses above prior to, during the term of, or following expiration of your lease with SRE.

Schedule 13.11

3181 Porter Drive
(Formerly 3181/3183 Porter Drive[1], 3215 Porter Drive[2] and 3221 Porter Drive[3], Palo Alto, CA 94304)

1. Site Clean-up Orders	Lead Agency	Order Number and Date
3165 Porter Drive (8/06/1990)	Department of Toxic Substances Control (DTSC)	#HSA 90/91-004
3215 Porter Drive (3/24/1989)	Department of Toxic Substances Control (DTSC)	#HSA 88/89-024
Hillview-Porter (HVP) (12/09/88)	Department of Toxic Substances Control (DTSC)	#HSA 88/89-016
Regional Order		[Last amended 6/30/97]

2. Fact Sheets

- 2000-08__ Fact Sheet __ HillviewPorter
- 2004-09__ Fact Sheet __3215 Porter
- 2005-02__Fact Sheet __3165 Porter

3. Public Reports Indices

- 3165 Porter Drive, Reports from 01-15-88 through 03-28-17
- 3215 Porter Drive, Reports from 02-26-87 through 06-08-17
- Hillview-Porter Parties, Reports from 10-87 through 07-14-17

4. Access Agreements

- Access Agreements for 3165 Porter
  - 1993-11-19__Enviro Access Agr (3165, 3181-3201, 3221 & 3215 Por)__Stanford-Teledyne
  - 1993-11-19__Short Form Of Access Agr (3165, 3181-3201, 3221 & 3215 Por)__Stanford-Teledyne
  - 1995-02-28__Enviro Access Agr & Work Plan__Stanford-Teledyne
  - 1995-02-28__Memo Of Termination Of Temp Access Agr___Stanford - Teledyne
  - 1995-02-28__Short Form Access Agr___Stanford – Teledyne

- Access Agreements for 3215 Porter
  - 1992-05-22__Access Agr (3200, 3333, 3350 3240 Hillview, 3215 Por, 1501 Pmr)
  - 2006-12-20__Access Agr (3215 Por & Some 1501 Pmr)__Hp-Stanford
  - 2009-10-08__Enviro Access Agr (3215 Por)__Hp-Stanford
  - 2010-02-10__Assign Of Access Agr Of Trtmnt Plant & Pipeline (3215 Porter)__Hp-Stanford
  - 2010-02-10__Remediation Access Agr__Hp-Stanford
  - 2010-02-10__Short Form Access Agr 20606980 (Certified By First American Title)__Stanford-Hp
  - 2010-02-10__Short Form Access Agr 20606980 (Recorded Copy)__Stanford-Hp
  - 2016-05-31__1994-08-12 Access Agr Term Ltr As Of Sept 1 2016__Stanford-3300 Hillview Grp

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[1] This property is within the Hillview Porter Study Area, and does not have its own site specific order. For further information please visit: http://www.envirostor.dtsc.ca.gov/public/

[2] This site is within the HVP and has its own order associated with 3215 Porter. For further information please visit: http://www.envirostor.dtsc.ca.gov/public/

[3] This property is within the Hillview Porter Study Area, and does not have its own site specific order. For further information please visit: http://www.envirostor.dtsc.ca.gov/public/

- Access Agreements for Hillview Porter Region
  - 1993-07-01__Access Agr (3215 Por)__Stanford-Hvp
  - 1993-07-01__Access Agr For Treatment Plant & Pipeline (3215 Por)__Hp-Hvp
  - 1993-07-01__Recorded Memo To Treatment Plant & Pipeline (3215 Por) 13208487__Hp(Grantor)-Hvp
  - 1993-07-01__Recorded Memo To Treatment Plant & Pipeline (3215 Por)13208489__Su(Grantor)-Hvp

5. Reports Commissioned by Stanford University

Asbestos Reports for 3181-3183, 3215 & 3221 Porter

3181-3183 Porter

- 2016-08-03__Asbestos and Lead Survey for Planned Demo Project (ACC)
- 2016-11-03__Asbestos Materials Clearance Letter (ACC)
- 2017-03-28__Asbestos Materials Removal Letter (ACC)
- 2017-07-11__Stanford Porter Dr Asbestos Abatement Project Documentation (ACC)

3215 Porter

- 2009-10-27__Asbestos Survey and Evaluation (ProTech)
- 2016-08-02__Asbestos Roofing Survey and Universal Waste Inspection (ACC)
- 2016-11-03__Asbestos Materials Clearance Letter (ACC)

3221 Porter

- 2016-08-02__Asbestos and Lead Survey for the Planned Demo. Project (ACC)
- 2016-11-03__Asbestos Materials Removal PROGRESS Letter (ACC)
- 2017-03-28__Asbestos Materials Removal Letter (ACC)
- 2017-07-11__Stanford Porter Dr Asbestos Abatement Project Documentation (ACC)

Reports prior to 2016 for 3181-3183, 3215 & 3221 Porter

3181-3183 Porter Reports:

- 2011-05-24__Proposal for Phase I and Phase II (AMEC Geomatrix)
  2011-09-21__Phase I Environmental Site Assessment (AMEC Geomatrix)
- 2011-10-04__Hazmat Assessment (Bayview)
- 2011-12-23__Phase II Environ. Assessment (AMEC Geomatrix)

3215 Porter Reports:

- 2005-04-19__Soil Vapor and Indoor Air Quality Assessment HP Bldg 15 (SECOR)
- 2008-02-22__Indoor Air Quality Assessment (CH2M Hill)
- 2009-11-09__Letter Report Summarizing Indoor Air Sample Results (AMEC)

3221 Porter Reports:

- 1995-10-06__3221 Porter Drive Sump Removal (Syntex USA, Inc.)
- 1995-11-07__Report of Subsurface Investigation (Syntex USA, Inc.)
- 2011-09-21__Phase I Environmental Site Assessment (AMEC Geomatrix)
- 2011-12-23__Phase II Environmental Site Assessment (AMEC Geomatrix)
- 2012-01-26__Geophysical Survey (NORCAL Geophysical Consultants, Inc.)
- 2015-08-13__Technical Memorandum: Results of Additional Site Characterization (Haley&Aldrich)

Reports since 2016 for Porter Redevelopment [this vendor-based list applies to activities within the three addresses in this project]

Department of Toxic Substances Control (DTSC)

- 2016-06-16__DTSC tentative approval for Pipeline & GWTS
- 2016-07-15__HP Plume Bioremediation Pilot WP Approval
- 2016-07-15__HP Plume GW Reconfiguration WP Approval
- 2016-09-20__DTSC Response to Methane Monitoring
- 2016-10-19__DTSC Comments on Vapor Intrusion Evaluation

- 2016-10-31__Response to the Vapor Intrusion Evaluation Memo
- 2016-12-21__DTSC Memo on Vapor Intrusion Eval at Porter Redev
- 2017-02-23__Email to DTSC Re VIMS Drawings for Porter Redev

Haley Aldrich
- 2016-06-21__Status of Pre-Devel. Investigation Activities
- 2016-07-29__Report on Soil and Soil Vapor Sampling
- 2016-08-02__Stanford Porter Redevelop. Sub-Slab Ventilation System Design
- 2016-08-03__Site Management Plan, Porter Drive Redevelopment
- 2016-08-29__Vapor Intrusion Evaluation, Porter Drive Redevelopment
- 2016-12-16__Addendum to 7_16 Report on Soil and Soil Vapor Sampling
- 2017-03-31__Workplan for Soil Removal for PCBs
- 2017-06-02__Removal of Soil Impacted with Polychlorinated Biphenyls
- 2017-06-09__Transmittal of VIMS Design Drawings
- 2017-07-26__Dieldrin Target Excavation Trucking Letter
- 2017-07-27__Soil Excavation Completion Documentation

6. Reports Commissioned by Other Responsible Parties
- For 3165 Porter: Teledyne
  - 1993-01-27__Final Remedial Action Plan 1 (Harding Lawson)
  - 1993-01-27__Final Remedial Action Plan 2 (Harding Lawson)
  - 2014-02-13__4th Five-Year Effectiveness Evaluation Review- 12-2008 thru 11-2013 (Stantec)
  - 2014-07-03__Rev. 4th Five-Year Effectiveness Evaluation Review - 12-2008 thru 11-2013 (Stantec)
  - 2015-11-18__Vapor Intrusion Assessment Work Plan; Teledyne MEC Site (Stantec)
  - 2016-05-27__Soil Vapor Assessment Report (Stantec)

- For 3215 Porter: Hewlett-Packard
  - 2007-03-15__Chromium Monitoring Results and Recommendations, Bldg 15 (SECOR)
  - 2008-02-28__Chromium Assessment Report, HP Bldg 15 (SECOR)
  - 2008-08-28__Chromium Mitigation Plan, HP Bldg 15 (Stantec)
  - 2014-02-14__4th Five-Year Remedial Action Status and Effectiveness Eval. Report - Bldg. 15 & 28 (Stantec)
  - 2014-07-02__High Resolution Source Area Study Report, Bldg 15 (Stantec)
  - 2015-01-20__Rev. Enhanced Bioremediation Pilot Study Work Plan, Bldg. 15 (Stantec)
  - 2016-04-07__Enhanced In Situ Bioremediation Pilot Study Report, Bldg15 Site (Stantec)
  - 2016-06-06__Phase I Groundwater Remediation Facility Reconfiguration Workplan (Stantec)
  - 2016-06-10__Enhanced In Situ Bioremediation and Zero Valent Iron Pilot Study Workplan, Bldg 15 Site, (Stantec)
  - 2016-08-02__Addendum to Groundwater Remediation Facility Workplan
  - 2016-09-06__Phase II Groundwater Remediation Facility Reconfiguration Workplan (Stantec)
  - 2016-09-12__Methane Monitoring for EISB Pilot Testing at 3215 Porter (Stantec)
  - 2016-10-31__Soil Vapor Extraction_ Air Injection System Decommissioning Report, Bldg 15 Site (Stantec)
  - 2017-02-17__Rev. Extraction Well Installation and Hydraulic Assessment Report (Stantec)
  - 2017-02-27__Enhanced Bioremediation & Chemical Reduction Pilot Study Implementation Report,
    - Bldg 15 (Stantec)

7. Other
- 2016-29-06__Conveyance Line Re-Configuration Site Plan [Fig. 6]

Exhibit 31.1

CERTIFICATION

I, Bruce C. Cozadd, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 7, 2017

By: /s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATION

I, Matthew P. Young, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 7, 2017

By: /s/ Matthew P. Young

Matthew P. Young
Executive Vice President and Chief 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, Chief Executive Officer of Jazz Pharmaceuticals public limited company (the "Company"), and Matthew P. Young, Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017, 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: November 7, 2017

/s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director

/s/ Matthew P. Young

Matthew P. Young
Executive Vice President and Chief Financial Officer

(1) This certification accompanies the Quarterly Report on Form 10-Q 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-Q), 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.